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Clinical Assessment of Open Flap Debridement Using Magnifying Loupes and Surgical Operating Microscope: A Split-Mouth Randomized Controlled Clinical Trial

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ABSTRACT

Objectives: To overcome the drawbacks of the conventional flap surgery, newer surgical techniques like minimally invasive surgery were evolved to optimize the primary closure of the flap. Using a surgical operating microscope is one such technique, enhancing precession with clinical benefits. The current study aimed to compare the efficacy of a surgical operating microscope versus surgical loupes regarding periodontal treatment outcomes.

Materials and Methods: In this split-mouth randomized controlled clinical trial, flap surgery was planned for sites with a pocket probing depth (PPD)≥5mm under a surgical operating microscope and surgical loupes. All clinical periodontal parameters were recorded at baseline, and 3, and 6 months. The patients' perception of postoperative pain and wound healing were also assessed.

Results: The study comprised of 20 participants with mild to severe periodontitis. The reduction in the mean PPD was significantly greater at the test site than the control site at 3 months (P=0.05) and 6 months (P=0.005). At 3 months, there was a statistically significant difference in clinical attachment level (CAL) between the test and control sites (P=0.001). Flap surgery performed under a surgical operating microscope significantly enhanced early wound healing and caused less postoperative pain compared to flap surgery performed under surgical loupes (P<0.05).

Conclusion: All parameters improved at the test and control sites after the procedure. Nonetheless, the clinical parameters were noticeably better at the test site. Also, the test site had lower postoperative pain and enhanced wound healing compared with the test site.

Keywords: Debridement; Minimally Invasive Surgical Procedures; Surgical Flaps

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INTRODUCTION

Periodontitis is a multifactorial disease linked to the breakdown of tooth supporting structures. In order to understand the course of this disease and keep the dentition healthy and functional while maintaining proper esthetics, periodontal therapy is performed aiming to eliminate the microbial environment and risk factors for periodontitis [1,2].

Removing hard and soft supragingival and subgingival deposits from the root surface is the main goal of periodontal therapy in order to halt the course of the disease. The main goal of flap surgery, which is the most popular surgical technique for treatment of periodontal disease, is to provide access and expose the underlying bone and roots [3,4].

In order to successfully restore the damaged dentition, dentists must possess both clinical and theoretical skills in addition to good hand-eye coordination. Clear vision is also essential for the success of oral surgical procedures. A clear enlarged field of vision is necessary to enable early diagnosis of soft and hard tissue pathologies that could otherwise go undetected [5,6]. In this process, magnifying loupes and surgical operating microscopes can be of great help to enhance vision and improve the accuracy of dental procedures [7].

Due to enhanced patient awareness, there is a growing need for effective treatment options to restore function and appearance with minimal pain and patient discomfort. Periodontists can meet patient expectations by enhancing their knowledge and using a variety of magnification devices in minimally invasive procedures [8,9].

The primary goal of using a periodontal microscope is to increase the clinician's visual acuity. A clear, enlarged field of vision can help with early diagnosis of soft and hard tissue pathologies that could otherwise go undetected [1]. History of magnification dates back to 1694 when Anton von Leeuwenhoek built the first compound lens microscope. The first binocular microscope was used for ear surgery in 1921 by Carl Nylen, who is regarded as the father of microsurgery. The first microscope was used in dentistry in 1978 [10]. Loupes and surgical operating microscopes are two popular types of magnification equipment.

Since its introduction to the field of periodontics in 1992, microsurgery has gained widespread use in this field due to three main benefits. The first is the improvement of motor skills, which enhances the surgical skills demonstrated by smooth hand movements carried out with greater precision and less tremor. The use of microsurgical instruments and a smaller surgical field contributes to the second benefit, which is less tissue trauma at the surgical site. Also, microsurgical principles can be used to accomplish both passive and primary wound closures [3,4].

In general, the term "magnification-enhanced dentistry" refers to the application of two different kinds of optical magnification systems: surgical operating microscopes and loupes [3]. Loupes are the most common magnification method in dentistry essentially with two monocular microscopes with side-by-side lenses. Since convergent lens systems are used, the resultant magnified image will have stereoscopic qualities [5].

