

## Review Article

# A Personal Reflection of Greenlight 532 nm Laser for BPH Treatment

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Lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia are a bothersome symptom set that affect approximately one in every four males above the age of 50. First line treatment is typically medication, but when medications fail surgical therapy is the next option. Technological advances have made surgical therapy safer and more effective. One area that our group has particular interest and focus in is the application of the 532 nm laser in surgical therapy. The high power 532 nm laser is used to remove obstructive prostatic tissue and the laser energy is selectively absorbed by hemoglobin in the prostate tissue, resulting in effective tissue vaporization and removal. We review our experience with Greenlight laser system and its evolution from the original 60-watt laser to the most recent 180-watt Greenlight system with MoXy fiber.

## 1. Introduction

Our group's focus has been on men's health, specifically benign prostatic diseases. We continually look for novel treatments and approaches to dealing with lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH). Initial therapy typically involves medical therapy with alpha blockers, 5 alpha reductase inhibitors, and overactive bladder medications. For many patients, however, these do not provide adequate symptom relief, and surgical intervention is necessary to debulk the prostate to relieve bladder outlet obstruction secondary to a progressive growing prostate responsible for the obstruction and consequent symptoms. The classic, traditional, and minimally invasive procedures involve a prostatectomy that removes/resects the prostate with a wire loop to open the prostatic urethra for better flow. This is commonly known as transurethral resection of the prostate or TURP. This procedure had well known side effects and adverse events including fluid absorption, electrolyte imbalance, intraoperative and postoperative bleeding, and inadequate resection. This prompted the development of novel tools to remove tissue with fewer risks and the development of the original 532 nm laser. Based on a potassium-titanyl-phosphate (KTP) crystal, it provides the technology

to attain this improved method of prostatectomy, achieving the desired results with fewer risks. Over the last decade, our group has been involved in its development to improve this technology and we have sought to characterize its safety, efficacy, and durability with our clinical experience of this technology.

The 532 nm wavelength is preferentially absorbed by hemoglobin which acts as an intracellular chromophore or heat sink for laser energy within blood cells [1]. This photoselective laser energy is also transmitted through aqueous irrigants such as sterile water or saline without losing energy, making it an ideal laser light for a transurethral procedure that requires aqueous irrigation for visualization. In addition, this laser has a short optical penetration which restricts its high power vaporization energy to a superficial layer of tissue. This leads to efficient vaporization and hemostasis with a millimeter or two of coagulated tissue.

## 2. In Vitro Studies

With the advent of the 532 nm laser, our first concern was its safety profile and specifically the laser's ability to penetrate into tissue. We investigated the use of the 120 W laser

in 5 male beagles [2]. Under general anesthesia, all dogs underwent laparotomy and laser prostatectomy. The animals were postoperatively sacrificed and their prostates were removed, bisected, measured, and fixed in formalin. Following that, the prostates were serially sectioned at 2 mm intervals, totally embedded and whole mounted. Sections, which were stained with hematoxylin and eosin, were examined by a single pathologist in blinded fashion to determine depth of coagulation and vaporization for each lesion. The 120 W setting provided optimum efficiency in comparison to lower watt settings, vaporizing more tissue per unit time while maintaining a depth of coagulation between 1.2–2.5 mm. What was clear from the procedure was that the lower power laser was adequate for vaporization and that higher power to 120 increased vaporization efficiency to produce deeper laser energy effects. By being cognizant of the vaporization effects, effective and safe debulking could be controlled by varying power and distance from the target tissue lesion.

