

## ORIGINAL RESEARCH—SURGERY

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# Prospective Evaluation of Postoperative Penile Rehabilitation: Penile Length/Girth Maintenance 1 Year Following Coloplast Titan Inflatable Penile Prosthesis

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### ABSTRACT

**Introduction.** The most prevalent long-term complaint after successful inflatable penile prosthesis (IPP) surgery is reduction of penile length. The purpose of this study was to evaluate penile measurements in patients whose implantation experience included the aggressive new length measurement technique (NLMT) coupled with postoperative IPP rehabilitation (daily inflation) of the implant for 1 year. Moreover, we aimed to document objective data concerning dimensional changes of the phallus over time. Postoperative IPP rehabilitation has been discussed and presented at meetings, but no multi-institutional prospective data have been published.

**Aim.** Our goal was to assess results using the Coloplast Titan IPP, with NLMT, and postoperative rehabilitation.

**Methods.** After IRB approval, we conducted a prospective, three-center study of 40 patients who underwent IPP placement, with NLMT for end organ failure erectile dysfunction with the Coloplast Titan IPP. The patient was instructed to inflate daily for 6 months and then inflate maximally for 1–2 hours daily for 6–12 months. Fifteen penile measurements were taken before and immediately after surgery and at follow-up visits.

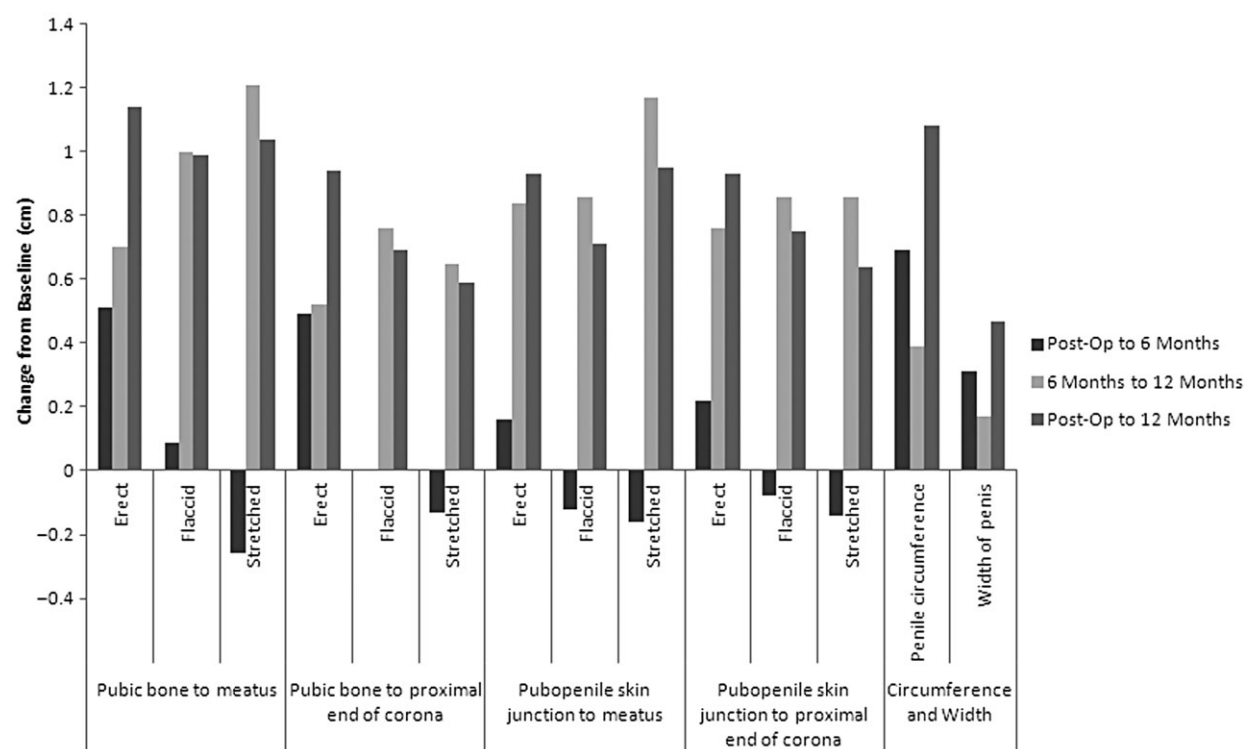
**Main Outcome Measure.** Penile length measurements after implantation compared with 12 months postimplantation.

