# Original article

# Semi-Spherical Radiofrequency Bipolar Device – a New Technique for Liver Resection: experimental *in vivo* study on the porcine model


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**Short Running Head**: Progress in new technique for liver resection.

**Key words:** liver resection, radiofrequency energy, surgical device, porcine model

# Abbreviations

AM – amplitude modification

CEITEC – Central European Institute of Technology

DaPZ – dilatation and proliferation of bile ducts

DisPZ – dispersion proliferation of bile ducts

IP – institutional substitution

KC – lymphocytes accumulation

KCT – kaolin test

MZ – department of health

PDS – polydioxanon

PZ – proliferation of bile ducts

RF – radiofrequency

RFA – radiofrequency ablation

RONJA – semi- spherical bipolar radiofrequency device

TACR – technological agency of Czech Republic

TKX – tiletamin- zolazepam

VSB – TUO – Technical University in Ostrava

ZC – thickening of the arteries

# Abstract

The incidence of colorectal carcinoma is still growing in the Czech Republic as also all around the world. With success of oncological treatment is also growing a number of potentional patients with liver metastases, who can profit from surgical therapy. The aim of this study was to confirm on porcine models that this method with using new surgical device is effective and safe for patients which have to undergo liver resection. The primary hypothesis of the study was to evaluate whether this new device is able to consistently produce homogeneous and predictable areas of coagulation necrosis without the Pringle maneuver of vascular inflow occlusion. The secondary hypothesis of the study was to compare the standard linear radiofrequency device and a new semi-spherical bipolar device for liver ablation and resection in a hepatic porcine model.

12 pigs were randomly divided into two groups. Each pig underwent liver resection from both liver lobes in the marginal, thinner part of liver parenchyma. The pigs in first group were operated with standard using device and in the second group we used new developed semi-spherical device. We followed blood count in $0^{th}$, $14^{th}$ and $30^{th}$ day from operation. $14^{th}$ day from resection pigs underwent diagnostic laparoscopy to evaluate of their state, and $30^{th}$ day after operation were all pigs euthanized and subjected to histopathological examination.

Histopathological evaluation of thermal changes at the resection margin showed strong thermal alteration in both groups. Statistical analysis of collected dates did not prove any significant ($p < 0{,}05$) differences between standard using device and our new surgical tool. We proved safety of new designed semi-spherical surgical. This device can offer the possibility of shortening the ablation time and operating time, which is benefit for patients undergoing the liver resection.

# Introduction

Radiofrequency (RF) energy is commonly used at present in the treatment of numerous medical disorders. Radiofrequency is high-frequency alternating electrical current which creates the desired clinical effect by passing through the tissue. As the current passes through, it heats the tissue around the active electrodes. Radiofrequency alternating electrical current has a frequency in the range from 300 KHz to 3 MHz.(1, 2).

Radiofrequency energy has been used in medicine for more than a hundred years. First, French physicist D'Arsanval described the effects of alternating current at a frequency of 250 kHz on biological tissue in Paris in 1891 (4)

Primary and secondary liver tumours present a challenging problem in clinical oncology because of their very high morbidity and mortality. Patients with unresectable tumours (because of tumour extent or localization, inadequate hepatic reserve or high patient co-morbidity) may be candidates for local ablative techniques, chemoembolization, systemic or local chemotherapy (4-9). Of the available local ablative techniques, RF thermal ablation (RFA) has become the most frequently used and widespread (5). Multiple trials have evaluated RFA for the treatment of unresectable primary and secondary liver tumours and proved that RFA can control hepatic malignancies with few associated complications (4,6,7,8,9).

In 1990, McGahan and Rossi, two independent authors, published experiments on animal models using radiofrequency currents for the ablation of primary and metastatic liver tumours. These experiments in animal models proved the safety and efficiency of percutaneous RF ablation (10,11).

The role of RF energy in liver surgery has expanded in recent years from simple tumour ablation to its use in the technique of RF-assisted liver resection. In 2002, Habib´s team used a specially modified bipolar RFA probe to manage a patient with gallbladder cancer who refused to have a blood transfusion (12). This method can be used in open or minimally invasive surgery. The pioneer in using RF energy for liver resection is Professor Nagy Habib, which is why it’s also called Habib’s resection surgery (13-21). The RF-assisted resection technique has been reported to be associated with minimal blood loss, low blood transfusion requirement, no need for intraoperative hepatic inflow occlusion techniques (such as Pringle's manoeuvre, dissection and clamping of the hepatic pedicle) and reasonable postoperative morbidity and mortality (16,18,19,20,21). The most widely used instruments used for RF-assisted liver resection at present are the Habib™ 4X and Laparoscopic Habib™ 4X. Radiofrequency-induced coagulative necrosis offers very effective haemostasis and biliostasis of liver parenchyma (20,22).

Based on data compiled by the National Center for Health Statistics between 1960 and 2004, the mortality rate due to liver cancer has been steadily increasing over the past two decades (23). Hepatic resection is currently the standard treatment for liver cancer. Radiofrequency energy in the form of RF ablation or RF-assisted resection has become one of the standard methods for the treatment of primary and secondary liver malignancies in the last 10-15 years.

The present study assessed the feasibility and safety of liver resection a new semi-spherical bipolar radiofrequency device (RONJA). The primary hypothesis of the study was to evaluate whether this new device (Fig. 1, 2) is able to consistently produce homogeneous and predictable areas of coagulation necrosis without the Pringle maneuver of vascular inflow occlusion. The secondary hypothesis of the study was to compare the standard linear radiofrequency device and a new semi-spherical bipolar device for liver ablation and resection in a hepatic porcine model. We aim to confirm that this new method is effective and safe.

***New device***

Our new proposed surgical device is specific with his arrangement, where the tool is formed by annular base plates with holes for guiding the electrode needles and two wings attached to the electrode assemblies and two lead wires for each electrode wing (Fig. 3, 4). Electrode needles are arranged in a square array, which are located on both sides of the edges of a regular 16-square radius. The shape and length of the electrode needles must be such that, after introduction into the tissue it forms a spherical shape in this tissue. Bipolar electrode needles are driven electrode in each wing separately and between the inner and outer semi-circle, with one pole ablation tools consist of one semicircle of needles. It may also other combinations excitation electrode needles of wings so that it always been sufficiently coagulated tissue for subsequent incision performed by surgeon.

**(Fig. 1)**

**(Fig. 2)**

**(Fig. 3)**

**(Fig. 4)**

# Materials and Methods

*In vivo* testing was conducted on a set of 12 pigs (*Sus scrofa domestica*) randomly divided into two groups of 6 pigs. The whole experiment was made up of three parts. Before each phase all animals were weighed and underwent blood sampling for haematological and biochemical tests. During the first part the animals in both groups underwent middle laparotomy and radiofrequency-assisted liver resection under general anaesthesia. Pigs in **group A** underwent liver resection using the new testing tool RONJA and in the control **B group** pigs were operated on with a commonly used surgical multiple needles tool for radiofrequency liver ablation. The second part of the study followed 14 days after intervention and was focused on control laparoscopy. In the last part, after 30 days after the operation, all the pigs were euthanized and samples were pathologically evaluated.

