GYNECARE

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INVESTIGATIONAL PLAN

An In-Vitro Comparative Study To Evaluate Gas Production By VersaPoint™ Electrodes

Protocol #2000-11

October 27, 2000

	APPROVAL:	DATE:
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TABLE OF CONTENTS

1. PURPOSE

1.1. Subject Device Names

Component	Vendor	Part Number
VersaPoint™ 5 Fr. Ball-Tip Electrode	Gynecare	00466
VersaPoint™ 5 Fr. Twizzle-Tip Electrode	Gynecare	00467
VersaPoint™ 5 Fr. Spring-Tip Electrode	Gynecare	00468
VersaPoint™ 0° Vaporizing Electrode	Gynecare	01950
VersaPoint™ Angled Loop Resecting Electrode	Gynecare	01985
24 Fr. Monopolar Cutting Loop Electrode	Circon	GMLE-24-015
24 Fr. Monopolar Roller Ball Electrode	Circon	GRE-24
24 Fr. Monopolar Roller Bar Electrode	Circon	GRB-24
24 Fr. Monopolar Grooved Vaporizing Electrode	Circon	GVE-B

1.2. Intended Use

VersaPoint™ is a bipolar electrosurgical system intended for endometrial resection and the removal of fibroids, polyps, and other benign pathologies from within the uterine cavity. Use of the devices in this comparative in-vitro study is for the purpose of determining the rate of gas creation by the both the VersaPoint™ electrodes and a collection of monopolar control devices under simulated use conditions.

1.3. Study Hypothesis

It is hypothesized that both the rate of gas production by VersaPoint™ electrodes is comparable to that of the monopolar control devices.

1.4. Study Duration

The overall duration of the study is expected to be no more than 2 weeks.

2. PROTOCOL

2.1. Equipment

Item	Vendor	PN
Versapoint™ Generator	Gynecare	00482
Monopolar Electrosurgical Generator	Valleylab	Force FX
Monopolar Electrosurgical Generator	Valleylab	Force II
500 cc Calibrated Graduated Cylinder	Nalgene	PP Series
Digital Thermometer	Omega	HH12
Digital Stopwatch / Timer	Hanhart	04A99
Polypropylene Tub		

2.2. Supplies

Item
Normal Saline (0.9%)
Glycine (1.5%)
Fresh (Unfrozen, <3 Day Old) Bovine Heart Muscle
Closed-Cell Foam Specimen Mats And Pins

2.3. Study Design

Sections of bovine heart muscle will be submerged in the appropriate fluid media (saline or glycine). A graduated cylinder containing the same fluid will be inverted directly above the tissue sample with the mouth of the cylinder positioned below the surface of the bath. The sample will then be treated with the subject electrode in a controlled fashion. Gas bubbles escaping the electrode will be captured by the cylinder providing a measure of gas volume produced. 20 samples will be treated at each generator / power combination.

2.4. Procedures

2.4.1. Experimental Set-Up

1. Secure a specimen mat at the bottom of a room-temperature tank of the appropriate fluid (saline or glycine). When preparing for use of a monopolar electrode, be certain to position a return pad on the specimen mat and connect it to the monopolar ESU.
2. Invert a 500 cc graduated cylinder containing the same fluid as is in the tank above the tissue sample. Be certain that the open end of the cylinder is below the fluid level in the tank and that there is a sufficiently large air bubble trapped in the top of the cylinder so that the bottom of the bubble reaches the graduations.
3. Setup the appropriate ESU according to the instructions in the user's guide.
4. For each electrode / power setting / generator combination, prepare 20 samples of fresh (<3 day old, unfrozen) bovine cardiac tissue. These samples should be approximately 30 mm x 30 mm x 10 mm. Prior to use, place all samples in a separate preparation bath of saline. *Tissue specimens must remain in the bath for between 1 and 3 hours prior to use.*

   Note: If possible, establish this setup and perform all work under a fume hood.

2.4.2. Procedures

Repeat the following steps 20 times for each electrode / generator / power setting combination as detailed in the table below.

Notes:

1. A new tissue specimen must be used for each trial.
2. A new electrode should be used for each combination (electrode / generator / power setting).

