

Use of Soft Penile Prosthesis in Grafting Surgery for Peyronie's Disease and Mild Erectile Dysfunction: Still an Option?

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Background: Plaque incision and grafting (PEG) is a primary surgical therapy for severe penile curvature in Peyronie's disease (PD); However, it can increase the risk of erectile dysfunction (ED), particularly in patients with pre-operative mild ED. Soft penile prosthesis (SPP) implantation is a viable treatment option in such cases. This study aims to compare the outcomes of PEG-only approach to PEG plus SPP implantation.

Methods: Between 2010 and 2019, 32 patients with PD and mild ED (5-item version of the International Index of Erectile Function scores: 17–21) underwent PEG surgery. Two groups were defined based on the surgery type: PEG-only and PEG plus SPP. The long-term outcomes included correction of penile bending, erection quality, intercourse ability, penile length and sensitivity. The overall satisfaction and impact of surgery on sexual activity and quality of life were also assessed.

Results: Of the 32 patients, 13 (40.6%) underwent PEG-only surgery, whereas 19 (59.4%) underwent PEG plus SPP. No significant differences were noted between the groups regarding pre-operative characteristics (all $p > 0.1$) or intra- and post-operative complication rates (all $p > 0.2$). The median patch area was larger in the PEG-only group (28 cm² vs. 16.2 cm²; $p = 0.001$), whereas patients in the PEG plus SPP group were more likely to receive a single patch implant (100% vs. 53.8%; $p < 0.001$). The penile length increased in 18 patients (61.6%), with significant differences between the two groups (30% vs. 81.2%; $p = 0.03$). Overall, 14 patients (53.8%) reported greater satisfaction with their sexual life post-operatively, with comparable rates between the groups ($p = 0.2$). No significant differences were found in the post-operative 5-item version of the International Index of Erectile Function scores or severe post-operative ED (all $p > 0.5$).

Conclusions: SPP placement during corporoplasty in patients with mild ED is safe and feasible, and it may be a suitable option for patients uncertain about inflatable prosthesis placement. The use of SPP resulted in longer penile lengths and necessitated smaller grafts. However, further data are required to understand the long-term clinical implications of this approach.

Keywords: erectile dysfunction; Peyronie's disease; Virilis; soft penile prosthesis

Introduction

Peyronie's disease (PD) involves an alteration of the albuginea tunica, leading to the substitution of elastic fibres by a fibrous tissue (plaque) that results in a changing of the penile shape during erection. Most curvatures occur dorsally (55%–75%), although curvature can also manifest laterally (30%) or ventrally (3%), occasionally causing anatomical deformations such as hourglass penis or notching [1]. The etiopathogenesis of PD remains unclear, with its multifactorial nature sharing various risk factors with erectile dysfunction (ED) [2]. However, penile micro-traumas are considered a principal cause [3], which demonstrated histologically similar aspects between post-

traumatic plaques and PD plaques, characterized by disorganized extracellular matrix, collagen and proliferation of inflammatory cells and fibroblasts. Treatment for PD ranges from medical to intra-lesional therapies, with surgical intervention for curvature correction considered in cases of non-progressive severe PD [4]. PD frequently co-exists with ED, necessitating concomitant penile prosthesis implantation during corrective surgery [5]. While patients with severe ED and PD receive upfront inflatable penile prostheses, those with mild ED pose a greater challenge. These patients may require either plaque incision and grafting (PEG)-only or PEG plus soft penile prosthesis (SPP) implantation. PEG surgery is known to carry a risk for de novo or worsening ED [6], and SPP implantation during

this surgery aims to mitigate the risk of post-operative erectile dysfunction. However, SPP implantation increases the risk of infection and may necessitate prostheses explantation [7]. Currently, there is a lack of evidence regarding long-term post-operative outcomes in patients with PD and mild ED, and the optimal surgical approach for such patients remains debated. Therefore, our study aims to compare long-term post-operative outcomes for PD in patients with mild ED, specifically comparing the PEG-only approach with PEG plus SPP implantation.

Materials and Methods

We included all patients with PD and mild ED (5-item version of the International Index of Erectile Function (IIEF-5) score: 17–21) who underwent corporoplasty at a single tertiary referral centre between January 2010 and December 2019. All surgeries were performed by a single surgeon with extensive experience in this type of surgery.