Pigs aged one year were provided by the Research Institute of Animal Production (Uhrineves, department of pig breeding, Kostelec, address: Komenskeho 1240, 51741, the Czech Republic, accreditation number 444/2011-MZE-17214, valid until April 6, 2016).

Our experimental project (no. 65/2012) was approved by the expert committee on animal welfare of the Veterinary and Pharmaceutical University Brno according to the law on the protection of animals against cruelty, as amended by § 18, paragraph 6 b), Act No. 246/1992 Coll. Then our experiment was approved by the Ministry of Education, Youth and Sport of the Czech Republic and was granted permission to carry out the experiment on 7$^{th}$ September 2012.

### *Phases of testing*

All phases of this experiment took place in the research operating theatre of the Faculty of Veterinary medicine of the Veterinary and Pharmaceutical University Brno. All surgical terms were performed in aseptic conditions according to a predetermined schedule and protocol. The surgical team was formed of pairs of surgeons from the surgical department of the University Hospital Ostrava as well as veterinary surgeons from the Veterinary and Pharmaceutical University Brno.

### *The first phase*

The surgical field and its surroundings were shaved before each surgical performance. The surgical field was made antiseptic by washing with iodopovidon (Betadine soap, Egis Pharmaceutical, Hungary), and chorhexidine (Nolvasan, Cymedica s.r.o., the Czech Republic) was applied to the surgical field. Anaesthesia was induced by intravenously given propofol (Norofol, Norbrook Lab. Ltd., North Ireland) (0.5 - 1 mg/kg) then anaesthesia was maintained by constant rate infusion of propofol (0,1 mg/kg/min). During the operation Hartmann solution (B.Braun, Germany) (10 ml/kg/h) was served to animals intravenously through a cannulated auricular vein. The operating field was protected by a drape, a single Foliodrape system for laparotomy - HARTMAN. Instrumentation AESCULAP B.Braun Medical was used to performing laparotomy. After preparing the surgical field it was penetrated into the abdominal cavity through upper middle laparotomy in the position of the animal on his back. Monopolar electrocoagulation electrosurgery EMED ES 350 with an output of 255 W was used to this performance. Laparotomy retractor was applied and surgeons performed the revision of the abdominal cavity.

### *Resection procedure*

For each animal two liver resections were always executed - one from the right lateral lobe and one resection of the left lateral liver lobe. All resections were performed in thinner part of the liver. A commonly used device was employed as the radiofrequency power generator. Liver resection was always executed in the following mode - after mobilization of the liver lobe, first it was planned by a resection line marked on the liver surface using electrocoagulation. The semi-spherical device was applied on the liver parenchyma afterwards.  We have implemented the first wing of the RF device and have proceeded by inserting the second wing, which together created a spherical pattern in liver parenchyma. The time measurement of ablation was associated with supply of radiofrequency energy.

The liver resection was carried out by radiofrequency-assisted resection technique without liver blood flow occlusion (Fig. 5). The main principle of this technique is coagulation (radiofrequency ablation) in the liver resection margin estimated using radiofrequency instruments with subsequent liver transection using a scalpel or surgical scissors (Fig. 6, 7) .Possibly bleeding from the resection line was treated with the radiofrequency instrument or electrocoagulation. Resected samples were fixed in 10% formalin solution, so that they could later be histopathologically examined for depth of necrosis of liver parenchyma. After checking and drying of the surgical field, the entire abdominal laparotomy was closed in layers - peritoneum and fascia technique "en masse" with 0 PDS continuous monofilament suture, subcutaneous tissue vicryls individual sutures and skin with non-absorbable monofilament fiber Ethilon 2/0 (Ethicon - Johnson & Johnson company, USA). Special antiseptic spray - Silver Aluminium Aerosol - bandage protection against contamination (Henry Schein, Inc., Germany) was applied on the surgical wound. Subsequently, the animals, under the control of the veterinary anaesthesiologist, were escorted from general anaesthesia and housed in standard breeding boxes with conventional terms and were also placed under veterinary supervision. Postoperatively, the animals were given intramuscularly amoxicillin (Betamox, Norbrook, Northern Ireland) (15 mg/kg) and meloxicam (Metacam, Boehringer Ingelheim, Germany) (0.4 mg/kg).

During the liver resection surgery of each animal the value of the total operating time and ablation time of lobes were measured and compared in both groups.

**(Fig. 5)**

**(Fig. 6)**

**(Fig. 7)**

### *The second phase*

14 days after liver resection the second phase was executed. The main aim of the second phase of this experimental study was to determine the status of healing or postoperative complications in the abdominal cavity of each animal. For this purpose, a diagnostic laparoscopy of each pig was performed to assess the postoperative findings. AESCULAP (B. Braun Medical., s.r.o., the Czech Republic) laparoscopy instrumentation was used for surgery - humane version of the endoscopic video unit TELE PACK X and laparoscopic optic HOPKINS with an outer diameter of 5 mm and a length of 290 mm (KARL STORZ Endoscopy, Germany) insufflations device Smith & Nephew, laparoscopic set with Veres FlexTray needle and trocars, harmonic scalpel, harmonic pliers HARMONIC ACE (Ethicon Endo-Surgery, LLC and Johnson & Johnson company, USA). Overall, 12 diagnostic laparoscopies were performed. As expected, many adhesions were found in the abdominal cavity between resected part of liver and omentum, or abdominal wall, respectively.

There were no liver abscesses, biliary leak, subhepatic abscess, hematoma or signs of peritonitis in any animal of both groups.

### *The third phase*

The last part of the testing was performed 30 days after the first operation. In this phase of our experimental study, autopsies of the 12 pigs were performed by a veterinary pathologist from the Institute of Pathological Morphology and Parasitology of the Veterinary and Pharmaceutical University Brno in the presence of a pathologist from the University Hospital Ostrava. Slaughtering was done by the protocol, *lege artis*. The animal carcasses were disposed of through a rendering service.

Nutritional status of the animals were described as good to very good according to body weight, clinical veterinary status and examination of blood sampling. In the *linea alba* they had a well healed suture without secretion. Only one pig, which had been injured in the transverse colon in the second phase, had in the subcutaneous space an abscess without caving into the abdominal cavity.

All animals were opened in the abdominal cavity then in the thoracic cavity, and then followed removal of the organs. In the abdominal cavity fibrous synechia was detected in parts of the resected liver lobes with peritoneum, some adhesions were found between the liver lobes and stomach, omentum or loops of jejunum. Resection margins in the liver lobes were mostly covered with fibrous tissue at the adhesions. Four female pigs had in their abdominal cavity a less serous effusion. The thoracic cavity in four pigs was without adhesions and effusions. The lungs of five pigs had pathological findings consisting of atelectatic bearings – acute inflammatory or chronic bronchopneumonia. Fibrinoid purulent pericardial effusion was observed in one of these pigs. Samples of the right and left hepatic lobe were collected in all pigs for histological examination. The tissue was fixed in 10% formalin solution.

