

A Controlled final Irrigation Protocol Reduces the Acute Pain Rate of Single versus Two-visit RCT of Teeth with Necrotic Pulp and Apical Periodontitis: A Multicenter Clinical Trial

Jorge Paredes Vieyra¹, Haydee Gómez Llanos Juárez², Francisco Javier Jimenez Enriquez³, Fabian Ocampo Acosta⁴, Mario Ignacio Manriquez Quintana⁵, Alan Hidalgo Vargas⁶

Abstract

Objective: To determine whether controlled final irrigation protocol after cleaning and shaping procedures would result in a reduced acute pain rate of single versus two-visit RCT of teeth with necrotic pulp and apical periodontitis: A multicenter clinical trial.

Methodology: Ninety patients were treated. Working length was established with electronic device and confirmed radiographically. For mechanical enlargement, the Twisted file adaptive, and Protaper Next instruments were used in brushing rotary movement and reciprocating mode correspondingly. For the control group, Balanced Force technique was employed. A controlled Final irrigation protocol was used in all groups. The same clinical protocol was used in three different cities of Mexico.

Results: The distribution of clinical samples was 45 teeth to one-visit and 45 teeth to two-visit treatment. Two cases (2.5%) experienced acute pain in teeth that receive an RCT. Of the earlier Asymptomatic/symptomatic teeth, the treatment was successful in eradicating pain in 83.33%. Statistical analysis of the healing results did not show any significant difference between the groups ($p=0.05$).

Conclusions: This study provided clinical evidence that an accurately instrumented one-visit root canal treatment can be as effective as a two-visit treatment. The use of substances with antibacterial activity is a valuable tool to control endodontic infection.

Clinical relevance: A controlled final irrigation protocol after clean and shape the canals reduced the incidence of postoperative pain and the need for medication in patients presenting with a diagnosis of necrotic pulp and symptomatic apical periodontitis.

Keywords: Pain; One- visit versus two-visit; Success and failure rate; Flare-up

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Introduction

Acute pain is a circumstance that can occur after a root canal treatment (RCT) procedure, especially in necrotic teeth that suddenly change to a flare-up [1]. AAE [2] termed flare-up as a severe condition of an asymptomatic pulpal and or radicular pathosis after the RCT. Though the clinical success of an RCT is achieved by meticulous and systematic preparation and filling the canals, the primary worry for the patient is continuously about post-endodontic pain.

Some etiological factors that play a part in acute pain including pre and post-endodontic pain, pulp condition, and presence of

1 Endodontics, Autonomous University of Baja California, School of Dentistry, Tijuana campus, Mexico

2 Pediatric Dentistry, Tijuana School of Dentistry, Mexico

3 Department of Oral Surgery, Mexico

4 Department of Histopathology, Mexico

5 Prosthetics, Oral Rehabilitation, Mexico

6 Clinical Assistant, Autonomous University of Baja California, Campus Tijuana, Mexico

*Corresponding author:

Jorge Paredes Vieyra

 jorgitoparedesvieyra@hotmail.com

Tel: 011526641230750

Endodontics, Autonomous University of Baja California, School of Dentistry, Tijuana campus, Calle segunda, Parque Internacional Industrial, Tijuana BC CP 22390, Mexico

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infection, insufficient cleaning extrusion of organic materials, and filling outside the canal. Scientific reports have demonstrated that acute pain is ranging from 1.4% to 16% [3,4].

Removal bacteria from the canals is pondered the very significant step in RCT [5-7]. Periradicular periodontitis, including host

reactions to infection of the root canal system of the affected tooth [8] and provide to the exacerbation of the case. Reasonably, the management of apical periodontitis should be the elimination of the origin of the infection. NaOCl is the irrigant that has the anti-biofilm capacity [9-11].

The absence of regulation in biofilm prototypes [12], controls related to post-formation biofilm exploration, and the numerous modes that NaOCl is carried *in Vitro* studies could explain the discrepancies encountered [13].

The reduction of microorganisms, together with the interruption of biofilms, is accomplished by mechanical instrumentation and flushing using microbicide mixes in the canal between visits [13,14].

