

Materiovigilance and Patient Safety in Dentistry: A Cross-Sectional Analysis of Adverse Events Related to Resin-Based Materials Used in Dentures

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ABSTRACT

Context: Dentistry is the most device-dependent healthcare specialty, particularly in resin-based prostheses, dentures, and restorative materials. Most adverse events reported were due to extended exposure to chemical, mechanical, and microbial factors. However, despite the Materiovigilance Program of India (MvPI), dental device-related adverse events are underreported, limiting the availability of safety data.

Methods: A retrospective cross-sectional study was conducted at Krishnadevaraya College of Dental Sciences in Bengaluru from June to September 2025. The study involved 211 denture patients and 52 dental technicians. Data on demographics, types of dentures, resin-based materials used, and reported adverse events were gathered from patient records and analyzed using JMP statistical software.

Results: Among the patients (n=211), the most common adverse event was mucosal redness (10.9%), followed by mucosal color change (8.1%), pain (6.2%), and altered taste (5.2%). Events were more noticeable at the one-week follow-up than at 24–72 h. Among the technicians (n=52), occupational hazards included headaches (13.5%), strongly associated with self-cured resin exposure (p<0.001), and contact dermatitis (17.3%), which was more often allergic than irritant.

Conclusion: The study highlighted the dual risks and adverse events associated with dental resins for both patients and dental technicians, which, although uncommon, are clinically significant. Strengthening safety in dental practice can be achieved by improving reporting systems, providing additional training for technicians, and conducting early patient check-ins.

Keywords: Materiovigilance, resins, dentures, adverse events, occupational hazards

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INTRODUCTION

Both pharmacovigilance and Materiovigilance (Mv) ensure patient safety, a critical part of contemporary healthcare. Drug-related adverse events were reported by Pharmacovigilance, and medical device-related adverse events were reported by Materiovigilance. The effective functioning of medical devices during application and the safety of patients are ensured by these processes (1–3). Unlike drugs, medical devices interact with the body

through physical, chemical, and mechanical mechanisms over an extended period of time. Design flaws, manufacturing errors, improper maintenance, inadequate user training, or off-label usage often result in adverse effects. Vigilant monitoring is fundamental to preventing patient harm, strengthening regulatory systems, and increasing public faith in medical technologies (4–6).

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The most device-dependent specialty, such as dentistry, is often neglected in countries like India despite progress in global materiovigilance. This is due to the limited reporting of Post-marketing safety evaluation and adverse events for dental materials. The FDA's MAUDE system in the United States, the European EUDAMED system, and China's SFDA systems have organized databases for reporting, analyzing, and recalling faulty devices after they are on the market. Adverse outcomes—ranging from mucosal irritation and allergic reactions to mechanical fractures and systemic toxicities from monomer leaching—are often underreported. This creates a significant gap in patient safety frameworks, particularly in India, where the Materiovigilance Programme of India (MvPI) reports only minimal entries related to dental devices (7–8). Ultimately, materiovigilance strengthens healthcare systems by fostering trust, reliability, and accountability in device use (9–11).

Adverse events such as mucosal irritation, allergic responses, mechanical breakages, and general toxicity due to monomer leaching often go unreported. Dental professionals and lab technicians were regularly exposed to liquid methyl methacrylate monomer, polymer powders, initiators, and acrylic dust during mixing, packing, finishing, and repair procedures in prosthodontic practice. Methyl methacrylate is a volatile liquid monomer that is frequently inhaled during the procedure; its contact with the skin and regular exposure can cause allergic contact dermatitis, respiratory hypersensitivity (5,6,12). The Materiovigilance Program of India (MvPI) database has very few reported adverse events (13–15). The lack of reporting and the absence of a structured materiovigilance system in dentistry worsen this issue, as adverse events remain undocumented, hindering regulatory steps and material innovation (16–18).

The present study was undertaken to evaluate adverse events associated with resin-based denture materials and to highlight the importance of materiovigilance in promoting patient and occupational safety and supporting a culture of reporting in dental practice.