For comparison and statistical evaluation data were collected including results of blood samples, the values recorded during surgery and postoperatively and also the histopathological evaluation. Throughout the experiment the weight of individual animals was recorded. Examination of blood sampling was carried out at the Department of Haematology at the Clinic of Immunology and cytology laboratories for small animals at the Veterinary and Pharmaceutical University Brno.

# Results

The overall blood analysis showed no marked differences in the observed values before resection, on the 14$^{th}$ day after surgery or the 30$^{th}$ day.

The average total operating time (time from start of operation–intubation until the last stitch) in the groups of pigs operated on with the newly designed instrument, was 57.5 minutes, in contrast to the control group, where the average time was 69minutes. Average ablation time (time was measured from the first burning liver resection until removal) was as follows: left lobe ablation time for the testing group was 8.83 minutes, 7.33 minutes right lobe. Left lobe ablation time in control group B was 11.67 minutes and the right lobe ablation time was 8.5minutes. As seen from the average time the tested instrument RONJA has shorten ablation time in left lobe 2.84 minutes and 1.17 minutes in right lobe than generally using device. With newly designed instrument was also shorten operating time 11.5 minutes than with using standard device (see Tab. 1). Statistical analysis using the median test (p-value was computed by Fisher's exact test) failed to demonstrate any significant differences between the two groups.

Blood losses during the liver resections were less than 20 ml.

The power delivery of the radiofrequency energy generator was optimized during the surgical procedure. To gain more effective coagulation of liver tissue using new device the supply power was reduced to 80 W compared with the standard used device with the need to output of 90 W. In the postoperative period all animals had a weight gain. In the tested group A the weight gain was on average 5.83 kg and in the control group B 6.62 kg (Tab. I).

**(Tab. I)**

***Complications***

During the liver ablation only one complication occurred. A spleen was deserozated in a pig in the tested group A. In this animal serous effusion of 250 ml was observed during pathomorphological evaluation.

The control laparoscopy showed postoperative adhesions in all 12 animals. No serious postoperative complications occurred. Only one adverse event appeared during an inspection laparoscopy. Transverse colon of one pig in experimental A group was injured when establishing capnoperitoneum. It was treated with a suture thread of monofilamentosis PDS 3/0 PDS and 4/0 (Ethicon Endo-Surgery, LLC and Johnson & Johnson company, USA).

The death of one pig in the control B group occurred in the postoperative period after laparoscopy performance. An autopsy was executed by a veterinarian from the Institute of Pathological Morphology and the Parasitology Faculty of Veterinary Medicine and an acute catarrhal-purulent bronchopneumonia, tonsillitis and rhinitis were detected.

The cause of death was determined as animal circulatory failure due to respiratory insufficiency in the postoperative period in connection with probable mycoplasmal infections. The abdominal cavity after surgery was examined without pathological findings. Resected samples of the liver were loaded into 10% formalin solution and secured for further histological examination.

### *Histopathology*

Histopathological evaluation was performed by pathologists from the Institute of Pathological Anatomy of the University Hospital Ostrava. Examination of thermal changes at the resection margin showed strong thermal alteration in both groups (Fig. 8). The depth of thermal damage from the resection margin of resected samples exceeded 10 mm in all cases, with a median of 14 mm damage in the group of the newly designed instrument. The results are shown in table 4. With this method in areas without significant thermal alteration congested liver tissue dominates. In this tissue coagulated blood was rarely present in the central vein and also occasionally along the wall thermal alteration of the bile ducts, in one case with mild inflammatory cellulization.

**(Fig. 8)**

The thermal alteration in samples of the control group B was mostly up to 10 mm. Similarly, thermal alteration of the bile duct was up to 10 mm, in only one case was thermal alteration of bile ducts in intact tissue observed**.** In preserved liver tissue significant congestion and periductal round cell infiltration was detected. To summarize, the depth of the thermal alteration was on average 4 mm larger in the cases of the newly tested instrument, dispersion of values was 12 -17 mm. In the method of the control group the thermal alteration was up to 10 mm, also in intact tissue congestion, but to a lesser degree, and mild round cell cellulization periductal and perivasal. The autopsy material from the tested A group was formed by the depth of necrosis with a median of 14 mm and 13.5 mm. Furthermore we encountered a proliferation of bile ducts and vascular thickening in healthy hepatic tissue. The results are shown in tables 2 and 3. In samples of the control B group disability necrosis was confirmed with a median depth of 13 mm and 14 mm in healthy tissue and also expansion and proliferation of bile ducts. Statistical analysis using the median test (p-value was computed by Fisher's exact test) did not show any significant differences between the groups (Tab. II).

**(Tab. II)**

**(Tab. III)**

**(Tab. IV)**

***Statistical analysis***

Data are presented as mean ± standard error of mean (S.E.M.) and median for continuous variables and as counts and percentages for categorical variables (complications). Data between the standard device group and RONJA group were compared using the median test for continuous variables and Fisher's exact test for categorical variables. Statistical analyses were performed with IBM SPSS software version 18.0. A two-sided value of $p < 0.05$ was considered statistically significant for all analyses.

**(Tab. V)**

**(Tab. VI)**

**(Tab. VII)**

The statistical analysis definitely showed that there were not any differences between tested group A and standard group B. Thus, after statistical confirmation we can claim that we have suggested a new liver ablation device for resectable tumours in liver tissue which is comparable as far as its parameters with the standard device. In detected data we can see, that ablation and operation time was shorter with new device RONJA unlike the standard using device, but because there were small number of pigs in our experiment file, it was not confirmed by statistical analysis.

# Discussion

This experimental study proved the feasibility and safety of the newly developed semi-spherical bipolar device for liver ablation and resection. No statistically significant differences were observed between the new tested device compared to the generally used device. The overall blood analysis showed no marked differences in the observed values before resection, on the 14$^{th}$ day after surgery or the 30$^{th}$ day. By our point of view, the ablation and operating time was shorter when using the RONJA device but the difference was not statistically significant. The reason may be due to the low number of pigs used in the study. A spherical area of coagulated necrosis was produced in all livers which marked the line for surgical resection of liver parenchyma.

Many authors have used a porcine model in feasibility and safety studies of devices for radiofrequency ablation. Varadarajulu et al. (2009) performed RFA of pig liver using the retractable umbrella-shaped electrode array with effective coagulation necrosis of large areas (24). Burdío et al. (2008) compared a new radiofrequency (RF)-assisted device specifically designed for tissue thermocoagulation and division of the liver with a state-of-the-art saline-linked device. The tested RF-assisted device was shown to address parenchymal division and hemostasis simultaneously, with lower blood loss and faster transection time than saline-linked technology in that pig model (25). Solazzo et al. (2007) used a porcine model with the aim of prospectively maximizing the extent of created tissue coagulation by using a high-power (1000W, 4000mA) RF generator to optimize pulsing algorithms (26).

