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Clinical use of a new electrocoagulation plasma instrument

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Clinical use of a new electrocoagulation plasma instrument

The purpose of this work is to evaluate the efficacy and safety of the electrocoagulation plasma Onemytis in some surgical applications, and its influence on tissue healing. Onemytis is an electro-thermo-coagulation-ablation device with Airplasma technology which transforms the air column between the tip of the handpiece and the tissue in a conductor allowing to cut even without direct contact. The temperature of dissipation of tissue is 50 ° C.
The first phase of the study focused on three cases of mastectomy in which it was compared the histologic appearance of severed skin with three different methods, cold knife, surgical plasma Onemytis and radiosurgical Ellmann, in order to assess the effect on tissues. The second phase of the study, positively overcome the first stage, consisted in the use of the device in different plasma routine surgical procedures. The considered parameters were the cutting speed, the effectiveness of coagulation and the influence on the tissue healing until the removal of the skin suture and again a week later, and the possible intra and post-operative complications.
The histological examinations performed in three cases of mastectomy have shown the absence of necrosis in the incisions with cold blade, moderate necrosis in those performed with plasma bisturi and severe necrosis in those with radiosurgical. The clinical study with plasma bisturi involved other 19 dogs and 3 cats. The dogs were aged between 6 months and 13 years, the cats from 4 to 9 years. The device has been used for skin incision for laparotomy (8 cases), excision of benign skin tumors (4 cases), neoplasms of the oral cavity (3 cases), staphyloplastic (2 cases), cystostomy (5 cases). In all cases, the incision was made with good bleeding control, with times and healing mode comparable to those obtained with cold- knife for the skin incisions. In a single case there was a delayed healing for irritation by licking.
The Onemytis device has proven to be an effective and safe tool due to low tissue temperature dissipation. In surgical applications in which has been used it has allowed to obtain net cutting surfaces with good control of bleeding and without alteration of the healing times. The use in the visceral parenchymal surgery needs further study even if in our preliminary experience has proven effective and sufficiently delicate execution of cistotomy.

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Introduction

The most widely engraving tool used in surgery is the scalpel (cold knife). However, the incision with a blade, while being accurate and fast, tends to result in bleeding which can hinder and slow down further prosecution.

The main limitation of all electrosurgey and radio scalpel devices, and also of the surgical laser is given by the thermal damage developed at the tissue level, with temperatures of 100 ° C and more.

Since the early decades of the '900, with the insight of William T. Bovie[1], we have witnessed the birth of electrosurgery with the development of devices more and more precise and effective that would allow cutting and at the same time coagulation.

Fig.1 - Onemytis device with sterilizable handpiece

The main limitation of these devices (electro and radio- scalpels) is given by the heat generated at the tissue level with corresponding thermal damage[2,3].

The thermal damage is defined as an uni-molecular reaction where the tissue proteins irreversibly change from their native ordered state to an altered state[4]. Since the extent of thermal damage, which can vary from a reversible to irreversible tissue inflammation or tissue necrosis, is proportional to the temperature reached in the tissue level cut, the decisive heat dissipation is produced by the elettrocoagulation[2,3] tool. The electrosurgical unit, constituted by a radiofrequency current generator (from 300 kHz to 5 MHz), from an active electrode which conveys the current produced at the tissue and from a neutral electrode which has the function of collecting the current closing the circuit, causes a stilling temperature transmitted to the tissue of 100°C and beyond[3]. The main limitations of this device, in addition to the high temperature dissipation, relate to the safety for the patient.

The neutral electrode must adhere well to the patient's skin to prevent the output current, concentrated on a too small area, determines also an evident burn[3]. Despite using the same principle of operation, they are called radiosurgical tools that use frequencies above 3 Mhz[5]. Also these cause the tissue to a transmitted dissipation temperature of 100°C and more, but the greater wave frequency enables a reduction in the risk of burn injuries in case of neutral electrode badly positioned

Another limitation regarding the traditional electrosurgery is the neutral plate which, if not properly placed, could cause skin burns.

and a high concentration of energy in a very small point of 'active electrode, thus allowing a more precise cut. Laser surgery uses a physical

and optical sophisticated system that allows transmitting and amplifying electromagnetic (light) monochrome radiation that allows a very precise cutting with simultaneous coagulation[4].

