Gynecol Surg (2007) 4:9–16
DOI 10.1007/s10397-006-0262-5

REVIEW ARTICLE

Use of the BiClamp (a bipolar coagulation forceps) in gynecological surgery

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Received: 21 September 2006 / Accepted: 27 October 2006 / Published online: 13 January 2007

Abstract The integration of new technical possibilities into the overall concept is the determining factor in progress in surgery. The availability of the BiClamp and its specially designed electrical concept mean that we now have a new bipolar coagulation forceps at our disposal. Based on the principles of electrosurgery, we developed a new current modulation that has improved hemostatic properties. The new current modulation can be used for bipolar laparoscopic coagulation forceps, and also for new types of forceps for open surgery. The main area of use in open surgery is vaginal hysterectomy. Initial retrospective studies all showed that the newly designed forceps are a successful surgical instrument. The use of the BiClamp for vaginal hysterectomy leads to less blood loss and less postoperative pain, with similar results in these respects to laparoscopic surgery. In some studies, the duration of surgery was shorter than with conventional vaginal hysterectomy, and in others of similar length. Prospective, randomized controlled studies have, however, yet to be performed. We are of the opinion that confirmation of the results achieved so far will increase the spectrum of indications for this bipolar coagulation forceps, leading to greater patient benefit.

Keywords Electrosurgery · Hysterectomy · Vaginal hysterectomy · Laparoscopy · Surgical instruments · Hemostatic techniques

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Introduction

If we look back at the history of hysterectomy from its beginnings to the present day, we recognize a consistent process of development. A very dangerous operation to begin with, hysterectomy has now become a relatively simple technique that is safe and no longer puts a great deal of stress on the patient. Harry Reich was the first to perform laparoscopic hysterectomy in 1989 [1]. The vessels underwent bipolar coagulation and were then separated. Although the duration of the operation was much longer than with the conventional method, it involved much less blood loss, the patients had much less pain, and they recovered much more quickly. At first, the quick convalescence was attributed to the absence of a laparotomy wound, but it later emerged that the avoidance of ligatures with this method was the reason for the low degree of pain. The ligature-free hysterectomy was, however, an older concept, first proposed by A. Mayer in Tübingen, Germany, in the 1940s, and he successfully treated six patients in this way [2]. He used specially designed vessel clamps, which, like the originally named angiotribes, induced maximum crushing of the vessels, and then coagulated the vessels by applying monopolar current through the clamps. Unfortunately, this idea was not further developed and was forgotten.

On the basis of the smaller laparoscopic bipolar coagulation forceps, different companies developed optimized models for open surgery. At our hospital, we use the BiClamp, a bipolar coagulation forceps manufactured by Erbe Elektromedizin GmbH, Tübingen, Germany (Fig. 1).

We first began using the bipolar coagulation forceps for vaginal hysterectomies. Our expectations were fulfilled by our early surgical operations and confirmed the results made by others. The operations were problem-free, involved less blood loss than conventional methods, and the

Fig. 1 The BiClamp 200. The instrument has been modified in the meantime and different models are available, for example, a smaller model for thyroid surgery, and a larger one for vaginal surgery and laparotomy with a rippled surface and ceramic elements on the coagulation plane to grasp the tissue better. Instruments are also now available with a ceramic cover on the coagulation jaws for better cleaning and for prolonging the life of these reusable instruments

patients had less pain and convalesced much more quickly. Unfortunately, in the first few months of use, we also saw two patients with secondary hemorrhage, without serious consequences, but which we took as a warning. This led us to study the technique of bipolar coagulation much more closely and, together with Erbe, we developed a new method of coagulation.

Electromedical concept

Let us first take a look at the basic concept of electrocoagulation. It is not possible to use direct current for surgical purposes, since it causes electrolysis and burns. Low-frequency alternating current is also not suitable, since it causes muscular contractions. Only a high-frequency current of more than 100 Hz can be used, generated in bursts called packages (Fig. 2).