Generator	Electrode	Power Setting (W)
VersaPoint (VC1)	VersaPoint 5 Fr. Ball Tip	70
	VersaPoint 5 Fr. Twizzle Tip	150
	VersaPoint 5 Fr. Spring Tip	200
	VersaPoint 0-Degree Vaporizing Electrode	200
	VersaPoint Angled-Loop Electrode	200
Valleylab Force II (Pure Cut)	Circon 24 Fr. Monopolar Roller Ball	200
		300
	Circon 24 Fr. Monopolar Roller Bar	200
		300
	Circon 24 Fr Monopolar Resecting Loop	100
		200
	Circon Monopolar Grooved Vaporizing Electrode	200
		300
Valleylab Force FX (Pure Cut)	Circon 24 Fr. Monopolar Roller Ball	200
		300
	Circon 24 Fr. Monopolar Roller Bar	200
		300
	Circon 24 Fr Monopolar Resecting Loop	100
		200
	Circon Monopolar Grooved Vaporizing Electrode	200
		300

All monopolar electrodes should be driven with the Pure Cut waveform of the Valleylab generators. All VersaPoint™ electrodes should be driven with the VC1 waveform.

1. Measure the bath temperature before testing and record. Ensure that the temperature is between 17 and 27°C.
2. Secure the tissue sample on the specimen mat at the bottom of the bath and position it directly beneath the opening of the inverted graduated cylinder.
3. Carefully clean the electrode tip, making certain that it is free of debris and buildup. Examine the metal portions of the electrode tip for obvious pitting or deformation and the ceramic insulator for cracking. Note any electrode changes in the data sheets.
4. Record the lot number of the electrode in use.
5. Record the starting volume of gas in the graduated cylinder. All readings should be made at the bottom of the meniscus / bubble and debris field that forms on the bottom of the vapor pocket.
6. Create either 10 (all VersaPoint™ electrodes, 5 per side) or 5 (all monopolar electrodes, all on one side) treatment furrows in the tissue using the following procedure:
   a. Position the electrode against the tissue near the far edge of the sample.
   b. Activate the electrode and the stopwatch / timer simultaneously.
   c. Pull the electrode through the tissue for exactly 5 seconds, making a 25 mm long track.

   Notes:

   1. For all of the VersaPoint™ electrodes, carefully control contact with the tissue so that only the active portion of the tip is enclosed within the tissue. Do not bury the tips or allow the ceramic insulators to be completely enclosed.

2. When using the resectoscopic electrodes, maintain contact with the surface so that the lower half of the electrode is encased in tissue to the point of the mounting arms.
3. When using the loop electrodes, move of the electrode through the tissue toward the user for 4 seconds. Use the final second of power application to lift the electrode up through the tissue and detach the strip from the specimen. Be certain to keep the electrode activated for the entire final second. If the tissue does not detach from the specimen, do not reactivate the loop to detach it.

d. Return the electrode to the far end of the tissue before beginning the next track. *The maximum time between tracks should be less than 10 seconds (except for the time between cuts 5 and 6 with the resectoscopic VersaPoint™ electrodes where the tissue must be inverted).*

e. Be certain that all of the gas emanating from the tissue is being captured in the cylinder.

7. After completing the 5 or 10 furrows, make certain that any gas bubbles remaining at the treatment sights or clinging to the electrode are jarred free and captured in the collection cylinder.

8. Immediately record the ending volume of gas. All readings should be made at the bottom of the meniscus / bubble and debris field that forms on the bottom of the trapped vapor pocket.

Notes:

1. Do not allow the volume of gas in the cylinder to exceed 400 cc.
2. Both saline and glycine bath fluid should be changed after each 10 samples

2.5. Study Endpoints

The primary endpoints of this study will be the rate of gas by the various electrodes. Rates will be screened for errors and outliers. For intervally-scaled variables, distributions will be examined for normality and skewness. Before applying any formal inferential statistical procedures, the assumptions underlying the valid application of these methods will be assessed. If any assumptions are violated, data transformations will be explored or the data will be analyzed using non-parametric methods.

Due to the relatively small sample sizes and resulting low statistical power, descriptive statistics will be used as the primary tool to assess differences between the three treatment groups. Exploratory analyses will be performed using inferential statistical methods if all underlying assumptions of parametric statistics are met (e.g., normality, additivity, linearity, etc). All tests of statistical significance will be assessed using a Type I error rate of five percent (i.e., = 0.05).

