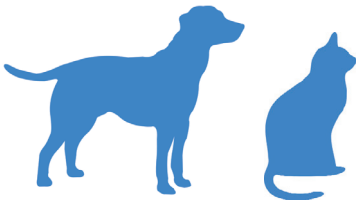
Vol 30, Issue 4, August 2016

VETERINARIA

Clinical use of a new plasma device



Aldo Vezzoni*, Med Vet, Dipl ECVS

Marco De Lorenzi, Med Vet

Luca Vezzoni, Med Vet

Introduction and aims of the study - The aim of this study was to evaluate the efficacy and safety of Onemytis plasma device in some surgical applications, and its effect on tissue healing. Onemytis is device which uses Airplasma® technology to transform the air column between the tip of the hand-piece and the tissue into an energy conductor, allowing incisions without direct contact. The tissue dissipation temperature is 50 °C.

Materials and methods - The first phase of the study involved a comparison of the histological appearance of the cut skin in three cases of mastectomy in which different methods of incision were used - cold blade, the Onemytis plasma device and an Ellman radiosurgical unit - in order to assess the effect of these instruments on the 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. Parameters evaluated included: cutting speed, effectiveness of coagulation and the influence on tissue healing in the postoperative period until removal of the skin sutures and again a week later. Any complications occurring during or after the surgery were recorded.

Results - Histological examinations performed in three cases of mastectomy showed the absence of necrosis in incisions made with the scalpel blade, moderate necrosis in those performed with the plasma device and severe necrosis in those made with the radiosurgical device. The clinical study with the plasma device involved 19 dogs and three cats. The dogs were aged between 6 months and 13 years, the cats were 4 to 9 years old. The plasma device was used for skin incision for laparotomy (8 cases), excision of benign skin tumours (4 cases), excision of neoplasms of the oral cavity (3 cases), palatoplasty (2 cases), and cystostomy (5 cases). In all cases, the incisions were performed with appropriate bleeding control and the healing times and modalities were comparable to those expected with a cold knife for skin incisions. In a single case healing was delayed by inflammation secondary to licking.

Conclusions - The Onemytis device was shown to be an effective and safe instrument due to low tissue dissipation temperature. In the surgical applications in which it was used it provided cleanly cut surfaces with appropriate bleeding control and without alteration of healing times. The performance of this device in parenchymal visceral surgery needs further study even though in our preliminary experience it was effective and sufficiently delicate when used for cystotomy.

INTRODUCTION

The cutting tool most widely used in surgery is the scalpel (cold knife). However, incision with a blade, while being precise and fast, tends to result in bleeding which can hinder and slow down continuation of an intervention. Since the early decades of the 1900s, starting from William T. Bovie's perspicacity[1], we have witnessed the birth of electrosurgery and the development of

Clinica Veterinaria Vezzoni srl
Via Massarotti 60/A, 26100 Cremona
*Corresponding Author (clinica@vezzoni.it)

Received: 22/02/2016 - Accepted: 22/05/2016

The main limitation of all electro- and radio-scalpels, and also of the surgical laser, is the thermal damage they create in tissues, since temperatures of 100 °C or more can develop.

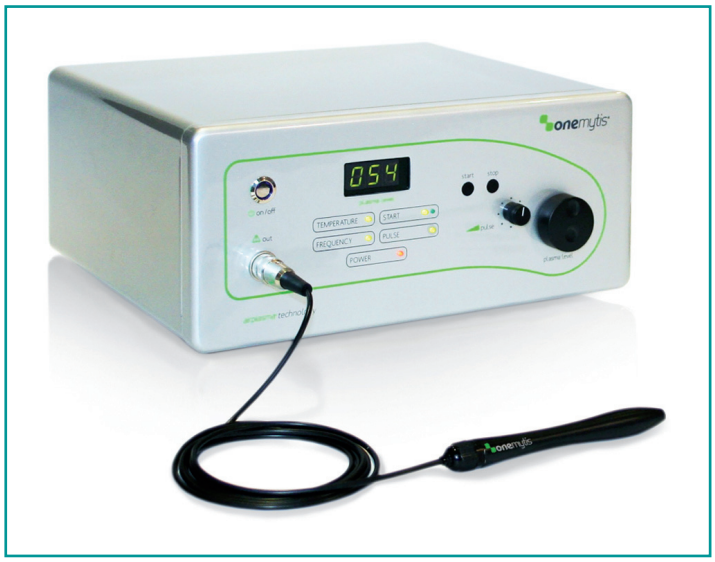


Figure 1 - Onemytis device with sterilisable hand-piece.