We have found out that the advantage of our new designed tool is in shortening operating time as well as saving healthy liver parenchyma in comparison with commonly used multiple needles linear devices. This linear device has four long needles ordered to form a rectangle, which destroys tissue in depth. The semi-spherical conformation of the device allows removal of necessary liver tissue only apart from common used linear tools. Time shortening is the consequence of reducing number of steps of coagulation, because new designed device coagulates in both wings. It means that if the deposit is up to 20 mm, there are only a few steps necessary to coagulate the whole deposit apart from the linear device.  This device was designed to be compatible with generally used power generators, so it does not increase the need of additional technical equipment. We should also mention disadvantages, in comparison with commonly used linear tools, arising from the specific layout of needles. The device is designated only for the surface and subsurface liver tumors or metastases with the size up to 20 mm, which limits practical application.

# Conclusion

We have developed a new semi-spherical bipolar radiofrequency device that adequately coagulates the hepatic resection plane in a porcine model. Our prototype system was able to coagulate the semi-spherical contour of liver parenchyma in the thinner part with successful coagulation of all blood vessels. This device shows promise in the effort to reduce healthy tissue liver parenchyma resection during liver surgery in a porcine model. Performing resection of liver parenchyma using the new semi-spherical device we confirmed this new method is effective and safe.

Future animal and clinical studies will need to evaluate semi-spherical liver RF resection with respect to the local recurrence of hepatic tumours.

***Practical application:*** The method described in this study could be used in open liver surgery without inflow occlusion for the treatment of small liver malignancies in a single application with the aim to save normal liver parenchyma. Further experimental studies are needed to confirm these results before clinical application of the method in the treatment of human liver malignancies.

# Conflict of interest

The authors report no conflicts of interest in this *in vivo* study.

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# References


1. Pearce J A. *Electrosurgery.* New York, John Wiley (1986).
2. Pearce J A. Electrosurgical unit. In: *Encyclopedia of medical devices and instrumentation*, 2nd Ed, pp. 156-177. Ed., Webster J G. New York, NY; John Wiley (2006).
3. D'Arsonval M A. Action physiologique des courants alternatifs. *C R Soc Biol 43*, 283-286 (1891).
4. Lencioni R, Cioni D. Percutaneous methods for ablation of hepatic neoplasms. In: *Surgery of the liver, biliary tract, and pancreas*, 4th Ed, pp. 1269-1277. Ed., Blumgart L H. Philadelphia, PA; Saunders (2007).
5. Friedman M, Mikityansky I, Kam A, Libutti S K, Walther M M, Neeman Z, Locklin J K, Wood B J. Radiofrequency ablation of cancer. *Cardiovasc Intervent Radiol 27*, 427-434 (2004). DOI: 10.1007/s00270-004-0062-0
6. Pereira P L. Actual role of radiofrequency ablation of liver metastases. *Eur Radiol 17*, 2062-2070 (2007). DOI: 10.1007/s00330-007-0587-0
7. Hao C Y, Ji J F. Surgical treatment of liver metastases of colorectal cancer: Stragegies and controversies. *Eur J Surg Oncol 32*, 473-483 (2006). DOI: 10.1016/j.ejso.2006.02.016
8. Lencioni R, Crocetti L, Cioni D, Della Pina C, Bartolozzi C. Percutaneous radiofrequency ablation of hepatic colorectal metastases: technique, indications, results, and new promises. *Invest Radiol 39*, 689-697 (2004). DOI: 10.1097/00004424-200411000-00007
9. Strasberg S M, Linehan D. Radiofrequency ablation of liver tumors. *Curr Prob Surg 40*, 451-498 (2003). DOI: 10.1016/S0011-3840(03)00050-9
10. Rossi S, Fornari F, Pathies C, Buscarini L. Thermal lesions induced by 480 KHz localized current field in guinea pig and pig liver. *Tumori 76*, 54-57 (1990).
11. McGahan J P, Browning P D, Brock J M, Tesluk H. Hepatic Ablation Using Radiofrequency Electrocautery. *Invest Radiol 25*, 267-270 (1990). DOI: 10.1097/00004424-199003000-00011
12. Navarra G, Jiao J C, Weber J P, Nicholls J P, Jensen S L, Habib N A. A novel approach to gallbladder cancer in a Jehovah's Witness. *Surg Endosc 16*, 1109-1110 (2002). DOI: 10.1007/s00464-001-4245-3
13. Ayav B P, Habib N A, Pellicci R, Tierris J, Milicevic M, Jiao L R. Impact of radiofrequency assisted hepatectomy for reduction of transfusion requirements. *Am J Surg 193*, 143-148 (2007). DOI: 10.1016/j.amjsurg.2006.04.008
14. Weber J C, Navarra G, Jiao L R, Nicholls J P, Jensen S L, Habib N A. New technique for liver resection using heat coagulative necrosis. *Ann Surg 236*, 560-563 (2002). DOI: 10.1097/01.SLA.0000032952.65498.C2
15. Milicevic M, Bulajic P, Zuvela M, Dervenic C, Basaric D, Galun D. A radiofrequency-assisted minimal blood loss liver parenchyma dissection technique. *Dig Surg 24*, 306-313 (2007). DOI: 10.1159/000103663
16. Pai M, Jiao L R, Khorsandi S, Canelo R, Spalding D, Habib N A. Liver resection with bipolar radiofrequency device: Habib™ 4x. *HPB (Oxford) 10*, 256-260 (2008). DOI: 10.1080/13651820802167136.
17. Yao P, Morris D L. Radiofrequency ablation-assisted liver resection: review of the literature and our experience. *HPB (Oxford) 8*, 248-254 (2006). DOI: 10.1080/13651820600703272.

