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The use of the radio surgical unit with the frequency 2,2 MHz for pathologies of the cervix

Methodical Manual

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This manual is for the use of the radio wave unit “radioSURG 2200” that has the working frequency of 2,2 MHz, that remains stable at all levels and the most delicate way for working on tissue, as the heating of the tissue in the incision area is minimized and allows for various interventions on the cervix, in the vagina and the outer reproductive organs, and ensures a good haemostasis result and high efficiency.

The radio wave surgery using the unit “radioSURG 2200” allows the performance as well as the ablation, and the excision of the affected area of the cervix to be carried out very gently and many complications can be avoided. The end result shows practically no alterations at cell level and the excised tissue can be used for histological examinations up to the edges.

Recently the radio waves unit “radioSURG 2200” has become very popular in the reconstructive pelvic floor surgery that allows for a practically blood-free dissection with minimal injury to the area outside of the cut.

The manual is intended for the mid-wife and gynaecologist, surgeons and oncologists.

Introduction

Cervix cancer is second place in the malignant tumours of the reproduction organs of women, the first place in life shortening of women and fourth place in the structure of oncological diseases of women in the world.
At present the viral etiology of cervix cancer is proven. Papillomavirus infection is one of the wide spread and socially important infections that are transmitted by sexual intercourse and that can cause carcinoma in the anogenital area. Cervix cancer is not a lightening process and its development takes up to 10 to 15 years after viral infection. Thus modern diagnostics and therapies of the premalignant pathology (the cervical intraepithelial neoplasia) are the major means in the cervix cancer prophylactics.
For diagnostics and therapy of the intraepithelial neoplasia, ablation and excision methods are used. Ablation and coagulation means destruction of the affected areas through electro, laser e.g. cryogenic exposure. A disadvantage of the ablation is the impossibility to examine the tissue pathologically. The excision procedure which guarantees the excised tissue can be used for further histological examinations includes scalpel and laser conization and procedures with an electrical loop (LEEP – Loop Electrical Procedure e.g. LLETZ-Large Loop Excision of the Transformation Zone).
Using the electro-surgical therapy methods with benign diseases of the cervix causes a series of problems, with the consequences

- The damaging effect of the electro current of the underlying tissue;
- The post-operative period scab bleeding;
- The deterioration of chronic inflammatory process in the tubes and ovarian areas;
- The syndrome “coagulated neck”;
- The trophic damaging in the underlying tissue with the local affect;
- The stenosis and stricture of the cervix channel;
- Scarring alteration of the cervix tissue;
- The relative increase in an operational childbirth according to the application of this method in relation to the pathology of the cervix (4,5)

Furthermore, there is a significant disadvantage of an electro-surgical therapy method for cervix pathology, as the tissue removed is of inferior quality due to the excessive thermal destruction. Also to be taken into consideration is that after diathermy coagulation of the cervix, an Implantation-Endometrioses develops with 46 – 55% of the patients. (3) The relapse frequency after the application of this therapy with the sick patients with benign diseases of the cervix is 55% (4).
Another frequently used therapy method in the cervix pathology is the high-energy laser beam (CO_2, Aragon, Holmium, Potassium, Titanium Phosphate – Laser). The fundamental impact of the Laser device causes heat development, and with the help of which, cut and coagulation of the tissue takes place. The disadvantage of the use of the CO_2 Laser with the treatment of benign diseases of the cervix is the overheating of the surrounding tissue and the larger area of the necrosis edges. On many occasions it is related to the fact that the temperature of the tissue in the cervix is increased as a result of exposure to the high-energy laser beam, which leads to an irreversible denaturation of the protein structuring (2,5,11). The application of laser vaporization against the background of inflammatory diseases slows the epithelialization of the wound area and the regeneration process is significantly deteriorated (9).Result analysis of histological examinations of the tissue condition after the effect of laser application shows that in the underlying tissue, firstly a primary necrosis with dehydration, compression deformation and vacuolization of the mummified tissue (1) occurs. Subsequently in the area of circulatory disorders a secondary dis-circulatory necrosis with a distinctive area of demarcation inflammation that with a transformation of the laser application area forms to scar tissue.

