Final Report on Clinical Evaluation of Medical Device no. KHZP/2014/013/Hr

The clinical evaluation of the medical device was done according to the Act no. 268/2014 Coll. about medical devices and about the modification of some related laws as amended, according to the paragraph 22 Act no. 286/2014 Coll., which specifies requirements of final reports on clinical evaluation of medical device, according to the Government Regulation no. 54/2014 defying technical requirements on medical devices, as amended, according to the directive 93/42/EHS and according to the guidance document MEDDEV. 2.7.1 Rev. 3.

Name of medical device JETT PLASMA LIFT MEDICAL

Class of medical device II b

Code of the device category according to ČSN EN ISO 15225 04

Manufacturer
Compex ltd.
Palackého 105
612 00 Brno, Czech Republic

Examiner MUDr. Miloš Kravciv

Qualification, working experience

- 1976 – 1982
  - LF UK Hradec Králové
  - Military Medical Academy Hradec Králové
- 1982 – 1984
  - Military hospital České Budějovice
- 1984 – 1988
  - Doctor at the Bechyně airport
- 1988 – 2002
  - Department of Dermatology at Military University Hospital in Prague, position of an ordinary for dermatology
- Since 2002 LD Clinic Prague 7

Medical post gradual certifications:
1986 – certification in general medicine
1994 – certification of the 1st degree in dermatology

Date of the clinical evaluation start 1. 9. 2014

Date of the clinical evaluation end 17. 04. 2015

Plan of clinical evaluation JETT PLASMA LIFT MEDICAL

- Evaluation of the medical device from the point of view of its safety for the user and the third person during medical treatment in the range stated in the original documents for the device
- Verification of the suitability of the device for the stated purpose of use and in accordance with current clinical knowledge
- Evaluation of the suitability for the use in health care in the range specified in the original device documents
- Evaluation of the suitability for clinical use in the EU countries

The plan of clinical evaluation is created in accordance with the Act no. 268/2014 Coll. About medical devices and about the modification of some of related acts, as amended, and with the Regulation no. 316/2000 Coll., which sets the requirements of the final report on a clinical evaluation of a medical device.

Specified purpose of the use of medical device

JETT PLASMA LIFT MEDICAL is a medical device, which is used for the skin treatment based on the physical principle of a sequence of sparkle discharges generated by DC voltage. It is used mainly for the skin treatment, to stanch minor bleeding, removal of small warts, hemangiomas, (benign mesenchymal tumors of blood vessels) and undesired skin structures. The device also helps with cosmetic treatment of the following cosmetic indications: removal of scars and striae (little scars on the surface on skin created by cracking of elastic fibers under the skin surface as a result of an extreme load of skin), which are no older than approx. half a year, lightening of red veins, lightening of pigment spots and stimulation (elimination of wrinkles).
Cosmetic indications are not a subject of the evaluation of compliance.

More specific list of indications /indications of a clinical character/

- angioma senilis
- verrucae seborrhoicae
- verrucae plane
- angiokeratoma
- teleangiectasie
- lentigo
- fibroma molle
- keratoacanthoma
- conydolamata accuminatum
- moluscum contagiosum
- verrucae vulgaris
- verrucae filitormes
- pulpitis
- naveus capillaris
- naveus araneus
- basalioma superficiale – only after a preceding histological examination
- carcinoma spinocellularis - only after a preceding histological examination
- lymphangioma
- keratosis actinica
- keratosis senilis
- keratosis sebborhoica

Contraindications:

- pacemaker, holter monitor of ECG
  or other implanted electrical devices
- epilepsy
- pregnancy
- presence of metal implants in the treated area

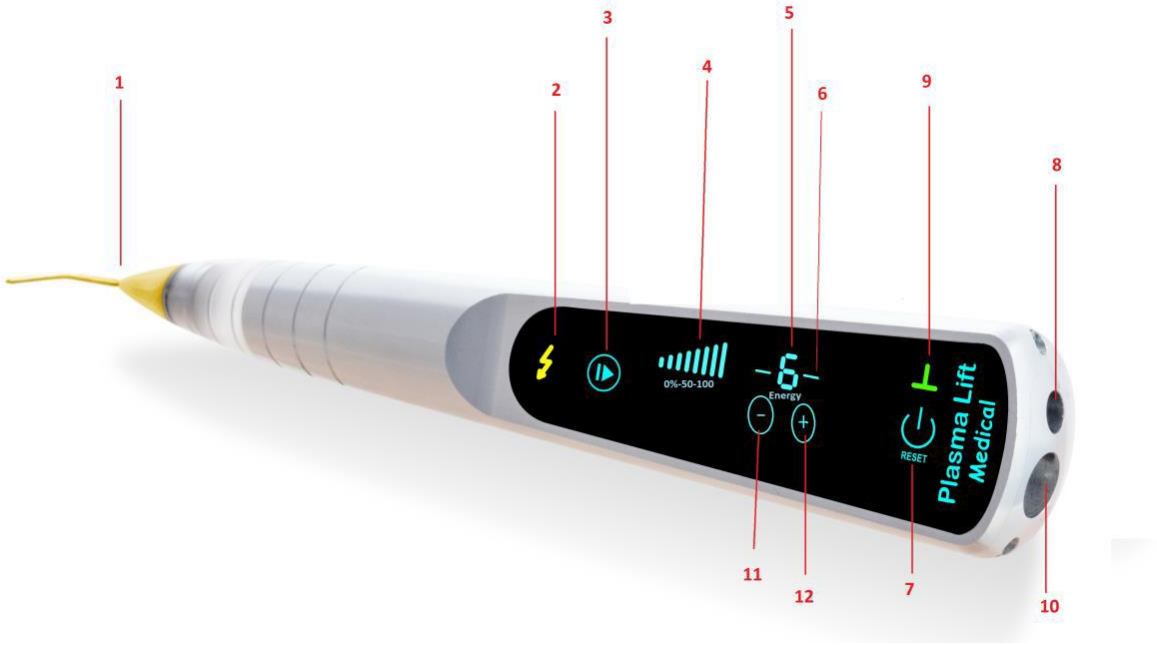
The trained operator of the device is obliged to provably make sure that the treated patient does not suffer from any of the aforementioned indications and informed consent about this must be signed.

Characteristics of the medical device

Characteristics of the device meet the requirements according to the Government Regulation no. 54/2014 Coll., as amended and stated technical norms and regulations. Under the circumstances of a usual use specified by the manufacturer, its use is safe.
Characteristics, type, character and parameters of the medical device are suitable for the purpose of the use and they are in accordance with current clinical knowledge.

Description of he device

JETT PLASMA LIFT MEDICAL is a device used for minor dermatological and surgical interventions. Its effects are achieved with the use of sparkle (plasma) discharge in combination with thermal energy able to destroy skin cells if it is set to the highest intensity values. Sparkle (plasma) discharge is very narrow and it affects the treated area in the pointed targeted way. Because of that surrounding healthy tissue is not damaged, contrary to the use of high-frequency electrosurgical units with the sparkle discharge conically extending towards the surface of the treated tissue.
Plasma is an ionized gas comprising of ions, electrons (or neutral atoms and molecules), which is created by the removal of an electron from an electron shell of gas atoms or by the separation of molecules (ionization).
The plasma discharge itself is created with the help of a high voltage of 4 to 5.5 kV.
The output of plasma discharge between working electrode (the tip) of the device and the surface of skin ranges between 0.4 to1.8 W.
During the treatment it is necessary to increase the conductivity of skin b the application of a special conductive gel. Between the tip of the device and the surface of skin with a thin layer of applied gel a thin sparkle (plasma) discharge emerges.
The distance of the tip from the skin is approx. 2 mm.
The electric circuit is closed by the grounding strip on the patient´s hand. As soon as the discharge emerges, it penetrates the conductive gel in the treated spot and it affects the skin directly.
The danger of patient´s high-temperature burns in the area of application when the intensity is set to level 7 or 8 cannot be decreased by any technical measures, as the high intensity of plasma discharge is a principle of the medical treatment. It is used also with electrofulguration, electrodessication and electrocoagulation during which skin cells are destroyed on purpose. The use of such a high intensity of sparkle (plasma) discharge must be confirmed by the user after its setting.
The setting of the parameters of the device before and after the treatment is made by a touchscreen.