Patients underwent detailed medical and sexual history assessments, as well as physical and andrological examinations. Two groups based on the type of surgery were defined based on the surgery type: PEG-only and PEG plus SPP. The decision to implant soft prostheses was made by the surgeon based on the andrological examination and patient interview. Surgeons provided thorough counselling on surgical alternatives during the informed consent process, after which patients could choose the preferred approach in collaboration with the surgeon.

The available data included the following:

(1) Pre-operative characteristics: Age (years), body mass index (kg/m^2), time to treatment (months), first symptom, pre-operative IIEF-5, presence of diabetes, smoking, direction of penile bending, curvature grade ($^\circ$), size and thickness of the plaque (mm), inter-cavernose septum involvement, aesthetic deformations and previous therapies.

(2) Intra-operative characteristics: Surgical time (min), patch size (cm^2), number of patches used and complications.

(3) Post-operative characteristics: Complications, re-intervention rate, correction of penile curvature, erection quality, ability to reach sexual intercourse, post-operative IIEF-5, penile sensitivity and shortening, overall satisfaction and impact of surgery on sexual habits and quality of life.

The surgical and functional outcomes were evaluated using the Peyronie's Disease Questionnaire and Erectile Dysfunction Inventory of Treatment Satisfaction Questionnaire [8]. Follow-up data were collected through phone interviews.

Surgical Technique

The previously described surgical technique for PEG-only surgery was used [8]. Briefly, penile de-gloving was performed following a sub-glandular incision. Hydraulic

erection was induced by intra-cavernosal saline injection via a 14-gauge trans-glandular butterfly needle to identify the maximum penile curvature point. After complete mobilization of the dorsal neurovascular bundle, a double Y-shaped albugineal incision was made to achieve penile straightening. The xenograft was then shaped and sewn to cover the albugineal defect with a 3-0 absorbable single-threaded running suture. A second hydraulic erection was induced to confirm the correction of penile bending, after which Buck's fascia and circumcision were performed in a standard manner. For patients who received both PEG and SPP, the technique followed the description by Austoni *et al.* [9]. After de-gloving through a sub-coronal incision, ventral corporotomies were performed in the proximal portion of the corpora cavernosa. Subsequently, progressive calibration with Hegar dilators up to 10 Fr was performed to allow for the insertion of SPP (Virilis I®, Giant medical, Cremona, Italy) and enhance penile recurvatum. SPPs were shaped to be approximately 1 cm longer than the corpora cavernosa to ensure sufficient stretch in the penile shaft. A relaxation double Y-shaped albugineal incision was then made to correct penile curvature, and the graft was applied into the albugineal defect as described above.

Statistical Analyses

Descriptive statistics were used to explore differences in pre-operative and intra-operative characteristics between the two groups. Differences in post-operative patient-reported outcomes, along with follow-up time, were evaluated. Medians (interquartile range (IQR)) and means (\pm standard deviation (SD)) were used for continuous variables, and frequencies were used for non-continuous variables. The *t*-test and Mann–Whitney U-test were used to explore differences in means and medians, respectively. The chi-squared test was used to evaluate differences in frequency distribution between the two groups. $p < 0.05$ was considered statistically significant. Statistical analyses were performed using SPSS version 25 (IBM Corp., Armonk, NY, USA).

Results

Out of 33 patients who underwent corporoplasty between January 2010 and December 2019, one case underwent salvage corporoplasty for residual curvature after previous surgery with PEG and grafting at another centre and was thus excluded. Therefore, a total of 32 patients were analyzed. Table 1 summarises the pre-operative characteristics of the study population. Of the 32 patients, 13 (40.6%) underwent PEG-only surgery and 19 (59.4%) underwent PEG plus SPP. No difference was found between the two groups among pre-operative characteristics ($p > 0.1$). The median (IQR) age at surgery was 56 (52–62) years, and the median (IQR) pre-operative IIEF-5 score was 18 (17–20). Most patients had dorsolateral (53.1%) or dorsal (21.9%)

Table 1. Pre-operative characteristics of the study population.