The LB-1910 surgical microscope (Labomed, Inc., Los Angeles, CA, USA), commonly referred to as an operating microscope, is an optical microscope made especially for use in surgical settings, particularly microsurgery. This surgical microscope's distinctive qualities include a high contrast image, a large depth of field, and superb stereo effects that can be used for inspection and surgery in a variety of fields. This microscope has the ability to move up and down, right and left, and back and forth. The counter-balanced spring arms feature a high intensity, coaxial cold light illumination with no heating on the operating surface, and are simple to adjust [4, 5].

Three main advantages of illumination, magnification, and improved accuracy in the use of surgical techniques—collectively referred to as the microsurgical triad—are provided by an operating microscope. Fiber optic illumination is a common feature of surgical operating microscopes, and has enhanced techniques to concentrate light on particular regions. The loupes and the operating microscopes are used to accomplish the second part of the microsurgical trinity, which is magnification. Each type of optical magnification has its own benefits and drawbacks [4].

Although ample literature is available on open flap debridement performed under conventional means, this study was unique in comparing the efficacy of open flap debridement under magnification loupes and surgical operating microscope to enhance the periodontal treatment outcome. The current study aimed to compare the efficacy of a surgical operating microscope versus surgical loupes regarding periodontal treatment outcomes.

MATERIALS AND METHODS

This study was accepted and received ethical clearance from the Clinical Trials Registry-

India, with Ref No. CTRI/2019/09/021156. Also, the Institutional Ethics Committee approved the study with the Ref No. VDC/IEC/2017/10.

Trial design:

This was a split-mouth randomized controlled clinical trial.

Eligibility criteria and settings:

The inclusion criteria were as follows: Patients with moderate to severe periodontitis who were otherwise healthy and continued to have pockets deeper than 5mm in at least three teeth across several sextants following phase I therapy. The exclusion criteria were patients with a history of medical complications like diabetes mellitus, smokers, pregnant women, and those who had periodontal surgery prior to the treatment.

Blinding and randomization:

This split-mouth randomized controlled clinical trial had a double-blind design. The patients and the first investigator/examiner were blinded. The participating clinician received randomly generated treatment allocations in sealed envelopes using the envelope randomization approach. The first investigator created the sequences, and the second investigator implemented them or assigned the research groups. As soon as the patient arrived, an envelope was opened, and complete medical and dental examination was followed by allocation of the therapy. All the clinical parameters and open flap debridement under loupes and surgical operating microscope were done by the principal investigator.

The factors were assessed and scored independently by two different examiners. To ascertain consistency between the assessors, the inter-examiner reliability was assessed using the Kappa statistics.

Outcomes (primary and secondary):

The primary outcome in this split-mouth randomized controlled clinical trial was clinical attachment level (CAL) gain at baseline and follow-up. Secondary outcomes included pocket probing depth (PPD) reduction, plaque index (PI), sulcus bleeding index (SBI), postoperative pain measured by a visual analogue scale (VAS), and early wound healing index (EHI). These parameters were compared to assess the clinical efficacy of open flap debridement when performed under magnification loupes and a surgical operating microscope.

Interventions:

The study comprised of 20 participants who met the eligibility criteria and had moderate to severe periodontitis. Patients were fully informed about the study objectives, and their informed consent was obtained. The patients' complete medical and dental history was obtained as well. A thorough periodontal examination was performed on the participants, and the following radiographic and clinical parameters were recorded.

The Silness and Loe (1964) PI [6], PPD determined by measuring the distance between the pocket base and gingival margin, and CAL determined by measuring the distance between the pocket base and the cementoenamel junction were all recorded. The Muhlemann and Sons SBI [7] and EHI [8] were also recorded. Pain was quantified using a VAS [8].

Pre-surgical measurements: Teeth with active dental caries were restored and defective restorations were replaced in all patients. Periodontal re-evaluation was performed 4-6 weeks after non-surgical periodontal therapy (NSPT). PI, PPD, CAL, and SBI were recorded using a UNC-15 probe to the nearest millimeter. Two sites with persistent PPD≥5mm with a minimum of three teeth in a quadrant were scheduled for flap surgery.

Test site: NSPT, surgical and supportive periodontal therapy under a surgical operating microscope (LB-1910 Surgical Microscope; Labomed, Inc., Los Angeles, CA, USA) at ×4- ×6 magnifications.

