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Third-Generation Medium Cross-Linked Polyethylene Demonstrates Very Low Wear in Total Hip Arthroplasty.

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Original Research

Third-Generation Medium Cross-Linked Polyethylene Demonstrates Very Low Wear in Total Hip Arthroplasty

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ABSTRACT

Background: Cross-linked polyethylene (XLPE) liners have shown lower wear rates than conventional polyethylene liners in total hip arthroplasty. The primary aim of our study was to report our most recent analysis of wear rates and clinical outcomes of a third-generation XLPE liner. Secondary aims were to investigate the rate of adverse events related to mechanical failure or oxidation of this liner.
Methods: A series of 266 total hip arthroplasties using a specific XLPE liner were retrospectively reviewed. Radiographs were examined to determine linear and volumetric wear rates and presence of osteolysis. Clinical outcomes, revision rates, mechanical failures, and risk factors for accelerated polyethylene wear were additionally investigated.
Results: The mean age at the time of surgery was 65.8 years and the mean follow-up was 5.5 years. The mean linear wear rate was 0.003 mm/year and the mean volumetric wear rate was 0.42 mm^3/year, and there was no evidence of osteolysis. Harris hip scores increased from 50.9 preoperatively to 96.0 at the latest follow-up. The revision rate was 0.4%, with no liner rim fractures and no liner dissociations/loosenings. Femoral head material, head size, age, body mass index, and time since implantation had no effect on wear rates.
Conclusion: Wear rates for this third-generation XLPE liner were low at mid-term follow-up, and no adverse sequelae of oxidation or deleterious mechanical properties were observed. This remained true regardless of femoral head size and material or patient age and body mass index. Further analysis will be necessary to ensure continued wear resistance, oxidative stability, and mechanical strength at long-term follow-up.

Introduction

Improvements in biomaterials, implant design, and surgical technique in total hip arthroplasty (THA) have revolutionized the treatment of end-stage arthritis [1]. Currently, more than 300,000 THA procedures are performed annually, and by 2030, the number is expected to increase to 572,000 per year [2]. Polyethylene (PE) is one of the most widely used bearings in THA worldwide [3].

More than 50% of THA revisions are performed because of aseptic implant loosening [4]. PE debris produced from wear of the acetabular insert and associated periprosthetic osteolysis is considered a leading cause of aseptic loosening [5-8]. In an attempt to reduce wear, several manufacturers have manipulated the material properties of the PE insert through gamma irradiation–induced cross-linking, followed by remelting or annealing treatments which minimize free radical formation [1].

Medium and highly cross-linked PE (XLPE) and thermally treated PE liners are now approaching 15 years of clinical use in THA [9]. Compared with conventional PE (CPE), first- and second-generation XLPE liners improved production by removing calcium stearate, eliminating consolidation defects through compression molding and ram extrusion, shifting from gamma sterilization in air to electron beam or gamma sterilization in a low-oxygen environment, using sequential irradiation protocols, and using thermal stabilization technology for free radical removal after radiation. Wear reductions from these changes were demonstrated by a systematic review by Kurtz et al. [10], who reported a mean linear wear rate of first-generation XLPE liners of 0.042 mm/y as compared with 0.137 mm/y in CPE. Subsequently, de Steiger et al. [11] demonstrated the clinical and economic impact of this decreased wear as first- and second-generation XLPE liners demonstrated significantly reduced

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revision rates compared with CPE in THA. However, no studies to date have examined the in vivo wear rates and clinical outcomes of third-generation XLPE liners in THA.

Each medium and highly XLPE has a different manufacturing process and should be evaluated individually [1,12]. The 3 most important material properties of the PE liner in THA are wear resistance, oxidation resistance, and biomechanical characteristics (ie, toughness) [1], each of which can be affected by alterations in material design. As the field of arthroplasty continues to be presented with an ever increasing number of new technologies, each must be closely analyzed to ensure that potential, unexpected detrimental outcomes do not outweigh anecdotal benefits.

The primary purpose of the present study was to evaluate a specific third-generation XLPE acetabular liner radiographically in terms of wear and clinically in terms of standardized patient-reported outcome measures and revision rates. Secondary aims were to investigate the rate of adverse events related to mechanical failure or oxidation of this liner. The authors hypothesized that this liner will demonstrate decreased wear rates and excellent clinical outcomes seen with previous generations of XLPE when compared with CPE liners in the medium term.