To summarize it is discovered, that the above mentioned is one of the main reasons to restrict this therapy method with benign diseases of the cervix in particularly formed with Nullipara.

One of the reasons the obstetrician and gynaecologists use the radio frequency therapy, is because the complete material removed with a histological examination is at disposal.
It distinguishes in principle in comparison to laser procedures and Cyro-destruction, where there is no material and from the electro-knife therapy in which the tissue is charred.

The new device “radioSURG 2200” operating in the MHz range allows for ablation as well as excision in the lesion area to be carried out to the gentlest extent possible.

In gynecology with the help of the device “radioSURG 2200” apart from surgery on the cervix, but also plastic surgery interventions for the reconstruction of the pelvic floor can be carried out.

Indication and contraindications for the use of the radio surgical device „radioSURG2200“

The radio surgical device can replace the scalpel, as the surgical interventions can be carried out without tension, pressure or, for example, movement of the tissue. Such a device is suitable for all types of surgeries, in particularly if it is necessary to make a very fine cut and bleeding is to be expected. One of the advantages of the radio surgery is the absolute sterile cut along the incisal edge of the electrode, which prevents spreading bacteria, which is possible with the use of a scalpel

Areas of Application for MHz Radio Wave Surgery:

1. Biopsy of the cervix, pathological formations of the vagina and the outer genital organs.
2. Loop excision, for example, cervix conisation with CIN and various other pathological types of the cervix.
3. Removal of the endometriosis heterotopias of the cervix.
4. Removal of polyps at the cervical canal and Portio Vaginalis.
5. Opening of a vagina cyst, vaginal prolapse
6. Removal of genital nevus
7. Removal of papilloma, condyloma of the cervix canal, the vagina and perianal areal
8. Excision of the granulation tissue in the area of the cervix, the vagina and perianal area.
9. Radio surgical therapy of the ectropium**,** deformation of the cervix.
10. Plastic surgery

Contraindications:

Medical contraindications

1. Inflammatory diseases of the cervix and the vagina, the internal genital organs.
2. Uterine bleeding of not identified etiology
3. Histological conformation of the malignant processes in the examination area
4. Cardio stimulator
5. Use of caustic or explosive materials

Technological contraindications:

1. If there is no suitable room for safety when using the electro-surgical equipment
2. There is no trained staff

Methods of radio wave surgery

The radio surgery method involves the use of radiofrequency energy to produce a “cold cut”, a cut with simultaneous coagulation and coagulation of the body tissue of humans.

What is radio frequency?

Radio frequency is the electrical current, that radioSURG 2200 device generates with 2, 2 MHz (2 200 cycles per second). The complete energy of 2, 2 million cycles per second is concentrated at the end of the electrode. As soon as contact with the tissue is made, the cell vaporizes. This happens, because the fluid in the cell expands, the cell explodes and vaporizes. The devices that work in the MHZ region do not add thermal injury to the surrounding area, as it has a quicker “Cutting”, or “Coagulation” effect. The electrode is only the conductor of the high frequency energy and does not become heated. It can be illustrated by an inflated balloon. The balloon does not burst when touched with an active electrode, because the heat disseminated when using the high-frequency waves spreads only into the inner tissue.

Advantages

1. Clean and clear operating field
2. Fast tissue regeneration
3. Working without pressure
4. Sterile operating field
5. No serious bleeding, even when working on fine vessels
6. Reduction of the risk of scarring

Advantages of radio surgery, that works in the MHz region:

1. Fewer sparks - no burning. The high frequency devices have incorporated induction generator electronic components, the lower electro-energy to maintain the lower electrical energy, which allows the reduction of the voltage peaks. With these devices the risk of an electric arc formation, which can produce a heat production to more than 1000°C is much lower. Consequently there are no side effects in the form of burns, necrosis or infection.
2. Voltage Control – The voltage of the radioSURG 2200 device can be regulated and stays in this relation stable during the application (deviations are only 2%). With thanks to the constant voltage level, clean cutting is possible, and the only difference from a cut with a scalpel is that the excised tissue can be histologically analyzed.
3. Minimal risk for injury through electrical current.
4. minimized resistance of the electric current