1) Applicator with a precise targeting end point – gilded removable tip
2) Indicator of sparkle discharge FLASH
3) Play/Pause button for activation and deactivation of sparkle discharge
4) Indicator of sparkle discharge effectivity (the current flowing through patient)
5) Indicator of sparkle discharge intensity (Labelled as Energy on the display)
6) Dash before and after the number stating the value of sparkle discharge intensity
7) ON/OFF button
8) Socket for plugging in the grounding cable to the neutral electrode conductively connected to the patient
9) Indicator of activity
10) Socket for power adaptor
11) Button for setting of a lower discharge intensity
12) Button for setting of a higher discharge intensity

<u>Basic technical parameters:</u>

Power supply: 100 to 240 VAC/50-60 Hz
Class of protection against electric shock: II
Type of device: with BF application part
Type of supply source: DA12-050EU-M, manufacturer EMERSON
Input of supply source: 100-240 V/50-60 Hz
Output of supply source: 5 VDC, up to 2,0 A
Power of supply source: up to 12 W
Voltage of plasma discharge generator: 0,8 – 5,5 kV
Power of plasma discharge: 0,3 – 1,8 W
Detection of connection neutral electrode with patient functioning: SCS system
Automatic switching off of high voltage at the tip of the applicator: after 20 s
Accelerated decrease of voltage at the tip of the applicator after turning off: after 1s
Size: length 245 mm, width 45 mm

Weight: approx. 350 g
Degree of protection: IP2X

Working requirements
Range of relative air humidity: 30% - 75%
Range of environment temperature: +10 ^{o}C to +40^{o}C
Range of atmospheric pressure: 70,0 kPa to 106,0 kPa

Working environment
The device is not designed for the use in the presence of flammable anesthetic mixtures with air or flammable anesthetic mixtures with oxygen or nitrous oxide.

Storage requirements
The device must be stored in the original package an indoor and dry place at the temperature of +5°C to +40°C and air humidity up to 80%.

DETAILED ELABORATION OF CLINICAL EVALUATION PLAN:

A – assess, whether there are any construction parameters of the medical device or treatment aim of patients which require a special attention.
Aim – in past, undesired incidents occurred with similar medical devices, when a grounding electrode on patient got loose.
The aim is to study these incidents and describe how JETT PLASMA LIFT is protected from the occurrence of such incidents.

B – assess whether data for the comparison of medical devices can be used for the support of safety or questions concerning the performance of the medical device.
Aim – JETT PLASMA LIFT MEDICAL is an electrocauter. Electrocauters have been on market for decades. For the comparison, it is necessary to pick a electrocauter with a worldwide use manufactured by a well-known manufacturer, which is on a market for decades. JETT PLASMA LIFT MEDICAL uses a well-established technology.

DEFINITION OF THE METHOD OF WORK WITH SOURCES
STEP no. 1: Collection of available literature dealing with clinical experiences with AC electrocauters in the regime of low power up to 3W, working with the method of electrodessication and the method of electrofulguration with a special attention to treatment applications stated at the beginning of this final report.
In the next step, it is necessary to study the literature and assess, whether it is suitable for the purposes of this clinical evaluation. It is necessary to assess every source picked as suitable in terms of its contribution to proving clinical effects and safety of the method.
In the following step, a real relevance of proofs from individual researches must be assessed based on the reliability of the author or clinic on which provided the clinical tests and considering also the fact, whether the tested electrocauter was manufactured by a world-known manufacturer with a lasting tradition.

In the last step, it must be assessed whether real clinical proofs from the picked source are able to verify the agreement with basic corresponding requirements. It is

necessary to have more clinical sources to be able to prove the aforementioned agreement on the basis of several independent sources.

Comparison of JETT PLASMA LIFT MEDICA with a device of an equivalent type PlexR®, HYFRECATOR 2000®, SM 75 MONO, SURGISTAT II

Manufacturer	Compex spol. s.r.o.	CONMED CORPORATION *
Country of origin	Czech Republic	USA
Type of device	Jett Plasma Lift Medical DC electrocauter	HYFRECATOR 2000® AC electrocauter
Therapeutic principle of the device	Sparkle discharge (plasma) in combination with thermal energy affects tissues, contactless application (electrode does not touch the tissue – electrofulguration) and contact application (electrode touches the tissue - electrodessication)	Sparkle discharge (plasma) in combination with thermal energy affects tissues, contactless application (electrode does not touch the tissue – electrofulguration) and contact application (electrode touches the tissue - electrodessication)
Purpose of use	Minor dermatological and surgical interventions	Both minor and major dermatological and surgical interventions
Working current	DC	AC, High-frequency
Working voltage	0,8 – 5 kV	3 – 8 kV
Mechanical design of the device	Compact design “everything in one”, the size of a pencil electrode	Compact design “everything in one”
Power of plasma discharge generator	0,4 to 1,8 W 1 pencil electrode covers the whole range of voltage of plasma discharge generator	0,09 to 35 W. Monopolar and bipolar design
Detection of grounding functioning	SCS System	- (has its own diagnostics E0 to E9)
Power supply	Power supply – AC adapter	230-240 V +-10% 50/60 Hz, 0.5 A
Size of the application handle	Length 24,5 cm, diameter 4,5 cm	Device: 10,2 cm ×22,2 cm ×19 cm Applicator: 2 × 15 cm
Size of charge	Does not use a charger	Does not use a charger
Weight of applicator	approx. 350 g	100 g
CE CERTIFICATION	NO	YES MEDICAL CE
		*European representative: MDSS GmbH Burckhandstrasse D – 30163 Hannover Germany

Comparison of JETT PLASMA LIFT MEDICA with a device of an equivalent type PlexR®, HYFRECATOR 2000®, SM 75 MONO, SURGISTAT II

Manufacturer	SURGISTAT II	SMT ltd..
Country of origin	USA	
Type of device	SURGISTAT II – 20 AC electrocauter	SM 75 MONO AC electrocauter
Therapeutic principle of the device	Sparkle discharge (plasma) in combination with thermal energy affects tissues, contactless application (electrode does not touch the tissue – electrofulguration) and contact application (electrode touches the tissue - electrodessication)	Sparkle discharge (plasma) in combination with thermal energy affects tissues, contactless application (electrode does not touch the tissue – electrofulguration) and contact application (electrode touches the tissue - electrodessication)
Purpose of use	Used for minor electrosurgical interventions in dermatology and ORL, to coagulation of minor bleedings and removal of small fibromas	Used for minor electrosurgical interventions in dermatology and ORL, to coagulation of minor bleedings and removal of small fibromas
Working current	AC, High-frequency	AC, High-frequency
Working voltage	Electrodessication 4,5 kV Electrofulguration 6,5 kV	750 V
Mechanical design of the device		Compact design “everything in one”
Power of plasma discharge generator	Fulguration: 0 – 40 W (410 kHz) Desiccation: 0 – 80 W (475 kHz)	0 – 30 W – coagulation 0 – 15 W – removal of small fibromas
Detection of grounding functioning	YES	Does not have a detection of patient connection
Power supply	230 – 240 V +- 10% 50/60 Hz	230 – 240 V +- 10% 50/60 Hz
Size of the application handle	10 × 5 cm	10 × 5 cm
Size of charge	Does not use a charger	Does not use a charger
Weight of applicator	200 g	100 g
CE CERTIFICATION	ANO MEDICAL CE 086	ANO MEDICAL CE
	European Representative: TYCO HEALTHCARE UK GOSPORT PO13 0AS UK	