ever more precise and effective devices that enable coagulation at the same time as cutting. The main limitation of these devices (electrosurgical and radiosurgical scalpels) is the heat generated in the tissues, with consequent thermal damage[2,3]. Thermal damage is a unimolecular process in which tissue proteins are irreversibly changed from their ordered native state to an altered state[4]. Since the extent of thermal damage, which can vary from a reversible tissue inflammation to irreversible tissue necrosis, is proportional to the temperature reached in the tissue being cut, the dissipation of heat produced by the electrocoagulation instrument is determinant[2,3]. An electrosurgical unit, consisting of a radiofrequency current generator (from 300 kHz to 5 MHz), an active electrode that transmits the current produced to the tissue and a passive electrode that has the function of receiving the current and closing the circuit, creates a dissipation temperature of 100 °C and above in tissues[3]. The main limitations of these devices, besides the high dissipation temperature, are related to the patients' safety. The passive electrode must adhere well to the patient's skin to prevent the output current, concentrated on a too small area, from also causing a major burn[3]. Despite having the same principle of action, instruments that use frequencies above 3 Mhz are called radiosurgical scalpels[5]. These, too, transmit dissipation temperatures of 100 °C and more to the tissues, but the higher wave frequency reduces the risk of burn injuries in the case of a poorly positioned passive electrode and causes a high concentration of energy at a very small point of the active electrode, thus allowing more precise cutting. Laser surgery uses a sophisticated physical and optical system that emits and amplifies a monochromatic electromagnetic radiation (light), which enables very precise cutting with simultaneous coagulation[4]. The limitations to the use of laser surgery are once again those due to the dissipation temperature transmitted to the tissue (100 °C and above) as well as the need to comply with certain safety rules for the patient and the operators (prevent contact with oxygen and alcoholic substances, smoke extraction system, protective glasses)[4].

Another limitation of traditional electrosurgery is the necessity for a return plate, which if not positioned correctly can cause skin burns.

Another cutting-coagulation system uses a flow of argon gas (argon beam coagulation) which provides monopolar coagulation in the absence of direct contact. The electrode tip, fixed into the hand-piece, is activated and the energy generated is transmitted through a flow of argon gas.

The gas captures electrons from the electrode and carries them to the tissue, while at the same time the gas flow removes blood and debris from the surgical field, producing a uniform coagulation surface. The potential complications of this system include the risk of argon gas embolism, particularly if the system is used in laparoscopic surgery[5,6].

Onemytis is a plasma device (Figure 1). It is based on Airplasma® technology, which consists in the transformation of air into an energy conductor through the generation of high-voltage pulses using a high-frequency sinusoidal oscillator. In this way the device can operate without direct contact with the tissue, using the interposed air column, and does not create a tissue dissipation temperature exceeding 50 °C on average[7]. The plasma device has already been used in human medicine and several publications have hi-

The plasma device acts by transforming air into an energy conductor as a result of the generation of high-voltage pulses. It works without direct contact with the tissue, through the interposed column of air, and the average dissipation temperature does not exceed 50 °C.

ghlighted its advantages over the conventional electrosurgical instruments[8-14]. The aim of plasma electrocoagulation is to enable effective cutting and surgery without altering tissue healing. The purpose of our study, based on similar studies in human medicine[8-14], was to evaluate both the effectiveness of the electrosurgery system and its effect on tissues in a series of clinical veterinary cases, through histological and clinical analyses.

Phase 1 of the study was performed to compare incisions made with a cold knife, an Ellman radiosurgical unit and the Onemytis plasma device. Biopsies were taken from the areas of the cutaneous incisions for mastectomy performed in three dogs and the specimens were examined histologically to assess the degree and extent of tissue damage.

MATERIALS AND METHODS

This study was conducted at Vezzoni's Veterinary Clinic using the Onemytis plasma device. The instrument consists of a central unit with commands to adjust the intensity from 0 to 100, a hand-piece that can be sterilised in an autoclave, the needle tip and a delivery pedal. The study was performed in two phases: the first to evaluate the histological effect at the incised surface, the second phase, once the histological examination of the cases in the first phase had shown adequate results, to evaluate the instrument in clinical use.