Material and methods

Patients and components

A retrospective review of our prospectively maintained, institutional review board–approved registry identified all THAs performed between May 2009 and November 2012 using a third-generation PE liner. Three hundred forty-three cases were initially identified; of which, 266 (80.1%) had actively followed up more than 4.5 years postoperatively and were included in the present study. Exclusion criteria included (1) the diagnosis of inflammatory arthritis, (2) revision THA procedures, and (3) inadequate radiographic or clinical follow-up.

Femoral head materials used included delta ceramic (43.6%) and metal (56.4%), with sizes ranging from 28 to 44 mm (Table 1). The more commonly used 32- and 36-mm head sizes accounted for 79.3% of all cases. The choice of material was nonrandomized and was based on the surgeon's preference taking into consideration patient factors including age and activity. Components were inserted through a direct anterior approach, and patients were treated with the same multimodal pain protocol after their procedure. All acetabular components used were cementless Pinnacle series implants (DePuy Synthes, a Johnson and Johnson Company, Warsaw, IN).

Patients were evaluated at standard postoperative follow-up, including, but not limited to, 6-week, 3-month, 6-month, and annual clinic visits. Assessment included standard history and physical examination, Harris hip scores (HHSs), and anteroposterior (AP) pelvis radiographs.

PE liner

The PE liner used in the present study is a third-generation moderately XLPE (Pinnacle ALTRX Polyethylene; DePuy Synthes, a Johnson and Johnson Company, Warsaw, IN), first introduced in 2007. The manufacturing process uses a base resin bar stock of GUR 1020 moderately cross-linked at 7.5 megarads (Mrad). This results in a cross-link density of 0.143 and is followed by remelting at 155°C in an oxygen-free, argon convection environment to minimize free radicals.

Table 1
Component factors used.

Head Size (mean ± SD)	34.6 ± 3.5 mms
Femoral head material (count, %)	Ceramic: 116 (43.6%) Metal: 150 (56.4%)
Head size distribution (count, %)	28 mm: 23 (8.7%) 32 mm: 83 (31.2%) 36 mm: 128 (48.1%) 40 mm: 25 (9.4%) 44 mm: 7 (2.6%)

PE wear analysis and radiographic evaluation

Radiographic evaluation was based on AP radiographic images of the pelvis obtained at the initial postoperative visit (at or around 6 weeks) and at the latest follow-up for all patients. Wear was determined using the methodology described by Gaudiani et al. [13]. Briefly, the computer-assisted Roman software was used to perform the concentric circle method [14] to generate 2 best-fit circles at the edge of the acetabular component and the femoral head (Fig. 1) and determine their displacement from one another (displacement vector). This software was chosen as it has been identified as the most dependable in terms of intraobserver and interobserver reliability in wear calculations when compared with several others [15]. Linear wear was defined as the difference between the 2 displacement vectors measured at the most recent follow-up (4.5 years or greater) and at baseline (about 6 weeks postoperatively), and volumetric wear was calculated based on a cylindrical wear pattern [13]. Best-case linear and volumetric wear rates included both positive and negative wear values, whereas worst-case rates treated negative values as zero [13]. Wear was measured on all radiographs by 1 author (O.J.). To assess the interobserver reliability of our measurements, an independent reviewer (A.S.) measured wear on a subset of radiographs, and results of the corresponding measurements were compared for precision.

Linear and volumetric wear rates were determined for the cohort overall. To determine if accelerated wear occurs with increased time since implantation, our cohort was also stratified into patients who received their implants less than 5.5 years before evaluation (n = 153) and those who received their implant greater than 5.5 (n = 113) years before evaluation. The 5.5-year cutoff was selected as previous studies have found a decrease in the oxidative stability, and subsequent increase in wear rates, in previous generations of XLPE liners at this time point [16,17]. Linear wear rates were compared across subgroups to determine if wear rates changed significantly with time.

Periprosthetic osteolysis was evaluated at the time of the most recent follow-up by 2 of the authors (O.J. and T.S.). AP pelvis radiographs were examined, and osteolysis was defined as any nonlinear radiolucency at the bone-prosthesis interface of at least 5 mm [2].