Bacteria reduction can obtain an increase in preparation size, and irrigation [15] can prevent an acute pain condition. Peters & Wesselink [16] confirmed that more than 30%-35% of the root canal walls continued intact even by modern rotatory methods. During cleaning and shaping the canal, remains and irrigating solutions can be sent beyond the apex through RCT. They can lead to postoperative complications, such as intense pain or flare-ups. Therefore, adequate care of the working length can diminish the expulsion of remains through the apical foramen.

Antibacterial irrigation using 2.5% NaOCl can reduce 40-60% of the teeth bacteria negative [16,17]. Dressing the canal with Ca(OH)_2 reduce radicular microbes to around 70% [15]. Single-visit RCT deals some benefits such as a reduced acute pain rate [18,19] and, less number of schedules.

Single-visit RCT is established on the clinical judgment that additional treatments would not increase the superiority of care [20]. Microbial elimination cannot probably be increased without calcium hydroxide dressing between visits [21].

This randomized control trial aimed to determine whether controlled final irrigation protocol after cleaning and shaping procedures would result in a reduced acute pain rate of single versus two-visit RCT of teeth with necrotic pulp and apical periodontitis. The null hypothesis: There is no significant difference in acute pain rate in one-visit compared to two-visits in teeth with vital and necrotic pulps with apical periodontitis.

Materials and Methods

A prospective multicenter, randomized control trial was designed and conducted by ethical principles and agreement with the Helsinki Declaration (www.cirp.org/library/ethics/helsinki). The university institutional ethics board reviewed and approved the study under the approval number 37/2020-1 and, was registered in the ClinicalTrials.gov with the Identifier: NCT04115904.

Three certified endodontists with a common private clinical practice of 20 years participated in the study and performed 30 root canal treatments. The same clinical protocol was developed in three different cities of Baja California Mexico.

The principal inclusion criteria were a) Radiographic proof of apical periodontitis (not exceeding 3 mm x 3 mm in size), and b) a diagnosis of pulpal necrosis established by the none response to hot and cold tests. Three certified endodontists of three cities

of Baja California qualified in the processes, aids, and methods investigated took part in this project. The endodontists selected tracked a pre-established method for the Balanced Force technique, Twisted File Adaptive[®] (TFA), and Protaper Next[®] (PTN) Instrument systems.

The study group selection was established on the following criteria:

- a) The requirements of the protocol were freely accepted.
- b) Patients in good health
- c) Teeth with vital and necrotic pulps with or without apical periodontitis
- d) Enough coronal tooth structure
- e) No AINES or antibiotics were used four days before the RCT. The control group includes symptomatic teeth with vital pulps requiring RCT.

Exclusion parameters were the failure to get the patients' approval and were excluded if they were younger than 18 years old, pregnant, had a positive history of antibiotic use within the past two weeks, diabetic, or other systemic disorders.

After clarifying the clinical actions, risks, and expounding all inquiries upraised, each participant signed a written informed consent form and was randomly allocated to either the one-visit or two-visit group by using a block of random numbers created by one of the investigators.

Randomization was achieved before the clinical inspection using the minimization way explained by Pocock [22]. The sample size was estimated with the method described by Walters [23] and Machin [24]. The test statistic was estimated with the method described by Chan [25]. The sample size was calculated to be 45, based on power $p < 0.05$.

The patient was required to fill out a preoperative questionnaire, including a visual analog scale (VAS) score (0-10), to record the level of preoperative pain. Patients with 7,8,9, or 10 were incorporated in the study.

Ninety of one-hundred and ten patients (48 women and 42 men), 18 to 60 years of age with 90 single teeth. The patients were allocated into three groups established on vitality test and radiographic evaluation:

Group 1: 30 non-vital teeth without periapical radiolucency requiring RCT using Twisted File Adaptive[™] (Kerr dental. USA).

Group 1a - 15 non-vital teeth without periapical radiolucency requiring one-visit RCT

Group 1b - 15 non-vital teeth without periapical radiolucency requiring two-visit RCT

Group 2: 30 non-vital teeth with periapical radiolucency requiring RCT using Protaper Next[®] (Dentsply Maillefer, Ballaiges Suiza).

Group 2a - 15 non-vital teeth with periapical radiolucency requiring one-visit RCT

Group 2b - 15 non-vital teeth with periapical radiolucency requiring two-visit RCT

Control group: 30 symptomatic teeth with vital pulps requiring RCT using Flex-R[®] files (Moyco/Union Broach, York PA, USA).

