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Thermal effects of a novel electrosurgical device for focused preparation in breast surgery tested in a specified porcine tissue ex vivo breast model using infrared measurement

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Abstract

Purpose This article investigates the qualities and thermal effects of a novel electrosurgical device (PT) which has been designed by ERBE Elektromedizin GmbH, Germany, for the preparation of critical locations such as in skin-sparing or nipple-sparing techniques and compares it to a standard device (SD) in a porcine ex vivo breast model using an heat map generated by infrared thermography.

Methods In total, 42 abdominal wall specimens of porcine tissue consisting of the skin and the underlying subcutaneous and muscle layer were alternately dissected using one of the devices and pre-settings. During the preparation with the two devices, the epicutaneous temperature was measured by an infrared camera (VarioCam, Jenoptik, Germany) and the maximum temperature as well as the slope of the temperature rise was analysed.

Results The use of PT shows significantly lower values for $\overline{\Delta T_{max}}$ compared to SD. This effect was independent from the chosen mode. Using the same instrument in different modes, the use of AutoCut mode showed a significant reduction of $\overline{\Delta T_{max}}$ at all indicated time points (SD: $p<0.0001$ and PT: $p<0.0001$). In summary, the combination of AutoCut + PT showed the lowest rise in temperature, whereas the combination of DryCut + SD led to the highest rise in temperature. The temperature difference between these two settings was 13.84 °C, which means a possible temperature reduction of 67% can be achieved by the right choice of device and its tailored mode.

Conclusions The novel PT shows a significant reduction in epicutaneous temperature and a significant reduction of the slope of temperature rise most probably by a more focused application of energy compared to SD.

Keywords Mastectomy · Electrosurgery · Porcine model · Infrared thermography

Background

Breast cancer is the most common malignant disease in women, for which a life time risk of 12.9% has been evaluated [1]. Surgery represents an elementary part of its successful therapy in addition to specific medication and radiotherapy.

Besides breast-conserving surgical procedures, mastectomy plays an important role in surgical concepts. Not only as treatment of breast cancer patients, but also in terms of prophylactic procedures of genetically predisposed patients with mutations in BRCA 1 and 2 genes, mastectomy has still outstanding significance [2].

As an alternative to modified-radical mastectomy (MRM), skin-sparing mastectomy (SSM) and nipple-sparing mastectomy (NSM) provide opportunities to preserve the native breast envelope without mutilation of the nipple–areola complex (NAC) and avoid multiple surgical procedures required for reconstruction [3]. The meaning and acceptance of NSM has rapidly increased over the last years [4] since it improves the self-image of patients. It positively influences psycho-oncological issues and helps to preserve the sensation of the nipple to prevent a negative effect on sexual function [5].

The use of energy-based tissue sealing and cutting instruments has become a well-established component of surgical

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approaches in gynaecology. Although there are plenty of different devices in daily use, there still seems to be potential to improve the preparation-quality of such devices.

The primary goal of improvement is a reduction of thermal damage to adjacent tissue without the loss of sufficient coagulation qualities by redesigning the settings and shape of an energy-based tissue sealing and coagulation instrument.

This article investigates the qualities and thermal effects of a novel electrosurgical device (PT) which has been designed by ERBE Elektromedizin GmbH, Germany, for the preparation of critical locations such as in skin-sparing or nipple-sparing techniques and compares it to a standard device (SD) in a porcine ex vivo breast model.

Materials and methods

The SD is a well-established completely electrical conductive instrument used for several indications in operative gynaecology and breast surgery.

The electrode of the prototype is enveloped by ceramic isolation, except for a defined part which is used for a focused cutting effect. The non-isolated part of the PT is designed as a small hook and thereby provides a more focused application by modelling the tissue during electrosurgical use.

Due to the high number of experimental preparations, several identical prototypes have been used for this ex vivo study (Fig. 1).

