REVIEW ARTICLE

# A narrative review on malleable and inflatable penile implants: choosing the right implant for the right patient

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A penile prosthesis/implant is an excellent option for men with erectile dysfunction refractory to medical treatment or with contraindications to medical management. In this narrative review, we discuss the different types of penile prostheses and the considerations for patient and device selection to maximize satisfaction. There are three main prosthesis types to choose from: three-piece inflatable devices, two-piece inflatable devices, and malleable/semirigid devices. The three-piece devices are the gold standard in advanced economy countries but require reservoir placement and manual dexterity, which can be limiting to some patients. The two-piece inflatable devices are a good option for patients who have standard-sized penises, lack significant penile pathology, have limited dexterity issues, or should avoid reservoir placement due to potential complications. The malleable devices are popular in countries where insurance coverage is limited but are increasingly used in advanced economy countries for length conservation in specific patient populations. Finally, not every patient needs an implant, and assessing partner sexual function is an important consideration for patient–partner satisfaction. Surgeons need to be familiar with the strengths and limitations of each device and the patient characteristics that will yield the best outcome from penile prosthesis surgery.

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## INTRODUCTION

The prevalence of erectile dysfunction (ED) in the United States in men aged 20 years or older has been previously estimated at 18.4%. This prevalence increases with age, affecting 70.2% of men aged 70 and older [1]. Penile prostheses/implants are an excellent option for men with ED refractory to medical treatment, with contraindications to medical treatment, or who prefer treatment with an implant [2, 3]. Patient satisfaction after implant surgery has been reported as high as 90% [4, 5]. One critical aspect of patient satisfaction is appropriate device selection. The purpose of this narrative review is to highlight important considerations for penile implant device selection to maximize patient satisfaction after implant surgery. Using PubMed, Google Scholar, and Wiley Online Library, we reviewed articles on penile implant surgery. Search terms included "penile implant," "penile prosthesis," "patient satisfaction," "device selection," and "erectile dysfunction." The articles included were original and published in English.

## REVIEW OF DEVICES

The types of penile prostheses can be broadly divided into two categories: inflatable and noninflatable (i.e., "malleable" or "semirigid"). The inflatable penile prosthesis (IPP) is used more often in North America and Europe than the noninflatable device; it has been reported that 90% of the devices implanted in the United States are of the inflatable variety [6–8] (Fig. 1).

Inflatable devices are popular, in part, because they more realistically capture the physiologic cycling between flaccid and erect states of the penis. A pump, implanted in the scrotum, when squeezed and released several times, will fill the corporal cylinders with a sterile solution, thus mimicking physiologic tumescence. A release mechanism allows the cylinders to deflate to a more flaccid state. The IPPs have an additional subcategory consisting of two-piece and three-piece devices. Two-piece devices have a small reservoir at the end of each cylinder or attached to the pump, while three-piece devices have a separate large reservoir that requires placement somewhere outside the scrotum, usually in the space of Retzius or abdominal wall. There is currently only one two-piece IPP available in the United States: the Boston Scientific AMS Ambicor™ (Marlborough, MA, USA). Three-piece devices consist of the Boston Scientific AMS 700™ series (AMS 700™ CX, AMS 700™ LGX, and AMS 700™ CXR), the Coloplast Titan® (available as Titan®, Titan® Touch/OTR (one-touch release), Titan® NB [narrow base]; Humlebæk, Denmark), and the newly introduced Rigicon Infla10® series (Infla10® X, Infla10® Anatomical expansion [AX], and Infla10® NarrowBody [NB]; Ronkonkoma, NY, USA) [3, 6, 9].

The noninflatable devices consistently have the same rigidity but can be bent into a desired position when not in use. The malleable devices currently available in the United States consist of the Coloplast Genesis®, the Boston Scientific Tactra™, and the Rigicon Rigi10® [7]. Other semirigid devices exist worldwide, including the ESKA Jonas prosthesis (Germany), Virilis I and II implants (Italy), Silimed and HR penile prostheses (Brazil), Shah penile implant (India), Promedon Tube prosthesis (Argentina), and the Zephyr ZSI 100 (Switzerland) [10, 11].