	Overall	PEG-only group	PEG + SPP group	<i>p</i> value
Patients, n (%)	32 (100)	13 (40.6)	19 (59.4)	-
Age				0.100
Median (IQR)	56 (52–62)	55 (49–58)	58 (53–64)	
Body mass index				0.900
Median (IQR)	26.1 (24.5–27.9)	26 (24.7–27)	26.2 (24.3–28.7)	
Time to treatment (months)				0.700
Median (IQR)	23 (14–30)	23 (12–29)	23 (14–37)	
Onset symptom				0.200
Pain	10 (31.3)	4 (30.8)	6 (31.6)	
Plaque	7 (21.9)	1 (7.7)	6 (31.6)	
Curvature	15 (46.9)	8 (61.5)	7 (36.8)	
Pre-operative IIEF-5				0.100
Median (IQR)	18 (17–20)	19 (18–20)	18 (15–20)	
Smoker, n (%)				0.300
No	13 (40.6)	6 (46.2)	7 (36.8)	
Former	14 (43.8)	4 (30.8)	10 (52.6)	
≤20	4 (12.5)	3 (23.1)	1 (5.3)	
>20	1 (3.1)	0 (0)	1 (5.3)	
Pre-operative diabetes, n (%)				0.300
No	27 (96.8)	13 (100)	14 (73.7)	
Yes (Hb1Ac <6.5%)	4 (12.5)	0 (0)	4 (21.1)	
Yes (Hb1Ac >6.5%)	1 (3.1)	0 (0)	1 (5.3)	
Penile curvature, n (%)				0.100
Dorsal	7 (21.9)	3 (23.1)	4 (21.1)	
Ventral	2 (6.3)	2 (15.4)	0 (0)	
Lateral	4 (12.5)	0 (0)	4 (21.1)	
Dorso-lateral	17 (53.1)	8 (61.5)	9 (47.4)	
Ventral-lateral	2 (6.3)	0 (0)	2 (10.5)	
Grade of curvature, n (%)				0.100
20–40	5 (15.6)	2 (15.4)	3 (15.6)	
41–60	5 (15.6)	1 (7.7)	4 (21.1)	
61–80	10 (31.3)	2 (15.4)	8 (42.2)	
>80	12 (37.5)	8 (61.5)	4 (21.1)	
Plaque size (mm)				0.500
Median (IQR)	26 (22.5–30)	25 (22–30)	28 (22.8–30.5)	
Plaque thickness (mm)				0.700
Median (IQR)	3 (2–3.5)	3 (2–3.5)	2.5 (2–3.5)	
Inter-cavernose septum involvement, n (%)				0.500
No	17 (53.1)	6 (46.2)	11 (57.9)	
Yes	15 (46.9)	7 (53.8)	8 (42.1)	
Deformity, n (%)				0.600
None	14 (43.8)	6 (46.2)	8 (42.1)	
Shortening	6 (18.8)	1 (7.7)	5 (26.3)	
Hourglass	6 (18.8)	1 (23.1)	3 (15.8)	
Both	6 (18.8)	3 (7.7)	3 (15.8)	
Previous oral treatment, n (%)				0.300
None	5 (15.7)	1 (7.7)	4 (21.1)	
PDE5I	20 (62.5)	10 (76.9)	10 (52.6)	
Immunosuppressant	1 (3.1)	0 (0)	1 (5.3)	
Vitamin E	5 (15.6)	1 (7.7)	4 (21.1)	
Other	1 (3.1)	1 (7.7)	0 (0)	

Table 1. Continued.

	Overall	PEG-only group	PEG + SPP group	<i>p</i> value
Intra-lesional treatment, n (%)				0.100
None	24 (74)	9 (69.2)	15 (78.9)	
Verapamil	3 (9.4)	0 (0)	3 (15.8)	
Steroid	3 (9.4)	3 (23.1)	0 (0)	
Multiple	2 (6.2)	1 (7.7)	1 (5.3)	
Previous physical treatment, n (%)				0.400
None	26 (81.2)	10 (76.9)	16 (84.2)	
Vacuum	1 (3.1)	0 (0)	1 (5.3)	
Penile extender	1 (3.1)	1 (7.7)	0 (0)	
ESWT	3 (9.4)	1 (7.7)	2 (10.5)	
Other	1 (3.1)	1 (7.7)	0 (0)	

IQR, interquartile range; IIEF-5, 5-item version of the International Index of Erectile Function; PDE5I, phosphodiesterase type 5 inhibitor; ESWT, external shock wave treatment; PEG, plaque incision and grafting; SPP, soft penile prosthesis.