### 3. Human Studies

**3.1. Safety.** After determining the extent of vaporization effects of the technology and what factors were important to maintain efficiency as well as safety in the animal model, we were interested in demonstrating and confirming the laser's clinical hemostatic ability. We next safely used the laser in patients on anticoagulation and we reported on our clinical experience. A series of 24 anticoagulated patients who underwent a laser prostatectomy using the 80 W Greenlight laser were studied retrospectively [3]. All patients had failed medical therapy for BPH prior to undergoing prostatectomy procedures. Eight of the patients were taking warfarin, 2 were taking clopidogrel, and 14 were taking aspirin. Of the 24 men, 8 (33%) had a previous myocardial infarction, 7 (29%) had cerebrovascular disease, and 7 (29%) had peripheral vascular disease. International Prostate Symptom Score (IPSS), maximum flow rate ( $Q_{max}$ ), postvoid residual (PVR), and any complications were evaluated and recorded preoperatively and during follow-up visits at one, three, six, and twelve months following the procedure. IPSS decreased steadily from 18.7 to 9.5 and  $Q_{max}$  increased from 9.0 to 20.1 mL/sec at 12 months. A decline was also seen in PVR, but was not statistically significant after one month. No patients developed clinically significant hematuria postoperatively and none developed clot retention. No transfusions were required and there were no thromboembolic events. One patient experienced transient postoperative urinary retention and required discharge with a catheter. There were two instances of retrograde ejaculation and two postoperative urinary tract infections. Results suggested that the risk of bleeding is not significantly greater in anticoagulated patients and that 532 nm laser is a safe and effective technique for the alleviation of symptomatic BPH in this population. Of note, this was one of the first procedures to treat actively anticoagulated patients with a transurethral prostatectomy. With this initial data, we sought to subsequently investigate the laser's use in high-risk anticoagulated patients in a larger sample size.

Our resulting prospective, larger scale study of 162 men included patients on two or more systemic anticoagulants [4].

Photoselective vaporization of the prostate using the 80 W Greenlight and the 120 W Greenlight laser systems had been performed by a single surgeon on all patients between 2002 and 2008. This cohort of patients included 31 (19%) taking warfarin, 101 (62%) taking aspirin, 19 (12%) taking clopidogrel, and 11 (7%) taking 2 or more anticoagulants. A large number of the patients (65%) had history of myocardial infarction. Additional patient history included cardiac arrhythmia, cerebrovascular disease, congestive heart failure, valvular disease, diabetes mellitus, and peripheral vascular disease. Patients were followed for 24 months postoperatively. Significant improvements were seen in IPSS,  $Q_{max}$ , and PVR. One month after surgery, we saw an increase in  $Q_{max}$  from 8.3 mL/sec to 15 mL/sec; this improvement was sustained throughout follow-up. IPSS decreased from 18 to 6 and PVR decreased from 124 mL to 75 mL at 24 months. Continuous bladder irrigation was required in 6 patients as a result of delayed bleeding; 3 of these patients needed transfusion and 1 required reoperation for fulguration of bleeding. Postoperative urinary retention in 2 patients required catheterization and 4 patients experienced postoperative urinary tract infection. Reflective of our preceding study, results supported the use of the 532 nm Greenlight laser for high-risk anticoagulated patients, even those taking two or more anticoagulation agents. This approach provided a technique to safely treat a patient group who were often not treated or not treated effectively due to their anticoagulation status.

Following our success with anticoagulated patients, we chose to pursue the laser's utility in men with large prostates. Men with large prostate reflect another traditionally high-risk population; standard of care for treatment of these patients favor a higher risk open surgical procedure or open prostatectomy. We assessed the safety and efficacy of the 80 W Greenlight laser for 64 patients with prostate volumes greater than 60 cm<sup>3</sup> who underwent photovaporization of the prostate (PVP) for symptomatic BPH [5]. All procedures were done by the same surgeon using a Laserscope Greenlight PV generator. IPSS,  $Q_{max}$ , and PVR were evaluated prior to surgery and at 1, 3, 6, and 12 months postoperatively. IPSS decreased by 8.5 points and  $Q_{max}$  increased by 8.5 mL/s within the first month after the procedure. No transfusions were required and all 64 patients were able to be discharged within 24 hours. There was no evidence of postoperative hyponatremia, which is an important outcome considering large gland size. Improvements were durable at 12 months, showing that high-power Greenlight PVP is a safe and effective method for the treatment of large-volume prostates, as well as an excellent alternative to open prostatectomy as well as monopolar TURP.

