Predictors of a Successful Bipolar Radiofrequency Endometrial Ablation

Prädiktoren einer erfolgreichen bipolaren Radiofrequenz-Endometriumablation

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ABSTRACT

Introduction The study's objectives were to determine the success rate following radiofrequency endometrial ablation to treat abnormal menstrual bleeding and to assess risk factors for failure of the method.

Materials and Methods 195 women who were treated with bipolar radiofrequency endometrial ablation between 01/2009 and 06/2016 were included in this prospective cohort study. Postoperative data from 187 women were collected at a median of 17.5 months (IQR 4.5–34.9; 1–82). Multivariate analyses of risk factors were performed. Success was defined as amenorrhoea or spotting.

Results Patient characteristics were as follows: mean age 44 years (SD ± 5), median parity 2 (IQR 2–3), median hysterometer 8.7 cm (SD ± 1.1), and median BMI 23.5 kg/m^2 (IQR 21–27). 30 patients (19.5 %) had intramural masses that could be measured with ultrasound. Postoperative success rate was 86.1 %. 10 patients (5 %) had a hysterectomy postoperatively – 6 for heavy bleeding, 3 due to prolapse, and 1 due to dysmenorrhoea. Multivariate analyses showed the presence of intramural masses in women < 45 years was a significant risk factor for therapeutic failure (p = 0.033; 95 % CI 1.08–12.57), with an increased risk of hysterectomy (OR 7.9, 95 % CI 1.2–52.7, p = 0.033).

Conclusion Bipolar radio frequency endometrial ablation was highly successful in the absence of an intramural mass (88 %). Even smaller intramural fibroids (DD: adenomyomas of a median of 15 mm) reduce the success rate (76 %), which is why preoperative ultrasound is recommended. In the presence of intramural masses, the risk of a hysterectomy for women < 45 years increases eightfold.

ZUSAMMENFASSUNG

Einleitung Ziel dieser Studie war es, sowohl die Erfolgsrate nach Radiofrequenz-Endometriumablation bei abnormer Menstruationsblutung als auch Risikofaktoren bezüglich Versagen der Methode zu eruieren.

Material und Methoden In diese prospektive Kohortenstudie konnten 195 Frauen, welche mit der bipolaren Radiofrequenz-Endometriumablation zwischen 01/2009 bis 06/2016 behandelt wurden, eingeschlossen werden. Postoperative Daten von 187 Frauen konnten im Median 17,5 Monate (IQR 4,5–34,9; 1–82) nach dem Eingriff erhoben werden. Multivariate Analyse der Risikofaktoren. Erfolg wurde als Amenorrhö oder Schmierblutung definiert.

Ergebnisse Patientendaten zeigen sich wie folgt: mittleres Alter 44 Jahre (SD ± 5), mediane Parität 2 (IQR 2–3), medianer Hysterometer 8,7 cm (SD ± 1,1), medianer BMI 23,5 kg/m^2 (IQR 21–27). 30 Patientinnen (19,5 %) zeigten sonografisch messbare intramurale Raumforderungen. Postoperative Er-

folgsrate 86,1 %. 10 Patientinnen (5 %) erhielten postoperativ eine Hysterektomie, 6 bei verstärkter Blutung, 3/1 Frauen wegen Senkung/Dysmenorrhö. Intramurale Raumforderungen bei Frauen < 45 Jahren zeigten sich in der multivariaten Analyse als signifikanter Risikofaktor für Therapieversagen (p = 0,033; 95 %-KI 1,08–12,57) mit erhöhtem Risiko einer Hysterektomie (OR 7,9, 95 %-KI 1,2–52,7, p = 0,033).

Schlussfolgerung Die bipolare Radiofrequenz-Endometriumablation ist sehr erfolgreich bei fehlendem Nachweis einer intramuralen Raumforderung (88 %). Auch kleinere intramurale Myome DD Adenomyome von im Median 15 mm reduzieren die Erfolgsrate (76 %), weshalb die präoperative Sonografie zu empfehlen ist. Bei Nachweis intramuraler Raumforderungen ist das Risiko einer Hysterektomie für Frauen < 45 Jahren 8-fach erhöht.

Introduction

Heavy and prolonged menstrual bleeding is a common disorder and makes up one fourth of the indications for hysterectomies [1].