Table 2. Intra-operative and post-operative characteristics of the study population.

	Overall	PEG-only group	PEG + SPP group	<i>p</i> value
Intra-operative surgical time, min				0.800
Median (IQR)	240 (240–260)	240 (240–268)	240 (240–260)	
Area of the patch (cm ²)				0.001
Median (IQR)	20 (15–18.2)	28 (20.5–43)	16.2 (12–21)	
Number of grafts used, n (%)				0.001
1	26 (81.3)	7 (53.8)	19 (100)	
2	6 (18.7)	6 (46.2)	0 (0)	
Type of graft, n (%)				0.300
Porcine dermal	9 (28.1)	4 (30.8)	5 (26.3)	
Bovine pericardium	20 (62.5)	9 (69.2)	11 (57.9)	
Human fibrinogen/thrombin	3 (9.4)	0	3 (15.8)	
Intra-operative complications, n (%)	0 (0)	0 (0)	0 (0)	-
Post-operative complications, n (%)	5 (15.6)	2 (15.4)	3 (15.8)	0.900
Type of post-operative complications, n (%)				0.200
Glans hypoesthesia	3 (9.4)	0 (0)	3 (15.8)	
Ischemic necrosis	1 (3.1)	1 (7.7)	0 (0)	
Scar tissue	1 (3.1)	1 (7.7)	0 (0)	
Re-intervention, n (%)	6 (18.7)	3 (23.1)	3 (15.8)	0.600

PEG, plaque incision and grafting; SPP, soft penile prosthesis.

curvature, with over half of the population affected by penile deformities (56.2%), such as hourglass penis, shortening or both. Table 2 depicts intra-operative characteristics. The overall median (IQR) operative time was 240 (240–260) min, consistent in both groups ($p = 0.8$). The median patch area was larger in the PEG-only group than in the PEG plus SPP group (28 cm² vs. 16.2 cm²; $p = 0.001$). Conversely, patients in the PEG plus SPP group were more likely to receive a single patch implant than those in the PEG-only group (100% vs. 53.8%; $p < 0.001$). The graft of choice was mainly bovine pericardium (62.5%) or porcine dermal (28.1%) xenografts, with similar rates among the two groups ($p = 0.3$). No difference was found regarding intra- and post-operative complication rates (all $p > 0.2$). Six patients (18.7%) needed re-intervention at follow-up, with two patients requiring inflatable penile prosthesis

implantation and one needing re-intervention for scar tissue removal in the PEG-only group (23.1%), and three patients needing SPP explantation in the PEG plus SPP group (5.8%) ($p = 0.6$) with subsequent inflatable prosthesis implantation.

Table 3 shows the follow-up results. Follow-up data were complete for 26 patients (81.3%). The median (IQR) post-operative follow-up was 55 (28–79) months and was consistent between the two groups ($p = 0.8$). Penile curvature was completely corrected in 73.1% of the patients, with similar success rates in both groups (80% vs. 68.8%; $p = 0.5$). The penile length was reported as increased by 18 patients (61.6%), with significant differences between the PEG-only and PEG-plus-SPP groups (30% vs. 81.2%; $p = 0.03$). Moreover, 53.8% of the patients reported a decrease in penile sensitivity at follow-up, with no difference be-

Table 3. Follow-up results of the study population.