It is possible to modulate the oscillating current in different ways (Fig. 3). The number of oscillations per package, their frequency, voltage, and their amplitude can be varied. Different effects can be achieved by different forms of modulation.

Higher voltages cause spark formation. Cell fluid vaporizes explosively, and this is the principle of the

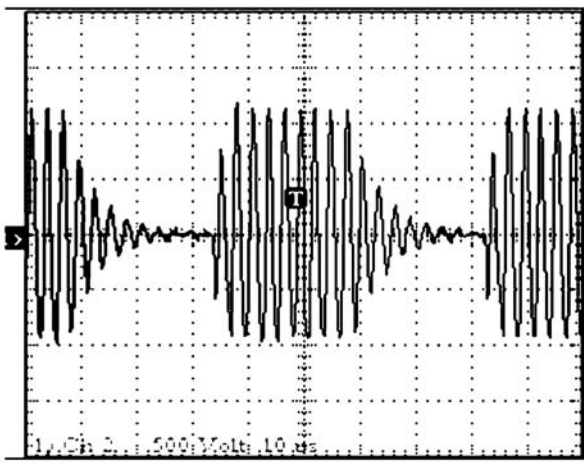

Fig. 2 The VIO generator (Erbe Elektromedzin GmbH, Tübingen, Germany; *right*) produces high-frequency alternating current (*left*), which is packed in small bursts and is passed through the application instrument, such as coagulation tweezers, an electric knife, or the BiClamp

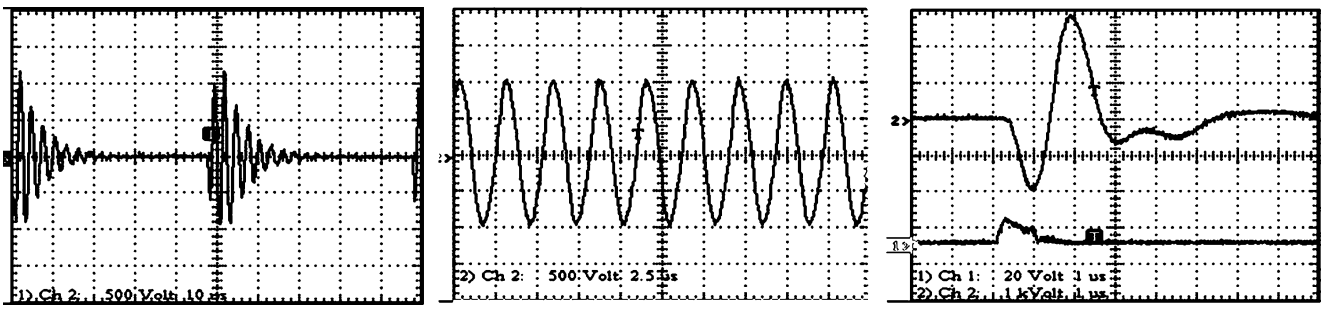

Fig. 3 Different modulation patterns for different types of coagulation and cutting

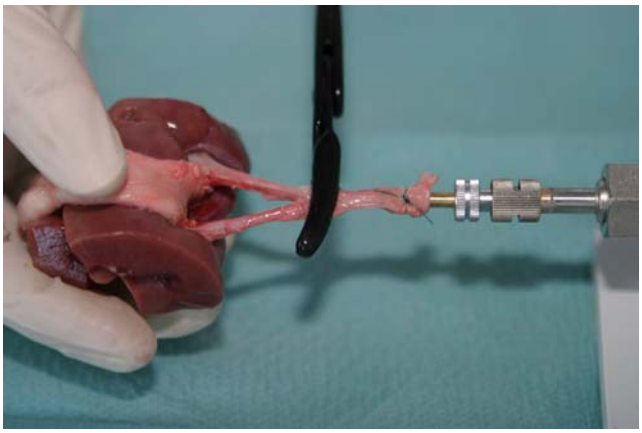

Fig. 4 Burst pressure measurement. With an open BiClamp, the porcine renal artery is coagulated. Fluid is then injected into the coagulated artery and the burst pressure is measured (from [3])