Special features of the radioSURG 2200 device

1. The working frequency of 2,2 MHz is stable in all stages and the most delicate for working with tissue, because the heating of the tissue around the cutting area is minimal. Ultimately there is practically no change on the tissue level and the excised tissue, up to the edges, can be histologically analyzed.
2. There is a linear control of the output power per Watt, meaning the number on the display fully complies with the performance value.
3. The adjustable depth of coagulation is in the region from 1 to 9 (Setting a higher level of coagulation causes a higher level of coagulation and a deeper penetration into the tissue). The higher the number for coagulation depth, the lower the performance comes from the device. The performance also depends on the load resistance, i.e. the electrical resistance

that the tissue produces. This load resistance depends on the type and tissue condition (Muscle, fat, moisture, discharges of the high frequency waves etc.) therefore the performance can be varied).

4. Controllable length of the coagulation impulses in the region between 0, 05 to 0, 45 seconds.
5. There are two hand pieces: one for cutting and one for coagulation. It is intended to save time for the doctors, as no time is lost to change the application parts, but only change the handles.
6. All hand pieces and electrodes are re-usable.

Description of the radio wave device radioSURG 2200

The radio surgery device radioSURG 2200 (Meyer-Haake GmbH Medical Innovations, Germany) is intended for cutting, excisions and contact coagulation of various pathological formation with the aid of the 2,2 MHz frequency. The device is compact and easy to use. The choosing of the functional mode of the device and the power control is done by the control buttons that are on the front panel. The activating of the function of the device is done by a foot pedal and the button on the electrode handle.

Operating Mode of radioSURG 2200

The high frequency radio wave device radioSURG 2200 had five operating modes:

Cutting:

The cutting mode allows for the finest and the smoothest of cuts, whereby the healing process is the fastest. This mode makes for a better result as with the use of a scalpel. When using this waveform a vaporization of only a few cell layers takes place as it produces the least lateral heating. The excised tissue made in this mode can be histologically examined.

1. Cutting and Coagulation:
   The cutting and coagulation current of the fully rectified wave allows for the simultaneous cutting and coagulation without necrosis. The coagulation process is so delicate, that only a thin whitish layer of coagulation tissue is visible.
2. Coagulation
3. Bipolar Coagulation
4. Bipolar Coagulation with Automatic Switch-Off

The coagulation level is in the region between 1 and 9, adjusted according to the situation. Heavy bleeding – higher level of coagulation, minor bleeding – a lower level of coagulation.

The impulse coagulation is something completely new for hemostasis. As a result of impulse coagulation, the high-performance power can be conducted for a limited time (setting in the region of 0, 05 to 0, 45 seconds) causing an immediate protein precipitation and sealing of the wound. In comparison to tissue, that has necrotic edges, there is a lesser possibility of the wound re-opening.

Electrodes for Gynecology

No.01 – Loop 17 x 15 mm, total length 145mm
1 Electrode ELGYN001
Gynecology electrode for excision

No.02 – Loop 10 x 10 mm. total length 145mm
1 Electrode ELGYN002
Gynecology electrode for excision

No.03 – Loop 15 x 15 mm. total length 145mm
1 Electrode ELGYN003
Gynecology electrode for excision

No.04 – Loop 20 x 15 mm. total length 145mm
1 Electrode ELGYN004
Gynecology electrode for excision

No.51 – Total length 100mm
ELBALL51 Gynecology electrode for excision
Ball electrode for coagulation

No.35 – Fine Wire
Bendable electrode, total length 128mm, loop diameter 9mm
ELHNOS35 long loop electrode

No.34 – Ball electrode, total length 100mm. Ball diameter 2,3mm.
ELHNOK34 Ball electrode