The plasma scalpel acts via the air processing in a conductor of energy due to the high voltage pulse generation, acting also without direct contact with the tissue, through the column of interposed air and not exceeding an average temperature of dissipation of 50 ° C.

The surgical Laser usage limits are once again given from the dissipation temperature transmitted to the tissue (100 °C and more) and by the need to comply with certain safety rules for the patient and the operators (avoid contact with oxygen and alcoholic substances, smoke extraction system, protective glasses)[4]. A further incision-coagulation system is the use of an argon gas flow (Argon beam coagulation) which allows to obtain a monopolar coagulation in the absence of direct contact. The electrode tip, embedded in the handpiece, is activated and the generated energy is transmitted through an argon gas flow. The gas captures electrons from the electrode and submits them to the tissue, while the gas flow removes blood and debris from the surgical field, producing a uniform surface coagulation. The potential complications of this system include the risk of gas Argon embolisms, particularly if used in laparoscopic[5,6] surgery.

Onemytis is an electro-surgery plasma device *(Fig.1)*. The technology on which it is based is called Airplasma and consists in the transformation of air in an energy conductor due to the generation of high voltage pulses through a high-frequency sine wave oscillator. In this way the device can also operate without direct contact with the tissue using the air column interposed and not exceeding an average temperature of 50°C[7] dissipation. The plasma scalpel already has a use in human medicine with several publications that have highlighted the advantages on the conventional electrosurgicals.[8-14] The purpose of plasma electrocoagulation is to allow cutting and coagulation in an effective way without altering the tissue healing. The aim of our study was to evaluate both the effectiveness of the electrocoagulation system and its effect on the tissues in a veterinary clinical series, through histological and clinical analysis, based on similar studies in human medicine.[8-14]

Materials and methods

The study was held at the Veterinary Clinic Vezzoni MDL, using the plasma device Onemytis. The instrument is made by the central unit with intensity adjustment commands from 0 to 100, sterilizable handpiece in the autoclave, from the needle tip and from the dispensing pedal. The study took place in two phases, the first to evaluate the histological effect on the

Phase 1 of the study: to perform a comparison between the cut with a cold knife, Ellman radiosurgical and Onemytis plasma device with biopsy in cutaneous incision to mastectomy performed on three dogs and histological examination to assess the degree and extent of istolesivity.

N°	Species	Race	Sex	Age	Surgery	Power	Cutting speed (mm/sec)	Bleeding	Healing	Complications
1	Dog	Crossbreed	F	8 a.	Laparotomy	70%	10	0	Complete	No
2	Dog	Labrador	F	10 a.	Laparotomy	70%	10	0	Complete	No
3	Dog	Border Collie	F	9 a.	Laparotomy	70%	10	0	Complete	No
4	Dog	Labrador	F	5 a.	Laparotomy	70%	10	0	Complete	No
5	Dog	Bouledogue	F	13m.	Staphyloplastic	70%	7	1	Complete	No
6	Dog	Crossbreed	F	6 m.	Laparotomy	70%	10	0	Complee	No
7	Dog	Boxer	F	7 m.	Epulis excision	50%	10	0	Complete	No
8	Dog	Golden	F	6 a.	Cistotomy	50%	10	0	Complete	No
9	Dog	Labrador	M	11 a.	Pharyngeal melanoma excision	50%	8	0	Complete	No
10	Dog	Crossbreed	F	8 m.	Laparotomy	70%	8	0	Complete	No
11	Cat	European	F	4 a.	Cistotomy	50%	10	0	Complete	No
12	Cat	Barbone Toy	M	6 a.	Excision of benign cutaneous neoplasm	85%	7	0	Complete	No
13	Dog	Bulldog	M	18m.	Staphyloplastic	70%	7	1	Complete	No
14	Dog	Cocker	F	11 a.	Pharyngeal melanoma excision	50%	8	1	Complete	No
15	Dog	Crossbreed	F	6 a.	Excision of benign cutaneous neoplasm	70%	8	0	Complete	No
16	Dog	Cocker	F	1 a.	Laparotomy	70%	10	0	Complete	No
17	Dog	Labrador	F	2 a.	Laparotomy	70%	8	1	Delayed	Licking
18	Cat	European	F	9 a.	Cistotomy	50%	10	0	Complete	No
19	Dog	Crossbreed	M	6 a.	Cistotomy	50%	10	0	Complete	No
20	Dog	German shepherd	F	7 a.	Excision of benign cutaneous neoplasm	85%	7	0	Complete	No
21	Cat	European	M	6 a.	Excision of benign cutaneous neoplasm	75%	8	0	Complete	No
22	Dog	Hound	M	11 a.	Cistotomy	50%	7	0	Complete	No