cutting method. This is termed cutting current. Slow heating produces coagulation current. By varying the form of modulation it is possible to produce zones of coagulation in the target tissue with either sharply defined or blurred margins. This influences the formation, shedding, and absorption of zones of necrosis. Combined effects can be achieved by choosing the appropriate modulation. Based on empirical findings, it is also possible to 'design' modulation patterns to achieve specific coagulation properties for special surgical techniques with specially designed devices.

In collaboration with Erbe, we developed a modulation pattern especially for the BiClamp that offers very reliable sealing of vessels. The new coagulation method is much safer than the method used so far [3]. Preparations of porcine renal arteries were coagulated using the new method under standard conditions (Fig. 4). We then determined the burst pressure of the coagulated vessels.

The traditional coagulation mode (mode 1) was compared with the newly developed, impedance-dependent dynamic mode (mode 3) (Fig. 5). The new sealing method was seven times better than the conventional method (Fig. 6). Vessels whose seals were unable to withstand a pressure of 200 mm Hg were considered seal failures. With the conventional bipolar mode (mode 1), 43 vessels showed

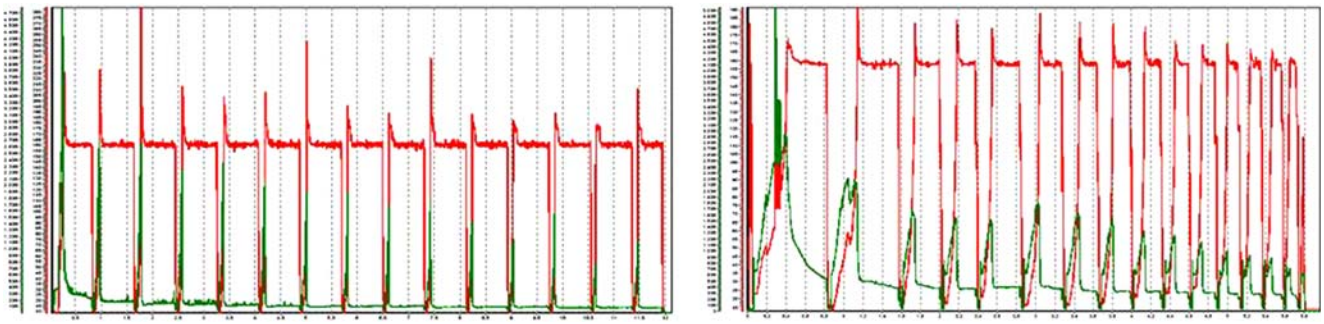

Fig. 5 Comparison of the modulation curves of the conventional bipolar coagulation mode (mode 1; *left*) and the newly developed, dynamic, 'intelligent' impedance-dependent energy intake method, the BiClamp method (mode 3; *right*). The *red line* is the voltage and the *green line* is current (from [3])