**Results.** Penile measurement changes were statistically significantly improved at 12 months as compared with immediately postoperative and at 6 months. A total of 64.5% of subjects were satisfied with their length at 1 year, and 74.2% had perceived penile length that was longer (29%) or the same (45.2%) as prior to the surgery; 61.3% and 16.1% of subjects had increased and unchanged satisfaction, respectively, with penile length as compared with prior to IPP surgery. All but two subjects (93.4%) were satisfied with the overall function and dimensions of their IPP.

**Conclusion.** This study suggests using the Coloplast Titan IPP with aggressive cylinder sizing, and a postoperative penile rehabilitation inflation protocol may help optimize patient satisfaction and erectile penile measurements. **Henry GD, Carrion R, Jennermann C, and Wang R. Prospective evaluation of postoperative penile rehabilitation: Penile length/girth maintenance 1 year following coloplast titan inflatable penile prosthesis. J Sex Med 2015;12:1298–1304.**

**Key Words.** Penis; Penile Implants; Erectile Dysfunction; Patient Satisfaction; Sexual Dysfunction

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**Figure 1** Changes in penile measurements

## Introduction

The inflatable penile prosthesis (IPP) became available in the early 1970s [1,2]. Over the years, the IPP has become more dependable mechanically with superior flaccidity and rigidity [3–5]. Very high patient satisfaction rates with IPP have been reported worldwide [5–7]. Despite the fact that after surgery, most patients admit they would have the procedure again, the complaint of penile shortening after implantation is common and can be very disturbing to the patient [5,8]. Indeed, one publication called the number one complaint after prosthesis implantation “the inability to duplicate the full length of natural erections.” [9] Deveci et al. published that 72% of patients thought their penis was shorter after implantation [10]. Wang et al. found a statistically significant decrease of penile length following IPP when compared with erection with intracavernosal injection at 12 months [11]. None of the published papers in the literature include more than a few postoperative penile measurements.

Because IPP surgery is an elective surgery, where patient satisfaction is of utmost importance, the prevalent complaint of reduced length should be addressed. We proposed that using the new

length measurement technique (NLMT) with Titan cylinders with minimized rear tip extenders (RTEs) and daily, prolonged cycling of the implant for 1 year postsurgery would maintain the patient’s immediate postoperative length and girth and minimize postoperative loss of length. We introduced a programmed post-IPP rehabilitation concept with prolonged cycling of the implant after implantation. We also investigated whether the above protocol coupled with the girth expansion of the Bioflex® cylinders (Coloplast, Minneapolis, MN, USA) and proven axial rigidity strength could cause tissue expansion and possibly maintain postoperative length and girth, as compared with measurements taken immediately after implantation [12].

## Aim

We attempt to publish for the first time comprehensive measurements evaluating a postoperative IPP rehabilitation technique after IPP surgery using a more aggressive penile length measurement technique (NLMT) to determine appropriate sizing. To the authors’ knowledge, this is the first prospective, IRB-approved, multicenter study

**Table 1** Inclusion and exclusion criteria

Inclusion criteria for the study were subjects who had:

Life expectancy of more than 5 years  
 Diagnosis of ED  
 Willing and able to meet the follow-up requirements  
 Written informed consent approved by the IRB of the respective site

Exclusion criteria for the study included patients who had:

Previous penile implant or penile lengthening surgery  
 Fibrosis of the penis (e.g., Peyronie's Disease, chordee, priapism)  
 Recent myocardial infarction or stent placement  
 Bleeding disorders or compromised immune systems  
 Insufficient manual dexterity to work a prosthesis for daily inflation

to be submitted for publication in the literature on this important subject.