Control site: NSPT, surgical and supportive periodontal therapy under dental loupes (Rose Micro Solutions, Buffalo, NY, USA) at ×3.5 magnification.

Surgical intervention: Each participant received NSPT. Operating loupes were used to treat control sites; whereas a surgical operating microscope was used to treat test sites.

One single examiner conducted all the

procedures at the control sites using ×3.5 magnification loupes and local anesthesia with 2% lidocaine with 1:200,000 epinephrine. Flap surgery was planned for sites where the PPD was greater than 5mm. A complete debridement was performed and a full-thickness mucoperiosteal flap was elevated. Next, a straightforward interrupted suture was applied to realign the mucoperiosteal flap and fix it with 4-0 Mersilk sutures (Ethicon, Inc., India).

At the test sites, the same surgical technique was used with a surgical operating microscope with varying magnifications (i.e., 4x-6x) to perform both NSPT and surgical periodontal therapy.

Postoperative care: Postoperative antibiotics (500mg amoxicillin three times a day) and analgesics (50mg diclofenac twice a day) were prescribed for all patients for 3 days. For one week, the patients were asked to rinse their mouth twice a day with a mouthwash containing 0.2% chlorhexidine gluconate and to refrain from brushing their teeth around the surgical site. After one week, the patients received oral hygiene instructions, and the periodontal dressing and sutures were removed.

Postsurgical measurements: At 7 days after surgery, a 10-point VAS with 0 showing no pain and 10 showing the worst pain was used to quantify the level of pain experienced by patients. At 7 days postoperatively, the EHI was used to assess wound healing. A UNC-15 probe (Clear-View™ Probe; Premier Dental Products Company, Plymouth Meeting, PA, USA) was used to assess all clinical periodontal parameters (PI, PPD, CAL, and SBI) at 3 and 6 months postoperatively.

Statistical analysis:

Paired t-test was used to compare the study groups regarding each parameter. All clinical parameters were compared within groups using repeated measures ANOVA. All clinical parameters were compared between groups using the sample t-test. For all analyses, P values equal or smaller than 0.05 were deemed statistically significant. Data were statistically analyzed using SPSS 21.0.

RESULTS

Initially, a total of 20 patients were evaluated for eligibility; all of which, met the inclusion criteria and were included in the study. The participants were randomly allocated to two groups in a split-mouth design in which each patient underwent open flap debridement at one site with magnifying loupes and on the contralateral site with a surgical operating microscope. All patients completed the study with no drop-outs. The allocation of patients, randomizing procedure, follow-up, and analysis are shown in the CONSORT flow diagram (Fig. 1).

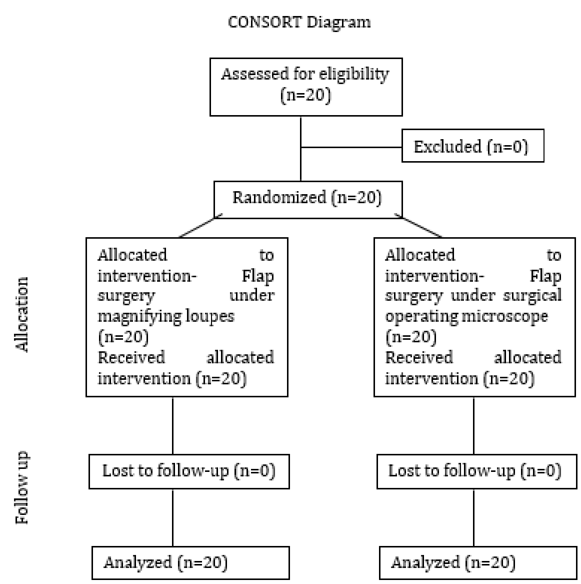

Fig 1. CONSORT flow-diagram of patient selection and allocation

The study included 40 sites in 20 patients with a mean age of 31±7 years, 10 of whom were males (50%) and 10 were females (50%) with 8 sites (40%) in the maxillary arch, and 12 (60%) in the mandibular arch. The factors were assessed and scored independently by two different examiners. The inter-examiner reliability was assessed using the Cohen's Kappa statistics with a value of 0.91 (P<0.001), indicating nearly complete agreement across the examiners [11].