Clinical outcomes

At a mean 5.5-year follow-up, all patients included were still living and had adequate clinical follow-up. To determine performance of the THA, HHSs were obtained and evaluated preoperatively and at the most recent follow-up (including functional, activity, and range of motion subscores), and revision rates were calculated. Two of the authors (O.J. and T.S.) determined rates of acetabular liner dissociation/loosening or fracture at the most recent follow-up for evaluation of the mechanical safety of this liner.

Determination of risk factors for accelerated PE wear

Univariate and multivariate analyses were performed to determine the effect of patient and component variables on wear rates. Patient factors examined included age, body mass index (BMI), sex, and laterality. Component factors included femoral head size and material. To evaluate for potential effects of oxidation on wear over

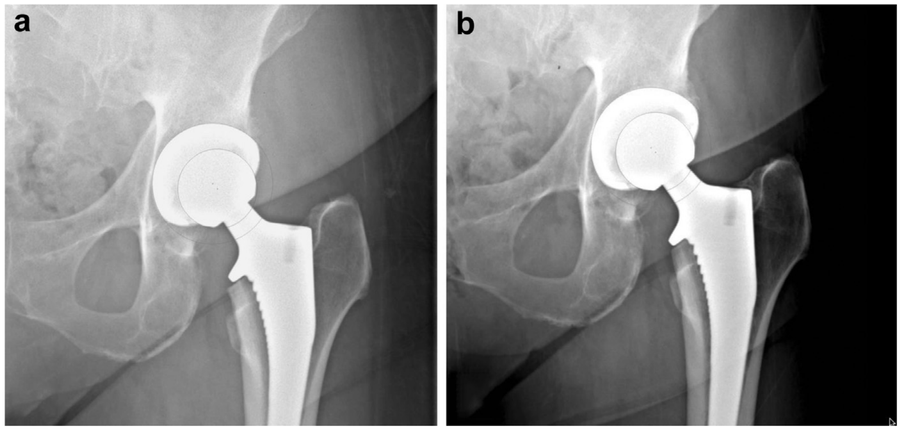

Figure 1. Anteroposterior pelvis radiographs of a left THA at 6-wk follow-up (a) and 4.9-y follow-up (b). Using the Roman Software, 2 best-fit circles were generated at the edge of the acetabular component (red circles) and the femoral head (blue circles) and the distance between their centers determined (distance between red and blue dots) at each time point. THA, total hip arthroplasty.

time, multivariate analysis of the relationship between time since implantation and PE wear was investigated.

Statistical analysis

All statistical analyses were performed using Stata v13.1 (StataCorp, College Station, TX). Descriptive statistics are displayed as means and standard deviations (SDs) for continuous variables and frequencies with proportions for categorical variables. Intraclass correlation (ICC) was performed to assess interobserver reliability of wear rate measurements between the reviewers. Standard statistical tests were used including Student t tests for continuous variables, and univariate and multivariate analyses for determination of risk factors. A P value of <.05 was considered to be significant for all statistical tests.

Results

Patient demographics and components used

In total, 266 hips accounting for 243 patients were analyzed. The mean follow-up for the cohort was 5.5 years (SD: 0.8; range: 4.5 to 8.1). The average age at the time of surgery was 65.8 years (SD: 9.9; range: 39 to 86) and the average BMI was 26.7 (SD: 4.6; range: 18.9 to 44.4). Table 2 summarizes patient characteristics.

PE wear and radiographic outcomes

Wear results for the cohort are summarized in Table 3. The mean best-case scenario linear wear rate was 0.003 mm/year (SD: 0.05, 95% confidence interval [CI]: −0.003 to 0.009), and the mean best-case volumetric wear rate was 0.42 mm^3/year (SD: 8.8, 95% CI: −0.53 to 1.59). There were no instances of femoral (0%) or acetabular osteolysis (0%). ICC coefficient for performing wear measurements was 0.988, indicating excellent inter-rater reliability using this software [18].