## Methods

This study is a prospective, nonrandomized, multicenter clinical trial conducted in the United States at three centers for urologic surgery. The study incorporated an aggressive method of cylinder sizing during implantation, which has been previously described (NLMT) designed to maximize length of the inflatable portion of the cylinder [13]. The prosthetic urologist needs to understand that NLMT is not oversizing and should review the cited paper for complete details as it has been previously published [13]. Daily inflation from the time of teaching at 6 weeks to 1 year is required, and

a maximum inflation protocol for 1–2 hours was instituted for the last 6 months. IRB approval was obtained at all study sites, and all patients provided informed consent. Subjects were recruited from high-volume implant practices at the three institutions where Titan IPPs were commonly implanted, and a similar implant and inflation protocol had been implemented. Inclusion and exclusion criteria are shown in Table 1. A total of 40 patients undergoing primary implantation of an IPP provided consent to participate and were enrolled/implanted from October 2007 through May 2009 with a minimum of 10 patients per site. Demographic and clinical data at baseline were collected. Also, at baseline, we obtained medical history, a baseline participant questionnaire, and baseline penile measurements of length in erect, flaccid, and stretched states, as well as flaccid circumference and width.

Surgical procedures were performed via penoscrotal (39) and infrapubic (1) approaches. Maximal cylinder size and minimal RTEs were used. No more than 2.5-cm RTE was allowed regardless of cylinder size. Following completion of the surgery and skin closure, the same penile measurements as taken preoperatively were obtained, with erect measurement conducted with the IPP in the fully inflated state. At total of 15 penile measurements (in cm) were recorded (see Table 2 for measurements).

Follow-up visits were required at 6 weeks, and 6 and 12 months postimplantation. Following the instructional visit at 6 weeks, the patients were instructed to daily inflate to the point of

**Table 2** Changes in penile measurements

Measurement	Post-op to 6 months			Post-op to 12 months			6–12 Months		
	N	Change (cm) ± SD	P value	N	Change (cm) ± SD	P value	N	Change (cm) ± SD	P value
Pubic bone to meatus									
Erect	33	0.51 ± 1.39	0.042	31	1.14 ± 1.94	0.003	31	0.70 ± 1.07	0.001
Flaccid	33	0.09 ± 1.36	0.699	31	0.99 ± 1.64	0.002	31	1.00 ± 1.11	0.001
Stretched	33	−0.26 ± 1.43	0.306	31	1.04 ± 1.94	0.006	31	1.21 ± 1.41	0.001
Pubic bone to proximal end of corona									
Erect	33	0.49 ± 1.30	0.038	31	0.94 ± 1.41	0.001	31	0.52 ± 0.96	0.005
Flaccid	33	0.00 ± 1.35	0.990	31	0.69 ± 1.69	0.031	31	0.76 ± 0.82	0.001
Stretched	33	−0.13 ± 1.52	0.626	31	0.59 ± 1.59	0.046	31	0.65 ± 1.07	0.002
Pubopenile skin junction to meatus									
Erect	33	0.16 ± 1.16	0.431	31	0.93 ± 1.41	0.001	31	0.84 ± 1.14	0.001
Flaccid	33	−0.12 ± 1.16	0.557	31	0.71 ± 1.48	0.012	31	0.86 ± 1.21	0.001
Stretched	33	−0.16 ± 1.17	0.433	31	0.95 ± 1.98	0.012	31	1.17 ± 1.44	0.001
Pubopenile skin junction to proximal end of corona									
Erect	33	0.22 ± 0.94	0.181	31	0.93 ± 1.5	0.002	31	0.76 ± 1.37	0.005
Flaccid	33	−0.08 ± 1.24	0.713	31	0.75 ± 1.58	0.013	31	0.86 ± 1.24	0.001
Stretched	33	−0.14 ± 1.11	0.466	31	0.64 ± 2.00	0.085	31	0.86 ± 1.72	0.009
Penile circumference	33	0.69 ± 0.81	0.001	31	1.08 ± 0.82	0.001	31	0.39 ± 0.64	0.002
Width of penis	33	0.31 ± 0.29	0.001	31	0.47 ± 0.32	0.001	31	0.17 ± 0.22	0.001

discomfort for a short period of time. At the 6-month visit, the subjects were instructed to inflate their IPP as hard as they could tolerate every day for the next 6–12 months for at least 1 hour and not to exceed 2 hours per day.

At each of the three postoperative visits, penile measurements were taken. In addition, at the 6- and 12-month visits, participant questionnaires were collected. In an effort to assess possible tissue expansion by the device, we determined the number of pumps the IPP took to fully inflate the device, as compared with immediately after the surgery.