Table 1

cutting surface, the second on the clinical use once obtained an adequate response by the histological examination of the cases of the first phase.

Phase 1: In order to preliminarily evaluate the effect on the tissues, there have been identified 3 cases of mastectomy in which, with the informed consent of the owner, the skin incision was divided into 3 parts using 3 different methods of cutting: cold knife, Onemytis and radiosurgical Surgitron FFPF EMV Ellmann with fully rectified waveform (cut / coagulation mode).

Phase 2 of the study: clinical application in surgical routine soft tissue, both in the skin, and in the oral and visceral mucosa.

From the 3 different parts have been taken some samples to the adjacent skin of the excised tissue cutting surface. The skin biopsies were fixed in 10% buffered formalin, and sent to a veterinary laboratory where they were routinely processed, embedded in paraffin, cut into 5 micron thick sections perpendicular to the cutting surface and stained with hematoxylin-eosin.

Histological analysis of biopsies showed the absence of necrosis in the incisions with cold blade, moderate necrosis with scalpel incision with plasma and severe necrosis with incision with a radio scalpel.

The histological samples were subsequently observed under the microscope by a pathologist unaware of the type of sampling carried out for the various samples. Histological analysis was aimed at assessing the presence and extent of necrosis on these tissues. Depending on the thickness of the tissue involved by necrosis detected was assigned a value of the damage that shall be equal to: absent, slight, moderate or severe.

Phase 2: on the basis of histological results which could highlight an istolesivity equal to or less than that of the radiosurgical commonly used in our clinic, it has been programmed to use Onemytis in several routine procedures

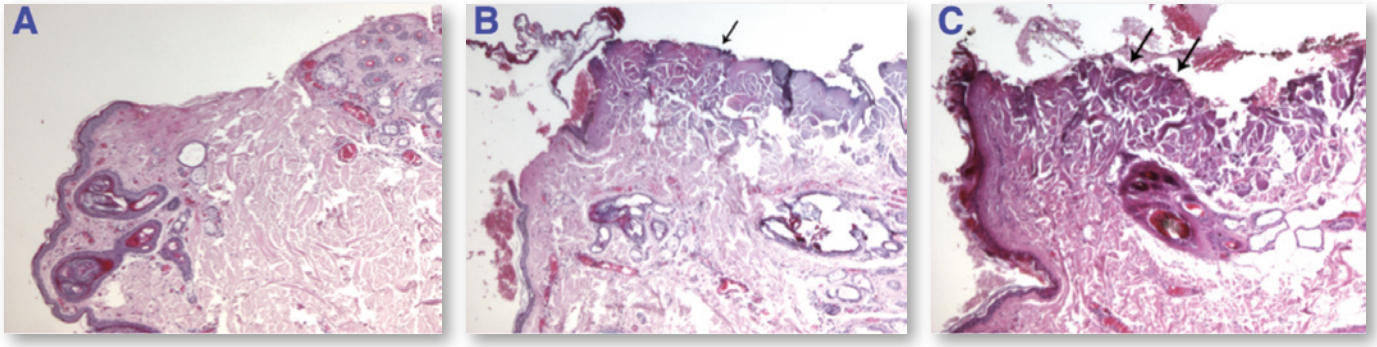

Fig.2, A-B-C - Skin: histology of acute damage caused by the use of cold blade (A), from plasma scalpel Onemytis (B) and radiosurgical Ellman (C). There are areas characterized by the loss of the edge of the cell of the dermal collagen fibers and epithelial keratinocytes (necrosis) near the section in FIGS margin B and C (the arrows). The thickness of the necrosis in the area of coagulation is greater in the incisions from radiosurgical (C) than from plasma scalpel incisions (B). There are no areas of coagulative necrosis in the incisions made with the scalpel blade (A). (hematoxylin-eosin, 50X).

concerning the surgery of soft tissues, evaluating the cutting speed , the effectiveness of coagulation and the influence on the tissue healing in post-operative up to a week after the removal of the skin suture.

