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Research Article

Post-Operative Effect of Ozone Therapy on the Extraction of Lower Third Molars

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Abstract

Objective: The objective of this pilot, split-mouth, single-blind, random study was to assess the post-operative effect of ozone therapy on the extraction of lower third molars regarding pain, oedema and trismus. **Methods:** The sample consisted of 15 patients undergoing bilateral extraction of lower third molars, in similar positions, according to Pell & Gregory classification. A mouth-split design was used so that one side received ozone gas injection and the other side received placebo in a simulation manner. Ozone gas was administered into the submucosal tissue adjacent to the masseter muscle by means of a 20-ml syringe after the extraction. Evaluations were performed by using the VAS pain scale at a post-operative period. Oedema and trismus were evaluated on the fourth and seventh days after the surgery and then compared to the pre-operative measurements. **Results:** the effectiveness of ozone could not be confirmed by using this study's protocol regarding the variables assessed (all p-values were greater than 0.05). **Conclusion:** new treatment protocols should be assessed in order to verify the possibility of post-operative improvement with ozone therapy after third molar extraction.

Keywords: Ozone therapy; Impacted third molar; Oral surgery, Swelling, Pain, Trismus

Introduction

The removal of third molars is a common procedure in the routine oral and maxillofacial surgery. Like any surgical procedure, third molar extraction causes tissue lesion and acute inflammatory responses, resulting in post-operative discomfort to the patient. The position and depth of the tooth to be extracted, bone density and surgeon's experience can influence the post-operative outcome. Among other complications, limited mouth opening, oedema and pain can be experienced by the patient in the post-operative period [1,2].

The prescription of medications such as steroidal and non-steroidal anti-inflammatory drugs as well as opioid and non-opioid analgesics for control of post-operative discomfort is indispensable. However, these medications can often cause side effects in the patients, such as allergies, gastro-intestinal discomfort, bleeding, nausea and vomit [1,2].

After surgical procedures, one should aim to improve the post-operative control in order not to cause a negative impact on the

patient's quality of life. For this reason, non-pharmacological methods such as use of low-intensity laser therapy and ozone therapy are being investigated to minimise pain, oedema and mouth opening limitation [1].

Ozone is a natural compound consisting of three oxygen atoms and is found in nature in gaseous form in the upper layers of the atmosphere [1,3-6]. This compound was first described by a German chemist called Christian Friedrich Schönbein in 1840. Ozone was studied and analysed by the FDA in the beginning of 20th century and used in dentistry for the first time in 1950 by the German dentist Edward Fisch [6,7].

Ozone can be applied to tissues topically or parenterally in the forms of gel, gas and liquid. Its concentrations vary from 1 to 100 μm/ml depending on its indication [5,7,8].

This compound has positive effects on the control of bacterial, viral and fungal infections as well as of ischemic, dermatological, pulmonary, renal, haematological and neuro-degenerative diseases. The antibacterial action of ozone is owned to the fact that it destroys the cell wall and cytoplasmic membrane of bacteria and fungi during its oxidative action [1,3,5,8,9].

Naik, et al. [5] state that ozone therapy can also be used for treatment of non-healing, chronic, ulcerative lesions, circulatory system disorders, burn and dermal injuries. These effects are due to the characteristics of ozone in interacting with blood cells and in presenting anti-inflammatory, analgesic and immune-stimulating actions, thus avoiding tissue hypoxia. This positive result demonstrably improves the control of pain and reduces the rate of infectious processes [1,3,7,10].

In dentistry, ozone therapy has been used to assist in the treatment of carious lesions, endodontic treatment, healing of epithelial wounds, treatment of periodontal diseases, irrigation of avulsed teeth and cleaning of prostheses. In oral surgery, ozone therapy can be used for haemostasis, improvement of local oxygen rate and prevention of bacterial growth [1,6,8,11].