Data were compiled, and standard statistical analyses were performed using SAS version 9.1 or above (SAS Institute, Cary, NC, USA) or another validated statistical software package. As no pre-defined hypothesis testing was in effect, power calculations were not relevant to determining sample size, and a minimum of 30 patients was deemed sufficient to characterize the population. Allowing for 20% participant attrition (lost to follow-up, death, etc.), 40 enrolled participants were needed to reach the minimum sample size of 30.

### Main Outcome Measures

The primary objective of this study is to evaluate the combined use of Coloplast Titan IPP, NLMT, and a postoperative daily inflation protocol for maintenance of penile length after implantation and at 12 months postimplantation. Length and girth measurements and number of pumps required for full inflation were the primary outcome measures. Patient responses to satisfaction questions were a secondary measure.

### Results

The average age of the selected subjects was 66.2 years. Major etiologies of ED were cancer treatment (50%), vascular disease (32.5%), diabetes (30%), and pelvic trauma/surgery (10%) (Table 3). Etiologies for ED were not mutually exclusive.

Penile measurement increases at 12 months, as compared with immediately postoperative represented statistically significant differences for erect, stretched, and flaccid penis. Pubic bone to meatus measurements increased by 1.14 cm ( $P = 0.003$ ), 0.99 cm ( $P = 0.002$ ), and 1.04 cm ( $P = 0.006$ ) for erect, flaccid, and stretched penis, respectively. Penile circumference ( $1.08 \pm 0.82$ ,  $P = 0.001$ ) and width ( $0.47 \pm 0.32$ ,  $P = 0.001$ ) of the penis also increased significantly (Table 2 and Figure 1). All

**Table 3** Subject demographics

Characteristic	Mean $\pm$ SD or n (%)
Age (years)	66.2 $\pm$ 11.4
Primary indications (not mutually exclusive)	
Vascular disease	13 (32.5%)
Diabetes mellitus	12 (30.0%)
Postcancer treatment	20 (50.0%)
Pelvic surgery	4 (10.0%)
Neurogenic	1 (2.5%)
Psychological causes	0 (0.0%)
Pelvic trauma	2 (5.0%)
Iatrogenic	0 (0.0%)
Other	5 (12.5%)

15 objective penile measurements from 6 to 12 months postimplantation showed statistically significant increases (Table 2).

In comparing baseline to 12 months after implantation, when patients were asked, “Over the past 4 weeks, how satisfied are you with your penile length?” most of the respondents (61.3%) reported improved satisfaction with penile length from prior to implantation (Table 4).

All patients received a Titan IPP with distribution among cylinder sizes 16 cm, 18 cm, 20 cm, 22 cm, and 24 cm at 10%, 20%, 32.5%, 35%, and 2.5%, respectively. Because of the study’s optimization of cylinder length and restriction of minimal RTEs, 90% of cylinder sizes used were 18–24 cm showing a preponderance of larger length cylinders. There was a statistically significant reduction in the amount of pumps to full inflation at 6 weeks postimplantation as compared with immediately postoperation. However, at 6 and 12 months, the amount of pumps needed statistically increased from postoperative measurements, suggesting there are more volume in the cylinders, which could represent an increase in penile measurement resulting from using the daily maximum inflation protocol (Table 5 and Figure 2).

**Table 4** Change in penile satisfaction from baseline to 12 months

Question	N	% (n/N)	P value*
Over the past 4 weeks, how satisfied are you with your penile length?			<0.001
Worsened	31	22.6 (7/31)	
Unchanged	31	16.1 (5/31)	
Improved	31	61.3 (19/31)	

\*The probability of a satisfactory response (“somewhat/completely satisfied”) was compared between baseline and 12 months using a generalized estimating equation model with a binomial outcome and accounting for repeated measures within a subject

**Table 5** Number of pumps to full inflation at each visit

Visit	N	Mean	Median	Standard deviation	Minimum	Maximum	Difference from baseline <i>P</i> value*
Baseline	40	22.0	20	12.4	4	69	N/A
6 Weeks	39	15.1	12	8.1	4	37	<0.001
6 Months	33	24.0	25	13.2	6	60	0.015
12 Months	31	27.6	27	14.7	10	69	<0.001

\*The probability that there was a difference in number of pumps required to reach full inflation between baseline and the 6-week, 6-month, or 12-month visit was calculated using a generalized estimating equation model with a negative binomial outcome and accounting for repeated measures within a subject  
N/A = not available