The evaluation of the bleeding, on visual basis, was ranked from 0 to 3 where the value 3 is attributed to bleeding consequent to the use of cold blade *(Table 1)*.

On the basis of the manufacturer's directions, Airplasma was used with a medium to high intensity (about 70% of maximum power) thin and delicate tissues, with the possibility of increasing the power operating on thicker and less sensitive tissues (for example the skin of the head), bearing in mind that increasing the power is better to reduce the time of contact with the tissue to avoid excessive istolesivity.

Results

Phase 1: In the study were included 3 dogs undergoing mastectomy with comparative study between incision with cold blade, radiosurgical and plasma scalpel. The tissue damage region was recognized as an area of eosinophilic to slightly basophilic with loss of cellular detail of the dermal fibrocytes and loss of the fibrillary appearance of the collagen. The overlying epidermis was characterized by a full-thickness necrosis of keratinocytes and the stratum corneum. The histological examinations performed on these three cases showed absence of necrosis in the incisions with cold knife, while the extent of the tissue damage was assessed as moderate in those carried out with plasma scalpel and severe in those performed with surgical units *(Fig. 2)*. The examination at the time of removal of sutures showed proper healing of the wound incision in all three areas, no major differences. These results have allowed us to move forward with Phase 2 of the study.

Phase 2: the clinical study with plasma device involved 19 dogs (excluding the three cases of mastectomy of phase 1 of the study) and 3 cats *(Table 1)*. The dogs ranged in age from 6 months to 13 years, the cats from 4 to 9 years. The device has been used in skin incisions for laparotomy *(Fig. 3, 8 cases)*, excision of tumors of the oral cavity *(Fig. 4, 3 cases)*, excision of benign skin tumors *(Fig. 5, 4 cases)*, staphyloplastic *(Fig. 6, 2 cases)*, cystostomy *(Fig. 7, 5 cases)*.

The cutting speed was good, although obviously lower than that with cold knife, from 7 to 10 mm per second.

All procedures have been completed and found no intraoperative complications.

The intraoperative bleeding, on a scale from 0 to 3, is equal to 0 to 1 in 18 cases and in 4 cases. The post-operative evaluation showed proper healing of all the incisions of the oral cavity and of all the skin incisions with the exception of a case of laparotomy, in which there was a delayed healing due to licking of the wound. The 5 cases of cystotomy have had an uncomplicated course and healing cystotomy was confirmed via ultrasound and urine analysis after 12 days.

The most interesting application is that of the oral cavity where surgery has allowed to obtain precise incisions and a good control of bleeding.