Phase 1. For the purpose of a preliminary evaluation of the effect on tissues, we identified three cases of mastectomy in which, with the informed consent of the owner, the skin incision was divided into three parts using three different cutting methods: cold knife, Onemytis and the radiosurgical Ellman Surgitron FFPF EMC with fully rectified waveform (cut/coagulation mode). Samples of skin adjacent to the surface of the cut tissue were taken from the three different parts. 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 haematoxylin-eosin. The histological samples were subsequently observed under a microscope by a pathologist

Table 1

N.	Species	Breed	Sex	Age	Operation	Power	Cutting rate (mm/s)	Bleeding	Healing	Complications
1	Dog	Mongrel	F	8 y.	Laparotomy	70%	10	0	Complete	None
2	Dog	Labrador	F	10 y.	Laparotomy	70%	10	0	Complete	None
3	Dog	Border Collie	F	9 y.	Laparotomy	70%	10	0	Complete	None
4	Dog	Labrador	F	5 y.	Laparotomy	70%	10	0	Complete	None
5	Dog	French Bulldog	F	13 m.	Palatoplasty	70%	7	1	Complete	None
6	Dog	Mongrel	F	6 m.	Laparotomy	70%	10	0	Complete	None
7	Dog	Boxer	F	7 m.	Excision of gingival tumour	50%	10	0	Complete	None
8	Dog	Golden	F	6 y.	Cystotomy	50%	10	0	Complete	None
9	Dog	Labrador	M	11 y.	Excision of pharyngeal melanoma	50%	8	0	Complete	None
10	Dog	Mongrel	F	8 m.	Laparotomy	70%	8	0	Complete	None
11	Cat	European	F	4 y.	Cystotomy	50%	10	0	Complete	None
12	Dog	Toy poodle	M	6 y.	Excision of benign skin tumour	85%	7	0	Complete	None
13	Dog	Bulldog	M	18 m.	Palatoplasty	70%	7	1	Complete	None
14	Dog	Cocker	F	11 y.	Excision of pharyngeal melanoma	50%	8	1	Complete	None
15	Dog	Mongrel	F	6 y.	Excision of benign skin tumour	70%	8	0	Complete	None
16	Dog	Cocker	F	1 y.	Laparotomy	70%	10	0	Complete	None
17	Dog	Labrador	F	2 y.	Laparotomy	70%	8	1	Delayed	Licking
18	Cat	European	F	9 y.	Cystotomy	50%	10	0	Complete	None
19	Dog	Mongrel	M	6 a.	Cystotomy	50%	10	0	Complete	None
20	Dog	German Shepherd	F	7 y.	Excision of benign skin tumour	85%	7	0	Complete	None
21	Cat	European	M	6 y.	Excision of benign skin tumour	75%	8	0	Complete	None
22	Dog	Hound	M	11 y.	Cystotomy	50%	7	0	Complete	None

F: female; M: male; y: years; m: months

Phase 2 of the study consisted in the clinical application of the device in routine surgery of soft tissues, both of the skin and of oral and visceral mucosa.

unaware of the type of sampling carried out to obtain the various specimens. The histological analysis was aimed at assessing the presence and extent of necrosis of the tissues. Depending on the thickness of the necrotic tissue, the extent of the damage was evaluated as absent, mild, moderate or severe.

Phase 2: On the basis of the histological results, if these showed similar or less tissue damage than that caused by the radiosurgical scalpel commonly used in our clinic, it was planned to use Onemytis in several routine procedures involving surgery to soft tissues, evaluating the cutting speed, coagulation efficacy and influence on post-operative tissue healing for up to a week after removal of the skin sutures.

Bleeding, evaluated visually, was ranked from 0 to 3, where 3 is attributed to bleeding consequent to the use of a cold blade (Table 1).

According to the manufacturer's instructions, Airplasma was used with a medium to high intensity (about 70% of maximum power) on thin, delicate tissues, with the possibility of increasing the power when operating on thicker, less delicate tissues (for example, the skin of the head), bearing in mind that increasing the power is indicated to reduce the time of contact with the tissue, thereby avoiding excessive tissue damage.