Comparison of JETT PLASMA LIFT MEDICA with a device of an equivalent type PlexR®, HYFRECATOR 2000®, SM 75 MONO, SURGISTAT II

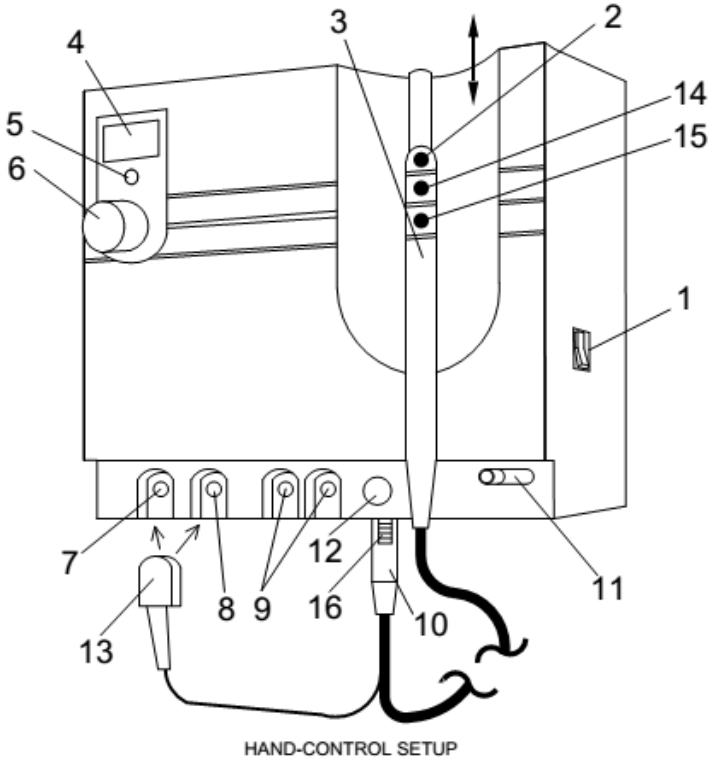
Manufacturer	GMV ltd.
Country of origin	Italy
Type of device	PlexR® Ac electrocauter
Therapeutic principle of the device	Sparkle discharge (plasma) in combination with thermal energy affects tissues, contactless application (electrode does not touch the tissue – electrofulguration) and contact application (electrode touches the tissue - electrodessication)
Purpose of use	Minor dermatological and surgical interventions
Working current	AC, High-frequency
Working voltage	750 V
Mechanical design of the device	Divided design: -charging (docking) station -3 types of pencil electrodes
Power of plasma discharge generator	< 2 W 3 pencil electrodes are necessary for the coverage of the whole range of plasma discharge generator voltage
Detection of grounding functioning	-
Power supply	Accumulator charged in a docking station
Size of the application handle	18 x 3,6 x 4 cm
Size of charge	27 x 27 x 27 cm
Weight of applicator	390 g
CE CERTIFICATION	YES – CE 0434(IIb)

Note: In clinical studies relevant for our purposes, the HYFRECATOR2000 model works in the LO regime, in which also very tiny power can be set; in our case 2 - 3 W. In these small power settings, methods of electrodessication and electrofulguration known in electrosurgery for decades are applied.

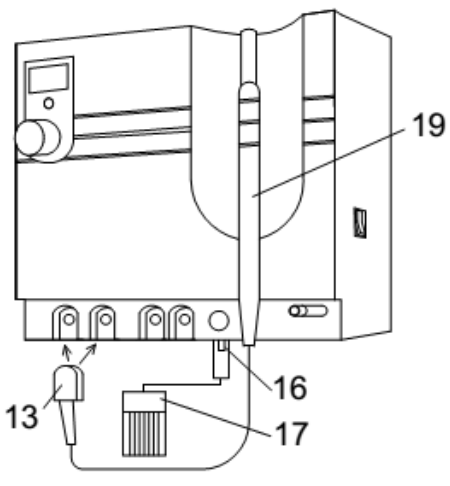
Clinical study is based mostly on clinical experience with AC electrocauter HYFRECATOR 2000, which is one of the best-known all over the world, has also MEDICAL CE and is relatively commonly used in Europe and Czech Republic. This is the reason why we provide its detailed description.

Among other things, it is used for the removal of fibroma and other skin protuberances and in the regime of monopolar fulguration - used power 2-3 W, in the LOW regime (low power for delicate surface interventions). It is equipped with two microprocessors – one for the control of functions and performance of the system, the other one for the interruption of activation, when there is a safety danger, inner self-diagnostic test – for the time of application the output power is continually monitored.

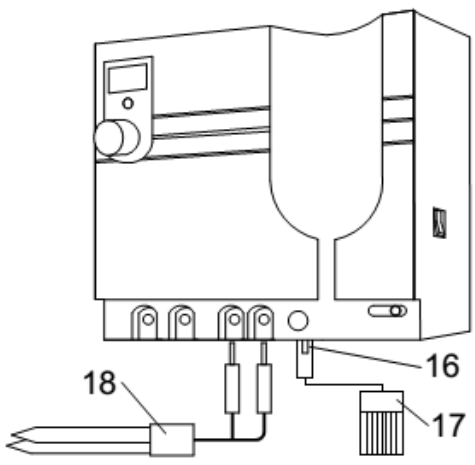
Figure 1: Front, Side and Bottom Panel Controls



HAND-CONTROL SETUP



FOOT-CONTROL SETUP



BIPOLAR SETUP

Front, Side and Bottom Panel Controls

1. ON/OFF SWITCH

Turns the unit on or off. When the Hyfrecator® 2000 is turned on, the unit automatically “powers up” to the setting last used.

2. POWER ACTIVATION BUTTON

When pressed, high frequency energy is emitted from the electrode. Additionally, an audible tone is generated and the active “on” indicator light illuminates.

3. POWER UP/DOWN SWITCHING HANDLE AND CORD

Remove or insert the power handle in the indicated direction.

4. POWER OUTPUT INDICATOR

Displays the power setting for the mode presently selected. Each mode automatically retains its own independent power setting that is set when the mode is selected again.

5. ACTIVE “ON” INDICATOR

Lights up when the power activation button is pressed.

6. POWER KNOB

Increases power by rotating clockwise; decreases power by rotating counter-clockwise. Power is increased by one watt increments in High and Bipolar modes, and in the Low mode at a power level greater than 10 watts. Power is advanced in one-tenths of a watt when less than ten watts in the Low mode.

7. HIGH OUTPUT TERMINAL

Insert the power up/down switching handle and cord single pin into this outlet for heavy desiccation and fulguration procedures requiring high intensity. Provides between zero and 35 watts with high voltage.

8. LOW OUTPUT TERMINAL

Insert the power up/down switching handle and cord single pin into this outlet for light desiccation and fulguration procedures requiring low intensity. Provides between zero and 20 watts with a voltage lower than the high output terminal.

9. BIPOLAR OUTPUT TERMINAL

For coagulation procedures using forceps. When using forceps, the forceps plug into both bipolar outlets (a footswitch is required when forceps are utilized). Bipolar provides between 0 and 35 watts with a voltage lower than the high or low output terminals.

10. SWITCHING CONNECTOR

The power up/down switching handle and cord socket plugs into this connector. Make sure to align the connector pins before inserting. NOTE: The optional footswitch plugs into this same connector.

11. TERMINAL SELECTOR SWITCH

Selects the desired output terminal and output mode. The displayed output will be the last used setting.

12. PATIENT PLATE

If a patient plate (also called neutral electrode or dispersive plate) is required or preferred for High or Low mode operation, depending upon the surgical procedure, simply plug the dispersive plate into this connector.

13. RF PLUG (Single Pin Accessory Plug)

Used to connect the HI or LO output terminal to the handle. This plug must be connected to an Output terminal for the pencil to deliver current. Note that both the Handswitching and Footswitching Pencils use the same RF plug connection.