The treatment spectrum for excessively heavy menstrual bleeding includes medical and surgical therapeutic approaches. Drug treatments include the atrophying effect of progestogens perorally or as an intrauterine pessary [2]. In the case of bleeding disorders due to a uterus myomatosus, the selective progestogen receptor modulator ulipristal acetate was used until recently with high rates of amenorrhoea [3, 4]. However, the new prescription of ulipristal acetate is no longer recommended in Switzerland since February 2018 by the European Pharmacovigilance Risk Assessment Committee (PRAC), since severe liver failure was described in four cases and in three of the cases, a liver transplantation was needed [5]. According to the German Federal Institute for Drugs and Medical Devices (BfArM), ulipristal acetate can currently be used, subject to risk conditions, such as regular liver function tests before, after and during the treatment, provided that there is no pre-existing impaired liver function [6]. Surgically, diagnostic as well as therapeutic curettage has been indicated, however with poor long-term results regarding the amount of flow [7]. Up until 30 years ago, in the event of therapeutic failure, there was no other surgical alternative than hysterectomy. In the 1980s, the methods of hysteroscopic endometrial ablation using YAG laser, transcervical endometrial resection or "rollerball" electrocoagulation were developed [8, 9]. However, these require visualisation of the uterine cavity and an experienced surgeon. Eight randomised studies investigated the safety, efficacy and costs of endometrial resection as an alternative method to hysterectomy in the treatment of bleeding disorders [10 – 12]. Over the long term, it was seen that approximately 15 % of the patients with endometrial resection via first-generation methods still required a hysterectomy and patient satisfaction 4 months postoperatively was in favour of hysterectomy. The Cochrane analysis from 2016 concluded that endometrial resection, endometrial ablation and progestogen IUD placement offer a less invasive and yet effective treatment option, in comparison to hysterectomy [13].

In the 1990s, various non-hysteroscopic alternatives came onto the market. They are fundamentally easier to use and significantly shorten the surgical time [14 – 17]. The most frequently used methods of "blind" endometrial ablation are those of the second generation: thermal ablation using an intrauterine balloon catheter (Thermachoice® and Cavaterm®) [18 – 20], microwave ablation (Microsulis Microwave Endometrial Ablation (MEA) system) [21, 22], bipolar radiofrequency ablation (NovaSure®) [15], diode laser ablation (ELITT™) [23, 24], cryoablation (HerOption™) [25] and hydrothermal ablation [24]. A list of first-generation and second generation techniques is given in ▶ **Table 1**.

▶ **Table 1** 1st and 2nd generation methods [32].

1st generation	2nd generation
Electrosurgery: ▪ Rollerball ▪ Resection Laser ▪ Nd:YAG laser ▪ KTP laser	Thermal balloon: ▪ Therma Choice® ▪ Cavatherm® ▪ (Vestablate®) Hydrothermal ablation Bipolar endometrial coagulation: ▪ Nova Sure® Microwave ablation (MEA) Diode laser ablation (ELITT®)

These different technologies were compared with one another in various randomised studies [19, 20, 22, 24]. Loffer and Grainger [20] were able to show, in a follow-up after 3 and 5 years, that endometrial ablation using balloon hyperthermia (Thermachoice®) is equivalent to rollerball endometrial coagulation. Patient satisfaction as well as the rate of amenorrhoea were evaluated for this purpose. Cooper et al. [22] demonstrated that the efficacy as well as patient satisfaction following transcervical resection of the endometrium were significantly lower than after microwave ablation [12]. A meta-analysis by Daniels et al. [26] was able to show that endometrial ablation using bipolar radiofrequency ablation with regard to the amenorrhoea rate after 12 months is more effective than endometrial ablation with intrauterine balloon catheters, hydrothermal ablation or cryoablation. Microwave ablation was also superior to endometrial ablation with an intrauterine balloon catheter as well as cryoablation, however not intrauterine laser ablation. The intrauterine laser ablation, by contrast, showed higher 12-month amenorrhoea rates than microwave ablation, endometrial ablation with intrauterine balloon catheters, cryoablation and hydrothermal ablation. However, there is a lack of data for a comparison of laser ablation with bipolar radiofrequency ablation.

The objective of this prospective cohort study was to identify prognostic factors for successful treatment of abnormal menstrual bleeding using bipolar radiofrequency endometrial ablation (NovaSure®) in a multivariate analysis.