Histological analysis of the biopsies taken from the sites of incision showed the absence of necrosis in the incisions made with a cold blade, moderate necrosis in the incisions made with the plasma device and severe necrosis in the incisions made with a radiosurgical scalpel.

RESULTS

Phase 1. Three dogs undergoing mastectomy were included in the comparative study between incision with a cold blade, radiosurgical scalpel or plasma device. The region of tissue damage was recognised as an area from eosinophilic to slightly basophilic with loss of cellular detail of dermal fibrocytes and loss of the fibrillar appearance of collagen. The overlying epidermis was characterised by full-thickness necrosis of keratinocytes and of the stratum corneum. The histological examinations performed on these three cases showed absence of necrosis in the incisions made with the cold knife, while the extent of the tissue damage was assessed as moderate in those carried out with the plasma device and severe in those performed with the radiosurgical unit (Figure 2). The examination at the time of removing the stitches showed proper healing of the wound in all three areas of incision, without macroscopic differences. These results allowed us to perform phase 2 of the study.

Phase 2. The clinical study with the plasma device involved 19 dogs (not including the three cases of mastectomy in phase 1 of the study) and three cats (Table 1). The dogs ranged in age from 6 months to 13 years, the cats from 4 to 9 years. The device was used for skin incisions during laparotomy (Figure 3; 8 cases), excision of tumours of the oral cavity (Figure 4, 3 cases), excision of benign skin tumours (Figure 5, 4 cases), palatoplasty (Figure 6, 2 cases), and cystostomy (Figure 7, 5 cases). All procedures were completed without intraoperative complications. Intraoperative bleeding, evaluated on a scale from 0 to 3, was considered to be 0 in 18 cases and 1 in four cases. The post-operative evaluation showed proper healing of all the oral cavity incisions and also of all the skin incisions with the exception of one case of laparotomy, in which there was delayed healing due to licking of the wound. The five cases of

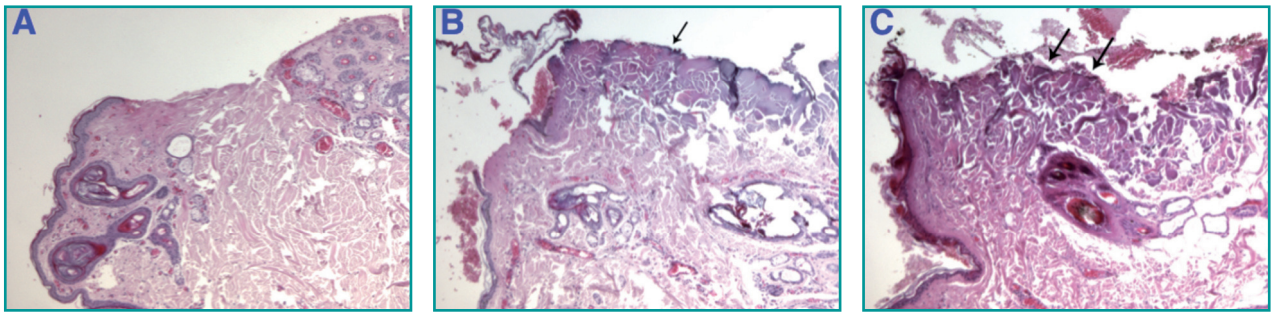


Figure 2, A-B-C - Skin: histology of acute damage caused by the use of a cold blade **(A)**, by the Onemytis plasma device **(B)** and by an Ellman radiosurgical unit **(C)**. Areas characterised by the loss of the cellular outline of dermal collagen fibres and epithelial keratinocytes (necrosis) are present near the margin of the section in figures **B** and **C** (the arrows). The thickness of the area of coagulation necrosis is greater in the incisions made with the radiosurgical scalpel **(C)** than in those made with the plasma device **(B)**. No areas of coagulation necrosis in the incisions made with the scalpel blade are present **(A)**. (Haematoxylin-eosin, 50X).