18. Vavra P, Ihnat P, Vavrova M, Martinek L, Dostalik J, Habib N. Hand-assisted laparoscopic liver resection using Habib´s technique: early experience. *Wideochir Inne Tech Malo Inwazyjne 7*, 8-12 (2012). DOI: 10.5114/wiitm.2011.25739.
19. Ihnat P, Vavra P, Rudinska L, Ostruszka P, Dostalik J. Radiofrequency-assisted liver resection: short-term results in a single institution. *Bratisl Lek Listy 114*, 19-22 (2013). DOI: 10.4149/BLL_2013_005
20. Ayav B P, Jiao L, Dickinson R, Nicholls J, Milicevic M, Pellicci R, Bachellier P, Habib N A. Liver resection with a new multiprobe bipolar radiofrequency device. *Arch Surg 43*, 396-401 (2008). DOI: 10.1001/archsurg.143.4.396.
21. Vavra P, El Gendi A, Papaevangelou A, Vavrova M, Martinek L, Ihnat P, Dostalik J. New Treatment Approach in Liver Metastases: Hand-Assisted Laparoscopic Radiofrequency Liver Resection. *Rozhl Chir 86*, 554-557 (2007).
22. Pai M, Frampton A E, Mikhail S, Resende V, Kornasiewicz O, Spalding D R, Jiao L R, Habib N A. Radiofrequency assisted liver resection: Analysis of 604 consecutive cases. *EJSO 38*, 274-280 (2012). DOI: 10.1016/j.ejso.2011.12.006.
23. Jemal A, Siegel R, Ward E, Hao Y, Xu J, Murray T, Thun M J. Cancer statistics, 2008. *Ca Cancer J Clin 58*, 71-96 (2008). DOI: 10.3322/CA.2007.0010.
24. Varadarajulu S, Jhala N C, Drelichman E R. EUS-guided radiofrequency ablation with a prototype electrode array system in an animal model (with video). *Gastrointest Endosc 70*, 372-376 (2009). DOI: 10.1016/j.gie.2009.03.008.
25. Burdío F, Navarro A, Berjano E, Sousa R, Burdío J M, Güemes A, Subiró J, Gonzalez A, Cruz I, Castiella T, Tejero E, Lozano R, Grande L, de Gregorio M A. A radiofrequency-assisted device for bloodless rapid transection of the liver: a comparative study in a pig liver model. *Eur J Surg Oncol 34*, 599-605 (2008). DOI: 10.1016/j.ejso.2007.05.008
26. Solazzo S A, Ahmed M, Liu Z, Hines-Peralta A U, Goldberg S N. High-power generator for radiofrequency ablation: larger electrodes and pulsing algorithms in bovine ex vivo and porcine in vivo settings. *Radiology 242*, 743-750 (2007). DOI: 10.1148/radiol.2423052039

# Figures and tables

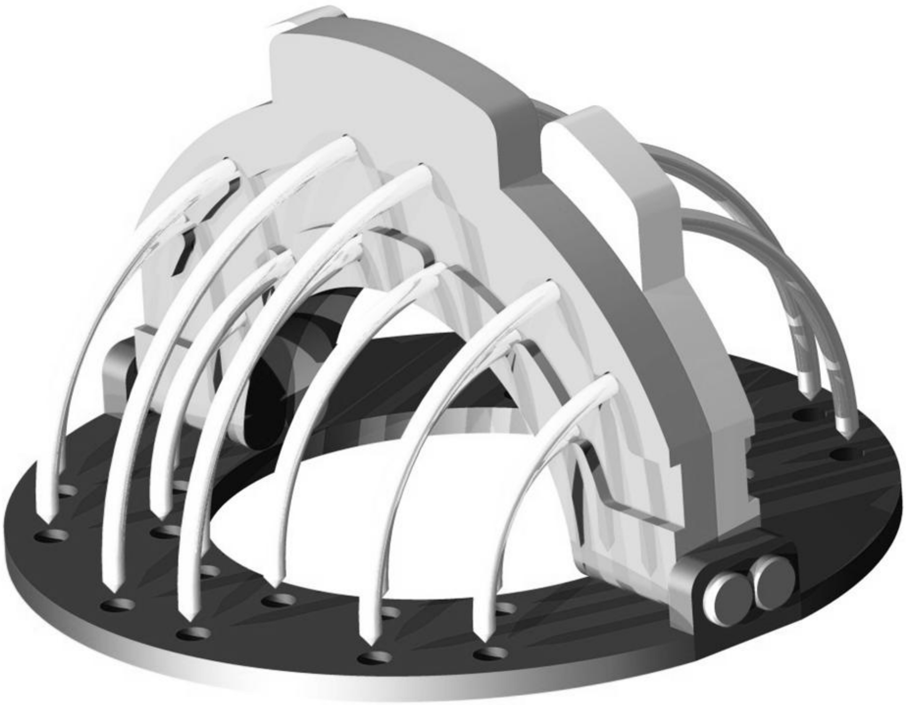

**Figure 1**. RONJA (semi-spherical bipolar radiofrequency device). Three dimensional model of new surgical device – view of the organization of electrode needles.