Periodontal parameters such as PI, SBI, PPD, and CAL were measured in all patients but were limited to the treated quadrants only (Fig. 2, Tables 1 and 2).

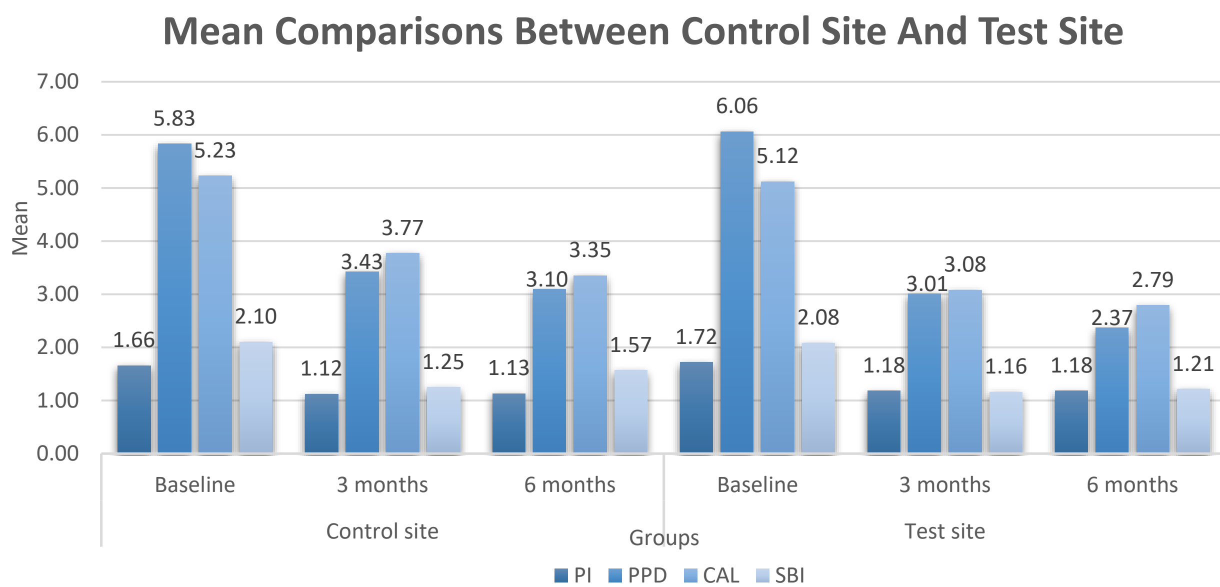

Fig 2. Graphical representation showing the comparisons of clinical parameters in the control and test sites; PI: Plaque Index; PPD: Pocket Probing Depth; CAL: Clinical Attachment Level; SBI: Sulcus Bleeding Index.

Table 1. Intra-group comparison of PI, PPD, CAL, and SBI

Site		**Mean ± SD**			
		PI	PPD	CAL	SBI
Control site	Baseline	1.66±0.30	5.83±0.55	5.23±0.58	2.10±0.42
	3 months	1.12±0.21	3.43±0.57	3.77±0.55	1.25±0.49
	6 months	1.13±0.47	3.10±0.65	3.35±0.80	1.57±1.01
	ANOVA test P value	P<0.001*	P<0.001*	P<0.001*	P<0.001*
	Δ1 P value	0.54±0.09 P<0.001*	2.40±0.32 P<0.001*	1.46±0.03 P<0.001*	1.46±0.03 P<0.001*
	Δ2 P value	0.53±0.17 P<0.001*	2.73±0.10 P<0.001*	1.88±0.22 P<0.001*	1.88±0.22 P<0.001*
	Δ3 P value	0.01±0.26 P=0.962	2.73±0.10 P=0.030*	0.42±0.25 P=0.007*	0.42±0.25 P=0.007*
Test site	Baseline	1.72±0.28	6.06±0.57	5.12±0.83	2.08±0.44
	3 months	1.18±0.27	3.01±0.46	3.08±0.65	1.16±0.71
	6 months	1.18±0.50	2.37±0.87	2.79±0.76	1.21±0.86
	ANOVA test P value	P<0.001*	P<0.001*	P<0.001*	P<0.001*
	Δ1 P value	0.54±0.01 P<0.001*	3.05±0.11 P<0.001*	2.04±0.18 P<0.001*	0.92±0.27 P<0.001*
	Δ2 P value	0.54±0.22 P<0.001*	3.69±0.30 P<0.001*	2.33±0.07 P<0.001*	0.87±0.42 P<0.001*
	Δ3 P value	0.00±0.23 P=0.993	0.64±0.41 P=0.001*	0.29±0.11 P=0.096	0.05±0.15 P=0.623