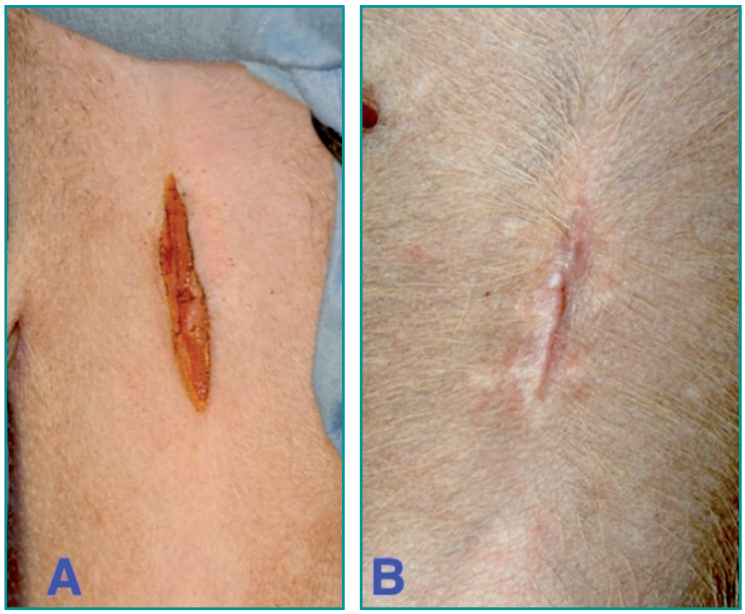


Figure 3 - **(A)** Skin incision for laparotomy; **(B)** Post-operative follow up after 14 days.

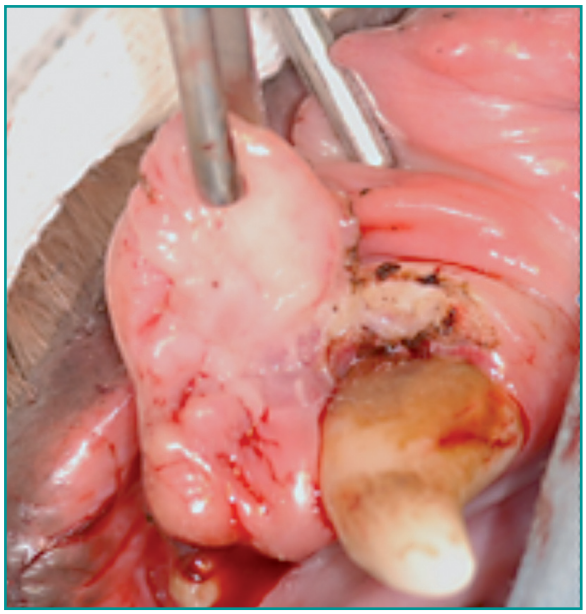


Figure 4 - Asportation of a benign gingival tumour.

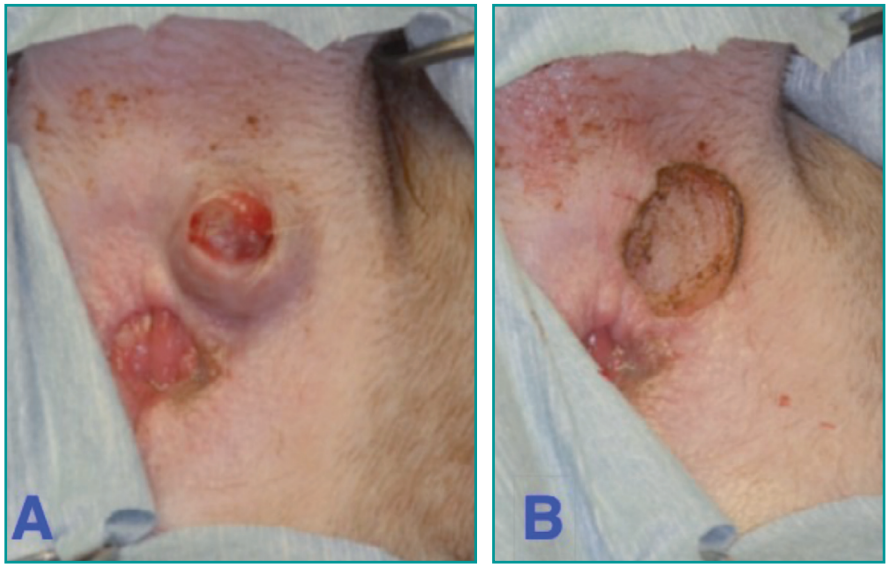


Figure 5 - Excision of a perianal adenoma.
(A) Ulcerated perianal adenoma; (**B**) After marginal excision.