	Overall	PEG-only group (n = 10)	PEG + SPP group (n = 16)	<i>p</i> value
Peyronie's Disease Questionnaire 1 (impact on emotional status), n (%)				0.800
Yes	14 (53.8)	5 (50)	9 (56.3)	
No	12 (46.2)	5 (50)	7 (43.8)	
Peyronie's Disease Questionnaire 2 (impact on relationship with sexual partner), n (%)				0.100
Yes	11 (42.3)	2 (20)	9 (56.3)	
No	15 (57.7)	8 (80)	7 (43.8)	
Penile curvature, n (%)				0.500
Corrected	19 (73.1)	8 (80)	11 (68.8)	
Decreased	5 (19.2)	2 (20)	3 (18.8)	
Equal	2 (7.7)	0 (0)	2 (12.5)	
Increased	0 (0)	0 (0)	0 (0)	
Penile rigidity, n (%)				0.500
Improved	5 (19.2)	3 (30)	2 (12.5)	
Stabilized	13 (50)	5 (50)	8 (50)	
Worse	8 (30.8)	2 (20)	6 (37.5)	
Pain during erection/penetration, n (%)				0.200
Yes	5 (19.2)	3 (30)	2 (12.5)	
No	21 (80.8)	7 (70)	14 (87.5)	
Penile sensitivity decrease, n (%)				0.600
Yes	12 (46.2)	4 (40)	8 (50)	
No	14 (53.8)	6 (60)	8 (50)	
Palpable penile nodule, n (%)				0.900
Yes	5 (19.2)	2 (20)	3 (18.7)	
No	21 (80.8)	8 (80)	13 (81.3)	
Penile length, n (%)				0.030
Increased	18 (61.6)	3 (30)	13 (81.2)	
Equal	5 (19.2)	2 (20)	3 (18.8)	
Decreased	5 (19.2)	5 (50)	0 (0)	
Willing to repeat surgery, n (%)				0.900
Yes	21 (80.8)	8 (80)	13 (81.2)	
No	5 (19.2)	2 (20)	3 (18.8)	
Recommends surgery to a friend, n (%)				0.900
Yes	21 (80.8)	8 (80)	13 (81.2)	
No	5 (19.2)	2 (20)	3 (18.8)	
Overall sexual life satisfaction, n (%)				0.200
More satisfied	14 (53.8)	3 (30)	11 (68.7)	
Equally satisfied	5 (19.2)	3 (30)	2 (12.5)	
Less satisfied	7 (26.9)	4 (40)	3 (18.8)	
Post-operative IIEF-5				0.500
Median (IQR)	17 (10–22)	18 (11–24)	17 (6–21)	
Severe post-operative ED, n (%)	10 (38.5)	4 (40)	6 (37.5)	0.900
Follow up (months)				0.800
Median (IQR)	55 (28–79)	42 (28–77)	59 (40–86)	

IIEF-5, 5-item version of the International Index of Erectile Function; PEG, plaque incision and grafting; SPP, soft penile prosthesis.

tween the two groups ($p = 0.6$). Overall, 14 patients (53.8%) were more satisfied with their sexual life post-operatively, with comparable rates between the PEG-only and PEG plus SPP groups ($p = 0.2$). Regarding patient satisfaction regard-

ing surgery, 80.8% would still be willing to repeat surgery for PD and would most likely recommend it to a friend with similar problems, with no difference between the two groups ($p = 0.9$). No difference was found in terms of post-

operative IIEF-5 score or severe post-operative ED (all $p > 0.5$).

Following the categorization of the population based on curvature direction and/or anatomical abnormalities, there were no statistically significant differences observed in terms of success rate, satisfaction with sexual life, and post-operative rates of erectile dysfunction (all $p > 0.1$).

Discussion

This study aimed to evaluate the outcomes of PD surgery in patients with mild ED by comparing two different surgical techniques. We demonstrated that PEG with or without synchronous SPP implantation is a viable option for men with PD and mild ED, with relatively low risk of complications and good patient and partner satisfaction. Our interest in this study stemmed from the lack of information regarding outcome comparisons in this challenging population affected by PD [10–12] and the fact that not all patients may be willing to accept irreversible options such as penile prostheses as a first-line treatment. Additionally, there is a scarcity of long-term outcome data comparing different techniques for PD treatment in this selected population. Despite the recent introduction of medical treatments for PD, such as external shock wave therapy [13,14] and collagenase clostridium injections [15,16], surgery remains the gold standard for patients with severe penile curvature or hourglass deformities [17–20]. While most cases can be addressed with PEG alone, in cases of ED, patients must be counselled regarding the possibility of concomitant penile prosthesis implantation to reduce the risk of post-operative ED worsening. Currently, there is no clear evidence supporting the choice of inflatable prostheses over SPP [21–25], and prostheses implantation exposes the patient to an irreversible condition and increased risk of infection and complications compared with PEG-only surgery [26]. Most of the available literature focuses on inflatable prostheses in PD, with limited data on patients with mild ED, whose management can be challenging in deciding whether to opt for penile prosthesis implantation. Therefore, we aimed to evaluate the results of two different approaches in this selected population. When contrasting our findings with the existing evidence in literature [27,28], numerous aspects of our study are noteworthy.