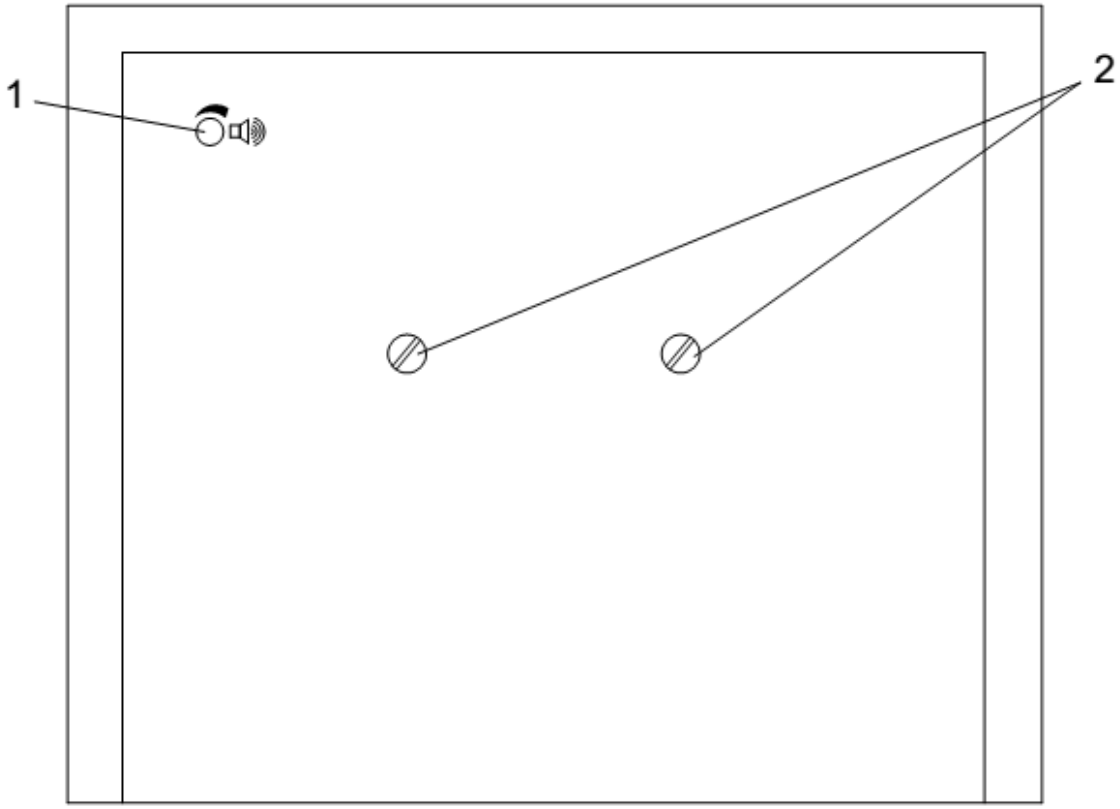
14. POWER UP BUTTON

Press this button to increase the power setting for the selected mode.

15. POWER DOWN BUTTON

Press this button to decrease the power setting for the selected mode.
16. RELEASE BUTTON
To remove an accessory switching connector, press this button to release the accessory, then pull the connector straight away from the unit.
17. FOOTSWITCH
Used to activate the unit when a Footswitched Pencil or Bipolar Forceps are used.
18. BIPOLAR FORCEPS
Must be used with a footswitch for activation.
19. FOOTSWITCHED PENCIL
Use when footswitch activation is preferred.

Figure 2: Back Panel Controls



Back Panel Controls
1. VOLUME CONTROL
Adjusts volume of the audible tone generated when the power activation button is pressed. To increase volume, insert a screwdriver and rotate clockwise until resistance is felt. Do not force adjustment past the resistance point. For safety reasons, the tone cannot be completely turned off.
2. WALL MOUNTING STUDS
Used with standard wall mounting kit, Cat. No. 7-796-20 (see the mounting kit for instructions). Instrument may also be mounted on optional mobile pedestal stand (Cat. No. 7-796-1). Note: The 7-796-20 mounting kit must be used to mount the unit on the mobile pedestal stand.

Monoterminal (Monopolar) with Dispersive Plate
Monoterminal applications with a dispersive plate (See Figure 4) are less common than monoterminal applications without a dispersive plate. Here, the high-frequency current starts from either the high or low output terminals, then travels through an electrode to your patient, where it exits through the dispersive patient plate and returns directly to the unit. Monoterminal applications with a dispersive plate improve the coagulation efficiency by providing a better path for the current flow. Its use is indicated when more effective coagulation is desired. The power setting should be reduced when a dispersive plate is used until the surgeon becomes accustomed to the increased coagulation efficiency that the dispersive plate provides. NOTE: The bipolar terminals should not be used in this application. It is important that the dispersive plate has maximum contact area with the patient, and that contact is maintained whenever activation occurs. Do not allow the patient to break contact while the unit is activated, or a burn could result at the last point of contact. Place the dispersive plate under a well vascularized muscle mass that is thoroughly clean and dry. Clean and shave site as necessary to provide adequate electrical connection. Avoid placement over scar tissue, bony prominences or other areas where pressure points on small areas might develop.

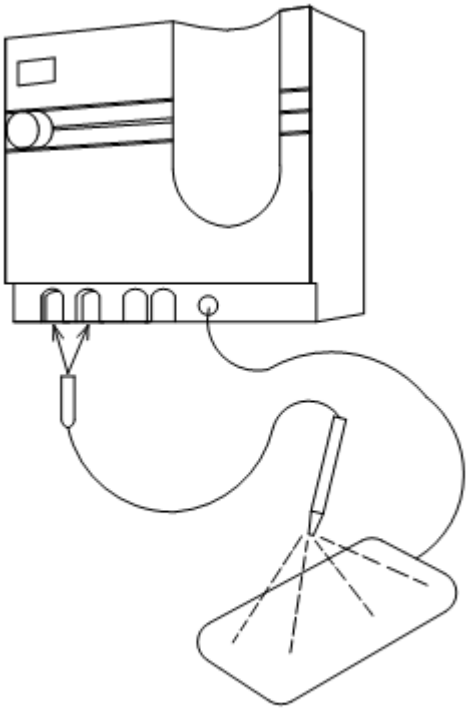


Figure 4: Monoterminal with Dispersive Plate Configuration

Desiccation
Desiccation comes from the Latin word “desiccare”, meaning to dry. It is a monoterminal without a dispersive plate technique. The electrode either touches, or is inserted into the tissue. The current evaporates the cellular fluids, blanching the treated area (see Figure 6). Typically, the depth of blanching is greater with desiccation than with fulguration.

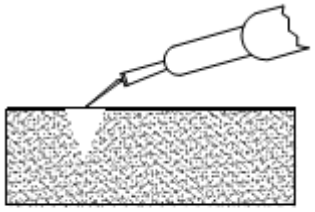


Figure 6: Desiccation

Fulguration
Fulguration comes from the Latin word “fulgur”, meaning an act of lightning. It is a monoterminal without a dispersive plate technique where the electrode is held slightly away from the surface being treated (see figure 8), resulting in sparking to the surface. When delicately fulgurating, you must precisely position the point of the active electrode close to the area being treated or the electrical arc may divert to adjacent tissue areas. If desired, you can quickly fulgurate broad areas by holding the electrode further from the skin. Fulguration limits tissue destruction to a shallow area under the spark and is normally characterized by an eschar.

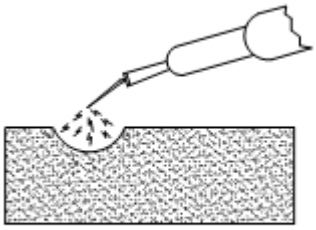


Figure 8: Fulguration

• Application - Factors such as power, treatment time, electrode size and the moisture content of the tissue influence the area and depth destroyed with one application. Additionally, the distance between the electrode and the tissue is important.
• Post-Operative Care - Same as desiccation.
• Healing - Same as desiccation.