Fig.3 - A - skin incision for laparotomy; **B** - follow-up to 14 days

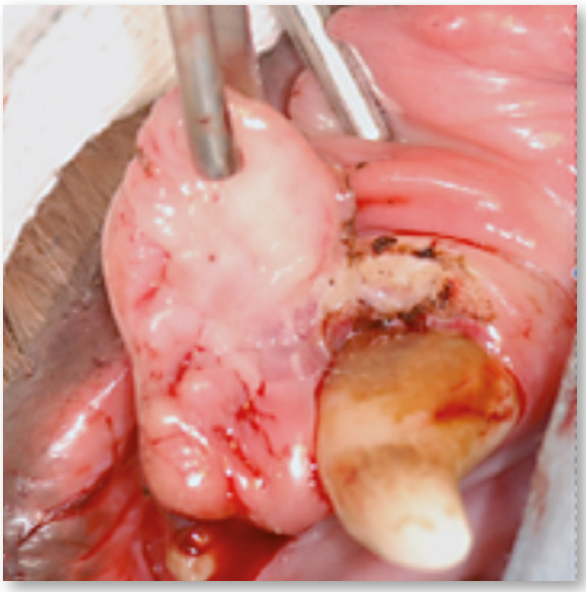

Fig.4 - removal of a benign gingival tumor

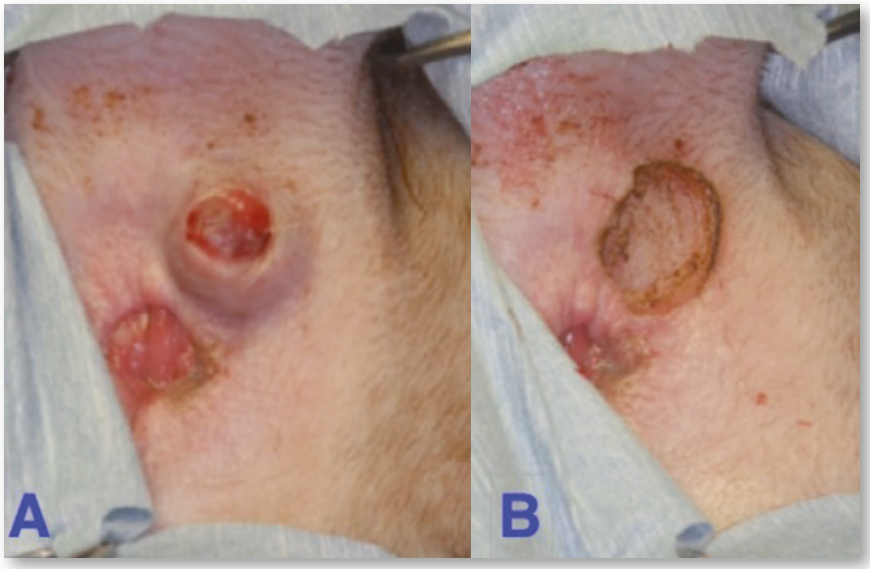

Fig.5 - removal of a perianal adenoma
A - ulcerated perianal adenoma; **B** - after marginal excision

The clinical study of 19 dogs and 3 cats involved 8 cases of laparotomy incision 3 cases of oral cancer, 4 cases of benign skin tumors, 2 cases of stafiloplastic and 5 cases of cystotomy.