MATERIALS AND METHODS

The Materiovigilance and Patient Safety in Dentistry research study used a cross-sectional observational design from June 2025 to September 2025 at Krishnadevaraya College of Dental Sciences and Hospital, Yelahanka, Bengaluru. Institutional Ethics Committee approval was obtained before the commencement of the study, Ref: KCDS/258/2025-2026. This study comprises two components: (i) a retrospective review of patient records and (ii) a questionnaire-based survey of dental technicians.

Component I: Retrospective Review of Patient Records

Researchers reviewed the dental records of patients who received resin-based dentures. The study included 211 patients who met the eligibility criteria. Data collected included each patient's age, gender, type of denture, and the resin material used. Information on the type, nature, severity, and timing of onset of any reported adverse events was also gathered from the patient's record.

Component II: Survey of Dental Technicians

Fifty-two dental technicians who were occupationally involved in handling and making resin-based denture materials participated in the pre-approved questionnaire. Dental technicians were questioned regarding their awareness of exposure to dental resins at work, their knowledge of side effects associated with dental resins, any occupational health problems such as skin rash, headache, or breathing irritation, how they report problems, the challenges they face in reporting, and the safety measures they follow during handling resin materials.

Inclusion and Exclusion Criteria

Patients aged 18 years and older with complete documentation of dentures and the resin materials used, complete treatment, and follow-up records were included in the study. Patients with incomplete records regarding adverse events were excluded from the study. Dental technicians who participated willingly were included, and those who submitted incomplete questionnaire responses were excluded from the analysis. As a retrospective review of patient records is done, a waiver of informed consent is granted.

Statistical Analysis

Data were analyzed using JMP statistical software. The Chi-square test was used to find associations between categorical variables, with $p < 0.05$ considered statistically significant.

RESULTS

This study included 211 patients who received resin-based dentures. The average age was 54.3 years, ranging from 23 to 75 years. Most patients were between 58 and 67 years old (29.85%), followed by those aged 48 to 57 (28.43%) and 38 to 47 (20.85%). Only 3.27% of patients were aged 68–77 years. This study includes 126(59.7%) men and 85 (40.3%) women. Many patients (72.03%) had complete dentures, and 27.96% used removable partial dentures.

Table 1 Descriptive Statistics of Study Population (n = 211)

Descriptive Statistics of Study Population (n = 211)			
Variable	Category / Value	Frequency (n)	Percentage (%)
Age (years)	Mean ± SD	–	54.3 ± 11.4

Table 1

	Range	–	23 – 75
Age Group (years)	18-27	2	0.9478
	28-37	14	6.635
	38-47	44	20.85
	48-57	60	28.43
	58-67	63	29.85
	68-77	28	13.27
Gender	Male	126	59.70
	Female	85	40.30
Denture Type	Complete Denture (CD)	152	72.03
	Removable Partial Denture (RPD)	59	27.96
	Total	211	100%