Materials and Methods

All patients who were scheduled for bipolar radiofrequency endometrial ablation in the electrosurgery programme between January 2009 and June 2016 at the Frauenfeld Cantonal Hospital, were prospectively surveyed. The study was approved by the local ethics committee (reference #01.53.01) and corresponding informed consent forms from the patients are on hand.

The data collected preoperatively were age, parity, body mass index (BMI) as well as the findings collected by one of the authors of the transvaginal ultrasound examination with measurement of the uterus, its dimensions, and measurement of any masses in the uterine wall or intracavitary space. The preoperative examination was performed with the aim of excluding patients with an excessively large uterine cavity (length: maximum 6.5 cm, minimum 4 cm, width: maximum 4.5 cm, minimum 2.5 cm). In addition, patients with an apparent deformation of the cavity due to intramural masses, endometrial polyps, uterine septae or a bicornuate uterus were excluded. The endometrial ablation with the NovaSure® system was performed under anaesthesia (laryngeal mask, intubation anaesthesia, spinal anaesthesia). The mean duration of surgery was 20 minutes. After hysteroscopy and curettage of the corpus were performed, the surgical technique was performed analogously to the manufacturer's guidelines (NovaSure®, Hologic Inc., Marlborough, MA, USA).

Intraoperative procedure

The cervical canal and the cavity were initially measured using the hysterometer and subsequent dilation of the cervical canal using Hegar dilators up to 8 mm. Then hysteroscopy with curettage of the endometrium was performed.

The length of the cavity on the NovaSure® disposable instrument is adjusted by subtracting the cervical canals from the hysterometer, whereby a max. length of 6.5 cm is possible. After introduction of the disposable instrument into the cavity, the introducer sheath is withdrawn so that the gold mesh electrode is exposed in the cavity. By advancing the stamp as well as horizontal and vertical movements of the Novasure® disposable instrument, an optimal triangular expansion of the frame on which the gold mesh is attached can take place. The width of the mesh between the two interstitial portions of the tube should be a minimum of 2.5 cm and a maximum of 5 cm; this can be read directly in the handle of the instrument. The width and length of the uterine cavity determined are now set on the device and the flow of energy is adjusted individually for each patient. To check the intactness of the cavity and for approximation of the endometrium to the mesh, a vacuum is generated. The bipolar radiofrequency ablation is performed under vacuum aspiration of the uterine wall and blood and secretions during the coagulation are also aspirated from the cavity using the vacuum. After removal of the gold mesh, a control hysteroscopy with photo documentation of the uterine cavity is performed.

During the follow-up examinations, patients were asked about the heaviness of the current menstrual flow: no flow, spotting, light menstrual flow (maximum of 3 pads/tampons per day), moderate menstrual flow (maximum of 6 pads/tampons per day) and excessive menstrual flow (>6 pads/tampons per day). The treatment was classified as successful if spotting or amenorrhoea occurred postoperatively. The follow-ups took place according to the attending physician. For study participants who did not wish to undergo a follow-up examination by a study doctor (n = 106), the follow-up data were queried annually, which is also why no quality-of-life data could be collected.

Statistics

The evaluations and statistical analyses were performed with the statistics software Stata 13 (StataCorp LLC, College Station, Texas, USA). For all continuous variables, the normality test was performed. The multivariate analysis which includes the variables of age, BMI, parity, hysterometer and intramural masses was performed using a logistical regression analysis, whereby the method of gradual backward elimination was used. An alpha value of less than 0.05 was defined as significant.

Results

Between January 2009 and June 2016, a total of 207 women were included in the study. A bipolar radiofrequency endometrial ablation was planned for these women. Seven women were unable to undergo the planned radiofrequency ablation for technical reasons (failure to generate a vacuum). In another 5 cases, the procedure could not be performed for anatomical reasons (cavity length less than 4 cm and/or cavity width less than 2.5 cm). In these cases, bipolar endometrial resection with the resectoscope was performed under the same anaesthesia. Radiofrequency ablation was performed in 195 patients and 187 patients came to follow-up examinations.

Patients

The mean age of the patients was 44 years, the mean parity was 2 and the median BMI was 23.5 kg/m^2 (▶ **Table 2**). The length of the uterine cavity, measured using a hysterometer, was 8.7 cm (SD ± 1.1). In 31 of 195 patients (15.9%) an intramural mass was diag-

▶ **Table 2** Patient characteristics and follow-up observation period (n = 195).