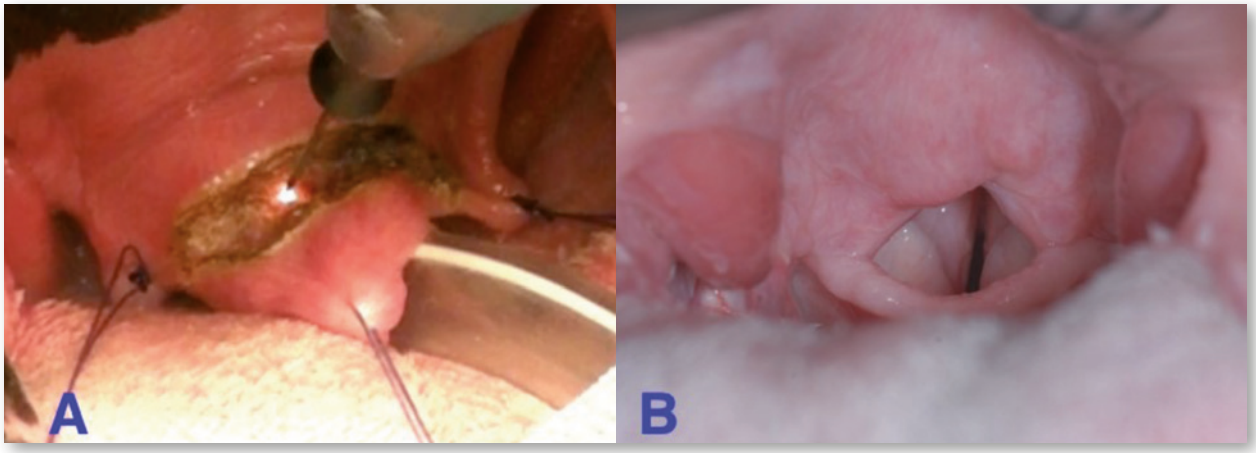

Fig.6 - A - staphyloplastic; **B** Control in 113 days

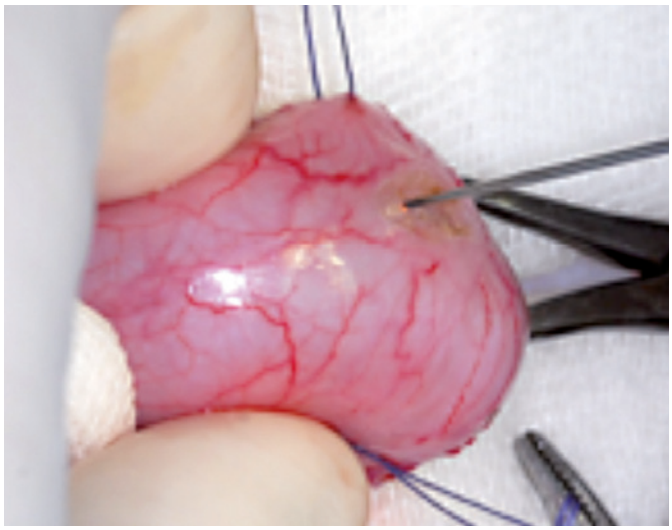

Fig.7 - cistotomy

Discussion

In accordance with other similar studies[9,10,11,12], the comparison of incision with cold blade, radiosurgical and plasma device showed the superiority of the last one compared to the radiosurgical in reducing tissue istolesivity. Histological examination of the biopsies in fact showed the absence of necrosis on the epidermis and dermis with the use of cold blade, a moderate necrosis with the use of the device Onemytis and severe necrosis with the use of surgical units, as confirmed by literature.[10]

The positive result at the histological level has allowed us to make a clinical test on all other cases. The Onemytis plasma device has proven to be a safe tool in its use, not having observed intraoperative or postoperative complications. The ability to modulate the delivered power (Plasma Level) has made it versatile also operating on more delicate tissues such as the bladder wall.

The cutaneous cutting speed was overall good, though obviously inferior to the incision with cold knife, and allowed to also get the coagulation of the subcutaneous plexus vessels. The adjustment of the instrument at 70% intensity has proven to be sufficient to perform a fast incision (from 7 to 10 mm per second) and free of bleeding, especially in anatomical regions with thinner skin such as that of the abdomen. Operating on tissues with a greater thickness, such as the skin of the head, a higher intensity was used (85%), making it necessary a greater number of fast passages on the incision line rather than increase the contact time in order to reduce to maximum the tissue aggressiveness.

It is observed an inversely proportional relationship between the etching speed and the coagulative capacity of the device. The use for skin incisions appeared useful for the removal of growths since it allows to perform a precise and bloodless path, while it is not appeared of particular utility for rectilinear routine incisions as in the case of laparotomy.

The healing times both in the skin and mucous membranes and the quality of wound healing have appeared comparable to those obtained with cold blade.

The most interesting application is highlighted in the oral surgery, where it is possible to obtain precise incision lines with a good control of bleeding; in particular in the removal of 2 marginal pharyngeal large melanomas (4-6 cm), in an anatomical region hardly accessible for the depth of the lesion and for reduced operating space. In the two cases of staphyloplastic it was possible to perform a sharp incision, with excellent coagulation and without the formation of scabs. The healing of the soft palate has proven to be fast and uncomplicated, and even

control after 113 days showed proper healing without exuberant tissue.

The possibility of using the plasma scalpel also on a visceral level in parenchymal organs and visceral looks interesting.

The removal of oral cancer in the three cases evaluated was fast and effective without bleeding and without the formation of surface scabs. The scalpel plasma was used to perform 2 cystotomies in cats and 3 dogs suffering from urolithiasis bladder. The device made it possible to do a precise, fast incision and with a good control of bleeding without being overly aggressive.

The healing of skin incisions in the 12 cases under examination showed time and quality of wound healing comparable to those provided for performing incision with cold blade, as also confirmed by the three cases of mastectomy incisions performed with three distinct modes. The aesthetic result appeared completely satisfactory, hesitating in scars comparable to those with traditional incision.

The patients showed no symptoms attributable to greater postoperative pain or increased sensitivity during convalescence.

The ability to use the device on a visceral level in parenchymatous and hollow organs (pancreas, liver, intestine) is interesting but needs further study because our experience is limited to the bladder incision

The device has no return plates, which prevents any passage of electric current through the body of the patient, in addition to preventing the risk of skin burns from contact with the plate observed with traditional electrosurgery.