The characteristic of ozone in reducing both pain and inflammatory process in the post-operative period is evidenced by the decrease in the production of inflammatory mediators, inactivation of pain mediators and improvement of local oxygen flow, which is essential for regeneration of the tissues [3,5].

In view of this, this study is aimed at assessing the post-operative effect of ozone gas on the extraction of lower third molars regarding pain, oedema and trismus.

Material and Methods

The present study used a methodology based on the norms set by the 2010 CONSORT-STATEMENT [12] and was registered on the site of the Brazilian Registry of Clinical Trials (Rebec – RBR-99 qvrnj) and approved by the Research Ethics Committee of the São Paulo State University (UNESP) Institute of Science and Technology according to protocol number CAAE 79322424.4.0000.0077.

For carrying out this pilot, split-mouth, single-blind, randomised clinical study, 15 patients referred for extraction of partially or completely impacted lower third molars, in similar positions (IIB) according to Pell & Gregory classification, were selected. The patients had their teeth divided into two sample groups, in which the ozone group had either tooth #38 or #48 randomly extracted and ozone gas was administered into the submucosal tissue between the extraction socket and the masseter muscle through a Luer 20 ml syringe, whereas the tooth on the opposite side was extracted and received application of placebo with a similar syringe (placebo group). In this way, the patients were blind to the injections as they were anaesthetised and could not identify the applications. The surgical procedures were performed with a minimum interval of three weeks, in which all the patients participated in both groups.

- Group O (ozone, n=15 teeth): patients undergoing lower third molar extraction (#38 or #48) with application of ozone gas submucosally in the regions of masseter muscle and alveolus by means of a Luer 20 ml syringe.
- Group P (placebo, n=15 teeth): patients undergoing third molar extraction (#38 or #48) with ambient air application as the placebo intervention simulating injection of ozone gas into the regions of masseter muscle and alveolus by means of a Luer 20 ml syringe.

Inclusion Criteria

1. Patients needing third molar extraction without gender distinction;
2. Patients using no analgesic or anti-inflammatory drugs in the past 15 days;
3. Patients presenting partially or completely impacted teeth in opposite semi-arches according to the Pell & Gregory classification [13];
4. Patients aged 18 to 30 years old;
5. Patients agreeing with participating voluntarily in the study and knowing about the risks and benefits involved after signing an informed consent form.

Exclusion Criteria

1. Patients presenting local or systemic changes contra-indicating the procedure;
2. Patients on medication interfering with the methodology;

3. Patients presenting erupted lower third molars;
4. Patients allergic to anaesthetics and medications;
5. Patients with contra-indication for use of ozone therapy;
6. Patients who smoke;
7. Patients pregnant or lactating.

Sample

The sample consisted of 15 patients who needed extraction of partially or completely impacted lower third molars bilaterally. The present study has a controlled, split-mouth, randomised and single-blind at the participant level, as patients were unaware of whether the infiltration consisted of ozone gas or placebo.

Sample Size Calculation

Patients with third molars meeting the inclusion and exclusion criteria were considered for the present study. The sample size was calculated by using the Sealed Envelope software (www.sealedenvelope.com), in which 30 teeth were necessary to obtain a 80-percent detection probability at a significance level of 5% [14]. This calculation was considered for a pilot, split-mouth study as it allows a reduction in the variability between treatments.

Randomisation

Eligible participants were randomly allocated to the intervention or control group using a computer-generated randomization sequence. Group assignments were concealed in sequentially numbered, opaque, sealed envelopes that were opened only after participant enrolment. The right side of all patients (i.e. tooth #48) was chosen for the initial surgery, whereas the left side (tooth #38) was chosen for the second one. This allowed that all the patients had each one of the sides (i.e. right and left) allocated into the ozone and placebo groups. Randomisation was performed by a researcher (3) not involved in the evaluation or surgical treatment of the patients. In addition of the blind allocation, the patients were not aware of the groups of the teeth.