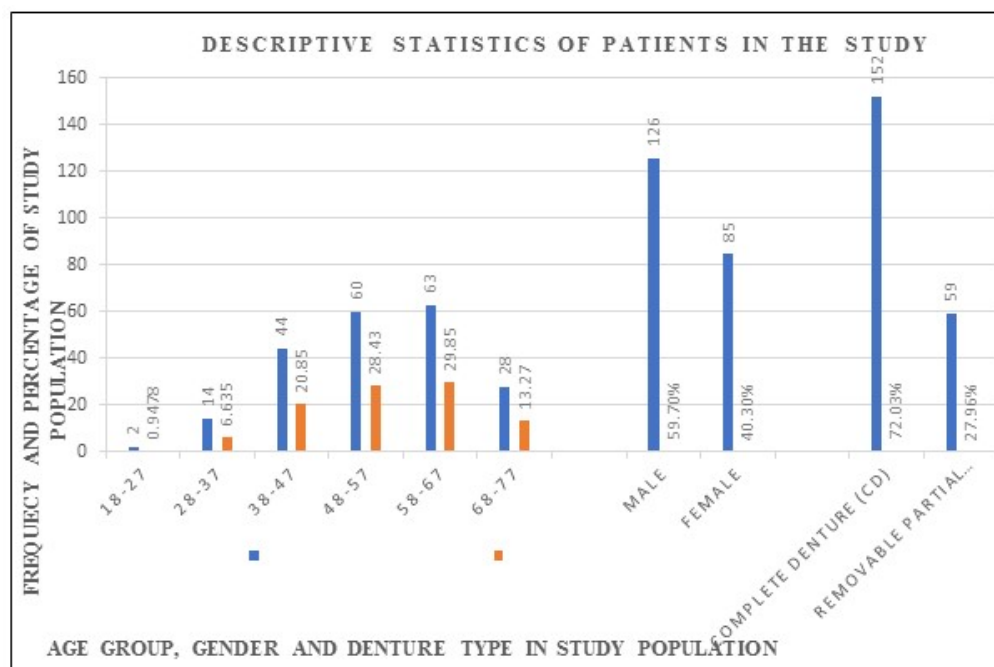


Figure 1: Descriptive statistics of patients in the study

Table 2 Prevalence of adverse events associated with Resin-Based Denture Materials (n = 211)

Adverse event	Number of adverse events reported	% of adverse events reported	Normal (n)	Normal (%)
Redness / Rubor in Mucosa	23	10.9	188	89.1
Change in Color of Mucosa	17	8.1	194	91.9
Pain in Mucosa	13	6.2	198	93.8
Change in Taste	11	5.2	200	94.8

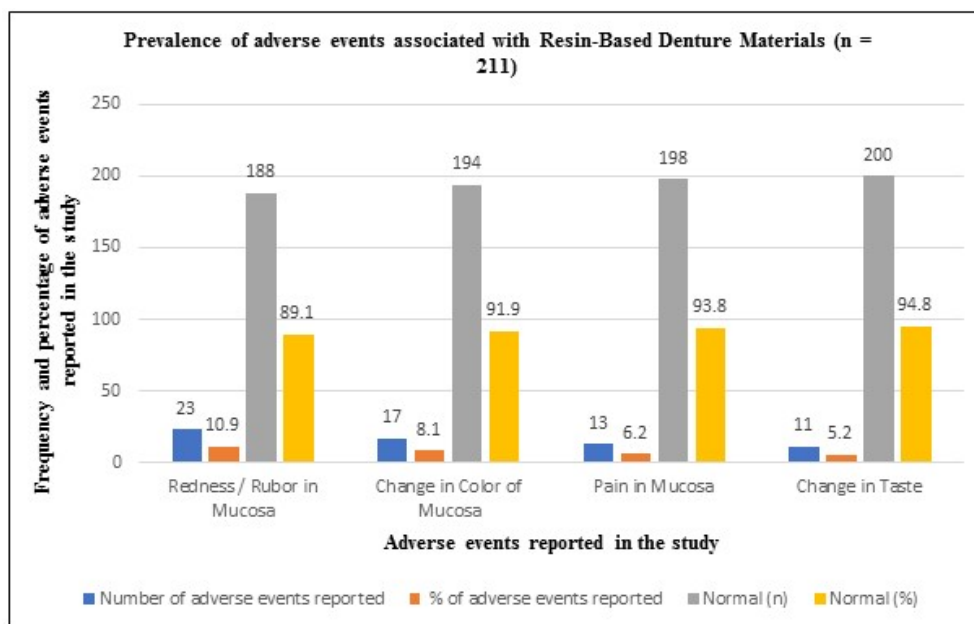


Figure 2: Prevalence of adverse events associated with Resin-Based Denture Materials

Adverse events associated with resin-based denture materials occurred infrequently in the study population and are listed in Table 2. Redness (rubor) of the mucosa was reported in 23 patients (10.9%), followed by changes in mucosal color in 17 patients (8.1%), mucosal pain in 13

patients (6.2%), and altered taste sensation in 11 patients (5.2%). Most patients did not report any adverse events, indicating a generally favorable safety profile for the denture materials evaluated.