No.32 – Needle electrode, total length 100mm.
ELHNON32 Needle electrode

BIO-CONE Electrode
Electro-knife

Modern Diagnostic Methods for Cervical Diseases

The pathology of the cervix is like an iceberg: only one insignificant part of the process lies on the surface and can stay undetected with a mirror examination (L.G. Kloss 1987). A routine examination in reflection does not allow by far establishing pathology.
The Diagnostic Principles:

1. Compilation of medical history, general and gynecology examinations.
2. Cytological Method. The efficiency of this examination method, in the opinion of various authors fluctuates between 79,2 to 96,3%. The effectiveness of this method depends on the quantity and quality of the material and qualification of the cytologist. The cytological method is not the perfect method; the error ratio is between 5 to 40%, beginning with the harmless viral proliferation up to the real cancer precursor.
3. Extended colposcopy
4. HPV-Test (Papilloma viruses) (quality and quantity). At present the polymerase chain reaction, PCR, is the most popular method for the HPV-Test. Digene Hybrid Capture II is the method for the quantitative HPV Test.
5. TruScreen
6. Examination for urogenital infections: Microscopy of the smear test, sowing of conditional pathogenic flora (medium inoculation).
7. Through sexually transmissible PCR infection diagnostics.
8. Histological examinations of a cervix biopsy and the curettage of the mucous membrane of the cervical canal.

Biopsy of the Cervix

A biopsy of the cervix – is an intra-vital removal of a small volume in the vagina area of the cervix for microscopic analysis for the purpose of diagnosis. The aim of the biopsy is in the morphological verification of the suspected clinical diagnosis. A targeted biopsy is performed from sites with abnormal colposcopy features.

Indications:

1. Abnormal colposcopy features
2. Poor colposcopy HPV features in combination with highly oncogenic HPV types
3. With abnormal findings of a cytological analysis (LSIL, HSIL) eg: a cytogram, that corresponds to the class 3-5 PAP Tests.

Contraindications:

1. Acute inflammatory diseases
2. Pronounced coagulopathy

Curettage of the cervical canal is recommended in the following cases:

1. CIN with a biopsy of the ectocervix
2. After removal of polyps in the cervical canal
3. A visually noticeable pathology , with spreading into the cervical canal
4. With abnormal findings of a cytological analysis of the cervical canal (LSIL,HSIL)
5. In case of an unsatisfactory colposcopy in connection with HPV and/or abnormal cytological findings
6. Therapy control (when suspecting a relapse)

Methods:

After an examination and the exclusion of contraindications under aseptic conditions with a local anesthetic, the cervix comes to light in the mirror, a colposcopy and a targeted biopsy is carried out. This method, as mentioned above, is better performed with a radio wave loop electrode.

Excision Methods:

The most widely used method for CIN therapy is the loop electro excision (LEEP,LLETZ), that resection of the abnormal tissue with a fine wire-loop of various forms and sizes for the removal of a part of the cervix is possible.

The radio wave method is the most acceptable, as it allows for a histological analysis of the complete removed tissue. The removal of the pathological parts with the radioSURG 2200, that works in the 2,2 MHz range, that remains stable in all modes, is the most delicate frequency for working on tissue, as the heat production within the cutting area is minimized. The end result, there is virtually no change at the cell level and the excised tissue can be used up to the edges in a histological analysis.
It is important to remove the transformed area in one block, as a removal with more fragments can cause difficulty in the pathological appraisal, and in the case of a micro invasive disease, the assessment of the exact invasion depth or the completeness of the excised tissue with a fragment is impossible. Thanks to a unique radioSURG 2200 BIO-CONE Electrode with a fixator for the protection shift during the procedure is an excision in one block, even by an aspiring gynecologist can be easily carried out. With the help of the various

sizes of the BIO-CONE electrodes, an individual treatment can be carried out and achieve accordingly better results.

Reconstructive Operations on Organs of the Pelvis Minor

In Russia 15 – 30% of women, have a prolapse of the vaginal and cervix wall and for women over the age of 50 the frequency increases up to 40%. For women of an advanced age the genital prolapse increases to 50% to 60%.