Control group CGa - 15 symptomatic teeth with vital pulps requiring one-visit RCT

Control group CGb - 15 symptomatic teeth with vital pulps requiring two-visit RCT

A clinical file was obtained, and a clinical examination achieved, and all teeth were in good periodontal health.

Treatment procedures

All clinical sessions were around 45 minutes to allow for a suitable time for the conclusion of the RCT for one or two visits. For each procedure, two carpules of Mepivacaine Hydrochloride 2% with Levonordefrin 1:20,000 (Septodont, Cambridge, Ontario, Canada) was administered. In situations in which supplementary anesthesia was required, intraligamental Mepivacaine 2% was applied. The tooth was clean with 5.25% NaOCl (Ultra bleach, Bentonville, AR, USA) after the rubber dam was positioned. Caries or restoration was eliminated, and access openings made with sterile high-speed carbide # 331 (SS White, Lakewood, NJ). Necrotic teeth with infected canals (groups 1 and 2) were prepared by crown-down technique with copious flushing by 5.25% NaOCl. SmearClear[™] (Kerr Endodontics, Orange, CA) lubricant was administered at the entry of all canals.

Working length (WL) was obtained with an apex locator (Root ZX, J Morita, Irvine, CA) and contrasted radiographically. The canals were instrumented manually using Flex-R[®] files until reaching an ISO #20 at the WL. A glide path to the WL was then established. Instruments are frequently used in a narrow unflared, and small or sometimes calcified canal, and therefore, they might be subject to sudden torsional stresses [26, 27].

For the control group, Balanced Force (BF) technique was employed. Canals were prepared and enlarged with hand Flex-R[®]. The canals were enlarged using a #40 file for tinny or curved canals and a #55 file for wide canals. The cervical thirds of the canals were flared with sizes #2-#3 Gates-Glidden burs (Dentsply Maillefer, Ballaigues, Switzerland). The canals were then rinsed with 2mL 5.25% sodium hypochlorite. The same files were used to a size #60 for the anterior teeth and premolars and to a size #45 - #55 for molars using SmearClear after each instrument. 17% EDTA (Roth International Ltd, Chicago, IL) was used as a lubricant.

For mechanical enlargement, the rotary files were employed with a micro motor (Elements Motor, Sybron Endo, Glendora CA, USA). Speed and revolution were established individually for each rotary file system employed. Twisted file adaptive, and Protaper Next instruments were used in constant brushing rotary movement and reciprocating mode correspondingly.

Dentinal remains were eliminated from the instrument using sterile gauze, continuously to the next instrument change or after 3-4 in-and-out (pecking) movements allowing the manufacturers' commendations. Each canal was washed with 2.5 mL 2.0% NaOCl. Irrigation was accomplished using a 27-G needle (Max-I-Probe; Tulsa Dental, York, PA) through access and a 31-G NaviTip needle (Ultradent Products Inc, South Jordan, UT) when reaching the WL

after each Ni-Ti file insertion.

Group 1: Twisted file adaptive (TFA) was used. SM1 (size 20, 0.04 taper) and SM2 (size 25, 0.06 taper) files were used consecutively with a single meticulous motion agreeing to the manufacturers' instructions.

Group 2: Protaper Next (PTN) was used. Sx files, X1, and X2 (ProTaper Universal system; Dentsply, Ballaigues, Switzerland) were used for preflare and preparation of thin and curved canals and X3 and X4 (40/0.06) for preparation of wide canals up to the WL. The instruments were operated using a constant rotary brushing motion at a speed of 300 rpm and were used in one tooth (single use) and then eliminated. WL was maintained through all the processes used by using a #10 K-type file at the initial WL estimated.

Final irrigation protocol

After the instrumentation phase, the pulp space was rinsed with 1 mL 2.6% NaOCl, activated ultrasonically with an Irrisafe ultrasonic 20.00 tip (Satelec, Merignac, France) at 50% power of the MiniEndo ultrasonic unit (Kerr Endo) to place the tip 3 mm from the WL for 30 seconds per canal. Then, BF, TFA, and PTN groups received final flushing with 1cc 6°C 17% liquid EDTA gently administered to the WL through a cold (6°C) sterilized metallic micro-cannula attached to the Endovac system (Discus Dental, Culver City, CA, USA) for one minute to remove the smear layer and decrease post-endodontic pain using apical negative pressure (19). Finally, 2 mL of cold (6°C) distilled water was applied in the same manner.