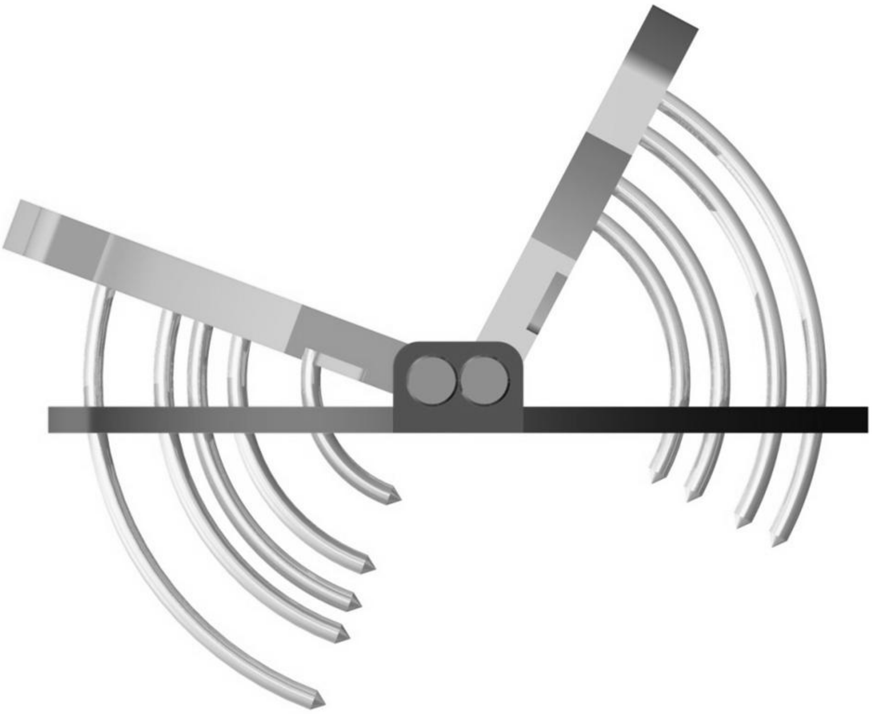

**Figure 2.** RONJA - Three dimensional model of new surgical device – the side view.

**Figure 3.** RONJA  - prototype of radiofrequency surgery tool – upper  side  view

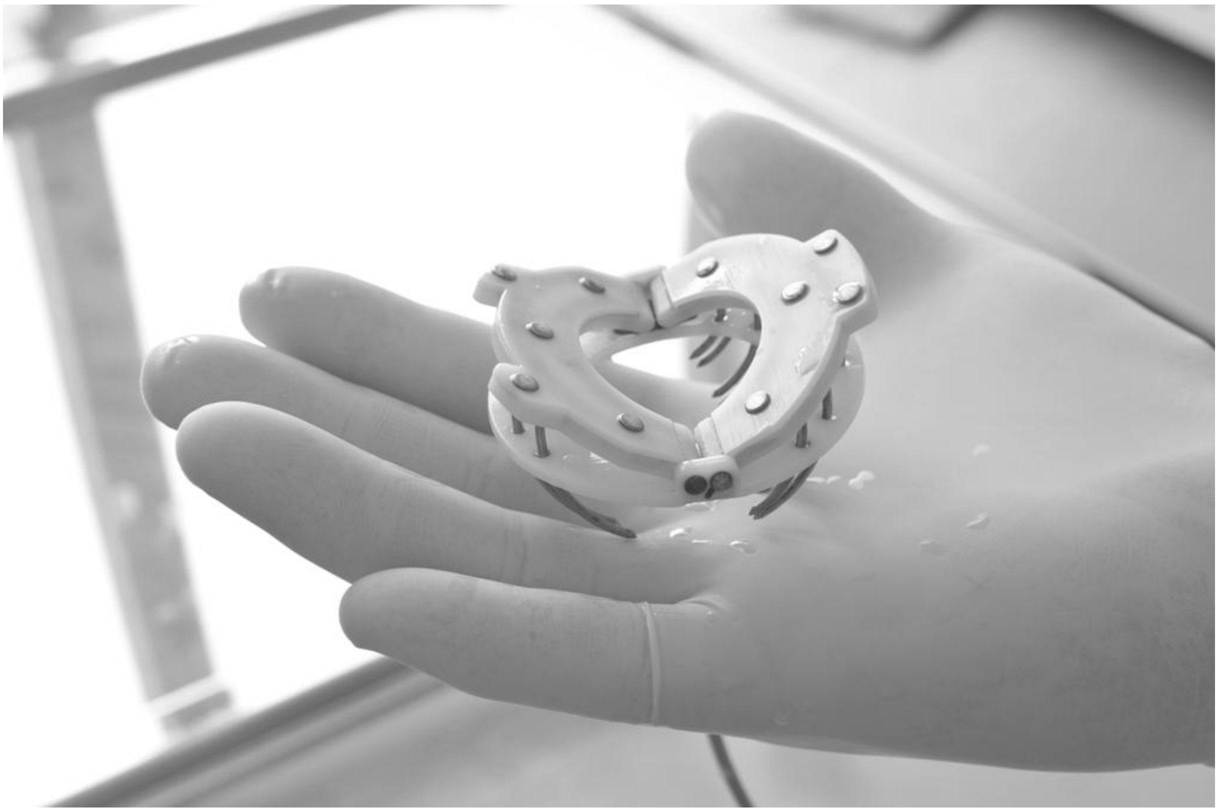

**Figure 4.** RONJA  - prototype of radiofrequency surgery tool – top side view

**Figure 5.** *In vivo* study – functional prototype – example of application on pig´s liver.

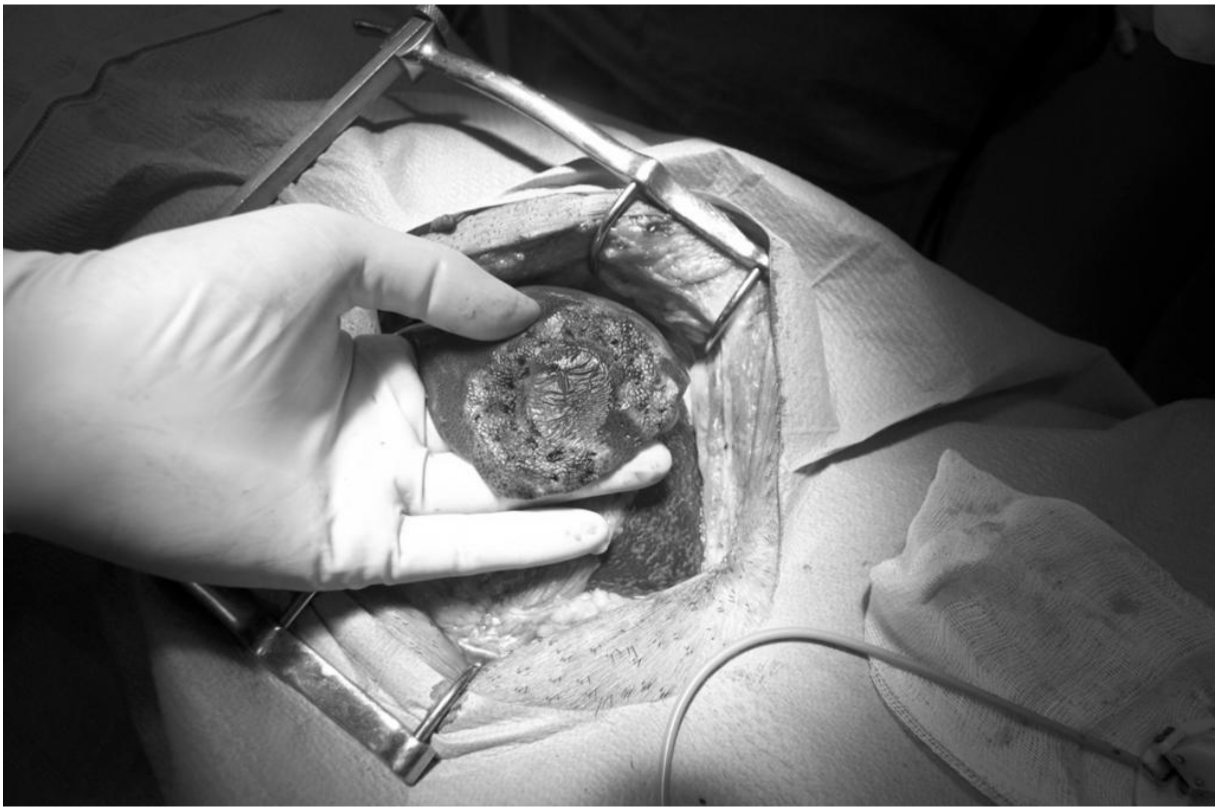

**Figure 6**. *In vivo* study – view on liver tissue after radiofrequency coagulation with new surgical semi-spherical device.