Statistical analysis: Repeated measures ANOVA; *significant at 0.05 level; Δ1: Mean difference between baseline and 3 months; Δ2: Mean difference between baseline and 6 months; Δ3: Mean difference between 3 months and 6 months; SD: Standard Deviation; PI: Plaque Index; PPD: Pocket Probing Depth; CAL: Clinical Attachment Level; SBI: Sulcus Bleeding Index.

Table 2. Inter-group comparison of PI, PPD, CAL, SBI, pain score, and EHI

Time	Mean ± SD difference between the control site and test site					
	PI	PPD	CAL	SBI	Pain	EHI
Baseline	0.06±0.02 P=0.529	0.23±0.02 P=0.212	0.11±0.25 P=0.646	0.02±0.02 P=0.863	1.60±0.47 P<0.001*	0.20±0.77 P=0.503
3 months	0.06±0.06 P=0.443	0.42±0.41 P=0.059	0.69±0.10 P=0.001*	0.09±0.22 P=0.630	-	-
6 months	0.05±0.03 P=0.723	0.73±0.22 P=0.005*	0.56±0.04 P=0.029*	0.36±0.15 P=0.243	-	-

Statistical analysis: Independent sample t-test. *significant at 0.05 level; SD: Standard Deviation; PI: Plaque Index; PPD: Pocket Probing Depth; CAL: Clinical Attachment Level; SBI: Sulcus Bleeding Index.

Periodontal parameters:

Primary outcome:

CAL: At both 3 and 6 months, the mean CAL significantly improved in the test and control sites (Tables 1 and 2, Fig. 2).

Secondary outcomes:

PI: At both 3 and 6 months, the mean PI significantly decreased in both the test and control groups compared with baseline (P<0.05). However, there was no statistically significant change in PI from 3 to 6 months in any group (Tables 1 and 2, Fig. 2).

PPD: There was a statistically significant reduction in PPD in both the test and control groups, from baseline to 3 months and from baseline to 6 months (P=0.000). The reduction in the test group was again greater than the reduction in the control group at both time points. On the other hand, there were no significant differences between the groups at baseline (P=0.212); a marginally significant difference at 3 months (P=0.059), and a statistically significant difference at 6 months between the two groups were seen such that the outcome favored the test group (P=0.005; Tables 1 and 2; Fig. 2).

SBI: Between baseline and 3 months, there was a statistically significant reduction in the mean SBI in both the control and test sites (P<0.05). There was no significant difference in SBI between the two groups at any time point (P>0.05, Tables 1 and 2, Fig. 2).

EHI: At 7 days after surgery, the test and control sites had a mean EHI of 1.50±1.24 and 1.70±0.47, respectively, which were not significantly different (P=0.503; Tables 1 and 2, Fig. 2).

VAS pain score: At 7 days after surgery, the test and control sites had a mean VAS pain score of 3.70±0.98 and 5.30±1.45, respectively, which were significantly different (P<0.000, Tables 1 and 2, Fig. 2).

DISCUSSION

The mean PI values significantly decreased from baseline to 3 months and from baseline to 6 months in the control group, which was consistent with the result of Aboalshamat et al [10]. There was a substantial reduction in the PI score after the intervention compared with baseline using ×3.5 magnifying loupes. Although there was a clinical increase in PI scores from 3 to 6 months, the change was not significant in this group. The test group's PI scores decreased from baseline to 3 months after using a surgical operating microscope. However, the results were not statistically significant from baseline to 6 months, and these findings did not align with those of Penmetsa et al, [12] who evaluated various magnifications and found no significant difference between the groups after 4 weeks.

However, oral hygiene has the biggest impact on the PI score. One can ensure complete plaque removal by employing magnification techniques, and in the current study, the PI scores decreased in both the control and test groups from baseline to 3 months. There was no significant change in PI scores between 3 and 6 months, indicating good oral hygiene behaviour being reinforced.