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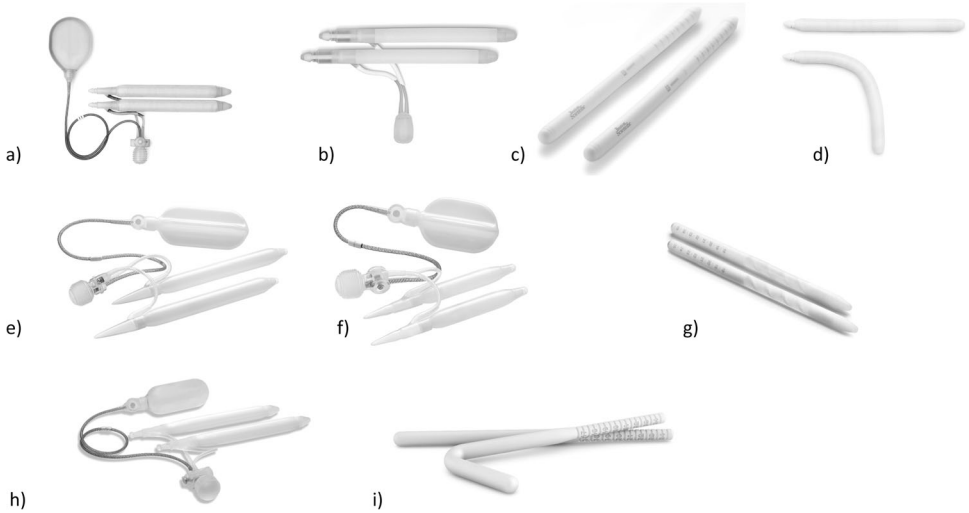


**Fig. 1 Images of different penile prostheses.** Boston Scientific: **a** AMS 700, **b** Ambicor, **c** Tactra, **d** Spectra. Coloplast: **e** Titan, **f** Titan Touch, **g** Genesis. Rigicon: **h** Infla10 series, **i** Rigi10.

## PATIENT COUNSELING FOR ALL DEVICES

Ensuring that patients have a realistic expectation of prosthesis outcomes is of paramount importance. The postimplant penile size is invariably shorter than the patient's former natural erection when fully potent [2, 6]. Generally, the expected erectile length with an implant can be demonstrated to the patient in the clinic by measuring their stretched penile length when flaccid. Patients should also be counseled that a prosthetic erection, unlike a physiologic erection, does not lead to any engorgement or increased size of the glans. It is also important to counsel patients that penile sensitivity, sex drive, and ejaculatory ability are unchanged after surgery [6, 11]. Finally, patients should be informed that when an implant is placed, the spongy tissue of the erectile bodies is destroyed; therefore, if the cylinders are removed later, the space will fill with scar tissue, and subsequent conservative ED treatment will no longer be effective [11].

## CONSIDERATIONS FOR CHOOSING A THREE-PIECE INFLATABLE PENILE PROSTHESIS

In most advanced economy countries, as long as cost is not a limiting factor, the three-piece IPP is considered the "gold standard" device [6, 12]. The most commonly implanted device in the United States is the three-piece IPP [13]. Various studies have examined the overall satisfaction with these devices, with contemporary satisfaction rates ranging between 76 and 98% [14]. In the United States, insurance coverage of three-piece devices varies depending on the insurance carrier and state of residence [15, 16]. Medicare is one of the largest U.S. insurers and currently covers penile implant surgery. Medicaid, however, does not have the same widespread coverage. Only 26 U.S. states report existing Medicaid coverage of these devices [16]. At one tertiary care center, only 48% of patients with commercial insurance were able to secure approval for IPP placement. The out-of-pocket cost for an IPP ranges from $10,000 to $20,000 for patients without insurance coverage [15]. Obtaining prior authorization from the insurance carrier is often necessary before proceeding with surgery, as these devices may be cost restrictive [16].

The three-piece IPP is the "gold standard," because it generally provides the best dynamic erectile response of all the available devices. Because of the fluid reservoir, the girth and rigidity provided by this device is typically better compared to the two-piece device. For this reason, three-piece devices are generally best for patients with larger penises [11]. Maximizing rigidity is especially important for patients with Peyronie's disease (PD), who require their device to provide penile straightening as well as erectile function. All three-piece devices except for the AMS 700™ LGX (and possibly the Infla10® AX by concept, as it has not been specifically tested), which lacks sufficient stiffness and has been shown to exacerbate penile deformity in PD patients, are appropriate to use in patients with PD [6, 17, 18]. In patients with severe corporal scarring (i.e., reimplant after the previous removal of an infected device, severe PD, or after priapism), a narrow-based device, such as the AMS 700™ CXR, Coloplast Titan Touch® NB, or Rigicon Infla10® NB, is often the best option, as these devices only require 10 mm of corporal dilation to be placed [6, 9, 19].