Variable	Values
Age – years	44 (± 5.3; 25–55)*
Hysterometer – cm	8.7 (± 1.14; 5–12)*
BMI – cm/m^2	23.5 (21–27; 16.6–47.2)†
Parity ▪ Para 0 (10.1%) ▪ Para 1 (12.8%) ▪ Para 2 (44.7%) ▪ Para 3 (32.4%)	2 (2–3; 0–3)†
Suspected fibroid on ultrasound n (%)	31 (15.90)
Diameter of intramural mass – mm †	15 (10–24; 5–50)†
Follow-up period – months †	17.5 (4.5–34.9; 1–82)†

* Average (standard deviation; distribution), † Median (interquartile range; distribution), § Data missing for 8 patients

▶ **Table 3** Success rate in the setting of fibroid suspected on ultrasound (n = 187).

Fibroid	≤ 45 years (n = 111)		> 45 years (n = 76)		Total* (n = 187)	
	# Success	%	# Success	%	# Success	%
No	83/94	88.3	55/63	87.3	138/157	87.9
Yes	12/17	70.6	11/13	84.6	23/30	76.7
Total	95/111	85.6	66/76	86.8	161/187	86.1

* Data for 8 patients missing, success defined as postoperative amenorrhoea or spotting and no repeat surgery

▶ **Table 4** Failure depending on age, presence of fibroids, parity, BMI and the hysterometer, multivariate analysis of the risk factors (n = 187§).

Risk factors	≤ 45 years (n = 111)			> 45 years (n = 76)		
	Hazard ratio	p-value*	95% confidence interval	Hazard ratio	p-value*	95% confidence interval
Fibroid	3.699	0.036	1.089–12.570	0.662	0.729	0.064–6.816
Parity	1.038	0.903	0.570–1.889	1.849	0.122	0.849–4.025
BMI	1.063	0.239	0.960–1.176	1.050	0.333	0.952–1.158
Hysterometer	0.984	0.949	0.595–1.627	0.767	0.464	0.377–1.560

* p-value: multivariate logistical regression model, § Data missing for 8 patients

▶ **Table 5** Likelihood of hysterectomy depending on age and risk factors for therapeutic failure in multivariate analysis (n = 187§).

Risk factors	≤ 45 years (n = 111)			> 45 years (n = 76)		
	Hazard ratio	p-value*	95% confidence interval	Hazard ratio	p-value*	95% confidence interval
Fibroid	7.872	0.033	1.176–52.701	2.252	0.540	0.168–30.254
Parity	1.241	0.643	0.498–3.092	1.267	0.673	0.422–3.806
BMI	1.065	0.455	0.903–1.256	1.000	0.991	0.851–1.178
Hysterometer	1.087	0.824	0.521–2.266	0.903	0.841	0.334–2.446

* p-value: multivariate logistical regression model, § Data missing for 8 patients

nosed preoperatively on the transvaginal ultrasound, consistent with a uterine fibroid.

Outcome

With a median follow-up period of 17.5 months, 86% of patients reported amenorrhoea or cyclical spotting: 88 patients (47.1%) indicated amenorrhoea, 77 (41.2%) spotting, 16 (8.6%) normally heavy menstrual bleeding and 6 (3.2%) persistent hypermenorrhoea. Two patients (1%) had to be treated postoperatively with antibiotics due to a pelvic infection.

During the follow-up period, 10 patients (5%) underwent a hysterectomy. The reasons for this were as follows: 3 patients had pelvic organ prolapse with unremarkable histology of the uterus (18–48 months after endometrial ablation), one patient had persistent lower abdominal pain with adenomyosis and 6 patients had persistent uterine bleeding (two with uterus myomatosus, one with adenomyosis, one with atypical endometrial hyperplasia and two with unremarkable histology).

In the multivariate analysis, the preoperative presence of an intramural mass was significantly associated with therapeutic failure among the 25–45-year-old patients, although its diameter was only a median of 15 mm (▶ **Tables 3** and **4**).

Accordingly, the risk of a hysterectomy performed during the follow-up period was increased 8-fold in the multivariate analysis in the younger patients if intramural masses could be identified preoperatively (▶ **Table 5**).