3. TEST RECORD SHEET

Electrode	
Generator	
Power Setting	

Date	
Time	
Recorded By	

Sample	Bath Temperature (°C)	Gas (cc)			Electrode Lot #	Comments
		Start Volume	End Volume	Difference		
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						

APPENDIX A: EXPERIMENTAL SETUP AND RATIONALIZATION

The experimental setup derived for this protocol is strictly intended to give an objective comparison of the rate of gas production for the electrodes tested. It is not intended to provide a precise estimate of gas production during ordinary hysteroscopic application of these tools. Still, efforts have been made to make the experimental model as representative of an actual use environment so that the results will be applicable to an assessment of the devices in actual use. Aspects considered

Tissue Selection
The composition and consistency of bovine cardiac tissue is comparable to that of endo / myometrial tissue, and thus provides a good model for the evaluation of hysteroscopic electrosurgical tools. All tissue employed will be fresh (< 3days) to provide tissue as representative of living tissue as possible.

Tissue Preparation
All tissue samples will be soaked in normal (0.9%) saline for a controlled time period prior to use. This will help to restore the moisture level in the tissue to one approximating that found in living tissue.

Fluid Bath
The fluid baths will be maintained at room temperature to simulate a room-temperature irrigant as is commonly employed in hysteroscopic surgery.

Bath Changing
Both the saline and dextrose baths will be changed following every 10 samples (twice per electrode / generator / power setting combination). This will serve to minimize the effects of accumulated debris and fluids extracted from the tissue from significantly affecting the electrical properties of the fluids and increase operator visibility of the treatment sight.

Sample Size
It is anticipated that normal variations in tissue impedance will result in relatively large standard deviations in the sample-to-sample data. The sample size of 20 was chosen to give statistical power to the gas volume readings and minimize the significance of this variability on result interpretation.

User Skills
Personnel executing this procedure will be trained in the techniques of tissue vaporization and resection. Each track will be a uniform 5 seconds so the speed of activation is consistent between electrodes. At least two teams will be employed, and these teams will divide the 20 runs for each electrode so that technique-driven bias will be minimized.

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SUMMARY REPORT

An In-Vitro Comparative Study To Evaluate Gas Production By VersaPoint™ Electrodes

Protocol #2000-11

November 10, 2000

	APPROVAL:	DATE:
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Medical Affairs: Richard Isenberg		
Quality Assurance: David Gronostajski		
Corporate Product Characterization: David Stoloff, D.V.M., D.A.C.V.S.		

TABLE OF CONTENTS

1. INTRODUCTION

This report documents a laboratory investigation performed per Gynecare Investigational Plan 2000-0011P: *An In-Vitro Comparative Study To Evaluate Gas Production By VersaPoint™ Electrodes*. In this study, the rates of gas production by VersaPoint™ electrodes *when driven at maximum power* were compared with those of a collection of monopolar electrodes at differing power settings.

2. TEST PRODUCT

Component	Vendor	Part Number
VersaPoint™ 5 Fr. Ball-Tip Electrode	Gynecare	00466
VersaPoint™ 5 Fr. Twizzle-Tip Electrode	Gynecare	00467
VersaPoint™ 5 Fr. Spring-Tip Electrode	Gynecare	00468
VersaPoint™ 0° Vaporizing Electrode	Gynecare	01950
VersaPoint™ Angled Loop Resecting Electrode	Gynecare	01985
24 Fr. Monopolar Cutting Loop Electrode	Circon	GMLE-24-015
24 Fr. Monopolar Rollerball Electrode	Circon	GRE-24
24 Fr. Monopolar Rollerbar Electrode	Circon	GRB-24
24 Fr. Monopolar Grooved Vaporizing Electrode (VaporTrode™)	Circon	GVE-B

3. DEVIATIONS & NOTES

3.1. Deviations

1. The second set of 10 samples treated with the VaporTrode™ electrode with the Force FX generator at 200 W demonstrated gas production rates which were grossly inconsistent with those obtained with the first 10 samples. The second set of trials was repeated with a new return pad and different electrode, and yielded results which were consistent with the first 10 samples.