Coagulation
Coagulation derives from the Latin word “coagulare”, meaning to clot. As seen in Figures 9 and 10, there are two types of coagulation:
Monoterminal Coagulation - Uses the dispersive patient plate (also called a “return electrode” or an “indifferent electrode”) as seen in Figure 9.

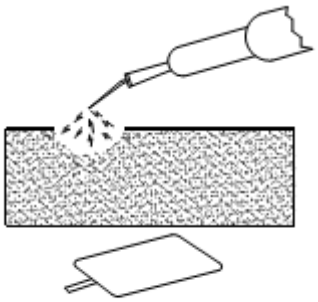


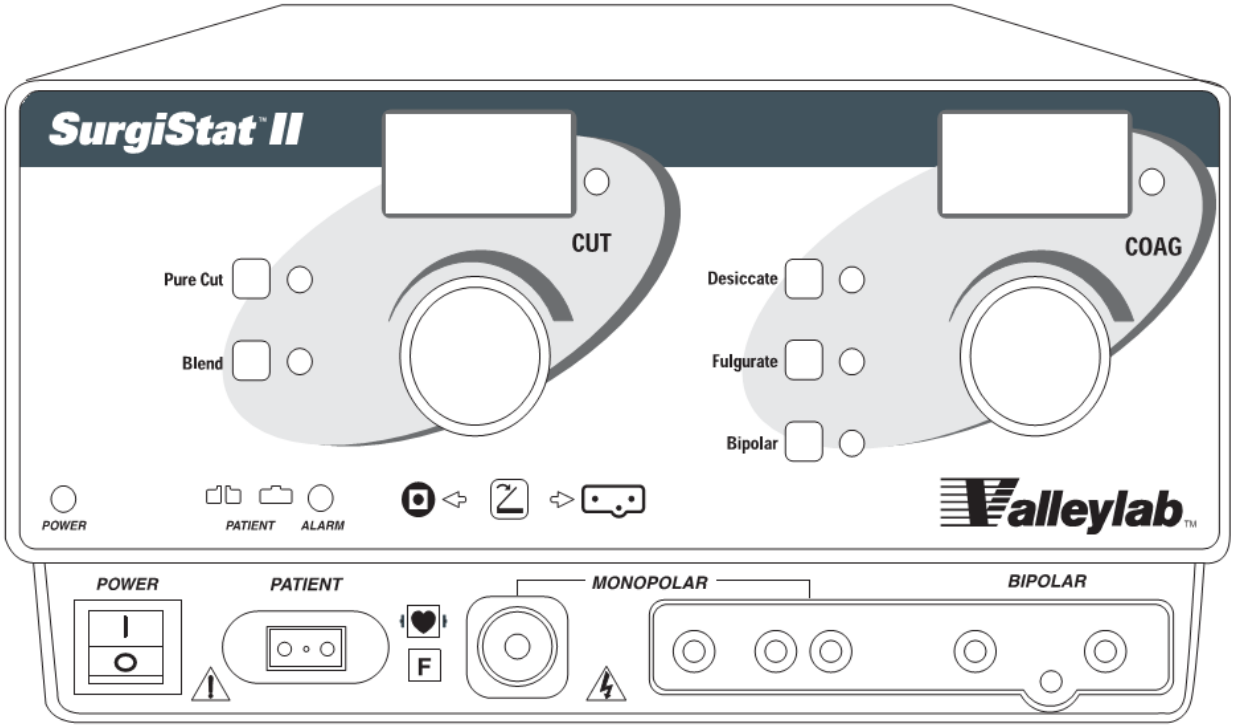
Figure 9: Monoterminal Coagulation

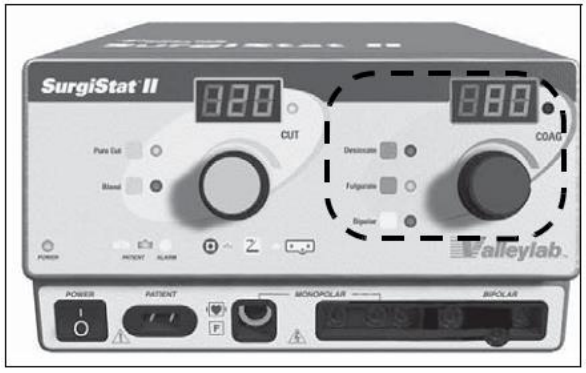
The second chosen electrocauter that is technically very similar to the Hyfrecator 2000, is model Surgistat II which also has a European certification. It is an American manufacturer with a long-year tradition with a European representative. We compared monopolar fulguration and monopolar desiccation at the applied power 1 – 3 W.

As these are relevant electrocauters with a number of clinical studies especially for the applications with a low power, the method of electrodessication and electrofulguration known in electrosurgery for decades are applied. We state a detailed description:

Valleylab – Surgistat II
CE 0086
Manufacturer Valley lab, division Tyco Healthcare Group LP
USA
European representative:
Tyco Healthcare UK Ltd, Gosport

P0AS130, UK


SurgiStat II
CUT
COAG
Pure Cut
Blend
Desiccate
Fulgurate
Bipolar
POWER
PATIENT
ALARM
Valleylab
POWER
PATIENT
MONOPOLAR
BIPOLAR
F



Desiccate Indicator
Illuminates when Desiccate mode is selected.

Desiccate Selector
When pressed, selects the Desiccate mode.

Fulgurate Indicator
Illuminates when Fulgurate mode is selected.

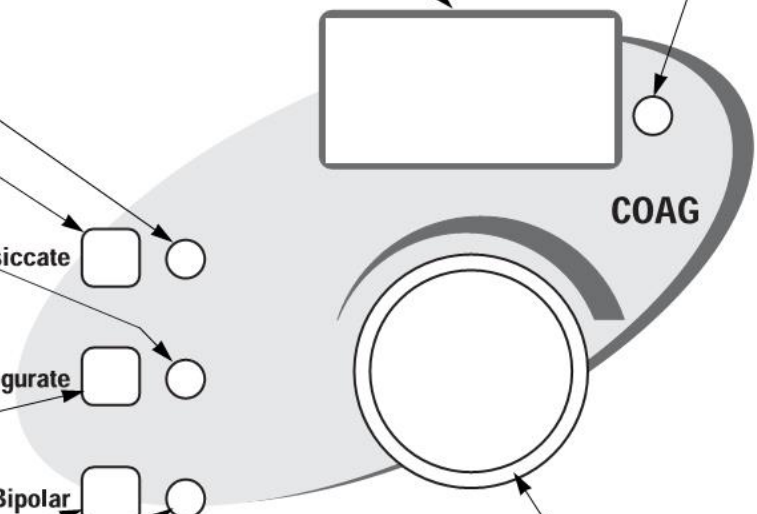
Fulgurate Selector
When pressed, selects the Fulgurate mode.

Bipolar Selector
When pressed, selects the Bipolar mode.

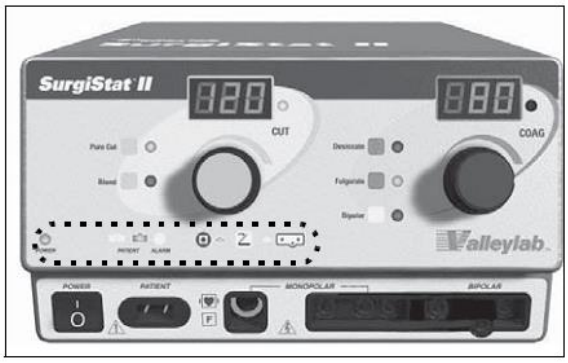
Bipolar Indicator
Illuminates when Bipolar mode is selected.

Coag and Bipolar Power Display (watts)
Indicates the power set for any Coag or Bipolar mode.

Coag and Bipolar Activation Indicator
Illuminates when Desiccate, Fulgurate, or Bipolar modes are activated.



Coag and Bipolar Power Control Dial
Increases or decreases the Coag or Bipolar power output in increments of one watt.



Bipolar Footswitch Control Indicator and Symbol
Illuminates when bipolar foot control is selected.