Table 3: Association of Age Group, Gender, and Denture Type with Adverse Events Related to Resin-Based Denture Materials

variable	Category	Redness n (%)	Color Change n (%)	Pain n (%)	Taste Change n (%)
gender	male n=126	13 (10.3%)	7 (5.6%)	11 (8.73%)	7 (5.56%)
	female n=85	10 (11.8%)	10 (11.8%)	2 (2.35%)	4 (4.71%)
	p value	0.7408	0.104	0.0588	0.07854
age group	18-27	1(50%)	0(0%)	0(0%)	0(0%)
	28-37	0(0%)	1(7.14%)	3(21.43%)	2(14.29%)
	38-47	3(6.98%)	8(18.60%)	3(6.98%)	2(4.65%)
	48-57	6(9.84%)	3(4.92%)	3(4.92%)	4(6.56%)
	58-67	7(11.11%)	4(6.35%)	4(6.35%)	3(4.76%)
	68-77	6(21.43%)	1(3.57%)	0(0%)	0(0%)
	p value	0.1168	0.1322	0.1789	0.5128
Denture Type	Complete Denture (CD) n=152	17(11.18%)	12(7.98%)	9(5.92%)	9(5.92%)
	Removable Partial Denture (RPD) n= 59	6(10.34%)	5(8.62%)	4(6.90%)	2(3.45%)
	p value	0.9262	0.9427	0.9347	0.7502

The association between gender, age group, denture type, and adverse events related to resin-based denture materials is represented in Table 3. Chi-square analysis revealed no association between adverse events and variables (all $p > 0.05$) across the study population. 11.8% of females reported redness of mucosa compared to 10.3% of males, and mucosal color change was observed in 11.8% of females compared with 5.6% of males. Pain in the mucosa was reported in 8.7% of males than 2.4% of females, whereas alteration in taste occurred in 5.6% of males and 4.7% of females. Although males appeared to experience pain more frequently, the difference was not statistically significant ($p = 0.059$). No significant associations were observed between gender and redness ($p = 0.741$), color change ($p = 0.104$), or taste alteration ($p = 0.785$). Redness of the mucosa was reported more with an increase in age from 7.0% in 38–47 years to 21.4% in 68–77 years. Mucosal color change was most commonly observed in the 38–47-year age group (18.6%), while pain and taste alteration were reported more in younger age groups. The associations between age group and redness ($p = 0.117$), color change ($p = 0.132$), pain ($p = 0.180$), and taste alteration ($p = 0.513$) were all non-significant. 11.2% of complete denture users and 10.3% of removable partial denture users reported redness of the mucosa. Similarly, 7.9% and 8.6% of patients reported mucosal color change, 5.9% and 6.9% reported pain, and 5.9% and

3.5% reported alteration in taste with complete and removable partial dentures, respectively. The frequencies of adverse events were therefore comparable between denture categories. No significant associations were seen between denture type and redness ($p = 0.927$), color change ($p = 0.943$), pain ($p = 0.935$), or taste alteration ($p = 0.750$).

Overall, the findings indicate that while minor variations in the prevalence of adverse events were observed across gender, age groups, and denture types, these differences were not statistically significant. This suggests that the occurrence of adverse events related to resin-based denture materials was not strongly influenced by demographic characteristics or denture category within the present study population.

Technicians study

A total of 52 dental technicians involved in the fabrication and handling of resin-based denture materials participated in the study. Descriptive analysis was performed to evaluate their demographic characteristics and prevalence of occupational health problems among dental technicians associated with handling resin-based denture materials is presented in Table 4. Contact dermatitis, headache, respiratory irritation, and eye irritation were among the commonly reported adverse effects.

Table 4

Descriptive Characteristics of Technicians (n=52)			
Variable	Category	n	%
Gender	Female	34	65.40
	Male	18	34.60
Age group			
31-40	Female	30	75
	Male	10	25
41-50	Female	4	33.3
	Male	8	66.7
Allergic Reactions Associated with Acrylic Resin Handling and Exposure	Self-cured Acrylic Resin (Yes)	13	24.10
	Self-cured Acrylic Resin (No)	41	75.90
	Heat-cured Acrylic Resin (Yes)	3	5.60
	Heat-cured Acrylic Resin (No)	51	94.40
Adverse Events	Irritant contact dermatitis	3	5.80
	Allergic contact dermatitis	6	11.50
	Redness	1	1.90
	Burning Sensation	2	3.80
	Mucosal Irritation	0	0.00
	Headache (Monomer)	7	13.50
	Skin Peeling	1	1.90
	Skin Itching	2	3.80