Surgical Procedure

A preoperative medication protocol established by the Institutional Hospital Infection Control Committee was implemented prior to the surgical procedures, which consisted of cephazoline 1g and dexamethasone 10 mg to be taken 1 hour before the surgery. Each surgical procedure was performed with a minimum interval of three weeks between sides to allow complete resolution of postoperative edema and restoration of normal mouth opening, thereby minimizing potential carryover effects and preventing interference between outcomes from the two surgical sites. The initial surgery was performed on the right side (tooth #48) and whose data allocation was randomised for Group O or Group P. An experienced oral-maxillofacial surgeon (researcher 1) performed the extractions with the help of an assistant (researcher 2). The sutures were removed after seven days.

Application of Ozone Gas

Ozone was applied in the form of gas at a concentration of 50 mg/ml (Philozon Medplus, Philozon Ind. Com. Geradores de Ozônio Eireli, Balneário Camboriú, SC, Brazil) by means of two 20-ml syringes. One syringe with 20 ml of ozonised gas was administered submucosally in the region between the extraction socket and the ipsilateral masseter muscle

The patient was evaluated for presence of pain, oedema and trismus on the fourth and seventh days after the surgery. Oedema was evaluated based on measurements between facial points [15]. Mouth opening was assessed by measuring the interincisal distance on the fourth and seventh days after the surgery. Pain was evaluated by using the Visual Analogue Scale (VAS) immediately and mediately, that is, at 1, 3, 6, 12, 24, 48 and 72 hours after the surgery. In the placebo group, the injection of ozone gas into the masseter muscles, with the operative wound still open, and into the alveolus after the suture were simulated.

Evaluation of Pain, Oedema and Trismus

The patients themselves rated their pain experience on the VAS as zero for “no pain” and ten for “the worst possible pain” during the post-operative period (at 1, 3, 6, 12, 24, 48 and 72 hours after the surgery) [16]. The patients were given a pain evaluation form to be completed throughout the post-operative period, that is, until the third day.

The oedema was evaluated by using the technique described by Ustün et al. [15], which is based on measuring the distances between lateral corner of the eye and gonion, between tragus and labial commissure and between tragus and pogonion soft tissue. The measurements of each side were added before the surgeries to obtain baseline values for comparison with those obtained during the post-operative period, thus revealing the presence and magnitude of the oedema in each period of evaluation. The measurements were made with a flexible ruler on the fourth and seventh days.

Trismus was measured before and after the surgical procedures, on the fourth and seventh days. The patients were seated for measurements, in which a millimetre ruler positioned between the incisal borders of the upper and lower central incisors.

Data on postoperative swelling, pain, and mouth opening were tabulated and analyzed using a paired t-test with Minitab Statistical Software (Version 21; Minitab LLC, State College, PA, USA).

Results

This split-mouth study evaluated ten females and five males (n = 15) with mean age of 23 years and 5 months old. The surgical procedure for the placebo group had a mean time of 38 minutes and 43 seconds, which was very similar to that for the ozone group, that is, 34 minutes and 37 seconds.

By analysing the results on pain, it was possible to observe that the placebo group showed less painful sensation up to the first 12 hours after the procedure (p-value = 0.719), as well as after 24 hours (p-value = 0.139) and 48 hours (p-value = 0.249). The ozone group demonstrated significantly lower pain scores across all postoperative assessment periods compared with the placebo group, except the third day (p-value = 0.384), but it was not possible to observe statistical differences between both groups for the study periods (Figure 1).