The clinical study of 19 dogs and three cats involved eight laparotomy incisions, three cases of oral cancer, four benign skin tumours, two cases of palatoplasty and five cases of cystotomy.

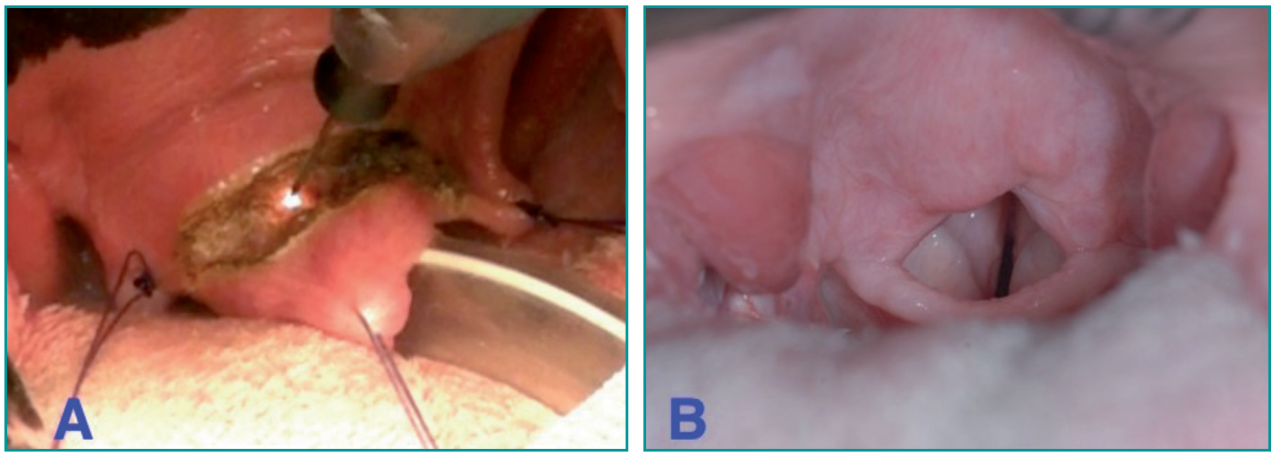


Figure 6 - **(A)** Performing a palatoplasty; **(B)** Follow up after 113 days.

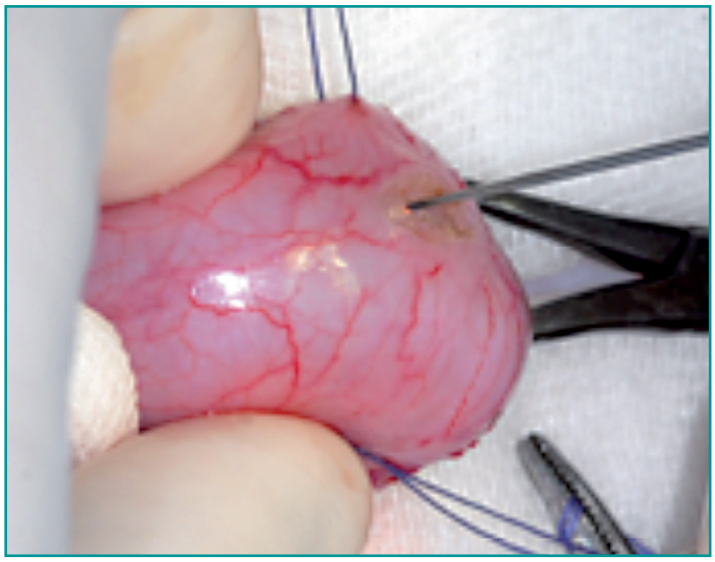


Figure 7 - Cystotomy.

cystotomy had an uncomplicated course and healing of the cystotomy was confirmed via ultrasound and urinalysis 12 days after the procedure.

DISCUSSION

In accordance with other similar studies[9,10,11,12], the comparison of incisions with a cold blade, radiosurgical unit or plasma scalpel showed that this last was superior to the radiosurgical scalpel with regards to reducing tissue damage. In fact, histological examination of the biopsies showed an absence of necrosis of the epidermis and dermis when a cold knife was used, moderate necrosis when the Onemytis device was used and severe necrosis when the radiosurgical scalpel was used, confirming previous reports in the literature[10].

The cutting speed was good (from 7 to 10 mm per second), although obviously slower than that of the cold knife.