On subgroup analysis, there was no difference in mean linear wear rates between the <5.5-year and >5.5-year subgroups (mean: 0.0030 mm/y, 95% CI: −0.004 to 0.011 vs mean: 0.0035 mm/y, 95% CI: −0.006 to 0.012, respectively; t-statistic: 0.0947, $P = .9246$)

Clinical outcomes

Mean and SDs of HHS measures analyzed preoperatively and at the latest follow-up are provided in Table 4. Total mean HHSs increased from 50.9 (SD: 12.2, 95% CI: 49.4 to 52.5) preoperatively to 96.0 (SD: 7.9, 95% CI: 95.0 to 96.9) at the latest follow-up.

There were 3 (1.1%) reported complications in our cohort: 1 hematoma (0.4%), 1 superficial surgical site infection (0.4%), and 1 dislocation (0.4%), which required revision surgery 6 years after the index procedure. There were no instances of mechanical failures (0%) including liner dissociations or fractures and no other revision procedures required in our cohort (0.4% revision rate).

Risk factors for PE wear

Analyses of patient and component factors revealed no significant risk factors associated with accelerated PE wear (Table 5). Age and BMI did not affect wear rates. Femoral head material and size similarly had no impact on wear rates. Of note, there was no relationship between time since implantation and PE wear rates with this liner over the 4.5- to 8.1-year follow-up time points analyzed.

Discussion

This study was undertaken to evaluate the midterm performance of a third-generation, moderately XLPE liner in THA, both clinically and radiographically. Our hypothesis was confirmed as the ALTRX Polyethylene liner demonstrated low linear and volumetric wear rates, excellent patient-reported outcomes, and a 0.4% revision rate at this 5.5-year time point in line with previous XLPE reports [13,19,20].

The results of our study demonstrate a mean linear wear rate of 0.003 mm/y. This may represent an improvement over the previous

Table 2
Patient characteristics.

Age (mean ± SD years)	65.8 ± 9.9
Follow-up time (mean ± SD years)	5.5 ± 0.8
BMI (mean ± SD kg/m^2)	26.7 ± 4.6
Gender (count, %)	Male: 115 (43%) Female: 151 (57%)
Laterality (count, %)	Right: 145 (55%) Left: 121 (45%)
Bilateral (count, %)	23 (9%)
Diagnoses (count, %)	Avascular necrosis: 9 (3%) Hip dysplasia: 26 (10%) Osteoarthritis: 228 (86%) Post-traumatic: 3 (1%)

BMI, body mass index.

Table 3
Linear and volumetric wear results.

	Best case (total, mm^3)	Best case (rate, mm/y)	Worst case (total, mm^3)	Worst case (rate, mm/y)
Linear wear (mean, SD)	0.017 ± 0.26	0.003 ± 0.05	0.11 ± 0.16	0.02 ± 0.03
Volumetric wear (mean, SD)	2.31 ± 50.5	0.419 ± 9.8	19.8 ± 30.7	3.75 ± 6.03

SD, standard deviation.

generation, Marathon liner (Marathon; DePuy Synthes, a Johnson and Johnson Company, Warsaw, IN), which demonstrated wear rates of between 0.04 mm/y and 0.05 mm/y at a similar time point [16,21,22]. This is in agreement with in vitro work by Liao et al. [23], who used a hip simulator test to demonstrate up to 53% improved wear resistance of this liner compared with the Marathon liner, and up to 96% improvements in wear rates over non-XLPE. In an observational study of the National Registry of Australia, de Steiger et al. [11] demonstrated the benefit of the decreases in wear of first- and second-generation XLPE, as the use of XLPE was associated with a lower rate of revision THA at 6 months compared with CPE, and this difference became more apparent with time (hazard ratio at 9 years was 3.02). In conjunction with the low wear rate observed in our cohort, there was a 0.4% rate of revision. These results provide early evidence that the clinical and economic benefit of decreased wear demonstrated by previous generations of XLPE liners may be maintained with the use of this third-generation XLPE liner.

The linear wear threshold for osteolysis is largely agreed to be > 0.1 mm/y [24,25], and Cross et al. [26] proposed that a volumetric wear rate of < 40 mm^3/y could eliminate osteolysis. The mean linear and volumetric wear rates in this study are well below these thresholds, and no osteolysis was identified through rigorous radiographic review. Longer-term follow-up of these patients will be important for examining if the proposed thresholds, originally applied to CPE liners, continue to hold true for all XLPE liners.