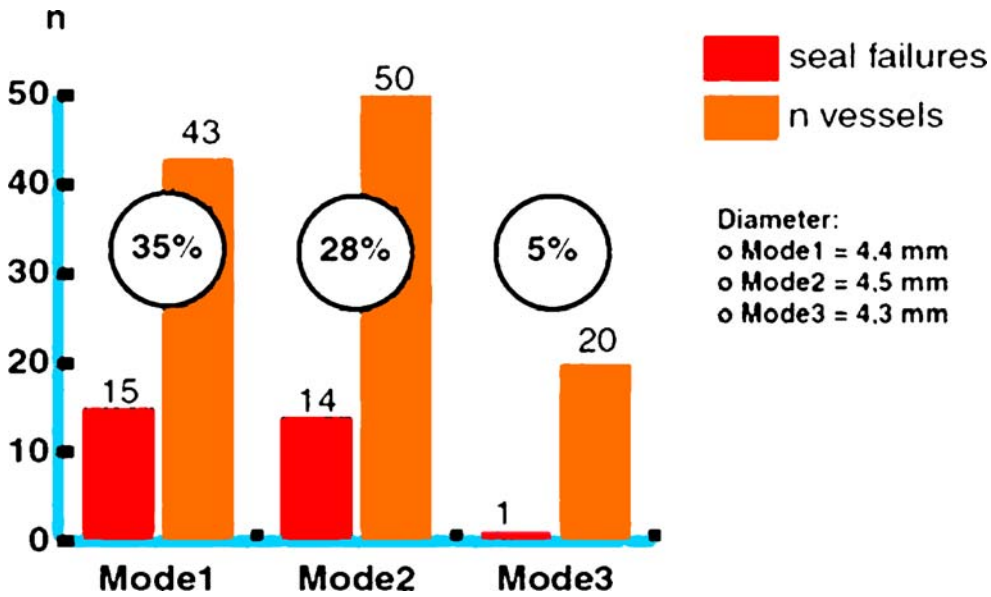

Fig. 6 Comparison of the different sealing modes

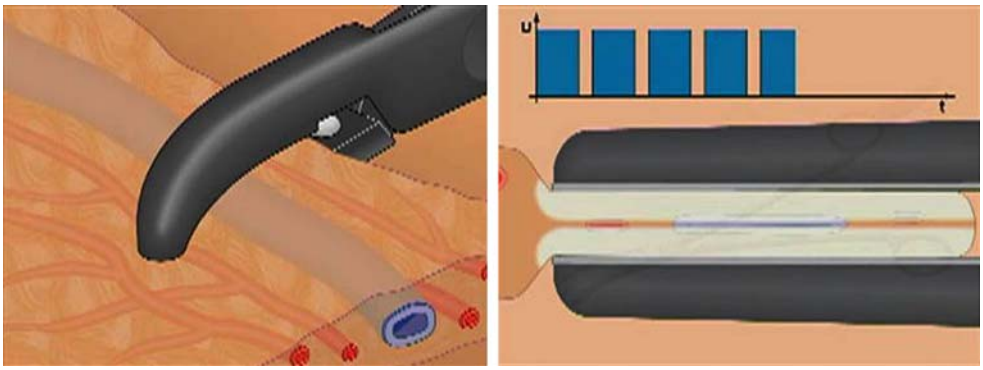

Fig. 7 Thermofusion. Using the BiClamp, the vein is grasped with the surrounding connective tissue and then undergoes bipolar coagulation with the tissue