The thermal effects of the novel electrosurgical cutting prototype (PT), as demonstrated in Fig. 2, were compared with an established electrosurgical standard device (SD) (Ref. Nr. 21191-002, ERBE Elektromedizin GmbH, Germany) in a porcine breast model.

Both devices were used in different pre-settings: DryCut and AutoCut. The devices were run by a Vio 300D HF-Generator (ERBE Elektromedizin GmbH, Germany).

In total, 42 abdominal wall specimens of porcine tissue consisting of the skin and the underlying subcutaneous and muscle layer (Fig. 3) were alternately dissected using one of the devices and pre-settings.

The domestic porcine tissue was taken from different terminal experiments conducted by Dr. Schenk experimental laboratory, Tübingen, and is registered as project C2/13 according to German law §4 Abs. 3 TSchG 3.9.2013.

Prior to the experiments the porcine tissue was stored in a fridge at 8 °C. Before conducting the tests the porcine tissue was left to reach room temperature. For the single experiments, the specimens were cut into pieces of 10×6×2 cm and the bristles were cut close above skin level without

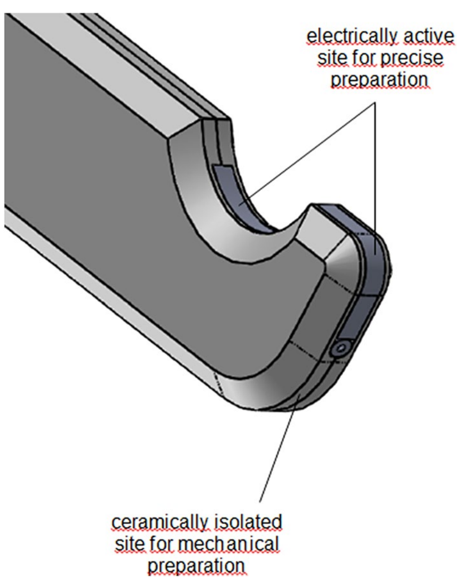

Fig. 1 Functional sites of the novel device, schematic figure (provided by ERBE Elektromedizin GmbH)

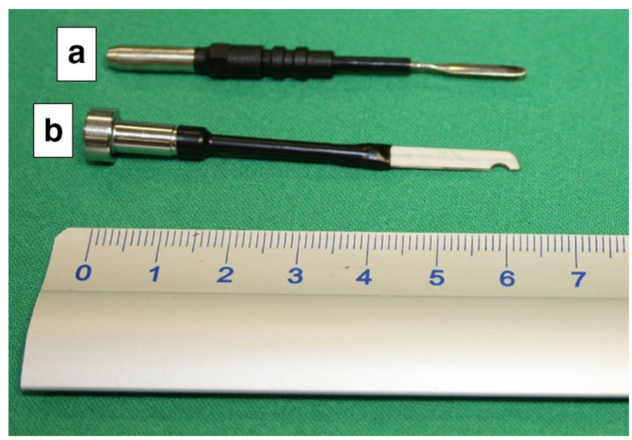

Fig. 2 **a** Standard device; **b** prototype

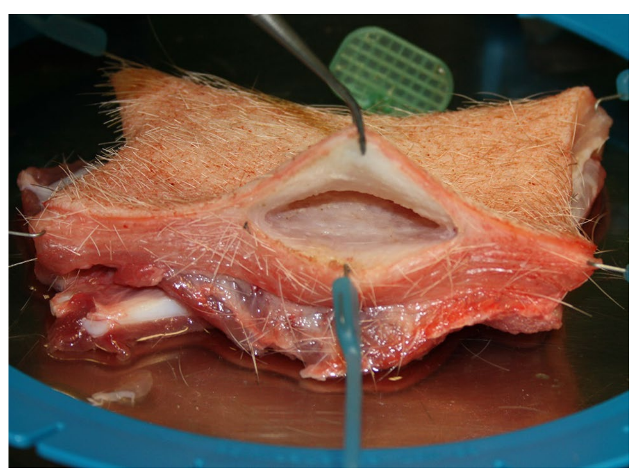

Fig. 3 Porcine tissue ex vivo breast model for preparation; in the background (green) the cannula is visible