For the one visit group, the canals were desiccated with sterile # 35 paper cone and filled at the same visit by using lateral condensation of gutta-percha and Sealapex sealer (SybronEndo, Orange, CA, USA). Access openings of anterior teeth were etched and restored with Fuji IX (GC Corp, Tokyo, Japan). For posterior teeth, a buildup restoration was placed by using the same etching technique and Fuji IX.

For the two-visit group, the canals were desiccated and medicated with a Calcium hydroxide powder (Roth, International Ltd, Chicago, IL) with distilled water paste in a creamy constancy. The mixture was made by using equivalent volumes of Ca(OH)₂ powder and distilled water and applied methodically into the canal using hand endodontic files.

The access openings were sealed with Cavit (3M ESPE, AG Seefeld, Germany), and each tooth was evaluated radiographically with post-treatment radiographs.

Participants of the two-visit group were programmed for a second visit to complete RCT at least one week after the primary appointment. At the second visit, the calcium hydroxide was removed with K-files and abundant irrigation with distilled water followed by final flushing with 1cc 6°C 17% liquid EDTA gently administered to the WL through a cold (6°C) sterile metallic micro-cannula attached to the Endovac system for one minute.

Complete elimination of the Ca (OH)₂, the canals were desiccated with sterilized paper cones, and the filling was completed with a similar procedure explained for the one visit group and

post-treatment radiographs taken. All teeth were restored appropriately.

The surveys requested for answers about the pain experienced during two weeks after completion RCT included: Rating for pain: 0: No pain, 1: Mild pain. Any discomfort that did not require urgent treatment. 2: Moderate pain. Illness requiring medication. 3 Acute pain. Pain that was not relieved by medication and needed palliative management. Cases with the manifestation of swelling were classified as flare-ups and treated appropriately.

After the conclusion of RCT, patients were invited to return for final rehabilitation as quickly as possible. The primary outcome degree for this research was ordered by using a variation of the Strindberg's study (28) used for radiographic healing assessment.

The secondary result measures were the presence of clinical symptoms. The complete rate of post-endodontic discomfort was documented and expressed as a percentage of the total number of teeth evaluated. An X² test was used to test trends in contingency tables using SPSS v. 25. The hypothesis tests were conducted at the 0.05 level of significance.

Results

The distribution of clinical samples was 45 teeth to one-visit and 45 teeth to two-visit treatment. Two cases (2.5%) experienced acute pain in teeth that receive an RCT. The rate of acute pain was moderately low in teeth with no previous RCT. The rate of acute pain was only definitely related to the treatment of earlier sensitive teeth (p=0.05). There was a significant difference regarding the rate of acute pain. Of the earlier Asymptomatic/symptomatic teeth, the treatment was successful in eradicating pain in 83.33%.

Post-endodontic pain happened in 16.65% of the cases and was significantly related to earlier symptomatic RCT and apical periodontitis (p=0.05). No statistically significant differences were encountered between groups about the occurrence of post-endodontic pain among anterior and posterior teeth.

The significant differences among the means of treatments were declared at P=0.05

Discussion

The aim of this randomized control trial was conducted to determine whether controlled final irrigation protocol after cleaning and shaping procedures would result in a reduced acute pain rate of single versus two-visit RCT of teeth with necrotic pulp and apical periodontitis. The same clinical protocol was developed in three different cities of Baja California Mexico. During the development of this research, each of the steps of the RCT was taken care of, as well as the chemo-mechanical phase to disinfect each canal. Following the basic principles of endodontics can ensure the proposed objective, comply with the manufacturers' recommendations, advise the patient to follow the instructions is teamwork.

The adopting of clinical methods during RCT depends not on their efficacy but also on the minimization of patients' discomfort. The prognosis of RCT in teeth with necrotic pulps is significantly worse

as compared with the vital condition. The clinician can enhance this scenario by application of the adequate protocol.

Clinical studies suggest that instrumentation and irrigation of the root canal system decrease the number of cultivable bacteria but infrequently be reached by using the currently available instruments, methods, and solutions [5,6,18]. Activation of the irrigating solution was used in this study, and bubble formation seems to cause a collapse of the biofilm structure [28-30].