Secondary aims of the present study were to investigate the rate of adverse events related to mechanical failure or oxidation of this liner. Radiation-induced mechanical property changes can include decreased fracture toughness, yield and tensile strength, and hardness of the polymer [1]. There are several case reports of XLPE liners irradiated at 10.0 Mrad or greater demonstrating liner dissociations [27] and others of liner rim fractures [28,29]. While much focus has been on manufacturing modifications to minimize wear, the importance of maintaining adequate mechanical properties to prevent catastrophic failures is notable. The present study contributes to this knowledge by being the first to report on the outcomes of a third-generation liner which is irradiated at 7.5 Mrad to produce moderate cross-linking of the PE material. The low wear rates observed were not accompanied by any observable increase in sequelae from adverse mechanical properties such as liner rim fractures or dissociations, which supports the theoretical advantage of moderate cross-linking on the mechanical properties of these liners. However, retrieval analysis was not performed for the present study, and reports of liner dissociations with the DePuy Pinnacle (Warsaw, IN) acetabular cup and liner construct have been described at other institutions [27,30].

Table 4
Preoperative and postoperative Harris hip scores.

Harris hip score measures	Preoperative	Latest follow-up
Functional (mean ± SD)	20.6 ± 2.4	31.0 ± 4.5
Range of motion (mean ± SD)	4.3 ± 0.7	4.8 ± 0.7
Activity (mean ± SD)	9.0 ± 2.4	13.1 ± 1.5
Total (mean ± SD)	50.9 ± 12.2	96.0 ± 7.9

SD, standard deviation.

Table 5
Multivariate analysis of risk factors for accelerated polyethylene wear.

Patient factors	*P*-value
Age	.840
BMI	.612
Sex	.821
Laterality	.915
Component factors	
Femoral head material	.989
Femoral head size	.316
Wear over time	
Time since implantation	.936

BMI, body mass index.

XLPE liner properties are affected by choice of thermal stabilization processes in addition to radiation doses [31]. The most commonly used thermal stabilization procedures are annealing (heating the material lower than the melt temperature) and remelting (heating the material higher than the melt temperature).

An increase in free radicals through irradiation decreases the long-term oxidative stability of XLPE liners, leading to accelerated wear over time [1,6,32]. Many second-generation XLPE liners, including the Marathon liner, used sequential annealing to reduce free radicals [33], in contrast to the remelting process used in this third-generation liner. Remelting theoretically has the advantage of extinguishing free radicals to a significantly greater degree than annealing, though annealing has been proposed to have a less detrimental effect on PE liner mechanical properties [31]. To evaluate the effect of thermal stabilization procedures on the oxidative stability of this liner, Greer and Sharp [34] compared the number of free radicals and oxidative indices of the material using remelting or annealing after irradiation. They demonstrated significantly reduced numbers of free radicals and oxidative indices in vitro when cross-linking and remelting compared with cross-linking and annealing (one-time or sequential) [34]. Wannomae et al. [17] used retrieved components from revision surgery to confirm the differential effect of thermal stabilization procedure on oxidative stability in vivo. Remelted liners retrieved up to 3 years after the index surgery demonstrated no change in their oxidative state, whereas annealed liners retrieved at similar time points showed embrittlement and evidence of significant oxidation.

In our study, we found no association between wear rates of this cross-linked and remelted liner and time since implantation, suggesting that we could not appreciate any adverse effects of oxidation on wear over time. This was observed on subgroup analysis (using a cutoff of 5.5 years), as well as when controlling for other risk factors for accelerated PE on multivariate analysis. In conjunction with these findings, there were no instances of femoral or acetabular osteolysis at any time point, suggesting this liner may not undergo accelerated wear over the 4.5- to 8.1-year time points analyzed. Accelerated wear over time, believed to be due to the effects of oxidation, was not observed, providing credence to the translation of the in vitro improvement in oxidative resistance seen with remelting to oxidative resistance in vivo in the medium term. Long-term studies are necessary to confirm oxidative stability and continued wear resistance at the crucial 10- and 15-year time points after THA.

Femoral head material and size have historically been considered determinants of PE wear, particularly with the use of CPE. However, this risk does not appear to be evident with XLPE [11]. Our study agrees by demonstrating no statistically significant association between femoral head size and PE wear. The current data support the use of larger diameter femoral heads without sacrificing mechanical properties or resulting in increased wear of this liner, which may impact dislocation rates [35].