To prospectively evaluate the efficacy and safety of the 80 W KTP laser in a large, multicenter series of patients, we collaborated with investigators from several medical institutions to follow 145 patients for a period of 12 months [6]. American Urological Association Symptom Index (AUA-SI) score, quality of life score (QOL), peak urinary flow rate ( $Q_{max}$ ), and postvoid residual urine volume (PVR) were assessed preoperatively and 1, 3, 6, and 12 months after the procedure. At 12 months, significant improvements were seen in AUA Symptom Index (AUA SI) scores, QOL scores,  $Q_{max}$ ,

and PVR. There were no perioperative complications and no blood transfusions were required. These 12-month outcomes shown by patients from 6 different institutions provided support for sustained efficacy and durability of the 80 W Greenlight laser.

Following the initial 12 month analysis, 139 of the initial 145 patients were followed for an additional 2 years to assess long-term efficacy and durability of the 80 W Greenlight laser [7]. At two years postoperatively, the mean AUA-SI score decreased from 114.3 to 24.8 mL and the transrectal ultrasound volume decreased from 54.6 mL to 34.4 mL. Complications included transient hematuria in 12 patients (8.6%), dysuria in 13 (9.3%), and urinary retention in 7 (5%) patients. The 33.8% of patients who were followed for 3 years displayed durable improvements in both symptom relief and urinary flow rate [6]. Only 4.3% of patients required retreatment. These results supported the use of the PVP technique for the treatment of BPH as a safe, effective, and durable option.

This trial was significant in that excellent efficacy and safety were demonstrated in a multi-institutional, multisurgeon prospective trial of a novel technology in which the clinical outcome represented the novel experience of a group of physicians. It demonstrated that good outcomes were obtained with a short learning curve and efficacy results comparable to the TURP.

We continued to evaluate the laser technology as it evolved into the newer 180 W Greenlight laser. The evolution for increased power is important because increased power allowed improved efficiency in vaporization, and the maintenance of a good safety profile was important to verify. To assess clinical safety, efficacy, and durability of the device, we collected and analyzed data from 120 patients treated with the 180 W Greenlight for LUTS secondary to benign prostatic enlargement. IPSS, QOL, PVR,  $Q_{\max}$ , PSA, and prostate volume were evaluated at 1, 3, 6, and 12 months. With statistically significant changes in IPSS,  $Q_{\max}$ , PVR, and prostate volume as early as 1 month following the procedure and postoperative complications occurring in less than 5% of the cohort, our high expectations for safety and efficiency were met [8].

**3.2. Comparative Evaluations.** When the 120 W high power Greenlight laser was developed it promised faster, more efficient tissue removal with no sacrifice to safety. We were interested in evaluating the new laser in comparison to its predecessor, the 80 W Greenlight laser. To this end, we followed 106 men with BPH who had been treated with either the 120 W or 80 W system in a comparative evaluation of safety and efficacy.  $Q_{\max}$ , PVR, ultrasound prostate volume, IPSS, and QoL were measured preoperatively and at 1, 3, 6, and 12 months. Data were collected and compared for two treatment arms of 53 patients. With a shorter laser time, the promise of improved tissue removal with equivalent safety and efficacy was met by the 120 W system [9].

In a larger series, we examined a total of 476 patients. 267 patients underwent the 80 W Greenlight PVP procedure and 209 underwent the 120 W Greenlight PVP. Similar durable improvements in symptoms and objective parameters were achieved in both groups. Again, the 120 W system demonstrated faster and more efficient vaporization [10].

Additionally, we presented a comparison of techniques for transurethral laser prostatectomy in a series of 97 versus 170 patients who underwent PVP versus transurethral laser enucleation of the prostate (TLEP), respectively, with the Greenlight laser system between September 2001 and May 2009. Data were collected on patient demographics, IPSS, PSA, and perioperative parameters.  $Q_{\max}$ , PVR, and prostate volume were also recorded. Similar changes in  $Q_{\max}$  and PSA were found between groups, but the TLEP technique demonstrated superiority in urinary symptom improvement, PVR, and efficiency [11].