**Figure 7.** *In vivo* study – view in operation field and condition of liver tissue after excision.

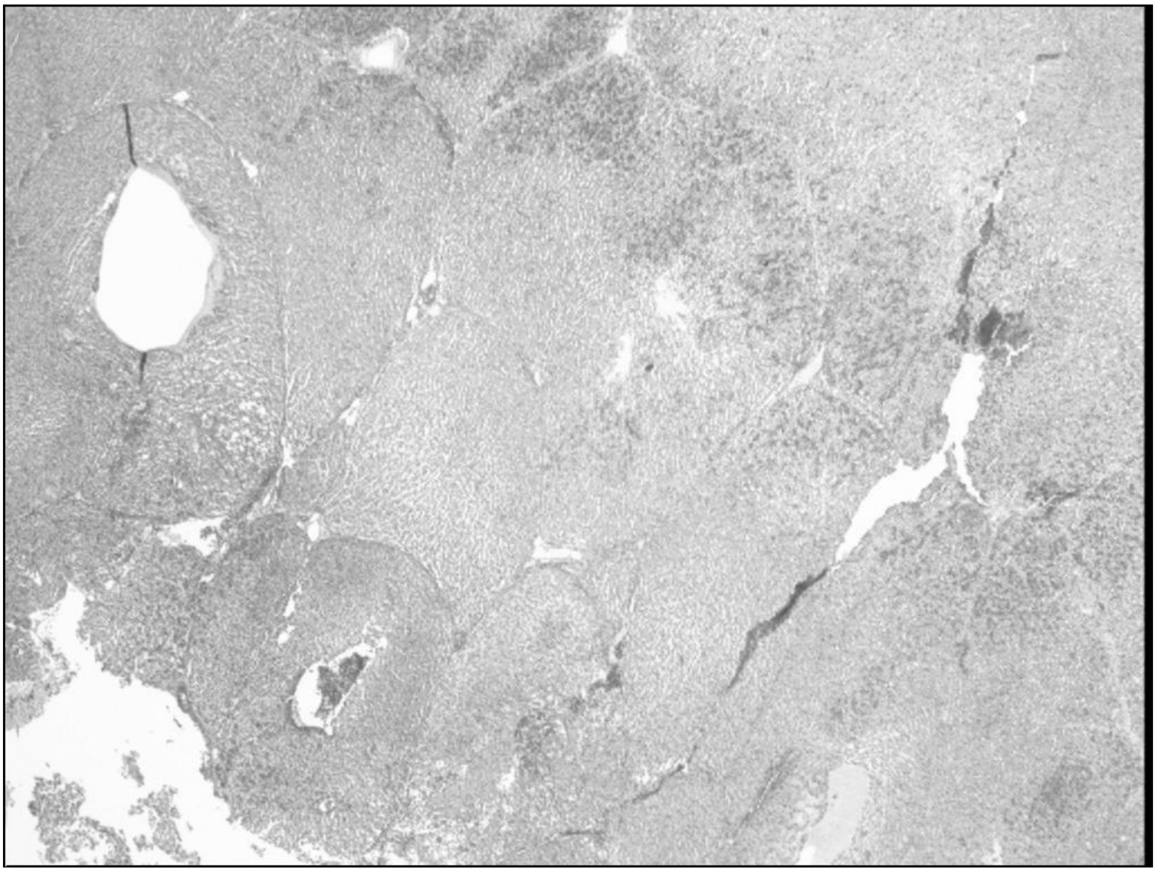

**Figure 8.** Microscopic section of liver biopsy, blood congestion bordered thermal alteration of liver tissue. Stained in Hematoxylin and eosin.

Table I. ***Obtained data***

| Rank | ID | Group | Weight 4.10 (kg) | Total operating time (min) | Ablation time of left lobe - LL (min) | Ablation time of right lobe -PL (min) | Supplied power (W) | Weight 18.10 (kg) | Total laparoscopy time (min) | Actual time of laparoscopy (min) | Weight | Total weight increment compared to original state (4.10.) (kg) | Liver weight 5.11. (kg) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 189 | B | 65 | 80 | 20 | 11 | 90 | 65 | 46 | 28 | 69 | 4 | 1,7 |
| 2 | 196 | B | 44 | 74 | 13 | 7 | 90 | 47,5 | 26 | 14 | 51 | 7 | 1,45 |
| 3 | 195 | B | 44 | 83 | 12 | 11 | 90 | 42 | 21 | 14 | 46,6 | 2,6 | 1,15 |
| 4 | 225 | B | 51 | 81 | 10 | 9 | 90 | 48 | 32 | 20 | 61 | 10 | 1,5 |
| 10 | 216 | B | 44 | 47 | 11 | 7 | 90 | 51 | 15 | 4 | - | - | - |
| 11 | 161 | B | 57 | 49 | 4 | 6 | 90 | 64 | 12 | 3 | 66,5 | 9,5 | 1,9 |
| **Av.** | | | **50,83** | **69** | **11,67** | **8,5** | **90** | **52,92** | **25,33** | **13,83** | **58,82** | **6,62** | **1,54** |
| | | | | | | | | | | | | | |
| 5 | 200 | A | 34 | 68 | 14 | 7 | 90 | 39 | 21 | 9 | 41 | 7 | 1,3 |
| 6 | 167 | A | 58 | 71 | 11 | 11 | 80 | 64 | 19 | 10 | 64,8 | 6,8 | 1,9 |
| 7 | 232 | A | 46 | 53 | 8 | 8 | 80 | 49 | 48 | 5 | 50,75 | 4,75 | 1,4 |
| 8 | 193 | A | 65 | 46 | 7 | 6 | 80 | 62 | 25 | 5 | 71,5 | 6,5 | 1,6 |
| 9 | 177 | A | 53 | 53 | 7 | 5 | 80 | 53 | 32 | 4 | 55 | 2 | 1,1 |
| 12 | 191 | A | 62 | 54 | 6 | 7 | 80 | 64 | 18 | 3 | 69,95 | 7,95 | 1,55 |
| **Av.** | | | **53** | **57,5** | **8,83** | **7,33** | **82** | **55,17** | **27,17** | **6** | **58,83** | **5,83** | **1,48** |

Table II. ***Material processing – autopsy samples – RONJA device.*** In all samples, fibrosis around necrosis, hyperaemia of healthy liver tissue, deposits of iron and KCT (kaolin test) responses around necrosis were confirmed.

| Sample no. | Maximum depth of necrosis from resection line in mm | | Other |
|---|---|---|---|
| | piece of right lobe | piece of left lobe | |
| 1 | 20 | 9 | DisPZ |
| 2 | 15 | 9 | PZ |
| 3 | 12 | 14 | DaPZ |
| 4 | 8 | 14 | DaPZ |
| 10 | 13 | 14 | PZ,KC |
| 11 | 13 | 22 | PZ |
| **∑** | **13** | **14** | |
| **Ø** | **11.8** | **13.6** | |

Table III. ***Material processing – autopsy samples – Standard device.*** In all samples, fibrosis around necrosis, hyperaemia of healthy liver tissue, deposits of iron and KCT (kaolin test) responses around necrosis were confirmed.

| Sample no. | Maximum depth of necrosis from resection line in mm | | Other |
|---|---|---|---|
| | piece of right lobe | piece of left lobe | |
| 5 | 15 | 14 | ZC,PZ |
| 6 | 13 | 11 | ZC,PZ |
| 7 | 10 | 13 | ZC,PZ |
| 8 | 11 | 18 | ZC,PZ |
| 9 | 15 | 13 | ZC,PZ,KC |
| 12 | 25 | 15 | ZC,PZ |
| ∑ | **14** | **13.5** | |
| **Ø** | **14.8** | **14** | |