At present for the reconstructive surgery of the pelvis, both synthetic endoprosthesis, as well as the patient's own tissue is used.

Every surgeon strives, to operate with an efficient and safe method. And this is not surprising, as every surgical intervention is connected with to risk of complications both during the operation and the post-operative period. One of the most important conditions for the success of an operation is the bloodless severing of tissue with minimal damage behind the cutting line. Such methods of the tissue dissection and hemostasis such as electro-surgery, laser, plasma and ultrasound have a number of disadvantages. The main negative consequence is the extensive area of the coagulative necrosis. This factor not only prevents the normal reparative course, but is also a reason for the development of post-operative complications.

Recently the"radioSURG 2200" radio wave device is the most popular. It has unique features:

- very fine and exact cut
- minimal traumatisation of the tissue by cutting;
- pain syndrome is significantly less, both during the operation as well as in the postoperative healing period;
- Dry and clean operation area, which leads to a good tissue coagulation ;
- The healing process of the post-operative wound is quicker, the scar formation is very accurate;
- The post-operative complications are lowered by the bactericidal influence of the radio waves;
- With the surface influence a fibrin layer is formed, under which the wound healing practically without complication or relapse takes place.

The effects referred to are also economically convenient for the use of the radio wave knife: There is a shorter operation time and also a shorter stay in hospital for the patient.

Research Results:

The research took place in the State Clinic No. 7 on the clinical basis of the Chair for Obstetrics and Gynaecology of the faculty for Paediatrics at the Pirogov Russian National Research Medical University (Head of Department – Member of the Russian Science Academy, Prof. G.M Savel` eva (ISO 9). 86 patients between the ages of 27 to 58 years took part. Indications for conisation of the cervix and the results of the cytological examination of type LSIL and HSIL are valid (Classification according to Bethesda-Classification). According to the type of energy used for the excision on the cervix, the women were divided into four groups at random. There were 26 patients in the first group that were treated with the "radioSURG 2200" (Germany) device, that works in the 2, 2 MHz region in monopolar cutting mode C3 – C4, with 60-70 Watt power with a BIO-CONE electrode. In the second group of 23 patients, the radio wave device "Surgiton" (USA) was used, with the frequency 4,0 MHz in

“mixed” mode with 38-40 Watt power. The third group consisted of 19 patients, where the excision of the cervix was made with the high frequency device “Fotek” (Russia), using 440 KHz frequency in “mixed” mode with 38-40 Watt power. An electro- diathermic excision was made on the fourth group of 18 patients. The tissue removed from all patients was histologically examined.

Results: The device radioSURG 2200 proved to be the most convenient as it had a unique BIO-CONE electrode that protected any deviation in the procedure. It was easy and simple to make an excision in one block. The excision of the cervix done by “Fotek”, “Surgiton” and the electro-knife were carried out with the help of an electrode. The technologies were comparable. According to subjective perceptions, the least smoke exposure was with the device from “Fotek” and the greatest smoke exposure was with the electro- diathermic excision. When using radio surgery and the high frequency technology we have observed the following: there was no carbonized black scabbing, and in most cases there was no additional effect to the hemostasis of the cervix. There was no great wound excretion or pain in the early post-operative period. After the application of wave methods healing of the cervix is a week quicker.

The performed morphological comparative analysis for research of the resection margins of the tissue of the cervix shows that the best results were achieved with the ”radioSURG 2200”. Thereby there were microscopically minimal post-coagulative alterations detected to the edges of the resected tissue and no artificial alterations to the complete areal of the histo-specimen. A larger area of coagulative necrosis was when using the devices “Surgiton” and “Fotek”. The deepest of the tissue injuries appeared in the application of the electro-diathermic excision.

Conclusion: Thus, the removal of the pathological area using the device radioSURG 2200 with 2,2 MHz frequency, that stays stable in all stages, is the most delicate method for working on tissue, as the heating of the tissue is minimal around the cutting area. The results show practically no alterations on the cell level and the excised tissue can be histologically examined up to the cut edges.