Another benefit of the three-piece IPP's fluid reservoir is that the cylinders can be emptied more completely after use, which removes pressure off the tunica albuginea and reduces the chance of device erosion. For this reason, some urologists recommend that patients with spinal cord injuries, who are more susceptible to device erosion because of absent cutaneous sensation, receive three-piece IPPs over other types [6]. The fluid reservoir of three-piece devices is not without its drawbacks, however.

For patients with complex anatomies, such as neobladder after cystectomy, kidney transplant, femoral-to-femoral bypass surgery, or inguinal hernia repair with mesh, the surgeon will likely want to avoid blind reservoir placement into the space of Retzius [11, 20]. Choosing an ectopic location for reservoir placement, such as the abdominal wall, or placing the reservoir into the space of Retzius under direct vision with a counter incision are options. However, inserting a simpler two-piece or malleable prosthesis obviates the potential complications that can arise with reservoir placements in patients with distorted anatomy [2, 3, 6].

Inflation and deflation of a three-piece IPP requires manual dexterity of either the patient or his partner to manipulate the pump, and this device is best avoided if there is concern that the patient might not have the hand strength necessary for full pump inflation (~8–20 pumps) and deflation [6, 11].

The AMS 700™ devices with Inhibizone™ antibiotic coating are contraindicated in patients with allergy or sensitivity to rifampin, minocycline, or other tetracyclines, as well as those with lupus erythematosus, as minocycline has been known to aggravate this condition [21]. The AMS 700™ series is also not available in every country because of certain regulatory issues [3].

Finally, the Coloplast Titan® uses a material known as Bioflex®, a biopolymer, for the cylinder wall. The rigidity of the Bioflex® material when flaccid may be uncomfortable for some patients due to a "dog-ear" effect at bends, leading to chafing against undergarments [22].

## CONSIDERATIONS FOR CHOOSING A TWO-PIECE INFLATABLE PENILE PROSTHESIS

Patient and partner satisfaction rates with the AMS Ambicor™ two-piece IPP are generally high, at 85% and 76%, respectively. Eighty-four percent of patients report good to excellent rigidity for coitus, with a less than 1% chance of mechanical failure cited in one series [12]. However, despite these favorable safety and efficacy outcomes, the Ambicor™ device accounts for less than 5% of penile implants today [23].

The AMS Ambicor™ two-piece IPP is typically chosen over a three-piece IPP when there are concerns with reservoir placement and patient manual dexterity issues [12]. The Ambicor™ is debatably easier to inflate, typically only requiring 2–5 pumps before reaching full rigidity. It is debatably easier to deflate as well, which is done by bending the penis [24–26]. These device characteristics can potentially make an inflatable device accessible for patients who lack the fine motor skills and hand strength necessary for inflating and deflating the three-piece IPP, which requires repetitive pumping of the scrotal pump to inflate and prolonged pinching of the release area to deflate [12]. This may be why the satisfaction rates with Ambicor™ have been especially high in patients >65 years old [27].

As mentioned above, this device also obviates the need for reservoir placement, which can be beneficial for low-volume implanters or for patients with complex anatomy, such as a history of pelvic radiation or prior surgery that obliterates the space of Retzius or introduces other hazards [28]. Ectopic reservoir placement remains an option for these patients, but a case-by-case assessment of the feasibility and safety of this option is important [2, 3, 12]. In addition, an ectopic reservoir may be cosmetically undesirable for a thin patient [3].

Studies have described the advantage of two-piece IPPs for erectile function in female-to-male transgender patients after neophallus construction. Complication rates are generally much higher in this patient population than in those with a native phallus, but outcome trends favored the use of the Ambicor™ device over other devices due to less mechanical failure [29]. However, since this research, a novel, phalloplasty-specific inflatable implant, the ZSI-475 FTM (Zephyr Surgical Implants, Geneva, Switzerland), has been developed [3, 30]. Initial data have been encouraging, but the use of this device is still in its infancy; hence, little can be concluded about complications, device longevity, and patient-reported outcomes [30].