Microorganisms are arguably the primary causative agents of acute pain and flare-ups [6,18]. Situations similar to apical projection of remains, modifications in the root canal flora, and environmental conditions affected by inadequate preparation, secondary intra-radicular toxicities, and possibly the increase in the oxidation-reduction potential within the root canal and leaky inter-appointment restorations lead the overgrowth of the facultative microorganisms.

The anatomy is an important factor limiting the attainment of proper disinfection [31,32]. An infected root related to apical periodontitis, bacteria can be situated not only at the canal end but also in recesses, dentinal tubules, isthmuses, lateral, and ramifications [33].

The present study was performed to evaluate the rate of acute pain in single vs. two-visits visit RCT. Significantly less acute pain was detected in the single visit in teeth with vital pulps. Our results coincide with Mattscheck [34], who found that RCT with post-endodontic pain happening soon after treatment can result in long term success, while treatment without such pain may fail. Glennon [15] reported that ache was the typical short-term result of RCT. Results showed that RCT done in one or two-visits with vital pulps is easy to clean than canals infected with necrotic pulps. Dressing the canals with calcium hydroxide can help to prevent pain and helps to disinfect them (Tables 1 and 2).

Pain is the principal, short-term problem of RCT unfortunately, the level of pain is fraught with hazards and chances for errors. Yoldas [35], who offered precise reasons to classify patients' pain. Besides, the RCT was efficient in eliminating discomfort in most of the previously sensitive teeth, which can also be explicated by the fact that maximum removal of irritants was completed in the first visit.

The findings of this study were comparable to those stated by earlier reports [36,37] were no significant differences in the rate of acute pain observed when associating single vs. two visit RCT (Tables 3 and 4).

Table 1 Distribution of teeth by Randomization Factors.

Tooth group	One - visit Treatment (n = 45) (%)	One – visit Follow up (n = 45) (%)	Two - visit Treatment (n = 45) (%)	Two – visit Follow up (n = 45) (%)
Group 1a	15 (33.33%)	14 (31.11%)		
Group 1b			15 (33.33%)	15 (33.33%)
Group 2a	15 (33.33%)	15 (33.33%)		
Group 2b			15 (33.33%)	14 (31.11%)
Control group 3a	15 (33.33%)	15 (33.33%)		
Control group 3b			15 (33.33%)	14 (31.11%)

Table 2 Occurrence of post-endodontic pain in different clinical conditions.

Clinical Condition	n	Pain after RCT			
		Absent	Mild	Moderate	Acute
Asymptomatic teeth withperiapical lesion	21	19 (21.11%)	1 (1.11%)	0	1 (1.11%)
Symptomatic teeth with periapical lesion	09	6 (6.66%)	1 (1.11%)	1 (1.11%)	1 (11.11%)
Asymptomatic teeth withoutperiapical lesion	11	8 (8.88%)	2 (2.22%)	1 (1.11%)	0
Symptomatic teeth without periapical lesion	19	14 (15.55%)	2 (2.22%)	2 (2.22%)	1 (1.11%)
Symptomatic teeth with vital pulps	30	28 (31.11%)	1 (1.11%)	1 (1.11%)	0
Total	90	75 (83.33%)	7 (7.77%)	5 (5.55%)	3 (3.33%)

Table 3 Distribution by age and presence of acute pain.

Patients age	n	Acute pain	No Acute pain
<20	15	1 (1.11%)	14 (15.55%)
21-25	3	0	3 (3.33%)
26-30	9	1 (1.11%)	8 (8.88%)
31-35	15	0	15 (16.66%)
36-40	17	0	17 (18.88%)
41-45	3	1 (1.11%)	2 (2.22 %)
46-50	14	0	14 (15.55%)
51-55	5	0	5 (5.55%)
56-60	9	0	9 (9.99%)
Total	90	3 (3.33%)	87 (96.66%)

p= 0.05

Table 4 Distribution of acute pain by number of visits.