More recently, we participated in a global, multicenter analysis to evaluate the new Greenlight XPS-180 W laser system in comparison with the former generation HPS-120 W system for the treatment of BPH by PVP, focusing specifically on the impact of prostate volume on both procedures. A total of 1,809 patients underwent Greenlight PVP at 7 international centers; 1187 cases were performed using the HPS-120 W and 622 cases were performed using the XPS-180 W laser system. The XPS system displayed a significant reduction in laser and operative time when compared to the HPS system, with similar total energy delivery per given prostate volume between the two systems, suggesting Greenlight XPS to be the more efficient option [12].

Consensus of this clinical experience has also been validated by a large worldwide registry of this technology by the Clinical Research Office of the Endourological Society (CROES) registry of Greenlight procedures.

## 4. Advanced Techniques

To make the 532 nm laser more effective for larger prostates as well as attain tissue for pathology, we developed a technique to remove large portions of tissue similar to an open prostatectomy [11] (Figure 1). The transurethral laser enucleation of the prostate (TLEP) technique begins with the creation of a midline groove at the 6 o'clock position to the level of the trigone. Vaporization is performed with quick, sweeping motions and proximal-distal movement of the fiber is used to create a groove. Once the midline groove has been created, a lateral groove on the 5 o'clock side of the median lobe is made. This second groove is aimed lateral to the ipsilateral ureteral orifice and deepened to the level of the trigone. The tissue in between the two grooves is vaporized using larger sweeps, beginning from the apex of the tissue. Next, the procedure's focus shifts to the lateral lobes with the creation of a groove at the 11 o'clock position. Vaporization of the right and left lateral lobes follows, stopping when the groove at the floor of the prostate is reached. With the starting groove at 1 o'clock, the technique is repeated on the opposite side. Once both lateral lobes have been vaporized, the anterior prostate is vaporized. Focus shifts to the apex, where apical tissue is vaporized with the cystoscope positioned at the verumontanum. To prevent the ejaculatory ducts from injury that can occur due to backscatter, it is important that the backside of the fiber does not face the verumontanum. Hemostasis is confirmed at the end of the procedure and any remaining tissue in the bladder is removed [11].