As with the three-piece devices, there are contraindications for two-piece IPPs as well. The optimal rigidity needed for penile straightening in severe PD is often not achieved with the two-piece device. In addition, cylinders are of a larger caliber and may be difficult or impossible to insert into a corporal body with significant scarring or narrowing [12].

Penile length is also important to consider before placement of an Ambicor™ device. Men with long narrow phalluses (stretch penile length, pubis to corona >15 cm) have decreased axial support, which can lead to buckling and unwanted deflation of the Ambicor™ device [12]. On the opposite end of the spectrum, for men with short penile length (stretch <9 cm), the amount of deflation allowed by the Ambicor™ device is typically not enough for a natural flaccid appearance; the firm distal tips, which do not deflate, may cause a shorter penis to continue to protrude and thereby difficult to conceal, which can be not only cosmetically unpleasing but can also result in chaffing against clothing [12].

## CONSIDERATIONS FOR CHOOSING A NONINFLATABLE PROSTHESIS

Though patient satisfaction with IPP devices is higher, satisfaction with noninflatable prostheses is still quite good, with one review reporting a satisfaction rate of 75.1% (range 66.1–88.7%) with these devices [4, 31]. No malleable device has proven to be superior to another in regard to satisfaction [32]. Because of statistically better satisfaction with the IPP, rates of semirigid implantation have decreased in the United States over the last decade [4]. The main reasons for selecting a malleable device over an IPP in the general population are cost, ease of placement, and simplicity of use for patients who desire it or have dexterity, strength, or mobility issues [2, 6, 33]. In addition, some patients are preoccupied with fear over the mechanical failure of an inflatable device and thus, for this reason, would be better suited with a malleable device [33].

The malleable device is more often used internationally because of its reduced cost and frequent lack of insurance coverage. In one hospital in Egypt, where there is no coverage, the price for a malleable device in 2018 was $1300, and the total cost of implantation was approximately $5750. In contrast, the cost of a three-piece IPP was $5800, and the total cost of implantation was approximately $12,500 [33]. In countries where IPPs are covered by insurance for PD, the use of malleable devices for PD is associated with patient and partner dissatisfaction and has largely been abandoned for this reason [34]. In the international population, however, the use of malleable devices in PD has been described with satisfactory results [33].

The use of malleable devices has found a niche in specific patient populations. One of these is the patient presenting with refractory ischemic priapism. In these patients, insertion of a prosthesis is easier to do acutely before the corpora have become fibrotic, and early device placement in these patients is supported by guidelines [2, 7]. In addition, patients with devices placed into fibrotic corpora report lower satisfaction rates, likely due to loss of penile length before implantation [4]. If a patient presents with severe fibrosis limiting even a narrow-body IPP cylinder placement, a malleable implant can also assist with corporal dilation before the placement of an IPP [3]. It has been suggested that inserting an implant earlier (within 3–4 weeks) in the presenting course of refractory ischemic priapism is more cost-effective than delayed treatment. The argument for using a malleable device, as opposed to going straight to an IPP, is the potential decreased risk of infection, preservation of penile length without patients needing to cycle the device, and the ability to exchange the malleable device for an IPP later when inflammation from the priapism has resolved. The surgeon should be careful with the patient who has undergone distal shunt surgery and should consider closing the shunt, as this has an increased risk for distal perforation during dilation or distal device erosion shortly after insertion. Some argue in favor of immediate placement of an IPP, mainly because of the greater patient satisfaction with IPPs and avoidance of risks and costs associated with additional implant procedures [7]. Also, some patients find the rigidity of the malleable device immediately uncomfortable after having priapism.