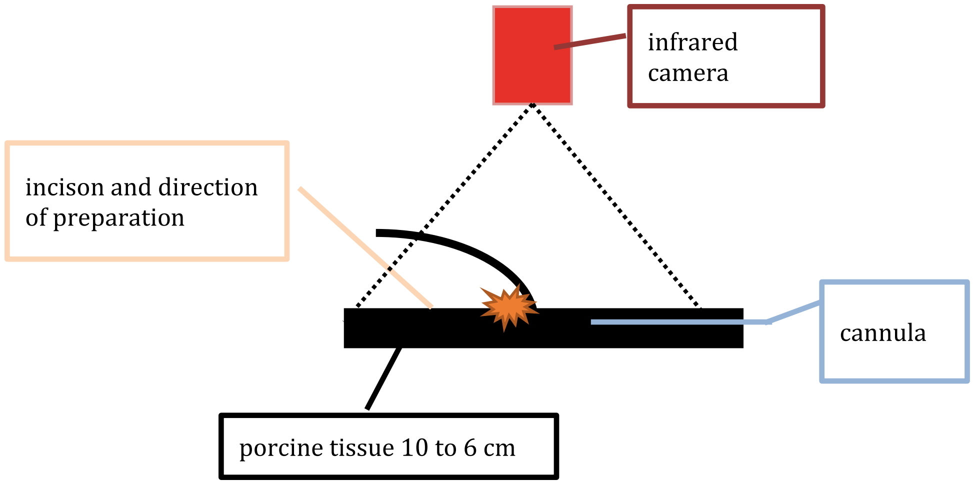

Fig. 4 Placement of the cannula in the setup for preparation and measurement of thermal effects by an infrared camera

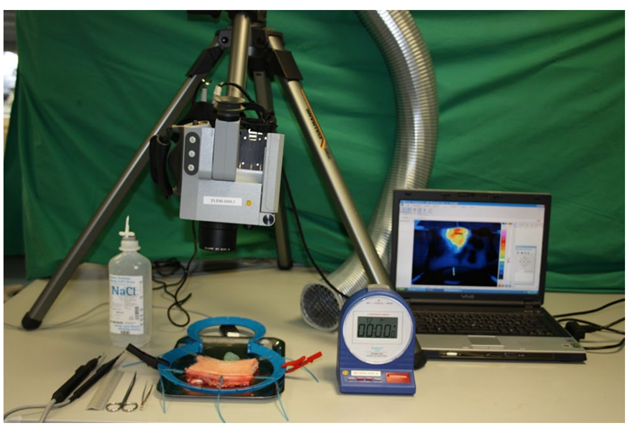

Fig. 5 Setup for the preparation of the porcine tissue and processing a heat map with an infrared camera

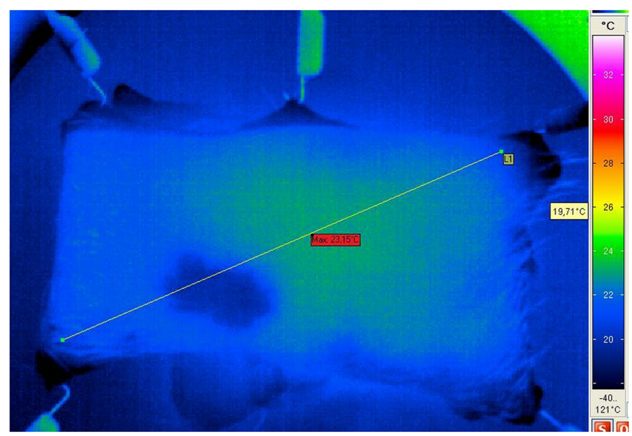

Fig. 6 Heat map during preparation measured by an infrared camera

harming the epidermis. Before preparation, a cannula was placed 3 cm deep on the opposite side of the incision and thereby marked a defined target line for the preparation (Fig. 4).