3.2. Notes

1. All testing was performed by 2-person teams. In an effort to minimize technique-driven biasing of the results, no single team performed all of the testing for a given electrode / generator / power setting. Specifically, the first 10 samples for each electrode / generator / power setting was done by one team while the second 10 were done by the other.
2. In order to increase timing accuracy during the 5-second treatment intervals, the second member of each team was responsible for both the timer and activation of the foot pedal while the first member was only responsible for maneuvering the electrode through the tissue in a controlled fashion.

4. TEST DATA

The following tables and graphs provides the mean rate of gas production (CC / Minute) for the electrodes tested during this investigation:

VersaPoint™ Electrodes

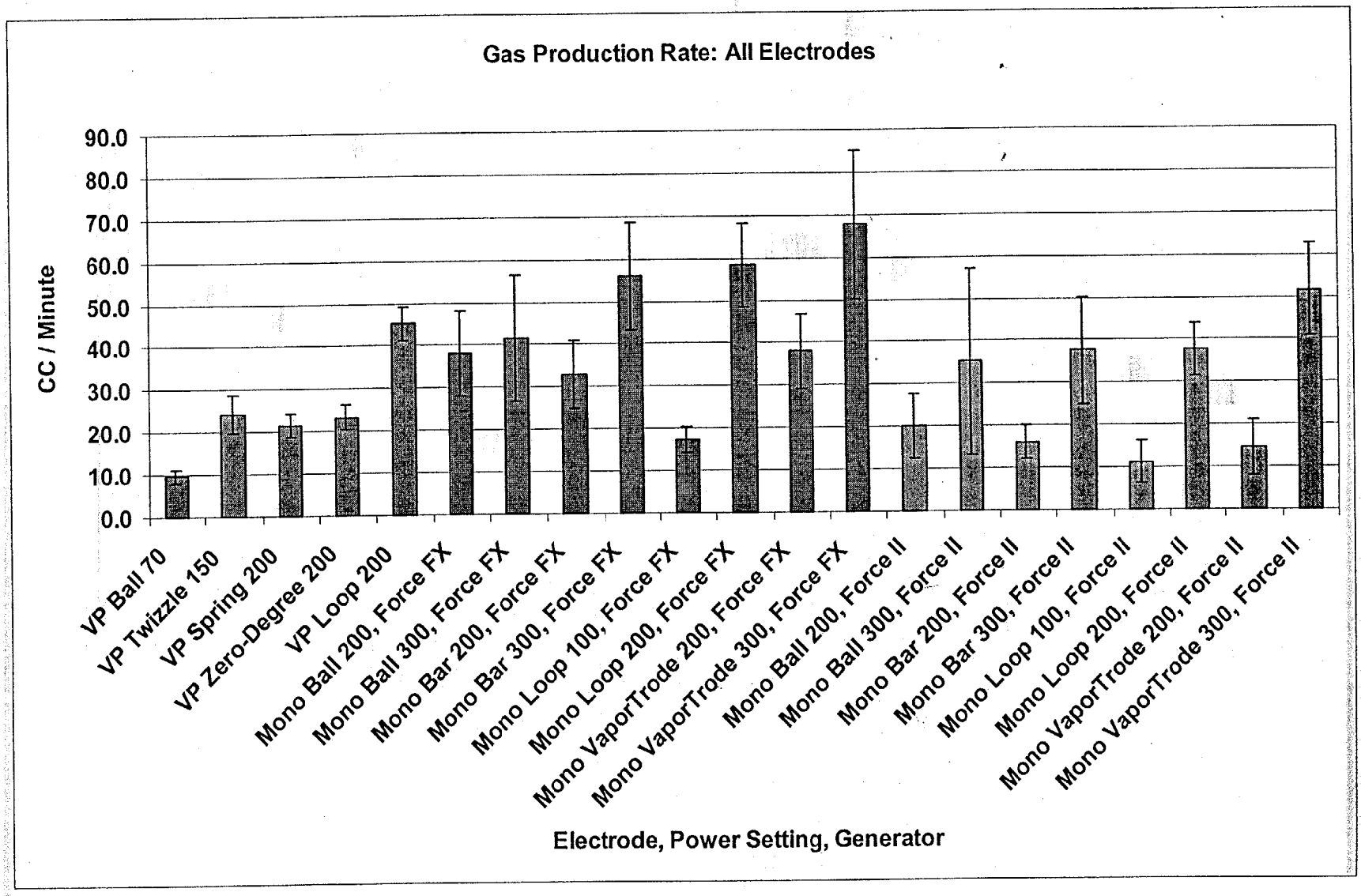
Sample	Ball Tip 70W	Twizzle Tip 150 W	Spring Tip 200 W	0-Degree 200 W	Loop 200 W
1	13.20	32.40	28.80	25.20	46.80
2	8.40	25.20	20.40	24.00	42.00
3	12.00	30.00	14.40	24.00	43.20
4	7.20	19.20	20.40	19.20	42.00
5	8.40	25.20	21.60	22.80	46.80
6	9.60	21.60	21.60	26.40	42.00
7	9.60	25.20	18.00	21.60	42.00
8	7.20	16.80	19.20	22.80	42.00
9	10.80	18.00	19.20	24.00	40.80
10	10.80	24.00	21.60	24.00	45.60
11	8.40	25.20	25.20	31.20	54.00
12	12.00	21.60	22.80	26.40	48.00
13	9.60	28.80	22.80	25.20	52.80
14	8.40	18.00	21.60	24.00	43.20
15	9.60	30.00	20.40	22.80	42.00
16	7.20	27.60	21.60	18.00	51.60
17	10.80	20.40	24.00	24.00	40.80
18	8.40	26.40	22.80	22.80	48.00
19	9.60	27.60	20.40	19.20	43.20
20	9.60	22.80	22.80	19.20	46.80
Mean	**9.54**	**24.30**	**21.48**	**23.34**	**45.18**
Std. Dev.	**1.67**	**4.44**	**2.88**	**3.03**	**4.05**