Table IV. ***Maximum depth of thermal alteration from excised liver tissue.***

| RONJA device, sample no. | Lobe 1 =dx, 2 = sin | Weight of resected particle (g) | Size of resected particle (cm) | Maximum depth of thermal alteration (cm) |
|---|---|---|---|---|
| 5/ V 200 | 1 | 16.1 | 7.0x4.0x1.6 | 1.3 |
| | 2 | 12.9 | 3.7x4.2x1.5 | 1.7 |
| 6/V 167 | 1 | 19.4 | 4.3x4.3x2.2 | 1.4 |
| | 2 | 16.7 | 5.8x4.2x1.7 | 1.4 |
| 7/V 232 | 1 | 25.7 | 8.0x4.0x1.9 | 1.5 |
| | 2 | 18.5 | 6.5x4.0x1.7 | 1.4 |
| 8/V 193 | 1 | 9.2 | 5.5x4.0x1.4 | 1.4 |
| | 2 | 12.5 | 2.8x4.0x2.2 | 1.5 |
| 9/V 177 | 1 | 12.7 | 5.0x4.0x1.6 | 1.7 |
| | 2 | 15.6 | 5.3x4.0x1.9 | 1.5 |
| 12/V 191 | 1 | 8.9 | 4.0x4.0x1.9 | 1.2 |
| | 2 | 12.3 | 4.3x5.0x2.2 | 1.2 |
| **Standard device, sample no.** | **Lobe 1 =dx, 2 = sin** | **Weight of resected particle (g)** | **Size of resected particle (cm)** | **Maximum depth of thermal alteration (cm)** |
| 1/V 189 | 1 | 4.8 | 4.5x2.5x1 | Up to 1 |
| | 2 | 10.7 | 4.0x4.0x1.3 | 1.2 |
| 2/V 196 | 1 | 7 | 4.5x3.0x1.7 | 1.5 |
| | 2 | 10.6 | 5.0x3.7x1.5 | 1 |
| 3/V 195 | 1 | 12.6 | 7.0x3.3x1.7 | Up to 1 |
| | 2 | 15.5 | 5.0x4.0x1.9 | 1.3 |
| 4/V 225 | 1 | 12.5 | 6.0x4.3x1.5 | Up to 1 |
| | 2 | 11.9 | 4.0x4.8x1.6 | 1 |
| 10/V 216 | 1 | 8.2 | 6.0x2.8x1.4 | Up to 1 |
| | 2 | 6.9 | 4.4x3.5x1.3 | Up to 1 |
| 11/V 161 | 1 | 12.2 | 6.5x3.5x2.5 | Up to1 |
| | 2 | 14.9 | 6.0x4.0x1.6 | Up to 1 |

Table V. ***Operating data.*** There was a significant difference (*p* = 0,005) in supplied power between the groups.

| | Standard device; | RONJA; | p-value |
|---|---|---|---|
| | mean ± S.E.M. (median) | mean ± S.E.M. (median) | |
| **Weight1 (kg)** | 50.83 ± 3.55 (47.50) | 53.00 ± 4.69 (55.50) | 0.567 |
| **Total operating time (min)** | 69.00 ±6.76 (77.00) | 57.50 ± 3.99 (53.50) | 0.567 |
| **Ablation time of left lobe (min)** | 11.67 ± 2.11 (11.50) | 8.83 ± 1.25 (7.50) | 0.567 |
| **Ablation time of right lobe (min)** | 8.50 ± 0.89 (8.00) | 7.33 ± 0.84 (7.00) | 1 |
| **Supplied power (W)** | 90.00 (unchanging) | 81.67 ± 1.67 (80.00) | **0.005*** |
| **Weight2 (kg)** | 52.92 ± 3.85 (49.50) | 55.17 ± 4.11 (57.50) | 0.567 |
| **Laparoscopic total time (min)** | 25.33 ± 5.08 (23.50) | 27.17 ± 4.66 (23.00) | 1 |
| **Actual time of laparoscopy (min)** | 13.83 ± 3.89 (14.00) | 6.00 ± 1.16 (5.00) | 0.567 |
| **Weight3 (kg)** | 58.82 ± 4.35 (61.00) | 58.83 ± 4.89 (59.90) | 1 |
| **Total weight increment (kg)** | 6.62 ± 1.46 (7.00) | 5.83 ± 0.88 (6.65) | 0.567 |
| **Liver weight (kg)** | 1.54 ± 0.13 (1.50) | 1.48 ± 0.11 (1.48) | 1 |

Table VI. ***Data concerning complications.*** There was no significant differences between the groups.

| | **Standard device; *n* (%)** | **RONJA; *n* (%)** | ***p*-value** |
|---|---|---|---|
| **Complications during surgery** | 0 (0) | 1 (16.7) | 1 |
| **Post-operative complications** | 1 (16.7) | 0 (0) | 1 |
| **Complications during laparoscopy** | 0 (0) | 4 (66.7) | 0.061 |
| **Post-operative adhesions (liver)** | 6 (100) | 6 (100) | - |
| **Post-operative adhesions (spleen)** | 2 (33.3) | 2 (33.3) | 1 |
| **Pathological findings – ascites** | 1 (16.7) | 2 (33.3) | 1 |
| **Pathological findings – abscess** | 0 (0) | 1 (16.7) | 1 |
| **Pathological findings in lungs** | 4 (66.7) | 2 (33.3) | 0.567 |

Table VII. ***Data concerning histopathological findings of thermal alteration.*** There was no significant differences between the groups.

| | **Standard device;** | **RONJA;** | **p-value** |
|---|---|---|---|
| | **mean ± S.E.M. (median)** | **mean ± S.E.M. (median)** | |
| **Thermal alteration at the resection margin (%) – right lobe** | 98.33 ± 1.67 (100.00) | 98.33 ± 1.67 (100.00) | - |
| **Thermal alteration at the resection margin (%) – left lobe** | 100.00 (unchanging) | 95 ± 3.42 (100.00) | - |
| **Maximum depth of necrosis (mm) – right lobe** | 13. ± 1.61 (13.00) | 14.83 ± 2.20 (14.00) | 1 |
| **Maximum depth of necrosis (mm) – left lobe** | 13.67 ± 1.94 (14.00) | 14.00 ± 0.97 (13.50) | 1 |
| **Weight of resected particle (g) – right lobe** | 9.55 ± 1.37 (10.20) | 15.33 ± 2.65 (14.40) | 0.567 |
| **Weight of resected particle (g) – left lobe** | 11.75 ± 1.29 (11.30) | 14.75 ± 1.05 (14.25) | 0.567 |
| **Maximum depth of thermal alteration (cm) – right lobe** | 1.08 ± 0.08 (1.00) | 1.42 ± 0.07 (1.40) | 0.08 |
| **Maximum depth of thermal alteration (cm) – left lobe** | 1.08 ± 0.05 (1.00) | 1.45 ± 0.07 (1.45) | 0.08 |