The space for dissection was also defined as the preparation of a subcutaneous cavity of 5–11 mm beneath the epidermis, thus mimicking an approach for SSM or NSM in humans. During the preparation with the two devices, the epicutaneous temperature was measured by an infrared camera (VarioCam, Jenoptik, Germany) (Figs. 5, 6) and the maximum temperature as well as the slope of the temperature rise was analysed.

The maximum epicutaneous temperature $T_{max}(t)$ was measured continuously by an infrared camera as demonstrated by Fig. 4. $\Delta T_{max}(t)$ describes the maximum change in temperature in relation to the temperature at the beginning of the preparation at $t = 0$:

$$\Delta T_{max}(t) = T_{max}(t) - T_{max}(0).$$

Statistics

The level of significance was set at $\alpha = 0.05$ (5%). The testing of normal distribution was conducted by using a Kolmogorov–Smirnov test.

The Student's t test, the f test, the Welch's t test and the Mann–Whitney test were used for calculating statistical significance.

Results

Epicutaneous temperature

The analysis of $\Delta T_{max}(t)$, as displayed in Fig. 7, results in higher values using the DryCut mode compared to the AutoCut mode in all settings, whereas the novel PT showed a more even temperature distribution. In contrast, the combination of the DryCut mode and the SD showed a steep rise in temperature up to $t = 30$ s.

The different instruments mainly defined the initial rise of the temperature curve.

In the DryCut mode, the PT showed a significant ($p = 0.0001$) reduction in the maximum temperature increase when measured epicutaneously (PT: $\Delta T_{max} = 9.62$ °C versus SD: $\Delta T_{max} = 20.62$ °C). There is also a significant ($p = 0.0011$) reduction in the maximum increase of temperature when measured epicutaneously in the AutoCut mode: PT: $\Delta T_{max} = 4.06$ °C versus SD: $\Delta T_{max} = 6.78$ °C (Fig. 8, Table 1).

The use of PT showed significantly lower values for $\overline{\Delta T_{max}}$ compared to SD. This effect was independent from the chosen mode.

Using the same instrument in different modes, the use of AutoCut mode showed a significant reduction of $\overline{\Delta T_{max}}$ at all indicated time points (SD: $p < 0.0001$ and PT: $p < 0.0001$).

In summary, the combination of AutoCut + PT showed the lowest rise in temperature, whereas the combination of DryCut + SD led to the highest rise in temperature.

The temperature difference between these two settings was 13.84 °C, which means a possible temperature reduction of 67% can be achieved by the right choice of device and its tailored mode.

Slope of temperature

The slope of the temperature rise using the DryCut mode was significantly ($p = 0.0202$) lower for PT than for SD (PT: 0.49 °C versus SD: 1.12 °C). Likewise, the slope of the temperature rise using the AutoCut mode was significantly ($p < 0.0006$) lower for PT than for SD (PT: 0.36 °C versus SD: 0.66 °C). However, there was no statistically significant ($p = 0.0691$) difference in the slope of temperature between DryCut + PT and Autocut + PT.