The positive histological findings allowed us to perform the clinical study in all the other cases. The Onemytis plasma device was found to be a safe instrument, since we did not observe any intraoperative or postoperative complications. The ability to modulate the power delivered (Plasma Level) made it versatile also when operating on more delicate tissues, such as the bladder wall. Overall, the cutting speed in skin was good, although obviously slower than a cold knife, and the instrument provided coagulation of the vessels of the subcutaneous plexus. Regulating the instrument to 70% intensity was proven sufficient to perform a fast incision (from 7 to 10 mm per second) free of bleeding, especially in anatomical regions with thinner skin such as that of the abdomen. When operating on thicker tissues, such as the skin of the head, a higher intensity was used (85%), making it necessary to perform several fast passages on the incision line, rather than increasing the contact time, in order to minimise tissue damage. It was seen that the incision rate and the coagulative capacity of the plasma device are inversely proportional. As far as concerns skin incisions, the device appears to be useful for the removal of tumours since it enables a precise, bloodless cut, whereas it does not seem to be of particular utility for routine, straight-line incisions such as in the case of laparotomy.

The most interesting application was in surgery of the oral cavity, in which the device enabled precise incisions and good control of bleeding.

The most interesting application was in oral surgery, where it was possible to obtain precise incision lines with good control of bleeding; in particular in the excision of the margins of two large pharyngeal melanomas (4-6 cm), in an anatomical region to which access was difficult because of the depth of the lesion and the limited operating space. In the two cases of palatoplasty it was possible to make a clean incision, with excellent coagulation and without the formation of scabs. The soft palate healed quickly and without complications, and the control 113 days after surgery showed correct healing without exuberant tissue. The removal of oral tumours in the three cases evaluated was fast and effective without bleeding and without the formation of surface scabs. The plasma device was used to perform two cystotomies in cats and three in dogs with bladder stones. The device enabled precise, fast incisions, with good control of bleeding, without being overly aggressive.

The healing times for both skin and mucous membranes and the quality of the wound healing seemed to be comparable to those obtained with a cold blade.

The time for and quality of healing of skin incisions in the 12 cases under examination were comparable to those expected for incisions performed with a cold blade, as also confirmed by the three cases of mastectomy incisions performed with three distinct devices. The aesthetic results appeared completely satisfactory, with scars comparable to those following traditional incisions. The patients did not show any signs attributable to greater postoperative pain or increased sensitivity during convalescence.

The possibility of using the plasma device also at a visceral level in parenchymal and hollow organs is interesting.

The possibility of using the device on viscera, in parenchymal and hollow organs (pancreas, liver, intestine) is interesting but needs further study because our experience is limited to bladder incisions.

Onemytis does not have return plates, which prevents any passage of electrical current through the patient's body, in addition to eliminating the risk, observed with traditional electrosurgery, of skin burns from contact with the plate.

The device has a full range of electrodes that enables both ablation and incision of tissues. Further advantages of this plasma device, compared to an argon gas flow coagulator, are its greater simplicity and the absence of an argon gas cylinder.

The limitations of this study include the small number of cases assessed, since more cases would have provided a better evaluation and critical insights, the fact that the device was used only for cutting and dissection and not for direct coagulation of deep vessels, and also that it was not used in other possible abdominal and thoracic interventions.

CONCLUSIONS

Based on both the instrument's specifications and our clinical experience, the advantages of the plasma device can be summarised as follows:

  - immediate microcoagulation of the incised tissue, with little bleeding;
  - ability to operate with the same efficacy on dry or wet tissues;
  - versatility in oral surgery;
- the absence of burns from stray radiofrequency energy;
- the absence of return electrode plates, improving the patient's safety;
- no transfer of electromagnetic fields to the animal's body;
- the electrical current is completely non-invasive;
- no contact with the treated tissue, since the instrument works even if it is a few microns to a few millimetres away from the tissue;
- there is an antibacterial effect at the intervention site due to ozone molecules produced by ionization of the air;
- convenience for outpatient use (no gas cylinders, nor shielding of the room; no need for protective glasses as required when using a laser scalpel);
- no special precautions for the operator or for the operating field;
- manageability and portability of the device.

DISCLOSURES

The Onemytis device used in this study was provided for a free trial by the manufacturer, Otech Industry.