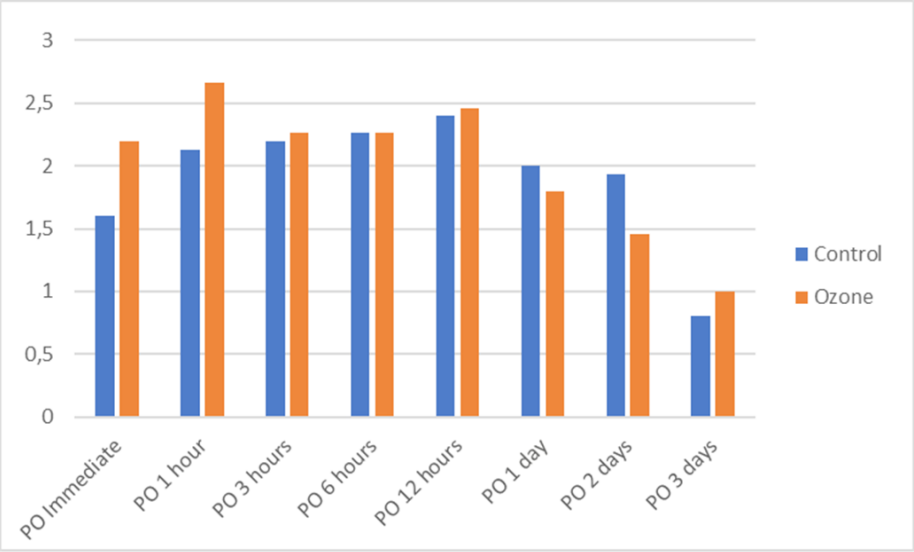

Figure 1: Pain in Visual Analog Scale (in mm).

As for trismus, similarly to the pain, the patients in the ozone group showed greater mouth opening as a 6-mm difference was observed on the fourth day after the surgery compared to 2 mm on the seventh day, but which was not statistically significant between the groups (p-value = 0.14 on day 4; p-value = 0.92 on day 7) (Figure 2).

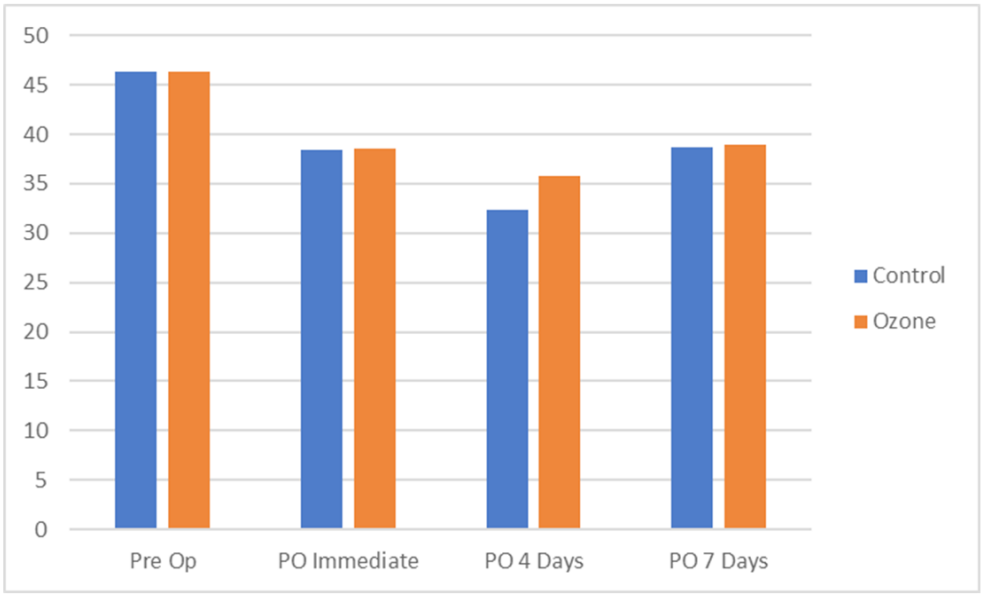

Figure 2: Mouth Opening (mm).

As for the oedema, a different result was observed as the placebo group showed higher values, mainly regarding measurements made after the surgery, but which was not statistically significant between the groups (p-value = 0.34 mediately; p-value = 0.68 on day 4; p-value = 0.82 on day 7) (Figures 3-5).