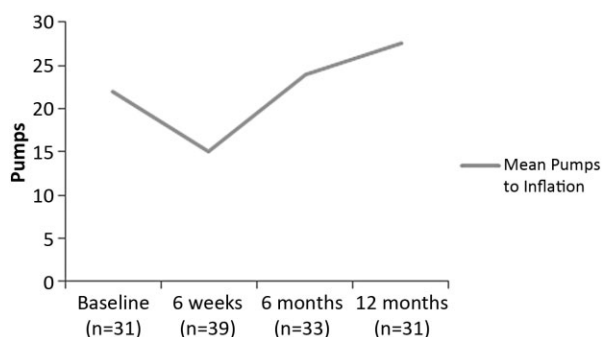
## Discussion

One aim of this study was to evaluate the Coloplast Titan IPP at maintaining penile length in participants treated for ED at 12 months after IPP implantation. Another goal was to analyze the specific changes in dimensions of the phallus following implantation of a Titan IPP following a protocol believed to maximize dimensions of the cylinder and the capsule surrounding it, the “post-operative IPP rehabilitation.”

An aggressive cylinder sizing technique was used to ensure the optimal length of cylinder was implanted, with a minimum of RTE length. The fact that 90% of cylinders were 18 cm and larger attests to successful implantation of the larger-sized available implants. These larger cylinders *may be* helpful for tissue expansion as these larger cylinders are manufactured to have larger width expansion (19.6–22.1 mm) than the smaller 14 and 16 cm Titan cylinders (16.9 mm). We postulated that by maximizing the amount of inflatable cylinder in the corpora to take advantage of the innate properties of the Bioflex material would enhance column strength, girth, and rigidity. Moreover, limiting a large amount of RTE length into the pendulous penis helps avoid a hinge effect from occurring. In addition, the participants were instructed to daily inflate their prostheses for the

first 4.5 months after the first instructional postoperative visit and then to maximum inflate the implants for the next 6 months leaving it inflated for at least 1 hour per day. Utilization of a postoperative IPP penile rehab consisting of daily maximum inflation may help create optimal tissue expansion of the corpora cavernosa in terms of resulting penile length and girth measurements.

Validating our prestudy beliefs, the penile measurements from immediately postoperative to 12 months increased statistically significant for flaccid, stretched, erect states, circumference and width. However, 61.3% of subjects reported satisfaction with penile length prior to having the IPP implanted, which suggests that in some instances, patient-perceived satisfaction with length does not correlate with the demonstrated significant increases in length. Penile measurement changes from 6 to 12 months also showed statistically significant improvement in the measured parameters, suggesting additional improvement beyond the development of the fibrotic membrane, or capsule, that eventually surrounds objects implanted in the body. The capsule is thought to take 3 months to develop; so, it is unclear whether the maximum inflation protocol adds to improved length as opposed to the simple daily inflation that was performed for the first 6 months postoperation. Experience with the early AMS Ultrex® “unlimited” lengthening cylinders has shown that lengthwise capsule stretching may not occur if the capsule is allowed to form around the flaccid, not lengthened, cylinder. That inability of these older Ultrex cylinders to lengthen the capsule caused the so-called “S” deformity where the cylinder lengthened in the restrictive capsule curling up like a snake [14]. In this Titan cylinder study, the daily inflation protocol, commonly referred to as “postoperative IPP rehab,” appears to help increase penile measurements. The axial rigidity of the Titan cylinder is well known to be much stronger than the early Ultrex cylinders, thereby appearing to avoid the “S” deformity.

**Figure 2** Mean pumps to full inflation

The prolonged and daily usage of inflatable penile prostheses may cause the cylinders to act as tissue expanders. Tissue expansion has been well documented in plastic surgery and breast reconstruction literature [15,16]. Every frequent implanter has seen instances where an implant is removed for mechanical reasons, and the corporal measurements following removal suggest the replacement cylinders should be 2–3 cm longer [17,18]. Some prosthetic urologists have seen this change with Peyronie's disease after IPP implantation. It has been shown that after placing an IPP in a patient with Peyronie's disease, 30° of curvature or less will improve to a completely straight penis with subsequent inflation over 8–12 months [19]. Hourglass, or cicatrix, deformities will similarly change into a symmetrical-width penis with postoperative inflation and usage. Wilson et al. have also documented that the shortened, fibrotic penis resulting from priapism or previous removal of an implant for infection will stretch with daily inflation after placing a downsized prosthesis [20]. The authors postulate that if diseased corporal fibrotic scar can expand, it stands to reason that healthier unscarred tissue should expand.