Malleable devices have also become increasingly popular for use in salvage operations for infected IPPs requiring explanation. Following device removal and aggressive irrigation of the infected space, placing a malleable device requires few components and minimal operative time while still preserving penile length [3, 7]. In this setting, the use of Coloplast Genesis® may be preferred over competitors because of its hydrophilic coating, which allows the absorption of antimicrobial solutions [7]. Salvage procedure with a malleable device has previously demonstrated a lower infection rate than replacement of an IPP (7 vs. 18%, respectively), but guidelines currently do not recommend using one device over the other [2, 35]. Using a malleable implant to salvage a device with an infected or eroded scrotal pump can be especially useful for avoiding complications associated with the immediate replacement of a foreign body in the scrotum [36]. It is important to note that salvage operation should be a shared decision between patient and physician, and providers should have a heightened level of concern when tissue necrosis or purulence is encountered

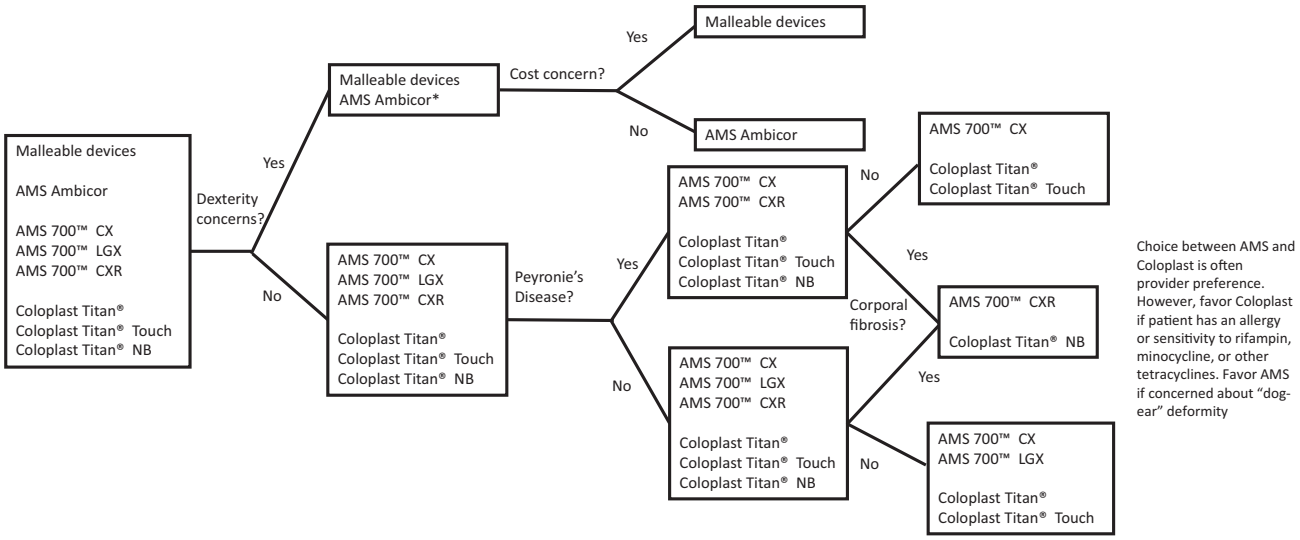


**Fig. 2** Algorithm to reference for assistance with selecting the appropriate prosthetic device for a given patient.

**Table 1.** Penile prostheses available in the United States and specific considerations for each.

| Type | Manufacturer | Model | Considerations |
|---|---|---|---|
| Semirigid | Coloplast | Genesis™ | No semirigid device is superior to others. Good option if cost or dexterity is an issue. Consider in patients with refractory priapism or after explantation of an infected inflatable device |
| | Boston Scientific | Spectra™ | |
| | Boston Scientific | Tactra | |
| | Rigicon | Rigi10™ | |
| Two-piece inflatable | Boston Scientific | Ambicor | Not a good option for size extremes (larger or smaller). Can debatebly overcome dexterity issues |
| Three-piece inflatable | Coloplast | Titan® | Hold button to deflate |
| | | Titan® Touch/OTR | One-touch button simplifies deflation |
| | | Titan® NB | For narrow/scarred corporal bodies, available with either OTR or standard button |
| | Boston Scientific | AMS 700™ | One-touch button simplifies deflation |
| | | AMS 700™ CXR | Narrow model, good for fibrosis |
| | | AMS 700™ LGX | Length and girth expansion; not recommended in Peyronie's disease |

within the corporal bodies or when the device is exposed [3]. One interesting observation in this patient population is the number of patients who keep their malleable devices after salvage operation. Though the malleable device is supposed to serve as a bridge for eventual IPP replacement, two studies showed that 50–70% of patients chose to keep their malleable device (based on their most recent follow-up, mean 8.4 and 24 months) [35, 36]. It remains to be elucidated if this is due to fear of reinfection, avoidance of more surgery, or satisfaction with the malleable device.