In 12 patients (6.5%), a progestogen IUD was placed intraoperatively additionally for contraception. Of these patients, 9 had amenorrhoea postoperatively and 3 had spotting. Only 6 of these patients were younger than 45. Excluding these 12 patients in the multivariate analysis did not demonstrate any change in the result. Because of the small number of cases of this collective, an analysis of the success rate was performed with a 2 : 1 paired sample according to age and intramural mass. No significant superiority of the combined therapy IUD plus endometrial ablation versus endometrial ablation alone was seen (95% CI 0.932–1.546; p = 0.157).

Discussion

In our prospective cohort study, bipolar radiofrequency ablation of the endometrium led to amenorrhoea or cyclical spotting in 86% of the patients. The amenorrhoea rate of 47.1% in our study was comparable with the result (43.8%) of the meta-analysis from 2012 from Daniels et al. [26]. Newer publications show amenorrhoea rates between 45–56% (▶ **Table 6**).

The multivariate analysis of the risk factors for therapeutic failure or hysterectomy showed that intramural masses significantly worsen the therapeutic success in patients younger than age 45 and increase the risk of a hysterectomy 8-fold. This is consistent with the results of Soini et al. [27]. In a Finnish population-based study, they found that the presence of fibroids, a young age, status post Caesarean section and tubal sterilisation are associated with an increased risk of hysterectomy following endometrial

▶ **Table 6** Results of studies with bipolar radiofrequency ablation.

Study	n	Comparison	End points	Follow-up period (months)	Results
Abbott et al. 2003 [33] Randomised study	55	Radiofrequency ablation vs. Thermal balloon (Cavaterm)	Amenorrhoea rate after 12 months Pain 4 hours post-operatively	12 (postop.)	Amenorrhoea: 43% vs. 12% (p = 0.04) Pain 48% vs. 78% (p = 0.01)
Bongers et al. 2004 [29] Kleijn et al. 2008 [30] Randomised study	126	Radiofrequency ablation vs. Thermal balloon (Thermachoice)	Amenorrhoea rate Patent satisfaction	12 (postop.)	Amenorrhoea: 43% vs. 8% (p < 0.001) Satisfaction 90% vs. 79% (p = 0.003)
			Amenorrhoea rate Hysterectomy rate Quality of life	60 (postop.)	Amenorrhoea: 48% vs. 23% (p < 0.001) Hysterectomy rate 9.9% vs. 12.9%, HR 1.2 Quality of life same (p = 0.73)
Clark et al. 2011 [17] Randomised study	81	Radiofrequency ablation vs. Thermal balloon	Amenorrhoea Duration of surgery	6 (postop.)	Amenorrhoea 39% vs. 21% (p = 0,1) Duration of RF on average 6.2 min shorter (p < 0.001)
Penninx et al. 2016 [34] Randomised study	104	Comparison of bipolar radiofrequency ablation vs. Thermal balloon (Thermablate)	Amenorrhoea rate Patient satisfaction Repeat intervention rate	12 (postop.)	Amenorrhoea rate 56% vs. 23%, RR 0.6, 95% CI 0.4–0.8 Patient satisfaction 87% vs. 69%, RR 0.44, 95% CI 0.2–0.97 Repeat intervention rate 10% vs. 12%, RR 1.02, 95% CI 0.9–1.2
Penninx et al. 2011 [35] Randomised study	160	Radiofrequency ablation vs. Hydrothermal ablation	Amenorrhoea rate Repeat interventions	60 (postop.)	Amenorrhoea 55,4% vs. 35,3%, RR 1,5, 95% CI 1,05–2,3 Repeat interventions 17% vs. 48%, RR 0.43, 95% CI 0.23–0.80
Muller et al. 2015 [36] Retrospective study	505	Radiofrequency ablation (289 pat.) vs. Thermal balloon (Therma-Choice) (216 pat)	Amenorrhoea rate Hysterectomy rate	35 (Median)	Amenorrhoea 45% vs. 27% (p = 0.001) Hysterectomy rate 13% vs. 19% (p = 0.066)
Ferguson et al. 2015 [37] Retrospective study	1994	Hysterectomy rate following radiofrequency ablation	Hysterectomy rate	48 (Median)	Hysterectomy in 203 pat. (10%) Indication: bleeding 117 (58%); pain 31 (15%), bleeding and pain 45 (22%), other 10 (5%)
Wyatt et al. 2016 [38] Retrospective study	144	Dysmenorrhoea rate before and after bipolar radiofrequency ablation	Dysmenorrhoea rate	72 (Median)	Pretherapeutic 69%; post-therapeutic 38% (p < 0.001)
Shazly et al. 2016 [28] Retrospective study	1178	Predictors for failure of the radiofrequency ablation	Failure: Hysterectomy or repeat ablation or drug-based ovarian suppression	52 (Median)	Hysterometer > 10.5 cm; HR 2.58 (p = 0.006) Cavity length > 6 cm; HR 2.06 (p = 0.002) Cavity width > 4.5 cm; HR 2.06 (p = 0.002) Cavity surface > 25 cm^2; HR 2.02 (p = 0.003) Surgical time < 93 s; HR 2.61 (p = 0.01)
Present study Prospective study	187	Predictors for failure of the radiofrequency ablation	Spotting, amenorrhoea rate, hysterectomy rate	17,5 (Median)	Spotting, amenorrhoea rate: intramural mass, age ≤ 45 years: HR 3.699 (p = 0.036), 95% CI 1.089–12.570 Hysterectomy rate: intramural mass, age ≤ 45 years: HR 7.873 (p = 0.033), 95% CI 1.176–52.701