Monopolar Electrodes, Valleylab Force FX Generator

Sample	Rollerball 200	Rollerball 300	Rollerbar 200	Rollerbar 300	Cutting Loop 100	Cutting Loop 200	VaporTrode 200	VaporTrode 300
1	38.4	36.0	40.8	91.2	24.0	74.4	40.8	55.2
2	43.2	48.0	31.2	72.0	16.8	74.4	36.0	55.2
3	38.4	55.2	36.0	52.8	14.4	79.2	33.6	81.6
4	40.8	40.8	26.4	57.6	19.2	55.2	26.4	38.4
5	36.0	40.8	36.0	57.6	16.8	74.4	36.0	36.0
6	31.2	31.2	48.0	72.0	16.8	57.6	33.6	69.6
7	36.0	36.0	38.4	57.6	24.0	60.0	33.6	69.6
8	45.6	24.0	36.0	55.2	19.2	55.2	33.6	64.8
9	26.4	24.0	24.0	48.0	16.8	57.6	16.8	67.2
10	38.4	24.0	19.2	52.8	19.2	43.2	28.8	96.0
11	52.8	86.4	48.0	55.2	14.4	57.6	52.8	86.4
12	67.2	60.0	36.0	52.8	12.0	57.6	48.0	103.2
13	26.4	36.0	36.0	38.4	19.2	52.8	38.4	81.6
14	36.0	48.0	31.2	48.0	19.2	48.0	36.0	81.6
15	45.6	57.6	28.8	43.2	16.8	62.4	43.2	69.6
16	28.8	33.6	36.0	45.6	14.4	52.8	33.6	60.0
17	31.2	31.2	24.0	40.8	14.4	48.0	43.2	69.6
18	38.4	40.8	36.0	57.6	19.2	52.8	48.0	60.0
19	36.0	38.4	21.6	50.4	14.4	50.4	45.6	57.6
20	24.0	36.0	24.0	72.0	16.8	55.2	50.4	50.4
Mean	38.04	41.40	32.88	56.04	17.40	58.44	37.92	67.68
Std. Dev.	9.95	14.89	8.06	12.61	3.10	9.89	8.80	17.33