Clinical condition	One – visit (n = 45) (%)	Two – visit (n = 45) (%)	Total
Absent	36 (40%)	39 (43.33%)	75 (83.33%)
Mild	4 (4.44%)	3 (3.33%)	7 (7.77%)
Moderate	3 (3.33%)	2 (2.22%)	5 (5.55%)
Acute pain	2 (2.22%)	1 (1.11%)	3 (3.33%)
Total	45 (50%)	45 (50%)	90 (100%)

p= 0.05

We corroborated that sensitive teeth with radiolucent spaces were more vulnerable to acute pain. Our scores are in agreement with Torabinejads' study [38]. A higher rate of post-endodontic pain in teeth with none peri-radicular lesions might be generated to a space reduction for pressure liberation when peri-radicular bone resorption is absent.

We found that the rate of post-endodontic pain and especially of acute pain, was related to the treatment of earlier symptomatic teeth. Reports have revealed that the existence of earlier pain can suggestively increase the possibility of post-endodontic pain [39,40].

Most studies have pointed on post-endodontic pain and acute pain [41,42], notwithstanding the circumstance that discomfort has been exposed to not affect on long term healing success [43-45].

Usually, numerous clinical conduct and inter-appointment coverings were used for rotten teeth, but throughout the years, the total of sessions has been reduced [46]. A two-visit model using an inter-appointment mixture with calcium hydroxide has been recommended as a usual practice [47].

Our results are in agreement with Peters and Wesselink [45] and Weiger and Rosendahl [46] in all the clinical concerns of the RCT

but not in a long period of time to evaluate them.

Figini [21] described two randomized controlled trials compared to radiographic data of periapical healing after RCT of necrotic teeth concluded in 1 visit or two visits. Volume is essential to eradicate bacteria, and the tip of an irrigating needle is placed 2-3 mm short of the apical end of the canal, and the irrigant is passively expressed. If the needle is placed too close to the apical foramen or the irrigant is forcibly expressed, the chance of extrusion increases [41]. Disinfection depends on chemicals and the amount of irrigating solution.

In the present study, age had no significant correlation with the rate of acute endodontic pain. Related results were also described by Eleazer and Eleazer [44].

In this study, the EndoVac (Discus Dental, Culver City, CA, USA) was used, a negative pressure irrigation method to avoid those adverse effects even when the needle was placed as far apically as the working length. Cryotherapy was used in this study, which allowed the inflammatory process to present in the three groups to have relief by applying cold at 6 degrees Celsius. Nielsen and Baumgartner [17] presented that there are significant differences in the cleaning effect at the apical 1 mm level using the EndoVac technique.

From the authors' point of view, it also seemed more relevant to clinically examine how an efficient irrigation/aspiration with different temperatures could help reduce and control intense preoperative pain. At the same time, postoperative pain is the consequence of a complex multifactorial development that is persuaded by factors inherent in patients, in the tooth to be treated, and in the intervening operator.

Our restrictive inclusion criteria helped control confounding factors that could have influenced the results attributed to the effects of the final irrigation step. Moreover, this is also the reason, despite being a randomized clinical trial in which all preoperative factors are supposed to be uniformly distributed in a multivariable study.

Such a strict approach in both selecting the patients participating in the study and analyzing the data in this randomized multicenter clinical trial allow us to conclude that controlled final irrigation protocol after cleaning and shaping procedures reduced the acute pain rate of single versus two-visit RCT of teeth with necrotic pulp and apical periodontitis.

Conclusion

This study provided clinical evidence that an accurately

instrumented one-visit root canal treatment can be as effective as a two-visit treatment. The acute pain rate was related to the treatment of earlier symptomatic teeth without peri radicular lesions. The use of substances with antibacterial activity is a valuable tool to control endodontic infection.

A standard and adequate RCT in one or two visits with NaOCl at different concentrations, irrigant activation, using EDTA to reduce debris, and final irrigation with cold distilled water provided a favorable response regarding lower rate of acute pain.

Compliance with ethical standards

Conflicts of Interest

Author Jorge Paredes Vieyra declares that he has no conflict of interest.

Author Haydee Gomez Llanos Juarez declares that she has no conflict of interest.

Author Francisco Javier Jimenez Enriquez declares that he has no conflict of interest.

Author Fabian Ocampo Acosta declares that he has no conflict of interest.

Author Mario Ignacio Manriquez Quintana declares that he has no conflict of interest.

Author Alan Hidalgo Vargas declares that he has no conflict of interest.

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