Patient Return Electrode Alarm Indicator
Illuminates when the system detects a patient return electrode alarm condition.

POWER *PATIENT* *ALARM*

Power Indicator
Illuminates when the unit is on.

Split-Plate Patient Return Electrode Indicator
Illuminates when the system detects a split-plate.

Single-Plate Patient Return Electrode Indicator
Illuminates when the system detects a single-plate.

Monopolar Footswitch Control Indicator and Symbol
Illuminates when monopolar foot control is selected.

Footswitch Control Selector
When pressed, switches between monopolar and bipolar foot control.

Setting Up

1. Verify that the generator is off by pressing the power switch Off (O).
2. Place the generator on a stable flat surface, such as a table, platform, or Valleylab cart. Carts with conductive wheels are recommended. For details, refer to the procedures for your institution or to local codes.

Provide at least 10 to 15 cm (4 to 6 in.) of space from the sides and top of the generator for cooling. Normally, the top, sides, and rear panel are warm when you use the generator continuously for extended periods of time.

3. Plug the generator power cord into the AC Power Cable Receptacle on the rear panel.
4. Plug the generator power cord into a grounded receptacle.
5. Turn on the generator by pressing the power switch On (|). Verify the following:

• All visual indicators and displays on the front panel illuminate.
• Activation tones sound to verify that the speaker is working properly.

6. If the self-test is successful, a tone sounds. Verify the following:

• A Cut mode is selected, and a Coag or Bipolar mode is selected.
• Each display shows a power setting. The unit automatically powers up to the most recently used power settings.

• The Patient Return Electrode Alarm Indicator illuminates red.
If the self-test is not successful, an alarm tone sounds. A number may momentarily appear in the Cut display and, in most cases, the generator is disabled. Note the number and refer to Troubleshooting, Section 6.
Once the self-test is successful, connect the accessories and set the generator controls. Refer to Preparing for Monopolar Surgery or Preparing for Bipolar Surgery later in this section.
Preparing for Monopolar Surgery
Applying the Patient Return Electrode
Monopolar surgery requires a patient return electrode.
Valleylab recommends using return electrode contact quality monitoring system (RECQMS) patient return electrodes to maximize patient safety. The REM system is designed to minimize the risk of burns at the return electrode site due to a reduction in patient contact area during monopolar electrosurgery. Using a patient return electrode without the RECQMS safety feature may result in a patient burn.

EVALUATION OF THE SOURCE RESEARCH

In the research, detailed in the publication JETT PLASMA LIFT MEDICAL (including appendix 2 and appendices – Preclinical evaluation), 7 articles – scientific publications - were chosen as relevant:

1. Comparison of potassium titanyl phosphate vascular laser and hyfrecator in the treatment of vascular spiders and cherry angiomas
Author: G. Dawn and G. Gupta
Department of Dermatology, Monklands Hospital,
Airdrie, UK
Published: 2003 – Blackwell Publishing Ltd.

Patients with vascular spiders or hemangiomas in exposed areas have often psychical troubles and they require their treatment. They are very often sent dermatological departments to manage their treatment process. These lesions in the exposed areas such as face and similar can be very unsightly and they may cause serious psychical problems. They are traditionally treated by electrosurgical interventions, for example by hyfrecator and very often also by laser interventions.

The aim of this study was to compare the efficiency of vascular laser and hyfrecator for treatment of these vessel lesions and to compare the patients´ satisfaction with the two ways of treatment.

Patients with two vascular spider or two hemangiomas were included into the study. Pictures of the state before the treatment were taken and patients filled in a questionnaire focused on psychical problems. One vascular spider or hemangioma was randomly chosen for the treatment with hyfrecator, the other one for the treatment with vascular laser.

Hyfrecator was set to 2 – 3 Watts, i.e. to the low power level. An immediate effect on affections was visible. Vascular laser was set to 16J/cm^2, the pulse length was 15 ms

and the diameter of the ray 3 mm. No anesthetics were used. Patients were treated 3 times in the time spans of two months. After 6 months, another pictures of both lesions were taken.

Outcomes

15 patients were treated altogether. Their medium age was 38 years. 13 patients had spider veins and 2 patients had hemangiomas. All lesions were in the exposed areas, mostly on nose. In the group treated by vascular laser, 5 affections were cured, another 5 got considerably better and 1 got slightly better. In the group treated by hyfrecator, 7 affections were cured, anther 3 got considerably better and 1 got slightly better. More affections were cured or got considerably better after the application of hyfrecator.

Most patients evaluated laser as the better one. In one case a hypertrophic scar appeared in the application spot after the application of hyfrecator.

Discussion

Hyfrecator was used for the treatment of spider veins and hemangiomas, because it is available at most dermatology clinics. It is stated that it is very effective for the treatment of minor vascular lesions, but it can potentially cause the occurrence of small scars. Vascular laser is available only at specialized centers and its use is still a relatively new way of treatment of vascular lesions. In this study, it was found out that both vascular laser and hyfrecator are effective for the removal of vascular lesions, however, the laser treatment requires less repetitions of the treatments.

2. **Surgical excision of extensive anal condylomata not associated with risk of anal stenosis**

Author: D. Klaristenfeld : S. Israelit: R. W. Beart: G. Ault:
A. M. Kaiser (*)
Department of Colorectal Surgery, Keck School of Medicine,
University of Southern California,
1441 Eastlake Avenue, Suite 7418,
Los Angeles, CA 90033, USA
Published: 12. 5. 2008

Surgical treatment of extensive convolutes of anal condylomata by extensive excisions is connected with a risk of anal stenosis appearance. The aim of this study is to assess this risk in case of patients who undergo extensive excisions and electrofulguration of anal wart.

Records of 41 patients (40 men and 1 woman) treated with extensive excisions and electrofulguration were evaluated. Data represent patients and the process of healing after interventions.

41 patients underwent excisions and electrofulguration to treat excessive anal condylomata with an average lasting of condylomata ranging from 1 to 36 months.

Most patients were HIV positive (97,6 %), 80% of them used antivirus treatment.

Half of the patients underwent no preceding treatment, a quarter of them already had preceding excisions or electrofulguration. 19 patients had relapsing condylomata. The bleeding after interventions was increased, however, there was no structure or anal stenosis.

Anal condylomata are one of the most common illnesses of HIV positive patients. There is a whole scale of therapeutic methods, ranging from surgical excision through application of trichloroacetic acid, liquid nitrogen, cytostatic or immunomodulators.

It is possible to cure a smaller extent of condylomata this was, however, extended condylomata are resistant to these methods. In such cases, surgical excision, electrocauterization or electrofulguration is more suitable.

The 41 patients had condylomata in last 5 years, patients with a small extent of condylomata were excluded from the research, just as the patients with anal cancer requiring radiochemotherapy.

Their average age was 33 years (20 – 49 years). Except for one, all of them were HIV-positive.

Their preceding treatments included podophylline, imiquimode, surgical excision, cryotherapy and interferone. 16 patients were treated more times in past.

Larger condylomata were removed by surgical excision, smaller ones by electrocauterization and electrofulguration. Lesions in anus and outside of it were removed. No other treatments were applied and clinical observation followed. In cases of two patients, carcinoma in situ without signs of invasive spreading was found.

There were 19 cases of relapse, bleeding occurred in 9 cases.

No complications of post-surgical healing or subsequent infections occurred.

None of patients reported subjective symptoms or objective findings indicating the occurrence of anal stenosis.

It was shown that the combination of surgical excision with electrofulguration is a very advantageous way to treat excessive condylomata. No complications and primarily no strictures or stenosis occur.

3. **A case of lymphangioma circumscriptum successfully treated with electrodessication following failure of pulsed dye laser**

Author: Jason Emer1 MD, Jaime Gropper1, Stephanie Gallitano2 BA, Jacob Levitt1 MD
1. The Mount Sinai School of Medicine, Department of Dermatology, New York, New York
2. The University of Illinois at Chicago, College of Medicine, Chicago, Illinois

Published: Dermatology Online Journal

Lympangioma circumscriptum is the most common skin lymphatic malformation. Its syndromes are mostly vesicles and lesions are often hemorrhagic and considerably painful.