Monopolar Electrodes, Valleylab Force 2 Generator

Sample	Rollerball 200	Rollerball 300	Rollerbar 200	Rollerbar 300	Cutting Loop 100	Cutting Loop 200	VaporTrode 200	VaporTrode 300
1	33.6	45.6	21.6	60.0	16.8	48.0	21.6	72.0
2	19.2	48.0	19.2	38.4	19.2	48.0	24.0	60.0
3	21.6	57.6	21.6	33.6	14.4	36.0	24.0	60.0
4	31.2	40.8	16.8	60.0	12.0	40.8	14.4	69.6
5	24.0	43.2	14.4	48.0	19.2	33.6	9.6	45.6
6	19.2	40.8	9.6	33.6	4.8	38.4	4.8	62.4
7	21.6	55.2	21.6	45.6	19.2	48.0	12.0	57.6
8	21.6	36.0	14.4	24.0	9.6	45.6	24.0	60.0
9	28.8	57.6	14.4	52.8	16.8	33.6	24.0	43.2
10	19.2	36.0	14.4	36.0	12.0	38.4	16.8	64.8
11	12.0	24.0	19.2	33.6	7.2	36.0	16.8	40.8
12	26.4	24.0	16.8	21.6	7.2	40.8	12.0	40.8
13	28.8	24.0	19.2	28.8	9.6	31.2	16.8	46.0
14	26.4	26.4	12.0	36.0	7.2	38.4	9.6	48.0
15	9.6	28.8	16.8	19.2	9.6	31.2	7.2	38.4
16	9.6	26.4	19.2	16.8	9.6	38.4	12.0	43.2
17	12.0	28.8	12.0	33.6	7.2	33.6	4.8	43.2
18	12.0	16.8	19.2	50.4	9.6	38.4	9.6	55.2
19	9.6	31.2	12.0	43.2	9.6	26.4	16.8	40.8
20	14.4	14.4	7.2	36.0	2.4	31.2	9.6	38.4
Mean	20.04	35.28	16.08	37.56	11.16	37.80	14.52	51.60
Std. Dev.	7.68	12.99	4.13	12.49	4.94	6.13	6.44	10.92


Gas Production Rate: All Electrodes
CC / Minute
90.0
80.0
70.0
60.0
50.0
40.0
30.0
20.0
10.0
0.0
VP Ball 70
VP Twizzle 150
VP Spring 200
VP Zero-Degree 200
VP Loop 200
Mono Ball 200, Force FX
Mono Ball 300, Force FX
Mono Bar 200, Force FX
Mono Bar 300, Force FX
Mono Loop 100, Force FX
Mono Loop 200, Force FX
Mono VaporTrode 200, Force FX
Mono VaporTrode 300, Force FX
Mono Ball 200, Force II
Mono Ball 300, Force II
Mono Bar 200, Force II
Mono Bar 300, Force II
Mono Loop 100, Force II
Mono Loop 200, Force II
Mono VaporTrode 200, Force II
Mono VaporTrode 300, Force II
Electrode, Power Setting, Generator

5. ANALYSIS

5.1. Overview

Objective side-by-side comparisons of the electrodes employed in this study requires that only electrodes of similar function and tissue effect be compared. This comparison is inherently difficult when analyzing the 5-Fr. VersaPoint™. electrodes (Ball, Spring, and Twizzle) since there are no equivalent monopolar devices used in hysteroscopy. Still, the data collected during execution of this study clearly indicates that these 5-Fr. electrodes generate gas at a rate which is consistently lower than or equivalent to that of the larger VersaPoint™ and monopolar resectoscopic electrodes.

Comparisons of the larger resectoscopic VersaPoint™ electrodes (0° Vaporizing and Angled Loop) with the resectoscopic monopolar devices can be easily obtained from the gas data. The VersaPoint™ Angled Loop electrode can be directly compared to the monopolar loop and the VersaPoint 0° Vaporizing electrode can be similarly compared to the monopolar grooved vaporizing bar (VaporTrode) and, to a lesser extent, the monopolar rollerbar and rollerball.

Unlike VersaPoint™ electrodes which are automatically driven by the generator at a default power value, power settings for monopolar electrodes must be established by the surgeon. Selection of power levels for the monopolar electrodes used in this study was based on the normal range of operation for these devices. Loops are typically used at power settings between 100 and 200 W, at the discretion of the surgeon. Vaporizing / desiccating tools such as the Rollerball, Rollerbar, and VaporTrode™ require significantly higher settings to resect tissue, and thus were driven at 200 and 300 W. It is clear from the data presented on page 7 that the rate of gas production is proportional to power. Since the intent of this analysis was to cover the worst-case scenario, it is appropriate that the maximum power settings would be utilized in our comparison.