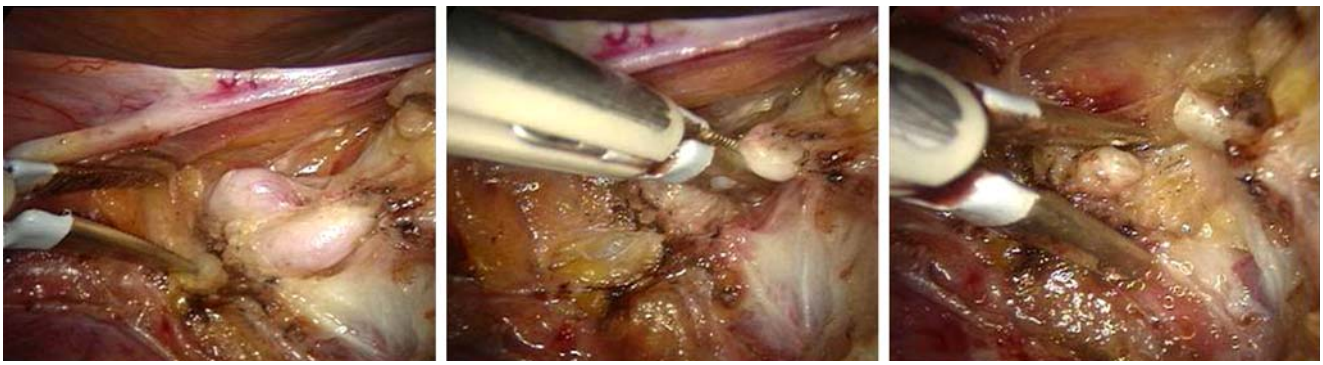

Fig. 8 Coagulation of the uterine artery with the laparoscopic BiClamp. *Left*: left uterine artery prepared by the Maryland BiClamp. *Middle*: Uterine artery grasped by the windowed laparoscopic BiClamp and coagulated. *Right*: Dissection of the uterine artery with scissors: no carbonization, no bleeding, with complete vessel sealing

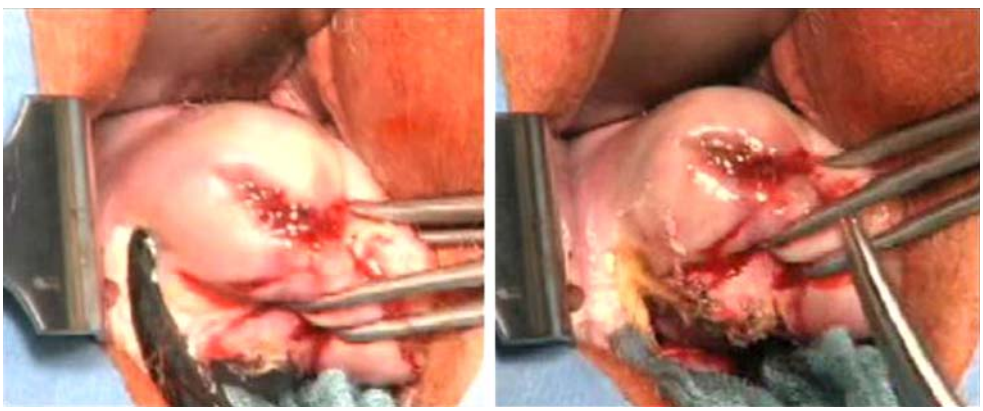

Fig. 9 Coagulation of the sacrouterine ligaments with the BiClamp and dissection with scissors. The cut is clean, without bleeding or carbonization

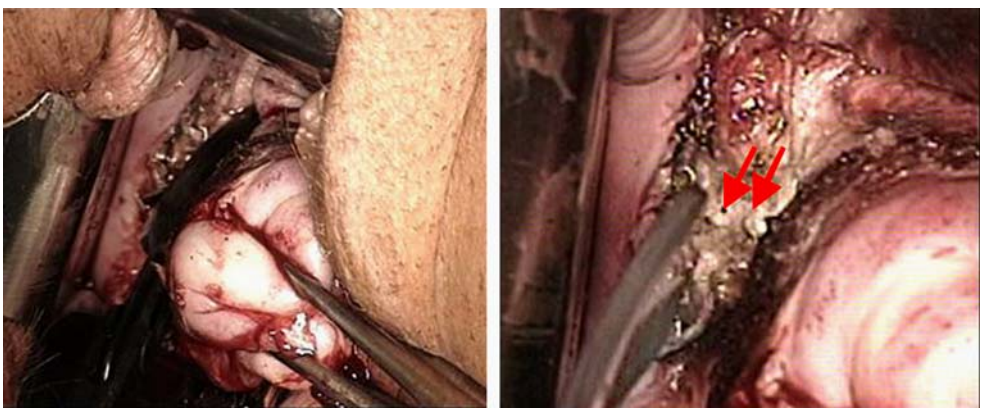

Fig. 10 Coagulation of the uterine artery with the BiClamp and cutting with scissors. The *red arrows* on the right show the dissected uterine artery. Here also, perfect vessel sealing