Since the malleable device never loses rigidity, it can cause deterioration and thinning of the penile tissue over the long term. Some patients may struggle with concealment and comfort. Finally, the lack of penile flaccidity can make future urological endoscopic procedures difficult (i.e., transurethral resection of the prostate/bladder tumors or semirigid ureteroscopy), which should strongly be considered in patients with a history of genitourinary pathology that increases their risk for needing these procedures [6] (Fig. 2 and Tables 1 and 2).

## WHEN TO ADVISE AGAINST PENILE PROTHESIS SURGERY

This review would not be complete without discussing when patients should be counseled against penile prosthesis surgery. Perhaps the most obvious is the patient with significant health comorbidities, reduced mental capacity, and contraindications for general anesthetic. As with all patients undergoing treatment for ED, evaluation of cardiac risk factors is important to avoid cardiac complications associated with exertion during sexual activity [2].

The treatment of male sexual dysfunction has been shown to favorably influence partner sexual function and satisfaction. In general, satisfaction after IPP placement is highly correlated between men and their female partners [37, 38]. However, men who are unsatisfied with their device often have female partners who report high levels of sexual dysfunction [37]. Knowledge of this correlation is important both preoperatively and postoperatively. Assessment of partner sexual function and desire is highly important to elucidate during the initial consultation period. If a man's partner suffers from dyspareunia or hypoactive sexual arousal disorder, then fixing his ED will likely fall short of increasing the couple's number of satisfactory sexual encounters. If an implant has been placed and the patient reports dissatisfaction, it is important to consider that his partner's sexual function may play a role in his disappointment.

In addition, the orgasm gap with traditional penetrative intercourse has been well described, with most women requiring some form of nonpenetrative clitoral stimulation to reach orgasm [39, 40]. If a patient's main reason for seeking a penile implant is to improve the sexual experience of his female partner, then there is

**Table 2.** Devices to consider based on existing patient characteristics.

| Patient characteristic | Device suggestions/ considerations |
|---|---|
| Corporal fibrosis | AMS 700™ CXR<br>Coloplast Titan® NB<br>Rigicon Infla10® NB<br>Malleable device |
| Peyronie's disease | All 3-piece devices except AMS 700™LGX and Infla10® AX<br>Malleable device (certain countries) |
| Prior low-abdominal or Retzius-obliterating surgery | Ectopic reservoir placement<br>AMS Ambicor™<br>Malleable device |
| Salvage operation after device infection | IPP replacement<br>Coloplast Genesis® semirigid device |
| Refractory ischemic priapism | IPP<br>Malleable device |
| Neophallus | Zephyr ZSI-475 FTM |

likely some room for education on the mechanisms of the female orgasm, the importance of partner intimacy, and the growing movement of "sexual outercourse," a term referring to the use of devices to facilitate orgasm of both parties without penetration [41]. The authors believe that the partner should be present for penile implant consultation whenever possible to ascertain if any of these barriers exist, which may result in reduced patient–partner satisfaction.

## CONCLUSION

A penile prosthesis is an excellent option for men with ED refractory to medical treatment or with contraindications to medical management. There are three main prosthesis types to choose from: malleable/semirigid devices, three-piece inflatable devices, and two-piece inflatable devices. The three-piece devices are the gold standard in advanced economy countries and especially for patients with PD; however, three-piece devices require reservoir placement and patient dexterity, which can be limiting in certain situations. A two-piece device is a good option for patients who have standard-sized penises, lack significant penile pathology, or should avoid reservoir placement due to potential complications. The malleable devices are popular where insurance coverage is limited but are becoming increasingly popular in the United States for length preservation in specific patient populations. Finally, not every patient needs an implant, and assessing partner sexual function is an important consideration for postoperative patient–partner satisfaction.

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## AUTHOR CONTRIBUTIONS

Both authors met all the following criteria: conceived and/or designed the work that led to the submission, acquired data, and/or played an important role in interpreting the results; drafted or revised the manuscript; approved the final version; and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

## COMPETING INTERESTS

The authors declare no competing interests.

## ADDITIONAL INFORMATION

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