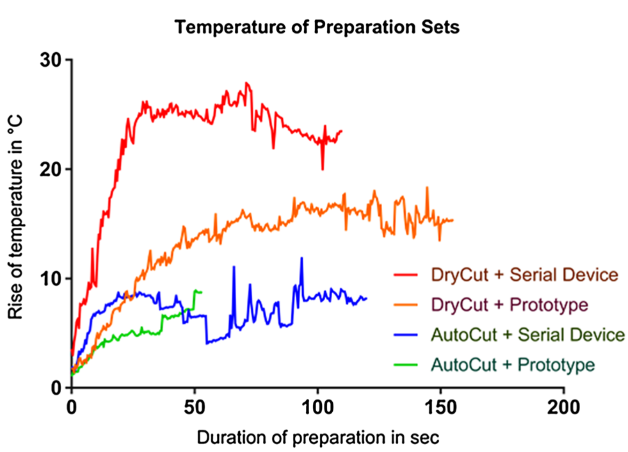

Fig. 7 $\Delta T_{max}(t)$ for different setups

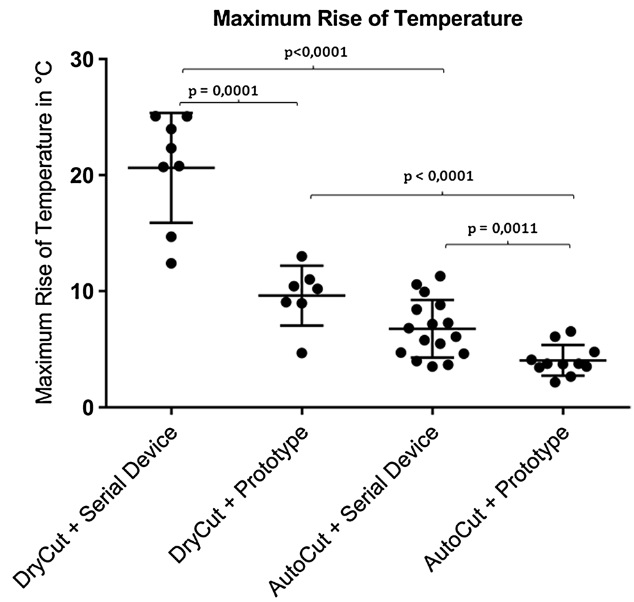

Fig. 8 Maximum rise of temperature $\overline{\Delta T_{max}}$ in °C displaying mean value, standard deviation and p values

In almost all cases, a phase of stable temperature was reached. If this was not possible, it was considered in the analysis so that after the elimination of one outlier in the group of AutoCut + PT, normal deviation was achieved (Fig. 9 and Table 2).

Discussion

Functional and morphological disorders of the female breast often require surgical treatment. Aesthetic aspects play an outstanding role in breast surgery [6].

The preparation of critical locations in breast surgery requires high accuracy from electrosurgical cutting devices to provide a maximum of oncological safety. When breast tissue is dissected from the overlying skin, for instance during SSM or NSM, it remains challenging to completely

Table 1 Mean value for $\overline{ØΔT_{max}}$ in °C standard deviation in °C

Mode	DryCut		AutoCut	
Instrument	Standard device	Prototype	Standard device	Prototype
N	8	7	16	11
$Ø\,\overline{\Delta T_{max}}$ in °C	20.62	9.62	6.78	4.06
$\sigma_d \overline{T_{max}}$ in °C	4.43	2.38	2.38	1.26

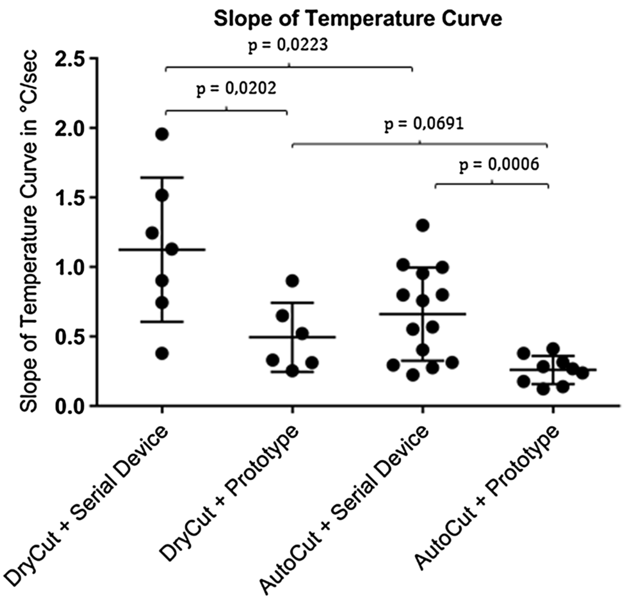

Fig. 9 Slope of temperature in °C/s with mean value, standard deviation and *p* values