Table 1 Comparison of outcome of conventional and BiClamp vaginal hysterectomy with regard to blood loss and postoperative pain

	Type of surgery	
	BiClamp (*N*=40)	Conventional (*N*=40)
Patient characteristics		
Age (years)	52.9 (32–87)	53.9 (36–80)
Weight (kg)	75.8 (36–132)	75.2 (48–120)
Uterus weight (g)	140 (35–360)	145 (35–840)
Details of surgery		
Only vaginal hysterectomy	19	19
Cystocele and/or rectocele repair	16	17
Other descent surgery	11	13
Tension-free vaginal tape	9	7
Estimated intraoperative bleeding (mL):		
All patients	107 (5–400)	177 (30–400)
Only vaginal hysterectomy (*N*=19)	58.6 (5–150)	99.5 (50–400)
Drop in hemoglobin (g/dL):		
All patients	1.56 (0–5.8)	1.64 (0–5.6)
Only vaginal hysterectomy (*N*=19)	1.0 (0–2.5)	1.3 (0.3–2.8)*
Postoperative analgesia from day 2		
All patients	24	32
Number of single doses	107	132
Only vaginal hysterectomy (*N*=19)	9	19
Number of single doses	26	94**

Modified from [6]
*p<0.05; ** p<0.01 (Mann-Whitney U-test)

good sealing and there were 15 seal failures (35%). With the 'intelligent' BiClamp mode (mode 3), seal failures were reduced to 5%.

This newly developed method with this specific vessel-sealing effect was immediately integrated into the Erbe VIO generators and is automatically activated when a BiClamp is used. Since we have been using it we have not seen any secondary hemorrhages, and, as far as we are aware, they have not been observed at other hospitals where this method has been used.

Table 2 Comparison of 453 prospectively studied vaginal hysterectomies using the BiClamp and 100 historical conventional vaginal hysterectomies

Variable (mean)	Vaginal hysterectomy	
	Conventional (*N*=100)	BiClamp (*N*=452)
Uterus weight (g)	188	219
Operation time (min)	57	44
Hemoglobin (g/dL)		
Preoperative	8.5	8.2
Postoperative	7.7	8.0
Difference	0.8	0.2
Analgesic treatment (days)		
IV	2.1	1.3
Oral	4.5	4.3

From [8]

Table 3 Preliminary results of a retrospective study comparing blood loss, duration of surgery, and postoperative pain in patients treated with laparoscopic supracervical hysterectomy (conventional and with BiClamp) and vaginal hysterectomy

Variable (mean)	Type of hysterectomy		
	Laparoscopic supracervical (*N*=30)	Conventional vaginal (*N*=30)	BiClamp vaginal (*N*=30)
Age (years)	45.9	48	45.8
Weight (kg)	66.2	73	78
Uterus weight (g)	155	187	174
Operation time (min)	84	56	55
Blood loss			
Estimated (mL)	64	96	59
Hemoglobin drop (g/dL)	1.0	1.4	0.9
Analgesics from second postoperative day (N)	20	29	17

In addition to pure coagulation to seal vessels, we must also mention 'thermofusion'. When arteries are coagulated, the highly developed, strong vessel walls swell and securely close the lumen. The effect on veins is different, however, as they do not have highly developed walls that can close the vessel. Secure sealing of vessels is achieved by not selectively coagulating the isolated vessel, but by including the surrounding connective tissue. With gentle coagulation avoiding carbonization, this tissue shrinks and tightens around the vein like a natural cuff, thus sealing it off. This process, which requires automatically regulated and dosed current driven by specially designed software, we term 'thermofusion' (Fig. 7).