We found a statistically significant reduction in the amount of pumps to full inflation at 6 weeks postimplant as compared with immediately postop. This can be explained by anesthesia allowing the physician to maximally distend the cylinders at the operating table, whereas postoperative soreness limits expansion at 6 weeks. At 6 and 12 months, the amount of pumps needed statistically increased from immediately postoperative measurements, suggesting there is more volume in the cylinders. There was a statistically significant change from 6 to 12 months (two to three pumps) vs. the change from baseline to 6 months (3–5) and baseline to 12 months (five to seven pumps) giving reason to question the value of maximum inflation daily for at least 1 hour when compared with simple daily inflation.

However, when we analyze the change in penile measurements from 6 to 12 months, there was a statistically significant increase in all 15 penile measurements. This appears to be attributed to the protocol of maximum inflation for at least 1 hour daily. Tissue expansion involves making the tunica albuginea more compliant so it will stretch and allow larger distention by the inflated cylinder. Experience with repetitive vacuum device application shows the tunica will respond with short exposures to the vacuum therapy. Sellers et al.

showed that 10 minutes a day of vacuum device application twice a day for 7 weeks promoted visible penile lengthening in the vacuum cylinder when marked weekly in first-time implant patients. It also, and more importantly, allowed the implanting physician to upsize his cylinder approximately 3 cm when compared with the average implant without vacuum preparation [21]. The application of vacuum to a penis with corporal fibrosis has also been described to preserve length preventing some of the shrinkage that accompanies removal of an IPP for infection. The published literature is, at best, anecdotal, but the belief is widespread among frequent implanters. The pressure difference between a hydraulic pump push inside the penis compared with low pneumatic suction on the external penis should be more than a thousand-fold stronger.

At the very least, more studies and research should be done on postoperative IPP rehabilitation similar to that done in this study. Another important point is that maybe the IPP should be left partially inflated for the first several weeks to try to get a larger capsule forming around the IPP cylinders to start with; however, there is the possibility that a "tight" capsule could form around the reservoir. Due to these data, one of the authors now leaves the IPP cylinders about 80% inflated for the first 6 weeks but has encountered mild reservoir capsule contraction that required forcible deflation at 6 weeks. Again, more study must be done to determine how much to leave the IPP inflated postoperation and when to teach the patient. Nevertheless, postoperative IPP rehabilitation appears to increase penile measurements in this study group and is gaining in popularity among prosthetic urologists.

Limitations of the study include the fact that high-volume implant surgeons were used and the results may not be generalized to low-volume implanters. Another limitation is the fact that the patients were not randomized. A third limitation is that no patients with corporal fibrosis, Peyronie's disease, or tunical defects, or revision cases were included. Further studies on patients with the conditions we excluded should be done. In addition, the measurements were taken by the implanting surgeons and could involve surgeon bias; so, in future studies, measurements may optimally be performed by a neutral third party. Finally, the number of pumps can vary from visit to visit due to a wide number of circumstances and may not provide the best measurement of cylinder volume.

## Conclusion

This study suggests that the use of the Coloplast Titan cylinder, combined with optimization of cylinder length, and daily inflation for 1 year postoperation result in patient satisfaction with penile length and girth of the implanted erect penis. Penile measurements before, at time of surgery, and 1 year later suggest this regimen can maintain or even increase girth and length when compared with the patient's immediate postoperative measurements.

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**Conflict of Interest:** The author(s) report no conflicts of interest.

## Statement of Authorship

### Category 1

#### (a) Conception and Design

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#### (b) Acquisition of Data

Gerard D. Henry; Run Wang; Rafael Carrion

#### (c) Analysis and Interpretation of Data

Gerard D. Henry; Run Wang; Rafael Carrion

### Category 2

#### (a) Drafting the Article

Gerard D. Henry; Caroline Jennermann

#### (b) Revising It for Intellectual Content

Gerard D. Henry; Run Wang; Rafael Carrion; Caroline Jennermann

### Category 3

#### (a) Final Approval of the Completed Article

Gerard D. Henry; Run Wang; Rafael Carrion; Caroline Jennermann

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