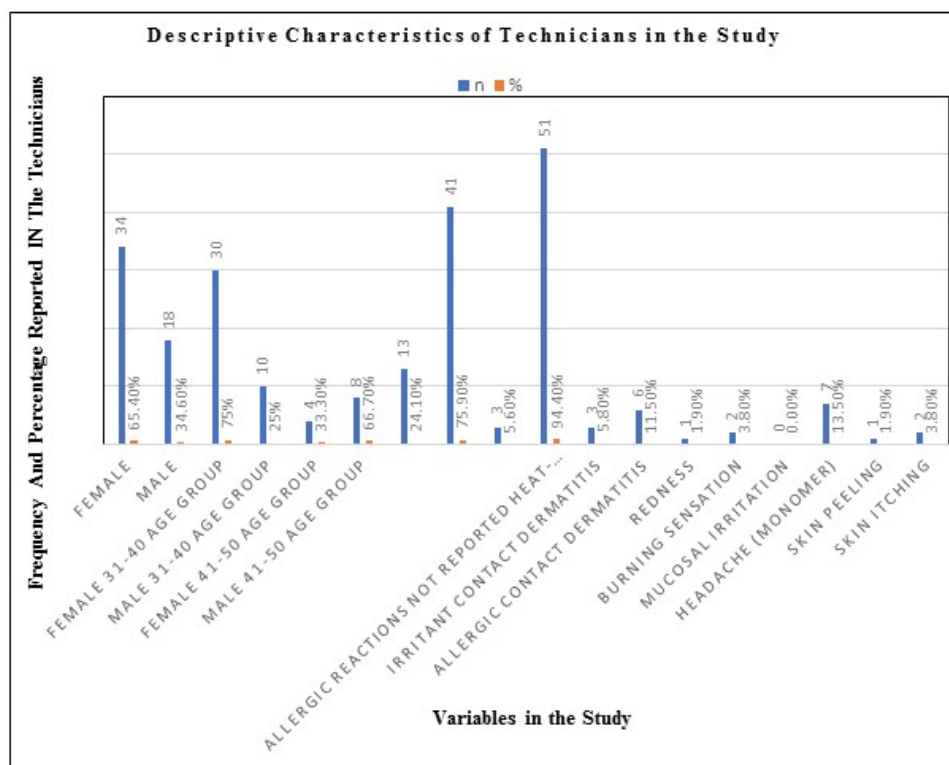


Figure 2: Descriptive Characteristics of Technicians in the Study

Among the 52 dental technicians, allergic reactions associated with acrylic resin handling and exposure were reported more frequently with self-cured acrylic resin (24.1%) than with heat-cured acrylic resin (5.6%). The majority of technicians did not report allergic reactions related to either resin type. The higher frequency of reactions associated with self-cured acrylic resin may be attributed to greater exposure to residual methyl methacrylate monomer during manipulation and processing procedures.

This finding may be attributed to the higher residual monomer content and greater potential for skin contact associated with self-cured acrylic resins. The majority of technicians did not report allergic reactions related to either resin type. Self-cured acrylic resins contain higher concentrations of residual methyl methacrylate monomer, which is known to cause irritant and allergic contact dermatitis among dental personnel.

Table 5: Association of Age Group and Gender with Occupational Adverse Events Related to Acrylic Resin Handling Among Dental Technicians

Adverse Event	31-40 Years (n=40) n (%)	41-50 Years (n=12) n (%)	Pearson p-value	Female (n=34) n (%)	Male (n=18) n (%)	Pearson p-value
Self-cured acrylic resin-associated allergic reaction	12 (30.0)	1 (8.3)	0.119*	10 (29.4)	3 (16.7)	0.313
Heat-cured acrylic resin-associated allergic reaction	2 (5.0)	1 (8.3)	0.664	2 (5.9)	1 (5.6)	0.962
Irritant Contact Dermatitis	3 (7.5)	0 (0.0)	0.328	1 (2.9)	2 (11.1)	0.229
Allergic Contact Dermatitis	6 (15.0)	0 (0.0)	0.154	5 (14.7)	1 (5.6)	0.326
Redness	1 (2.5)	0 (0.0)	0.58	0 (0.0)	1 (5.6)	0.165