Possible sources of error

A special set of rules has to be observed when using the BiClamp to avoid bleeding. When coagulating, the vessel must not be put under tension. The consistency of the tissue changes during coagulation and it is weakened so much during a transitional phase by thermal denaturation that it is torn by the slightest tension, and the vessel is not adequately sealed. Bleeding then ensues. The coagulated tissue can also not be subject to excessive degrees of mechanical stress. The coagulation zones can avulse, and the vessel lumen is left open and bleeds. Safety ligatures over coagulated vessel stumps do not increase the degree of security but lead to bleeding. The ligatures cut into the denatured, friable tissue and open up the vessels which then also bleed. Once this occurs, it is very difficult to grasp these stumps and reseal them.

Fig. 11 Ablation of the uterus with the BiClamp in the vaginal vault. The bipolar coagulation forceps is used to separate the lateral vaginal vault and, selectively, the anterior and posterior vaginal walls. *Left*: Separation of the ventral vaginal wall; *centre*: The vaginal stump is still open and the wound margins are completely blood-free. *Right*: ablated tissue

Clinical use

We report in the following on the use of the BiClamp during laparoscopic and open surgery, describing a very wide range of applications using this bipolar coagulation forceps together with specially designed software.

Since 2003, we have been performing laparoscopic hysterectomies at the Department of Obstetrics and Gynecology at Tübingen University Hospital, also using the laparoscopic BiClamp. Our preferred method is supracervical hysterectomy. The laparoscopic BiClamp has proved to be a safe and reliable instrument for the bipolar coagulation of vessels, including those of the uterus (Fig. 8).

Vaginal hysterectomy

Vaginal hysterectomy with the BiClamp is conducted in a similar way to the conventional procedure. The vaginal vault is opened ventrally with an electric needle, the urinary bladder is pushed to one side, the vesicouterine ligament is separated, and the pouch of Douglas is opened. The sacrouterine ligaments are then coagulated with the BiClamp and dissected with scissors (Fig. 9). The parametrial vessels and the uterine vessels are coagulated and dissected (Fig. 10).

If the uterus is large, it is dissected, either using morcellation or a suitable manual technique. The rotund ligament and the adnexa are coagulated with the BiClamp and then dissected. Only one suture is necessary: to close the vaginal stump.

Results of studies

In 2003, Clavé reported on a retrospective study in which two groups of 25 women underwent vaginal hysterectomy using the conventional method and 25 with the BiClamp using conventional modulation [4]. The patients experienced much less postoperative pain after use of the BiClamp and were able to be discharged earlier. However, since Clavé used long-acting regional and local anesthesia, this represents a considerable limitation on the validity of the conclusions with regard to the effects of bipolar coagulation, so that no clear difference could be made between the effects on the postoperative course. In a more recent study in 152 patients, he confirmed his earlier conclusions [5]. We were also able to show in a retrospective study with 40 patients in each group that patients who underwent surgery using the BiClamp had less blood loss during surgery, less postoperative pain, and were also able to be discharged earlier (Table 1); in the 19 patients who underwent only vaginal hysterectomy, the blood loss and postoperative pain were significantly lower [6, 7]. We used no local anesthesia or other injections.

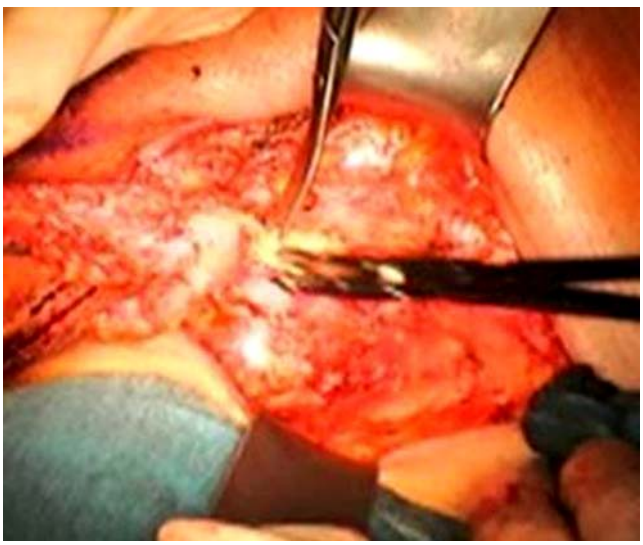

Fig. 12 Extensive inguinal lymph nodectomy during radical vulvectomy. The light coagulation surfaces show no carbonization and the surgical area is largely free of blood