The present results were consistent with those of a prior study by Corbella et al, [13] who found that scaling and root planing under magnifying loupes significantly reduced the sulcus bleeding scores from baseline to 4 weeks. In the current study, the control group's SBI scores decreased significantly from baseline to 3 and 6 months, as well as from 3 months to 6 months.

Ribeiro et al. [14] conducted a study to compare the performance of minimally invasive non-surgical and surgical approaches for treatment of intrabony defects. They reported that both minimally invasive non-surgical and surgical methods were successful for treatment of intrabony defects and led towards periodontal health with insignificant morbidity and acceptable patient satisfaction. However, the non-surgical treatment modality presented an advantage with regards to a reduction in chair time.

The current study recorded a marked decrease in PPD and improvement in CAL gain from baseline to 3 and 6 months and from 3 months to 6 months with the use of surgical operating microscope. The present findings were in line with those of Mamoun [15] who performed scaling and root planing under a surgical operating microscope. He also assessed the full-mouth bleeding score over a 3-month period and showed a statistically significant change between baseline and 3 months. In the current study, both groups that underwent flap surgery under a surgical operating microscope and magnifying loupes showed a statistically significant reduction in the mean PPD from baseline to 3 and 6 months. Both the test and control groups showed an average gain of 2mm in CAL, and 3 mm in PPD reduction.

According to the current findings, the control group experienced a statistically significant increase in CAL between baseline and 3 months and between baseline and 6 months. The test group also experienced a statistically significant CAL gain between baseline and 3 months, while from 3 months to 6 months, the CAL gain was not statistically significant. These findings are consistent with those of Ribeiro et al [14].

In order to maintain clot stability and reduce the likelihood of wound failure in early stages of healing, surgical management of a clot appears to be crucial. Magnification is one way to do this. Similar to the findings of a study by Hegde et al, [16] the present results revealed an additional benefit: less tissue damage as a result of low flap elevation during surgery performed under a surgical operating microscope.

Seven days after surgery, the test sites experienced less pain than the control sites. The current findings about the pain level of patients during surgery under a surgical operating microscope were consistent with those of a previous study [8].

In total, the obtained results showed that microsurgical tools and concepts enhanced the usefulness of magnifying equipment, whether they were surgical operating microscopes or magnifying loupes. They have clear benefits, including better visual acuity, better wound approximation, quicker wound healing, lower postoperative morbidity, and greater patient acceptance. They also continue to be a method that offers enhanced surgical access to guarantee sufficient subgingival instrumentation. Additionally, by promoting adequate wound stability and for uneventful tissue development and maturation, they create the conditions necessary for the primary goal of healing [17].

Reddy et al. [18] examined the clinical results after open flap debridement using the Modified Widman flap technique with and without magnifying loupes and reported results in agreement with the present findings. In terms of quick wound healing and patient comfort, the present results and those of Reddy et al. [18] showed that employing a microsurgical approach yielded superior results than a typical surgical strategy.

The findings of the present study and those of a case series by Chacko et al. [19] showed similar clinical results of open flap debridement and microsurgery in management of chronic periodontitis. At baseline and 3 months later, there was a significant drop in clinical parameters for both the test and control groups. The test group had a superior early EHI and less postoperative discomfort, indicating an improved outcome.

Although periodontal procedures can be performed with ease under the usage of magnification loupes, they offer some disadvantages; for instance, the higher the magnification the heavier will be the loupes causing difficulty for the clinician while performing the procedure [20,21]. Also, a steep learning curve is required for periodontal procedures to be performed especially under a surgical operating microscope, which can be attained over some time [22,23].

The split-mouth design of the current study was perfect for comparing the outcome of various magnifying systems. There is strong evidence that using a surgical operating microscope instead of magnifying loupes for periodontal flap surgery has clinical benefits, as evidenced by the current study's significant improvements in PPD, CAL gain over 6 months, minimum postoperative pain, and improved healing.

CONCLUSION

There were significant differences between the test and control sites with regard to CAL, PPD, pain perception, and wound healing. Greater CAL gain and PPD reduction was recorded at the test site, as well as better wound healing, and there was less postoperative pain at the test compared to the control site where magnifying loupes were used.

CONFLICT OF INTEREST STATEMENT

None declared.

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