Burning Sensation	2 (5.0)	0 (0.0)	0.43	0 (0.0)	2 (11.1)	0.048*
Mucosal Irritation	0 (0.0)	0 (0.0)	NA	0 (0.0)	0 (0.0)	NA
Headache Due to Monomer Exposure	7 (17.5)	0 (0.0)	0.119	4 (11.8)	3 (16.7)	0.622
Skin Peeling	1 (2.5)	0 (0.0)	0.58	1 (2.9)	0 (0.0)	0.463
Skin Itching	1 (2.5)	1 (8.3)	0.357	2 (5.9)	0 (0.0)	0.294

Table 5 shows the association between gender and occupational adverse events related to acrylic resin handling among dental technicians. Self-cured acrylic resin-associated allergic reactions (29.4%) and allergic contact dermatitis (14.7%) were more commonly reported among female technicians, whereas irritant contact dermatitis (11.1%), redness (5.6%), headache due to monomer exposure (16.7%), and burning sensation (11.1%) were relatively more frequent among male technicians. A statistically significant association was observed only between gender and burning sensation ($\chi^2 = 3.929$, $p = 0.048$), with all reported cases occurring among male technicians. No significant associations were observed between gender and the remaining occupational adverse events ($p > 0.05$).

DISCUSSION

Patients

The present study evaluated adverse events associated with acrylic denture use among denture wearers and assessed their association with demographic and clinical characteristics. Among the studied patients, redness of the oral mucosa, color changes, pain in the mucosa, and taste changes were observed as the major adverse events. However, no statistically significant association was found between gender, age group, denture type, and the occurrence of these adverse events ($p > 0.05$). The occurrence of redness and color changes is reported to be higher in females than in males, but these differences were not statistically significant. It clearly indicates that oral hygiene, dental maintenance, and duration play an important role in the occurrence of adverse events, rather than gender.

More adverse events were reported in the elderly patients, especially those between 58 and 77 years old. Notable age-related physiological changes, such as changes in saliva production, thinning of the oral lining, and increased susceptibility to irritation, are observed. But no significant association is seen between age and adverse events. A similar pattern is noted with denture type and adverse events, irrespective of whether complete or removable partial dentures are used. This clearly indicates that patient-related factors, such as dental hygiene and care, and sensitization to materials, are the main factors, rather than age, gender, or type of denture used. These issues can be solved by increasing awareness and knowledge of dental care and by identifying and solving the problems at an early stage.

Technicians

This study highlighted the occurrence of occupational adverse events associated with acrylic resin handling among dental technicians. The irritant and sensitizing properties of methyl methacrylate monomer exposure cause both local and systemic adverse effects. Allergic contact dermatitis and headache were highly reported occupational adverse events with self-cured acrylic resin.

Technicians aged 31–40 years reported a higher occurrence of adverse events than 41–50 years. Self-cured acrylic resin-associated allergic reactions, allergic contact dermatitis, irritant contact dermatitis, and headache due to monomer exposure were predominantly reported in the younger age group. However, no statistically significant association was found between age group and any of the occupational adverse events ($p > 0.05$). The higher frequency in younger technicians may reflect greater occupational exposure due to increased workload and active laboratory involvement.

Among dental technicians, both genders have no significant differences in the occurrence of adverse events. Self-cured acrylic resin-associated allergic reactions and allergic contact dermatitis were frequently reported by female technicians, while irritant contact dermatitis and headache were reported by males due to monomer exposure. Only the burning sensation and gender show a significant association. In male technicians, a significant association between burning sensation and gender was observed ($p = 0.048$). The adverse events observed in this study are the common occupational hazards seen with acrylic resin. Duration of exposure and handling practices greatly influence these adverse effects. However, these findings should be carefully validated and confirmed in a larger study sample. Other than allergic and contact dermatitis and headache, no dental technician has reported mucosal irritation.

Adverse events of acrylic denture materials among patients and dental technicians are examined in this study. This study highlights the need for materiovigilance in dentistry and the practice of reporting and early identification of adverse events. This study recommends raising awareness among dental technicians and patients about the maintenance and handling of acrylic resins. The use of protective equipment, such as gloves, masks, and eyeglasses, and proper ventilation for technicians during handling and exposure will definitely reduce the risk of the adverse events reported in the study. A similar study with

large sample sizes across multiple study centers is needed to identify any new adverse events during the study and to enhance materiovigilance practices in dentistry.

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CONFLICTS OF INTEREST:

The authors confirm that there are no known conflicts of interest associated with this publication.

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