We are dealing with a description of the illness that was at first cured by laser and then, very effectively, by electrodessication.

Lymphangioma circumscriptum was first described in 1879. It is one of the most common skin lymphatic malformation, when lymphatic vessels are widened in the dermis. Malign transformations are rare. The illness causes considerable subjective troubles. The symptoms appear in an early age already. The most common localizations are head and neck, then trunk, limbs and inner organs, Subjective syndromes are painful, itchy and burning and secondary infections occur very often.

This case was a 16 year-old female patient with manifestations on her right buttock, lasting from her early childhood, accompanied by strong pains and bleeding.

Biopsy showed dilatation of lymphatic vessels with an inflammatory infiltrate in its walls.

At first, the treatment was done by pulse dye laser in two sessions. Despite high values of laser setting, no clinical improvement occurred.

After that, the patient was treated by electrodessication. Three treatments were applied and there was a considerable improvement. 6 months after the application of electrodessication, the center was considerably smoothed, atrophic and violet color disappeared. The patient feels no pain and has no other troubles, and she is very satisfied with the outcomes of the treatment.

Another application of electrodessication or CO laser was offered to her. The patient refused another treatments. During the therapy major improvement of patient´s comfort was observed.

There are sources describing the treatment of lymphangioma circumscripta by CO laser, pulse dye laser and Argon laser. Their application is possible only with strong anesthetic applied, as it is very painful. After the application, scars, lasting redness and hyperpigmentation occur.

In our casuistic, in case of our patient, the application of pulse dye laser had no effects, despite its aggressive settings.

Also other treatment methods of lymphangioma circumscripta were described. Sclerotherapy, which is based on injections of ethoxyscelor into lymphatic malformations to destroy aberrant vessels. Also injections of corticosteroids, tetracycline, solutions of dextrose or hyperosmolar saline solutions were used with no major effect.

Liposuction was tested as well. It was presumed that suction of fat tissues would affect the sources of lymph in subcutaneous area. The effect was good, however, the treatment had to be done by a doctor trained in liposuction. Cryodestruction was also used, nonetheless, it showed no effect.

Electrodessication (hyfrecation) emits a low current of a high frequency and high voltage which leads to a protein denaturation in the application area. It is effective for smoothing and destruction of dilatations, and it decreases secretion, bleeding and pain.

4. An evidence-based review of medical and surgical treatments of genital warts

Author: Noah Scheinfeld JD MD 1, Daniel S Lehman MD2
1. St Lukes Roosevelt Hospital Center Department of Dermatology, New York NY. NSS32@Columbia.edu
2. Maimodides Medical Center Department of Urology

Published: Dermatology Online Journal

Human papillomavirus is a DNA virus surviving in human cells. It attacks cells of basal epidermis layer. More than 120 subtypes of HPV were identified. 30 of them attack genital epithelium. Some of them cause genital warts, others cervical dysplasia and spinocelular carcinoma. Infection caused by more HPV types may appear at the same.

Genital warts are transmitted by sexual intercourse in great majority of cases. Approximately 70% of people who had intercourse with an infected partner start suffering from genital warts. The incubation period ranges from 3 weeks to 8 months, in average 2 – 3 months. In last 35 years, its incidence increased, which may be caused by sexual intercourses in earlier age and increased number of sexual partners. An estimated prevalence of HPV infection in adult population in the USA is 10 – 20 %.

Genital warts occur in genital area, at groins, in anus and in oral cavity. They can be flat or resembling a cauliflower and their color can range from white, through red to brown.

Treatment methods and their evaluation

Podophylline

It is made of Podphyllum plan, it is not standardized, it is mostly solution. It is less effective than other treatment methods.

Podophylotoxin

It is an extract from podophylline, it has standard ingredient, it is in the form og gel, solution or lotion. It is preferred over podophylline.

Imiquimod

It is an immune response modifier. It is used in the form of lotions. It is applied 3 times a week for 16 weeks. The treatment time is very long. Women must take contraception before the use.

Surgical and destructive treatment

Electrosurgical method

It is used in local anesthesia. It is based on the method using DC current in the form of electrocauterization, in which electric current is transformed into heat destroying warts. Another form is use of an AC current device, which cuts the warts and coagulate them at the same time. The treatment lasts 3 – 6 weeks and the rate of success is 61 – 94 % of cases. In 14 – 22 % of cases, relapses occur. This is comparable to the application of laser.

Cryotherapy

Nitrous oxide or liquid nitrogen are used, which leads to the necrosis of warts. Application is done by an applicator or in the form of a spray. The advantage is in a simple use and destructive effect in the place of application, which is very desirable particularly in case of extended lesions. More treatments are done in the period of several weeks or months depending on the speed of healing.

CO laser

Its application leads to evaporation of warts tissues. It enables a precise targeting of the treatment, elimination of the virus and good cosmetic effect. The power settings range from 2 to 10 W. The treatment is more difficult and more expensive than electrosurgery or cryotherapy.

5. **Successful treatment of facial papules with electrodessication in a patient with birt-hogg-dubé syndrome**

Author: Pritchard, Sara E, Scott & White Memorial Hospital and Clinics
Mahmoudizad, Rod, Scott & White Memorial Hospital and Clinics
Parekh, Palak K, Scott & White Memorial Hospital and Clinics

Published: 2014 - Dermatology Online Journal

This is a case of 51 year-old female of a Hispanic origin who had lasting red-brown colored papulae on her nose and both cheeks, mainly in their centers. In a biopsy examination, it was found out that it is fibrofolliculomas and trichodiscomas. The patient underwent a genetic examination and a FLCN genetic disorder wa found out, which was confirmed by the Birt – Hogg – Dubé syndrome diagnosis. Then a UV examination of kidneys and a CT scan of abdomen and thorax was done, which did not show any damage of the examined organs. The first treatment was done by a dermabrasion, but there was no effect. Then the patient was treated by a hyfrecator set to desiccation of low power and she was very satisfied with the effects of the treatment. An important fact is that two years after the hyfrecator application, there was no relapse of the problem.

Birt – Hogg – Dubé syndrome was first described in 1977 as a syndrome including manifestations in face in the form of papulas, pulmonary cysts and kidney tumors. The numerosity of the aforementioned syndrome is not known yet and it is probably not precisely diagnosed, due to the variability of its symptoms. Diagnostic criteria for the diagnosis of the syndrome is one main criteria or two secondary criteria. The main criteria include:

1. Five or more adults with fibrofolliculas or trichodiscomas in family with at least one found histological finding
2. Pathological germinal line of FLCN mutation.

The secondary criteria include:

1. Multiple pulmonary cysts
2. Kidney carcinoma
3. 1st stage related with BHD syndrome.

Skin manifestations are often the reason for an examination genetic disorders, as it was in case of our patient. Skin lesions appear mostly around 20 years of age. The manifestations can be either on face, on forehead, neck or chest.

Biopsy examination found fibrofolliculomas and trichodiscomas in case of our patient. Genetic disorder FLCN was also found and it confirmed the diagnosis of the aforementioned syndrome. The sonographic kidney examination and CT scan of abdomen and thorax found no damage of the examined organs. The main problem of this patient were manifestations in her face, affecting mainly its appearance (cosmetic impression). Unfortunately, various ways of treatment of numerous papulae brought no improvement. Laser removal, curettage and cauterization are described in literature. The effects of carbon dioxide treatments and laser treatments were promising, however, after several months relapses of syndromes appeared.

The patient was first treated by dermabrasion, but it has only minimal effect. After that, the treatment was done by hyfrecator set to a low power and the patient was very satisfied with the effect. In the following two years, no relapse occurred. The hyfrecator treatment is simple, safe and attractive for its relatively lost, compared to other treatment methods and moreover no relapses occur. In addition to that, no complications in the form of pigmentation or scarring occurred.