When interpreting the results of this study, it is also important to note that the Force FX and other modern generators are microprocessor-controlled and will actually deliver power levels which are more true to the front panel setting than that of the Force 2. Force 2 actual power output will typically be less than the front panel setting, and thus users generally employ a higher power setting to get the same tissue effect as that obtained with the Force FX generator. The tests in this report only utilize front panel settings.

5.2. Statistical Comparisons

The tables provided in the following sections present the results of AnOVa statistical analyses (α = 0.05) performed on the maximum power setting data acquired during this trial. The entry provided in the result column should be interpreted as follows:

- More: The VersaPoint™ Angled Loop Electrode generated more gas than the subject electrode
- Less: The VersaPoint™ Angled Loop Electrode generated less gas than the subject electrode
- Same: The VersaPoint™ Angled Loop Electrode generated the same amount of gas as the subject electrode

5.2.1. Loop Electrodes

Electrode	Generator	Power	Gas Production Rate (CC / Min.)		Result
			Mean	Std. Dev.	
VersaPoint™ Angled Loop	VersaPoint™	200	45.18	4.05	
Monopolar Loop	Force FX	200	58.44	9.69	Less
Monopolar Loop	Force 2	200	37.80	6.13	More

5.2.2. Vaporizing Electrodes

Electrode	Generator	Power	Gas Production Rate (CC / Min.)		Result
			Mean	Std. Dev.	
VersaPoint™ 0° Vaporizing	VersaPoint™	200	23.34	3.03	
Monopolar Rollerball	Force FX	300	41.04	14.89	Less
Monopolar Rollerbar	Force FX	300	56.04	12.61	Less
VaporTrode	Force FX	300	67.68	17.33	Less
Monopolar Rollerball	Force 2	300	35.28	12.99	Less
Monopolar Rollerbar	Force 2	300	37.56	12.49	Less
VaporTrode	Force 2	300	51.60	10.92	Less

5.3. Results Of Electrode Testing

Performance among the monopolar vaporizing electrodes tested varied noticeably as a function of power setting and generator. Monopolar rollerball, rollerbar, and VaporTrode™ electrodes powered at 200 W by the Force 2 generator were not efficient at vaporizing tissue when compared to the VersaPoint 0° electrode and would most likely not be operated at this setting due to a lack of good clinical effect. Increasing the power to 300 W provided a more suitable vaporization effect. Performance of these devices when driven by the Force FX generator at 200 W was more acceptable, which is reflective of this newer technology generator's controlled output power.

It is also important to note that all of the VersaPoint™ electrodes were tested only at their maximum allowable power setting as a worst-case scenario. Surgeons may actually elect to use these electrodes at their default settings (30 – 50 W lower than the maximums) which will cause them to generate less gas. Demonstration of a lower rate of gas production with lower power settings was made in a pilot study preceding this protocol.

6. CONCLUSIONS

The data acquired during execution of this comparative protocol indicates that the rates of gas production by VersaPoint™ electrodes are comparable to and, in fact, generally lower than those of commonly employed monopolar devices. Specific conclusions are as follows:

- The 5 Fr. VersaPoint™ electrodes have no monopolar counterpart in hysteroscopy to allow comparison; however, when compared to the other electrodes (both monopolar and VersaPoint™) evaluated in this protocol, these devices show comparable or lower gas production rates.
- The rate of gas production by the VersaPoint™ Angled Loop electrode at its maximum power setting was lower than that of the monopolar loop at its maximum setting when driven by the Force FX generator. The VersaPoint™ Angled Loop generated more gas than the monopolar loop driven by the Force 2 generator; however, its rate of production is still substantially less than that of the rollerbar or VaporTrode™ electrodes with either the Force 2 or the Force FX generator (see chart on page 7). Since there has not been any clinical concern about these electrodes in combination with either of the generators, it is reasonable to conclude that the amount of gas produced by the Versapoint™ Loop electrode is not clinically significant.
- The VersaPoint 0° Vaporizing Electrode generated less gas than the monopolar vaporizing/ desiccating electrodes (rollerball, rollerbar, VaporTrode™) driven at 200 or 300 W with the Force FX generator, or at 300 W with the Force 2 generator.