ablation. However, all endometrial ablation methods were included in this study.

It is remarkable that the size of the intramural masses measured preoperatively was moderate, since larger fibroids, DD: adenomyomas preoperatively led to exclusion in our study. Nonetheless, intramural masses with a median diameter of only 15 mm demonstrated significant worsening of the success of treatment. The fact that an increase in the cavity surface leads to worse results was shown in a recently published retrospective study [28]. This study identified large cavity dimensions and short ablation times as risk factors for therapeutic failure of bipolar radiofrequency ablation. In our study, the hysterometer alone was not a significant prognostic factor, since excessively large dimensions of the uterine cavity were possibly already preoperatively excluded in our study by means of ultrasound.

One strength of the study is that all patients were preoperatively evaluated via transvaginal ultrasound by one of the authors. The evaluation of the success of the treatment as well as the indication of a subsequent hysterectomy was performed by the gynaecologist providing subsequent care and not primarily by the study team. We also consider this to be a strength of the study, since the conditions of daily clinical practice are reflected in a more realistic way as a result.

The weaknesses of our study are the lack of an objective measurement of the heaviness of the menstrual flow pre- and postoperatively. However, the subjective assessment of the amount of flow by the patient and the attending gynaecologist appears to us to be sufficient since it reflects daily clinical practice in a practical way. The analysis was divided according to age groups (< 45 years, > 45 years) to take the effects of incipient menopause into account. As expected, the influence of intramural masses was more pronounced in younger patients. Another weakness is the relatively brief follow-up period of a median of 17.5 months. However, 12 months appear to be an adequate follow-up period, since hardly any difference in the rate of amenorrhoea after 12 or 60 months postoperatively can be observed (▶ **Table 6**, [29, 30]). Moreover, no evaluation of the quality of life was performed since the patients were in part followed up on by private-practice colleagues. This also represents a weakness of the study.

Twelve patients underwent bipolar radiofrequency ablation as well as the placement of a progestogen IUD for contraception. Nine patients postoperatively demonstrated amenorrhoea and 3 demonstrated spotting. However, the 2 : 1 paired sample test did not demonstrate any significant differences between the patients with IUD with endometrial ablation and the patients who only underwent endometrial ablation. On the other hand, no reliable contraception is guaranteed by the bipolar radiofrequency ablation and based on our analysis, there is nothing to argue against its placement. In one small study [31], the progestogen IUD placement caused a single increase in the rate of amenorrhoea in the case of a hysteroscopic endometrial resection.

Conclusion

The results of this study show that the treatment results of bipolar radiofrequency ablation in young patients significantly worsen when small intramural masses are present and lead to a hysterectomy rate which is eight times higher. We therefore recommend performing an ultrasound examination preoperatively to exclude intramural masses, in addition to ascertaining the cavity dimensions.

Note

Published translation. Original manuscript written in German.

Conflict of Interest

The authors declare that they have no conflict of interest.

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