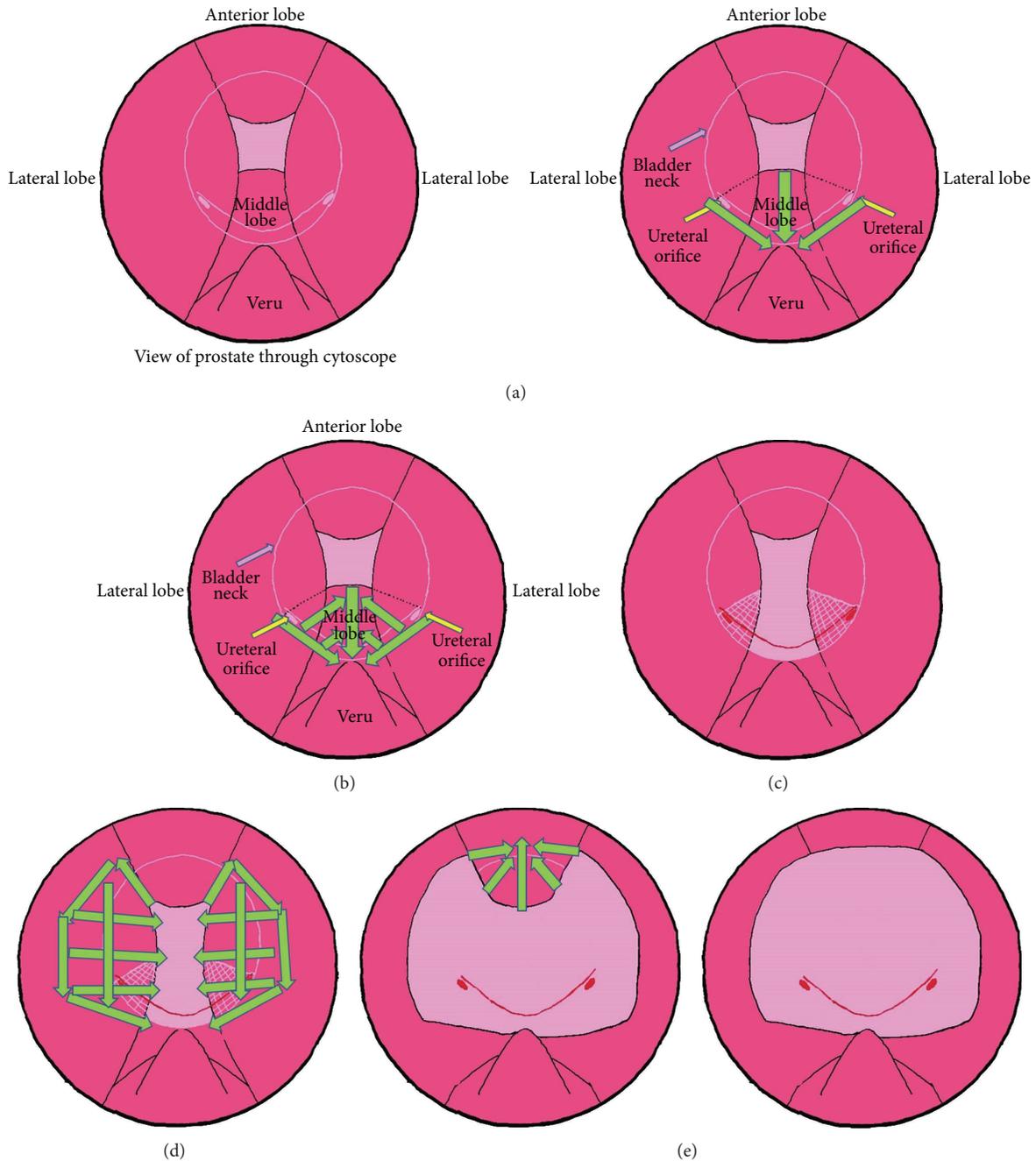


FIGURE 1: Transurethral laser enucleation/vaporization technique. (a) A wide incision is made through the median lobe until the bladder neck fibers can be seen. This channel should be wide enough to ensure a strong flow of cooling irrigant. Then, incisions are made lateral to the median lobe. It is important to visualize the ureteric orifices. (b) The intervening tissue between the incisions, if large, is divided into smaller chips. The chips are vaporized to reduce bulk before they are incised and placed into the bladder. (c) The median lobe is removed in this manner on both sides to view the ureteral orifices well from behind the bladder neck. (d) Multiple vaporization enucleation incisions are made starting at the 11 o'clock position of the lateral lobe down to the fibers of the prostatic capsule. The 11 o'clock incision is continued medially to join the median lobe defect at the 7 o'clock position. Intervening tissue is vaporized, incised, and pushed into the bladder. The same procedure is done to the other side to remove the contralateral lateral lobe starting at the 1 o'clock position to the 5 o'clock position. Apical tissue proximal to the verumontanum is carefully ablated with care to preserve the verumontanum. (e) Anterior tissue at the 12 o'clock position is then incised, vaporized, and enucleated as needed to connect the 1 o'clock to the 11 o'clock position. The goal is to achieve a TURP like cavity with removal of tissue to capsule and with view of the ureteral orifice as well as removal of any intravesical components. After resection is completed, the tissue chips are irrigated out with combination of transurethral evacuators and graspers. With careful lasering of tissue to small chips, use of a morcellator is unnecessary.

We compared the efficacy of PVP and TLEP techniques using the 80 W 532 nm Greenlight laser in a series of 267 patients who underwent PVP or TLEP procedures with the Greenlight laser system at Weill Cornell Medical College in an 8-year time period. Ninety seven patients underwent PVP and 170 underwent TLEP. All were men aged at least 50 years with moderate or severe LUTS, which was defined by an IPSS greater than 8 with significant bother. Inclusion criteria also included  $Q_{\max}$  of <10 mL/sec and obstruction found on urodynamics as defined by a Bladder outlet obstruction index of >40. We collected data on patient demographics, IPSS, PSA, and perioperative parameters including number of laser fibers used, total procedure time, and complications.  $Q_{\max}$ , PVR, and prostate volume were determined by transrectal ultrasonography. Follow-up was performed at 1, 3, 6, 12, 18, 24, and 36 months after the procedure. IPSS,  $Q_{\max}$ , and PVR were evaluated at each visit. Serum PSA was measured at 12, 24, and 36 months.