The device has a full range of electrodes that enables action on tissues in both ablation and cut. A further advantage of the device, when compared to the coagulator of the Argon gas flow, consists in the greater simplicity and the absence of the argon gas tank.

Study limitations consist of the small number of cases as more cases could provide more evaluation and critical insights, the use of one device for cutting and not for direct dissection and coagulation of deep vessels, and the lack use for other possible interventions of abdominal and thoracic surgery.

Conclusions

The advantages of the device, based on both the instrument specification, and of our clinical experience, are therefore summarized as follows:

- immediate microcoagulation of the affected tissue, with little bleeding;
- ability to operate with the same efficiency on dry or moist tissues;
- versatility in oral surgery;
- the absence of burns from stray RF energy;
- absence of return electrode plates for patient safety;
- no transfer of electromagnetic fields in the animal body;
- any kind of invasiveness, even partially, by electric current;
- no contact with the treated tissue, in that it works even if spaced from the same tissue from a few microns to a few mm;
- antibacterial effect on the intervention site due to ozone molecules produced by the ionization of the air;
- outpatient convenience (no gas cylinders,

or shielding of the room, nor need for protective glasses as in the case of laser scalpel to);
- no special precautions for the operator and for the operative field;
- handling and portability of the device.

Disclosure

The Onemytis device used for the study was provided as a free trial from the manufacturer Otech Industry.

Thanks

Many thanks to the collaboration of Dr. Annalisa Forlani who provided the histological findings.

Key points

- **The thermal tissue damage is the main negative aspect of the electronic and radio scalpel and also of the surgical laser for the temperature of 100°C and more generated on the tissues.**
- **The plasma scalpel generates a column of air as energy conductor, which acts without contact with the tissue and with a 50°C average temperature of dissipation.**
- **Histological examination of biopsy samples of incisions made in different ways, showed moderate istolesivity using plasma device compared to the serious istolesivity determined by the radiosurgical, notoriously less efficient in the literature than electrosurgery devices.**
- **The clinical application of plasma scalpel allows to operate without or with a significant reduction in the bleeding, both for skin incisions and for the mucous membranes and also visceral, with healing times comparable to those obtained by cold knife.**

Clinical use of new plasma coagulation device

To evaluate the efficacy and safety of Onemytis electrocoagulation plasma in some surgical applications, and its influence on tissue healing. Onemytis is an electro-thermo-coagulation-ablation device with Airplasma technology that transforms the air column between the tip of the handpiece and the tissue in a conductor, allowing incision without direct contact. The tissutal dissipation temperature is 50°C is the aim of this work.

The first phase of the study involved cases of mastectomy in which histologic appearance of severed skin was compared between three different methods, cold knife, scalpel plasma Onemytis and Ellman radiosurgical unit, in order to assess the effect on tissues. After positive completion of the first phase, the second phase of the study consisted in the use of the plasma device in different routine surgical procedures. Evaluated parameters included: cutting speed, effectiveness of coagulation and the influence on tissue healing in the post-operative period until removal of the skin sutures and again a week later. Possible intra and post-operative complications were recorded. Histological examinations performed in three cases of mastectomy have shown the absence of necrosis in the incisions with scalpel blade, moderate necrosis in those performed with plasma scalpel and severe necrosis in those with radiosurgical unit. The clinical study with plasma scalpel involved other 19 dogs and 3 cats. The dogs were aged between 6 months and 13 years, the cats from 4 to 9 years. The device has been used for skin incision for laparotomy (8 cases), excision of benign skin tumors (4 cases), excision of neoplasms of the oral cavity (3 cases), palatoplasty (2 cases), cystostomy (5 cases). In all cases, the incision was performed with appropariate bleeding control, healing times and modalities were comparable to those expected with cold knife for the skin incisions. In a single case there was a delayed healing for inflammation secondary to licking.

The Onemytis device has proven to be an effective and safe tool due to low tissue temperature dissipation. In surgical applications in which has been used it provided net cutting surfaces with appropriate bleeding control and without alteration of healing times. The use in the visceral parenchymal surgery needs further study even if in our preliminary experience it has proven effective and sufficiently delicate in execution of cistotomy.

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