We were able to confirm these results in a large prospective study with more than 450 patients who underwent vaginal surgery using the BiClamp (Table 2) [8]. The decrease in hemoglobin was much smaller and the patients needed fewer analgesics, especially IV drugs, after BiClamp surgery. We also showed that the duration of surgery using the BiClamp was shorter than with the conventional method. Since the number of patients treated was small, it is difficult to draw conclusions on intraoperative complications. The results did, however, show a trend indicating that complications are at least not more frequent with the BiClamp.

Wojdat and Volz [9], and Sagae [10] reported similar results. Taken together, we conclude that the BiClamp is a safe and reliable surgical instrument that is not associated with a higher rate of surgical complications than previous methods. Patients who underwent vaginal hysterectomy using bipolar coagulation forceps lost less blood during surgery, had less postoperative pain, and were able to be discharged earlier. The operation time was also shorter than with conventional methods.

We also gained the subjective impression that working with the bipolar coagulation forceps in the restricted anatomical conditions posed by vaginal surgery was easier than the conventional vaginal approach. The surgery was therefore also not just easier in general; it was also possible to remove larger uteruses via the vagina than was previously routinely possible.

We compared blood loss, duration of surgery, and postoperative pain in a retrospective pilot study in laparoscopic supracervical hysterectomy, conventional vaginal hysterectomy and vaginal hysterectomy with hemostasis using the BiClamp (Table 3). The preliminary findings show that the vaginal BiClamp hysterectomy combines the advantages of the laparoscopic approach, with less blood loss and less postoperative pain, and the advantages of vaginal hysterectomy, namely the short operation time.

These preliminary findings led us to combine these advantages in practice. Vaginal hysterectomy using the BiClamp can be performed at least as rapidly as conventional vaginal surgery, and blood loss during surgery and postoperative pain are not only much lower than with the conventional method, they are also comparable with those seen after the laparoscopic approach, which is more time-consuming.

Other applications of the bipolar coagulation forceps

We are now also using the bipolar coagulations forceps for open surgery (Fig. 11), and for other operations, e.g., vulvectomy and inguinal lymph nodectomy (Fig. 12).

Our present subjective impression is that the BiClamp is a very useful instrument for the above types of surgery, and this has been confirmed by reports from other groups [10]. Patients undergoing abdominal hysterectomy also appear to lose less blood and have less postoperative pain than with conventional methods using sutures and ligatures. Patients who have undergone vulvectomy and inguinal lymph nodectomy with the BiClamp also appear to develop less secretion of lymph than when conventional methods are used. Other groups have reported successful use of the open BiClamp for axillary lymph nodectomy and the bipolar coagulation forceps are also being used for more major abdominal cancer surgery and exenteration.

Outlook

Our experience and that of other groups demonstrate that bipolar coagulation with the BiClamp combined with current modulation driven by specially developed software is a reliable surgical instrument. It offers patients considerable advantages over conventional methods: less blood loss, less postoperative pain, and more rapid convalescence. It also offers economic advantages over conventional methods: less use of analgesics, shorter hospital stays, and possibly also a shorter duration of surgery. The introduction of bipolar coagulation, also into open surgery, therefore represents a new option for surgeons and will have a greater role to play in the future in surgical operations.

Acknowledgements The authors would like to thank Alistair Reeves for translating and editing this paper. The authors hereby declare that all experiments and investigations described comply with legislation in the Federal Republic of Germany. The authors are also grateful to the German Ministry of Education and Research (BMBF) for generously supporting this research within the 'Minimally invasive technology and therapeutic methods' Project (Grant No. 16SV 1352).

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