6. Electrosurgery for the Skin

Author: BARRY L. HAINI'R, M. D. Medical University of South Carolina, Charleston, South Carolina
RICHARD B. USATINH, M. D. University of California, Los Angeles, UCLA School of Medicine

Published:

The article describes basic methods of electrosurgery with a special focus on electrodessication and electrofulguration. It defines their use for removal of surface lesions on skin and vascular lesions, predominantly hemangiomas and spider veins. The basis of the treatment is always removal of excessive tissues by electrofulguration and subsequent use of electrodessication. Electric resistance of human tissues converts electric energy used in electrosurgical applications into an effect in human tissue molecules. Both intracellulose and extracellulose proteins are denatured, which leads to coagulation and desiccation of tissues. Electrosurgery has numerous ways of applications in dermatology.

Electrodessication and electrofulguration – when electrode gets near or touches venectasia or spider nevi (vein anomalies). It is used if veins have less that 3mm in diameter.

Electrofulguration and electrodessication are monopole techniques of electrosurgery, when only ne electrode is used, whereas in case of electrocauterization, two electrodes are used.

Electrodessication and electrofulguration are used to treat these diagnoses (Chart 1 in the original):

Benign lesions-
fibtroma molle
haemangioma
naevus araneus
condylomata accuminata
molluscum contagiosum
naevi
granuloma pyogenicum
keratosis seborrhoica
venectasie
verrucae vulgares
verrucae planae

Pre-malign lesions-
actinic keratoses

Malign lesions-
basalioma superficiale

Contraindications of the use are pacemaker and melanoma.

Further, there is a CPT coding based on the size of lesions in Chart 2.

Chart 3 in the original represents preventions of complications in electrosurgery. Also advantages of electrosurgical applications considering patient´s comfort, safety, price of the devices for electrosurgical applications are describe here.
Another topic mentioned in the article is anesthesia used in electrosurgery. Mostly lidocaine and epinephrine are preferred. In Czech Republic, it is mostly Mezocaine and Supracaine.
Moreover, the applicable power of the discharge is focused on. It is very low (10 – 20 Watts). In another part of the article, there is a detailed description of electrosurgery for chosen diagnoses.

Hemangioma
It is mostly a cosmetic problem, as hemangiomas are benign. It is treated by electrocoagulation and electrodessication at the bottom of hemangiomas.

Granuloma pyogenicum
It is a strongly vascularized, benign tumor. In this case, mostly electrosection and electrocoagulation in local anesthesia is used.

Basocelular carcinoma
Excision by electrosection with subsequent electrocauterizaion in local anesthesia is used. In case of small carcinomas, it is possible to apply electrofulguration as well.

7. Monopolar and bipolar treatment

Author: Jack E. Sebben, M. D.

Published: 4. 4. 1989

Expressions monopolar, bipolar, monoterminal and biterminal are usually used for the description of high-frequency electrosurgery, where positive and negative poles are not defined. Electrical energy in high-frequency electrosurgery enters into tissues and excites through a treatment electrode. Instead of the term “polar”, the term “terminal” is used. The expression “monopolar” is used in relation to electrodessication and electrofulguration, electrocoagulation and section, where there is a low voltage and high current. Figures 1 to 3 show schemas of monopolar and bipolar electrodes with their installation and short description. The article depicts the differences between individual types of electrodes from the theoretical pint of view and from the point of view of their effect. It also describes the voltage and current rate for individual electrodes used in electrosurgery. It depicts the suitability of monopolar and bipolar electrodes for individual types of surgical methods and also the suitability of their shapes for individual surgical methods and interventions. Mostly hemangiomas and lymphagiomas are taken into consideration. Further the effect of monopolar and bipolar electrodes on tissues and also the range of the effect are described.

In this study, mostly the comparison of the HYFRECATOR 2000 device and the Surgistat II device was focused on at the end. These two devices have a large number of clinical data for comparison and moreover, they have the European certification. In both cases, the regime of electrodessication and electrofulguration was in the center of attention. Both devices are excited by AC current, i.e. the sequence of sparkle discharges is generated by AC current. Monopolar regime with a disperse electrode was focused on. The sequence of sparkle discharges generated by AC current creates a sparkle shower – the sequence of sparkle discharges creates a cone affecting a spot of minimal diameter of 5 mm, however, it is mostly the spot with a diameter bigger than 8 mm. Both devices, HYFRECATOR 2000 and Surgistat II, are capable to provide the treatments of indication identical with indication stated in the evaluation JETT PLASMA LIFT MEDICAL by electrofulguration, electrodessication and electrocoagulation at very low power settings.

In the preclinical evaluation of JETT PLASMA LIFT MEDICAL, there is a detailed description of the fact that a sparkle flow has a diameter of approx. 1 mm in case of excitation by DC voltage and therefore it treats only a very small application spot of approx. 2 mm^2. It means that the electrofulguration discharge is much thinner than those generated by compared devices - AC electrocauters excited by AC current,

which are able to treat the minimal spot of 25 mm^2, in many cases even 64 mm^2. Compared to the considered devices, JETT PLASMA LIFT is able to generate considerably thinner electrofulguration discharge and smaller spot of electrodessication in the contact with skin. Therefore, the surrounding tissues are only minimally damaged.

JETT PLASMA LIFT MEDICAL generates maximal power at minimal spot by continuous ray of electrofulguration. That is why it can reach similar effects as the compared devices from the comparison chart with a much lower output power. JELL PLASMA LIFT takes account of lasting negative experience with electrocauters and it automatically turns off, if any problems occur and it shows the message about the problem on its display.

A. Control of patients grounding – the system checks, whether the patient is conductively connected to the device by a self-adhesive electrode. If the electrode disconnects, the system turns off automatically and the message “TAPE” appears on the display. In past, patients were burnt it patients got disconnected.

B. Control of hardware malfunctions

If there is a hardware malfunction, the system turns off automatically and the display shows the message “SrvC”. The device can be turned on no more and it must be handed in to an authorized service.

Based on the aforementioned facts, it can be stated that the device has comparable and in some cases even better safety parameters compared to the considered devices, and it can therefore be considered safe.

Evaluation of the medical device:

The medical device is suitable for the use in the range stated in the original documentation of the device.
Based on the studied sources and known quality of medical devices in this field, it can be said that the product is suitable for clinical use in European Union by trained doctors well-informed about the known risks and advantages of sparkle discharge applications to the treated areas.

List of sources:

1. Jett Plasma Lift Medical; User manual
2. PlexR.http://www.gruppogmv.com/chirurgianonablativa/en/plexr-plexer-strumento-per-chirurgia-non-ablativa
3. PlexR.https://www.google.cz/search?hl=cs&q=plexr&gbv=2&sa=X&oi=image_result_group&ei=O77tVMLxDobkaLKmgng&ved=0CBQQsAQ&tbm=isch
4. PlexR. http://romedtech.de/produkte/plexr.html
5. Another sources are stated in appendices.

The list of used abbreviations, definitions and technical terms:

KH – clinical evaluation
MD – medical device
KHZP – clinical evaluation of medical device

Contents of the final report:

Name of the evaluated medical device
MD class
Code of the device category according to ČSN AN ISO 15225
Identification of the ordering party
Identification of the provider
Identification of the manufacturer
Name of the examiner, his qualification, work experience and permanent residence
Identification of assistant, his address
Date of beginning and end of the evaluation of MD
Plan of clinical evaluation of MD
Specified purpose of use of MD
Characteristics of MD
Description of the device
Evaluation of MD
List of sources
List of used abbreviations, definitions and technical terms
Contents of the final report
Number of pages, appendices and supplements
Date of the report completion
Stamp and signature of the ordering party
Stamp and signature of the provider
Signature of the examiner
Distribution slip

Number of pages: 27

The report was written by: MUDr. Miloš Kravciv

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