Table 2 Mean slope of temperature in °C/s and standard deviation

Mode	DryCut		AutoCut	
Instrument	Standard device	Prototype	Standard device	Prototype
N^+	7	6	14	9
N^-	1	1	2	2
Ø slope in $\frac{°C}{s}$	1.12	0.49	0.66	0.36
σ(Ø slope) in $\frac{°C}{s}$	0.52	0.25	0.34	0.33

N+ number of preparations with stable phase of temperature, *N*− number of preparations with no phase of stable temperature

remove the glands. However, preserving the skin envelope including the inframammary fold and a thin layer of subcutaneous fat is important for the blood supply of the skin and the nipple in NSM as well as for the preservation of nerves [7].

In this study, we investigated a PT which was designed to improve accuracy in tissue preparation, especially because different tissue sites require variable devices and settings. The experimental setup was established to show the ability of reducing temperature, thus reducing collateral damage of the blood supply and of skin nerves.

So far, prototypes of high-frequency application devices were mostly tested by measuring depth and geometry of the cut, as well as the mechanical resistance of the tissue and the depth of coagulation effects [8, 9].

Szyrach et al. [10] introduced a computer-controlled cutting system which enables high-frequency application devices to be used under strict standardized conditions.

However, such a highly standardized computer-controlled experimental preparation can present with different thermal effects compared to the manual use of a device in reality. Indeed, various application speeds as well as non-uniform movements will also influence the tissue effects [11, 12]. This consideration led to the chosen experimental setup under real and manual conditions in contrast to a standardized computer-controlled application of energy. The direct effects of high-frequency devices such as coagulation and carbonization are well examined [13, 14]. However, these kinds of examinations do require standardized protocols. Thus, the measurement of temperature by an infrared camera provides a sufficient approach for a comprehensive observation in a dynamic setup which is designed as close as possible to in vivo.

Since we could show that the PT significantly reduces the epicutaneous temperature and shows a lower slope of the rise of temperature compared to the SD, we presume less "acute" thermal damage to adjacent tissue in humans as well. This assumption is in accordance with the findings of El-Brawany et al. [15] who described the qualities of thermal conductivity in porcine and human cutaneous and subcutaneous tissue. An explanation of the findings in this study may be the more focused application of energy due to the new PT's shape and geometry compared to the SD. It must be taken into consideration that later or "long-term" (in contrast to acute) thermal tissue effects are rather influenced by the choice of the application mode (AutoCut versus DryCut) which makes it inevitable to select an appropriate mode according to the specific tissue and the desired effects in every day practice.

It needs to be pointed out that the findings in this study are based on a simplified biological experimental ex vivo model. Particularly, the use of electrosurgical devices in non-perfused tissue at room temperature has to be taken into consideration critically. However, the combination of this technically advanced instrument with the best application mode settings is very likely to provide a decrease in thermal breast surgery complications, especially for SSM and NSM where the skin layer has to be preserved.

Conclusion

The newly designed PT for breast tissue preparation shows a significant reduction in epicutaneous rise of temperature, most probably by a more focused application of energy compared to SD. Long-term thermal effects are not only influenced by the shape and the geometry of a device, but also strongly by the choice of the application mode. The best-fitting combination of device and mode seems to decrease the risk of thermal complications.

Although advantages of the prototype have been found, it is not possible to make a statement about its absolute effects in vital human tissue. Therefore, an in vivo investigation is needed and is currently planned by our institution.

Author contribution DK and AF carried out the experiments. SMH wrote the manuscript with support from MW and in consultation with MH and SYB. MDE and BK conceived the original idea and supervised the whole process.