ACKNOWLEDGEMENTS

We thank Dr. Annalisa Forlani, who provided the histological findings, for her collaboration.

KEY POINTS

- Thermal tissue damage is the main drawback of electro- and radio-surgical scalpels, and also of laser surgery, since temperatures of 100 °C or more develop in the tissues.
- The plasma device generates a column of air as the energy conductor, which acts in the absence of direct contact with the tissue and with an average dissipation temperature of 50 °C.
- Histological examination of biopsy samples taken from the incisions made with the different instruments showed that the tissue damage caused by the plasma device was moderate, whereas the radiosurgical scalpel created severe tissue damage, even though this latter is well-known to cause less damage than an electrosurgical scalpel.
- In clinical use, the plasma device allows surgery without bleeding or with a significant reduction in bleeding, both for skin incisions and incisions of mucous membranes and viscera, with healing times comparable to those obtained when using a cold knife.

REFERENCES

1. Bovie WT, Cushing, H. Electrosurgery as an aid to the removal of intracranial tumors with a preliminary note on a new surgical-current generator. The Journal of surgery, gynecology and obstetrics 47: 751-84, 1928.
2. Bevilacqua I. Il danno termico nella pratica chirurgica. Tesi di laurea Facoltà di Ingegneria, Università di Padova; 2011, http://tesi.cab.unipd.it/29541/.
3. Bello E, Ruggeri A. Elettrobisturi: aspetti generali e soluzioni per il problema dell'aumento di temperatura. Tesi di laurea in Ingegneria Biomedica. Università degli Studi di Padova; 2011-2012.
4. Gans Z. Using The CO_2 Laser for Veterinary Soft Tissue Surgery: a Review. Israel Journal of Veterinary Medicine Vol. 62 - No. 3-4, 2007.
5. Dubiel B, Shires P, Korvick D, et al. Electromagnetic energy sources in surgery. Veterinary Surgery 39, 909-924, 2010.
6. Falbo B, Vene M, Visini R, et al. Experimental study of the effect of the Argon Beam Coagulator on organic tissues from the viewpoint of surgical utilization. Annali Italiani di Chirurgia. Jan-Feb; 75(1): 59-62, 2004.
7. Dogan L, Gulcelik MA, Yuksel M, et al. The Effect of Plasmakinetic Cautery on Wound Healing and Complications in Mastectomy. Journal of Breast Cancer June; 16(2): 198-201, 2013.
8. Stevens WG, Gear AJ, Stoker DA, et al. A prospective controlled trial of the PEAK Plasma-Blade in the evaluation of breast cancer surgical specimens with touch prep. The 11th Annual Meeting of American Society of Breast Surgeons. 2010. Abstract #206.
9. Sangoi A, Vose J, Atmodjo D, et al. A randomized controlled trial of the PEAK Plasma-Blade in open breast biopsy compared to scalpel and traditional electrosurgery. The 11th Annual Meeting of American Society of Breast Surgeons. 2010. Abstract #209.
10. Loh SA, Carlson GA, Chang EI, et al. Comparative healing of surgical incisions created by the PEAK Plasma-Blade, conventional electrosurgery, and a scalpel. Plastic and Reconstructive Surgery, 124: 1849-59, 2009.
11. Ruidiaz ME, Messmer D, Atmodjo DY, et al. Comparative healing of human cutaneous surgical incisions created by the PEAK Plasma-Blade, conventional electrosurgery, and a standard scalpel. Plastic and Reconstructive Surgery, 128: 104-11, 2011.
12. Yilmaz KB, Dogan L, Nalbant H, et al. Comparing scalpel, electrocautery and ultrasonic dissector effects: the impact on wound complications and pro-inflammatory cytokine levels in wound fluid from mastectomy patients. Journal of Breast Cancer, 14: 58-63, 2011.
13. Maness WL, Roeber FW, Clark RE, et al. Histologic evaluation of electrosurgery with varying frequency and waveform. The Journal of Prosthetic Dentistry, Vol 40 n. 3: 304-308, Sept 1978.
14. Silverman EB, Read RW, Boyle CR, et al. Histologic Comparison of Canine Skin Biopsies Collected Using Monopolar Electrosurgery, CO_2 Laser, Radiowave Radiosurgery, Skin Biopsy Punch, and Scalpel. Veterinary Surgery 36: 50-56, 2007.