Improvements in median IPSS and PVR were seen in the TLEP group (5.0,  $P < 0.001$ ; 55.5,  $P = 0.02$ ) but not in the PVP group ( $P = 0.40$  and  $0.30$ ). Similar improvements in median  $Q_{\max}$  and PSA were seen in both groups. Final IPSS was lower for the TLEP group ( $P < 0.001$ ); other final parameters were statistically equivalent between groups. The most common complications seen in both groups were Clavien grade I (e.g., urinary tract infection, hematuria, and urgency/dysuria). No differences were seen between groups in the rates of complications and no blood transfusions were necessary. Results showed both techniques to be safe and effective. Although changes in  $Q_{\max}$  and PSA were similar between the two techniques, the superior improvement in urinary symptoms and PVR seen in patients who underwent TLEP provided support for the utility of our technique [11].

## 5. Side Effects

While TURP resects prostate tissue by cutting across the prostatic parenchyma, opening prostatic venous sinuses, laser prostatectomy seals blood vessels while coagulating the transition zone. The hemostatic ability of the laser has been demonstrated even in studies of anticoagulated patients, providing resection without the bleeding complications seen with TURP and other procedures [3, 4].

In our experience with the 80 W Greenlight laser, side effects included early postoperative urinary symptoms (frequency, urgency, and irritation), dysuria, hematuria, and urinary tract infection [6]. Retrograde ejaculation occurs in in up to 90% of patients following TURP and is a concern for many considering the procedure [6, 13]. Eighty-watt Greenlight laser data shows that retrograde ejaculation does pose a potential problem for patients who have undergone laser prostatectomy as well, but the incidence is closer to 27% [13].

## 6. Future of 532 nm Laser

Recent modifications to the laser have resulted in the 180 W 532 nm lithium triborate (LBO)-based laser system, which has a feedback mechanism allowing for the control of energy

as it exits the redesigned water cooled, high-power fiber. These redesigns were directed to provide a higher power for improved clinical efficiency for resection as well flexibility to address different tissue compositions. The addition of an intermittent coagulation pulsing regime also allowed for effective hemostasis while limiting adverse effects. Additionally, the feedback mechanism allows fibers to last longer and to provide a visual feedback to improve the surgeon's vaporization efficiency.

Our experience with this version of the laser system has proven it to be extremely efficient. While the maximum setting is 180 W, we have found that settings at or above 120 W require the sacrifice of hemostasis for a higher level of efficiency. Above 120 W we have noticed a marked decrease in coagulation with the increasingly rapid vaporization, as well as a potential decrease in hemostasis.

This does cause some concern that a misfire when the system is at 180 W setting could cause serious damage to the bladder and/or ureteral orifices without immediate recognition. However, it should be noted that the actively cooled fiber reduces the likelihood of mechanical failure and, in most cases, one fiber is sufficient for treatment.

## 7. Strengths and Limitations

Although the 532 nm laser does not have the established evidence base enjoyed by the "gold standard" TURP, it has thus far displayed positive indications for safety and utility in the treatment of BPH, even in high-risk patients on anticoagulants and with large prostates. As a new technology with now over a decade of clinical experience, it is quickly becoming an alternative gold standard to monopolar TURP while expanding the population of patients to include high risk and anticoagulated patients. Technological advancements and developments in technique have made the system a viable option for many patients seeking surgical treatment for relief of LUTS secondary to BPH. Our experience with the 532 nm laser reflects the advances we strive to support in the treatment of these men, particularly high-risk patients for whom other procedures may not be suitable.

## Conflict of Interests

The authors declare that there is no conflict of interests regarding the publication of this paper.

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