Clinically, our findings revealed no variances in long-term outcomes when the implantation of SPP is provided alongside PEG. However, we observed a reduction in graft size and number in patients receiving SPP implantation compared with those undergoing PEG surgery alone, despite both groups having similar plaque sizes pre-operatively. This finding has interesting clinical implications, suggesting that with a larger sample size, there could be an improvement in post-operative ED due to greater preservation of the tunica albuginea. Furthermore, the use of soft prostheses allows patients to still benefit from resid-

ual erection, utilizing cavernous tissue that would otherwise not be utilized with hydraulic prostheses. Since these patients all suffer from mild ED, the contribution of cavernous tissue to erection will not be completely null, but could act as a cofactor during sexual intercourse, improving patient satisfaction levels.

Furthermore, given the positive outcomes observed in both groups, the positioning of SPP can be considered both during the initial corporoplasty and at a later time. Counselling with patients is therefore crucial in determining whether to proceed with immediate placement or defer it. However, the most significant aspect related to these findings is that in patients who are undecided about receiving an inflatable prosthesis, the option of SPP can serve as a valid alternative, especially in cases of mild ED. Additionally, the need for inflatable prostheses was similar in both groups, as was the rate of post-operative severe ED. This suggests that such occurrences might indicate a progressive deterioration of erectile function rather than inadequate surgical management. Moreover, there is no clear evidence supporting the superiority of hydraulic prostheses over malleable prostheses as the primary choice. Therefore, a more conservative approach can be pursued relatively safely, particularly in patients with mild ED, considering the extent of pre-operative ED.

Furthermore, we observed an increase in penile length in patients undergoing SPP implantation. This could serve as an incentive for patients who are uncertain about undergoing prosthesis placement, as perceived improvements in penis length may lead to higher satisfaction rates. Although not statistically significant, patients with SPP reported higher sexual life satisfaction than those with PEG only. However, an important consideration in this type of surgery is the economic aspect. The cost of surgery is higher in the PEG plus SPP group than in the PEG-only group, which may influence the choice of procedure, considering the economic and resource availability of the healthcare facility. Nonetheless, SPP implantation may prevent worsening erectile dysfunction, potentially averting the need for future implantation of a hydraulic penile prosthesis, which carries even greater costs than SPP. Moreover, SPP positioning can maintain penile elasticity and compliance, facilitating a future transition to a hydraulic penile prosthesis [29].

Nevertheless, our study has some limitations. First, the retrospective nature of the study may have been affected by selection bias. Second, the overall population considered was relatively small. Finally, the follow-up time was relatively short. These limitations suggest that while our results are intriguing, they serve as a starting point for expanding the population and extending the follow-up time in future studies. Doing so will increase the statistical power of the study and confirm the clinical insights presented in this manuscript.

Conclusions

In summary, the incorporation of SPP during corporoplasty in patients with mild ED is not only feasible and safe but also emerges as a viable option for those uncertain about inflatable prosthesis placement. SPP usage in this group could effectively harness residual erection and enhance their sexual function. However, as previously mentioned, future studies with larger population samples are imperative to yield statistically robust data.

Availability of Data and Materials

The authors confirm that the data supporting the findings of this study are available within the article. Raw data that support the findings of this study are available from the corresponding author, upon reasonable request.

Author Contributions

LS and MD—contributed for data collection, statistical analyses, study design, data interpretation, and writing and critical revision of the paper; FP, PP, LF, GG and AF—contributed for critical revision of statistical analyses, data interpretation, and paper writing; FC—contributed for study design, data interpretation, and critical revision of the paper. All authors gave final approval of the version to be published. All authors participated fully in the work, took public responsibility for appropriate portions of the content, and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or completeness of any part of the work were appropriately investigated and resolved.

Ethics Approval and Consent to Participate

This retrospective study adhered to the guidelines and principles of the Declaration of Helsinki and the standard ethical conduct for research involving humans. After approval by the Ethical Committee for Clinical Research of our institution (CE-AVEC), all patients provided informed consent to use their data anonymously for this and future studies (93/2012/U/Oss).

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Conflict of Interest

The authors declare no conflict of interest.

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