The choice of metal or ceramic femoral head prostheses similarly had no observable effect on wear rates. Gaudiani et al. [13] used 44 matched pairs to demonstrate that wear rates of second-generation XLPE were similarly equivalent with use of 32- or 36-mm metal and ceramic heads at 6-year follow-up. Our findings contradict those of in vitro work by Liao et al. [36], who demonstrated a 33% reduction in volumetric wear rates of this liner with ceramic heads compared with metal heads using a hip simulator test of 5 million cycles. It is possible that our sample size and follow-up time were not sufficient to observe differences in wear rates by head material. The true impact of head material on wear and longevity of this PE liner may be determined in subsequent, long-term studies.

There was no statistically significant association between increased BMI or younger age and increased wear in this cohort, in contrast to what has been reported with the use of CPE. Younger patients typically have increased activity levels, placing increased load on the PE bearing [37]. Greiner et al. [38] demonstrated significant wear reductions at 10 years in patients younger than 50 years who received XLPE compared with a historical control who received CPE, despite similar activity levels. de Steiger et al. [11] demonstrated an even greater improvement in revision rates in patients younger than 55 years who received XLPE vs patients older than 55 years who received CPE . The maintenance of very low wear rates regardless of patient age in our cohort supports the use of this liner in the younger patient population.

The relationship between PE wear rates and BMI has proven less conclusive. It has been proposed that decreased activity levels in this population may counteract the effect of increased weight when considering total loads on the PE bearing, accounting for the lack of an effect demonstrated by a previous work [37]. There was no observable relationship between BMI and wear rates in our cohort, which may be due to the wear resistance demonstrated by the liner or due to differences in the activity level which were not directly measured in this study. Future studies should attempt to control for activity level to truly discern if a relationship exists between BMI and accelerated wear with XLPE.

There are several limitations to this study. Our results represent retrospective outcomes from a single, high-volume surgical center which may not allow for generalization to a broader patient population. In addition, although the Roman software has been validated [15], it has limitations and relies on high-quality and consistent radiographs. The presence of negative wear values is a known limitation of Martell and Roman methods for measuring wear [13,39-41]. Although Martell software analysis pertaining to cup inclination and version for many of the patients in this study group was available, we did not include the data because the overall wear rates were so minimal that a review of cup inclination and version was unlikely to provide meaningful information. In addition, we only examined AP pelvis radiographs, limiting sensitivity of detecting osteolysis in our cohort (vs computed tomography scan). We also did not directly examine oxidation levels or biomechanical values of the liners but instead indirectly examined adverse events related to oxidation and deleterious mechanical properties. However, our intention was to ensure that the current widespread clinical use of this liner was validated by demonstrating low wear rates and a lack of significant adverse effects of its use. In addition, our group will continue to follow these patients to determine if the properties demonstrated in the present study continue to the 10- or 15-year time intervals. Strengths of this study include a large sample size of sequential patients with inclusion of all cases over the time points examined, an adequate cohort for follow-up at this time point, and precise radiographic measurements as demonstrated by excellent ICC between measurers.

Conclusion

In conclusion, we have found very low midterm wear rates of this third-generation, medium XLPE liner and excellent clinical outcomes in this cohort, with a 0.4% revision rate at a minimum of 4.5 years and a mean of 5.5 years. The decreased wear rates demonstrated were not accompanied by any observable increase in sequelae from oxidation or adverse mechanical properties such as liner rim fractures or dissociations. This remained true regardless of femoral head size and material or patient age and BMI. Further analysis will be necessary to ensure continued wear resistance, oxidative stability, and mechanical strength at long-term follow-up.

Conflict of interest

Steven L. Barnett reports royalties from Corin Orthopaedics; paid consultancy for Corin Orthopaedics and Zimmer-Biomet; and research support not directly related to the present study from Corin Orthopaedics, Zimmer-Biomet, and DePuy Orthopaedics. Robert S. Gorab reports royalties, paid consultancy, and research support not directly related to the present study from Depuy Synthes, a Johnson & Johnson Company. Travis Scudday reports research support not directly related to the present study from Exactech. All other authors declare no potential conflicts of interest.

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