Compliance with ethical standards

Conflict of interest Markus Enderle is president of research at ERBE GmbH. Andreas Fech is employed engineer at ERBE GmbH. The other authors declare to have no conflict of interest.

References

1. Rhiem K, Schmutzler RK (2015) Risk factors and prevention of breast cancer. Der Onkologe 21(3):202–210
2. Schott S, Vetter L, Keller M, Bruckner T, Golatta M, Eismann S, Dikow N, Evers C, Sohn C, Heil J (2017) Women at familial risk of breast cancer electing for prophylactic mastectomy: frequencies, procedures, and decision-making characteristics. Arch Gynecol Obstet 295(6):1451–1458
3. Murthy V, Chamberlain RS (2013) Defining a place for nipple sparing mastectomy in modern breast care: an evidence based review. Breast J 19(6):571–581
4. de Alcantara Filho P, Capko D, Barry JM, Morrow M, Pusic A, Sacchini VS (2011) Nipple-sparing mastectomy for breast cancer and risk-reducing surgery: the Memorial Sloan-Kettering Cancer Center experience. Ann Surg Oncol 18(11):3117–3122
5. Didier F, Radice D, Gandini S, Bedolis R, Rotmensz N, Maldifassi A, Santillo B, Luini A, Galimberti V, Scaffidi E, Lupo F, Martella S, Petit JY (2009) Does nipple preservation in mastectomy improve satisfaction with cosmetic results, psychological adjustment, body image and sexuality? Breast Cancer Res Treat 118(3):623–633
6. Schmidt JL, Wetzel CM, Lange KW, Heine N, Ortmann O (2017) Patients' experience of breast reconstruction after mastectomy and its influence on postoperative satisfaction. Arch Gynecol Obstet 296(4):827–834
7. Jud SM, Hatko R, Maihöfner C, Bani MR, Schrauder MG, Lux MP, Beckmann MW, Bani G, Eder I, Fasching PA, Loehberg CR, Rauh C, Hein A (2014) Comprehensive visualization of paresthesia in breast cancer survivors. Arch Gynecol Obstet 290(1):135–141
8. Wendt-Nordahl G, Häcker A, Fastenmeier K, Knoll T, Reich O, Alken P, Michel MS (2005) New bipolar resection device for transurethral resection of the prostate: first ex vivo and in vivo evaluation. J Endourol 19(10):1203–1209
9. Michel MS, Köhrmann KU, Weber A, Krautschick AW, Alken P (1996) Rotoresect: new technique for resection of the prostate: experimental phase. J Endourol 10(5):473–478
10. Szyrach MN, Tolba RH, Voigtländer M, Neugebauer A, Enderle MD (2010) Evaluation of the hemostatic and coagulation effects of AUTO CUT and DRY CUT using a computer-controlled cutting system. Urology 75(5):1217–1221
11. Ng EY, Tan HM, Ooi EH (2010) Prediction and parametric analysis of thermal profiles within heated human skin using the boundary element method. Philos Trans A Math Phys Eng Sci 368(1912):655–678
12. Weiss R, Weiss M, Beasley K, Vrba J, Bernardy J (2013) Operator independent focused high frequency ISM band for fat reduction: porcine model. Lasers Surg Med 45(4):235–239
13. Rothmund R, Schoeller D, Neugebauer A, Scharpf M, Fend F, Schenk M, Wallwiener D, Kraemer B (2012) Evaluation of thermal damage in a pig model. J Invest Surg 25(1):43–50
14. Rothmund R, Kraemer B, Neis F, Brucker S, Wallwiener M, Reda A, Hausch A, Scharpf M, Szyrach MN (2012) Efficacy and safety of the novel electrosurgical vessel sealing and cutting instrument BiCision. Surg Endosc 26(11):3334–3343
15. El-Brawany MA, Nassiri DK, Terhaar G, Shaw A, Rivens I, Lozhken K (2009) Measurement of thermal and ultrasonic properties of some biological tissues. J Med Eng Technol 33(3):249–256