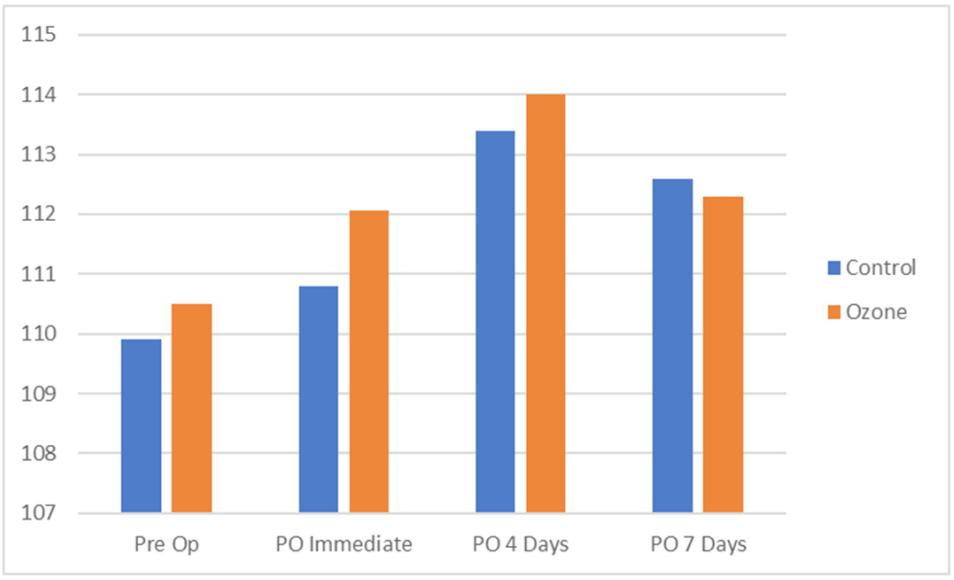

Figure 3: Edema Assessment: Tragus - Commissure (mm).

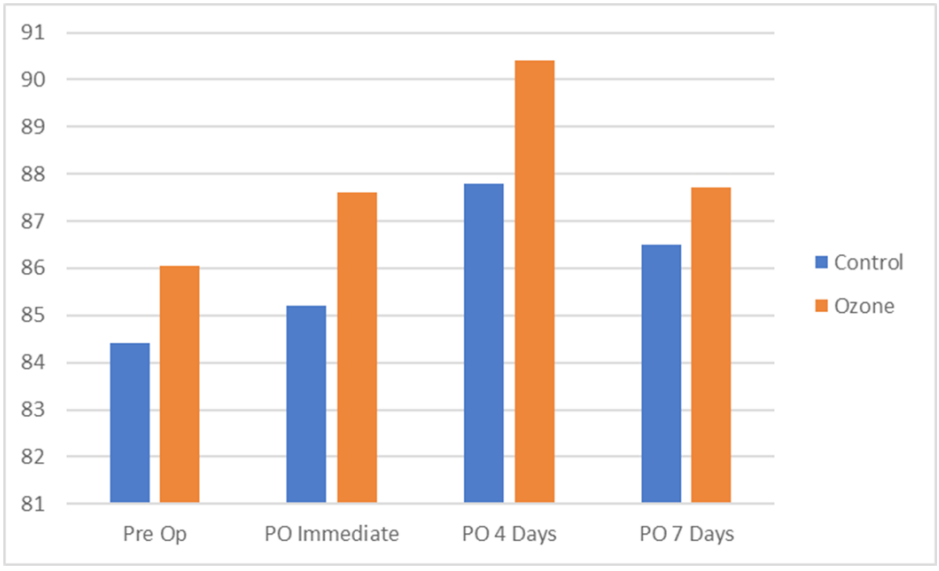

Figure 4: Edema Assessment: Commissure – Angle (mm).

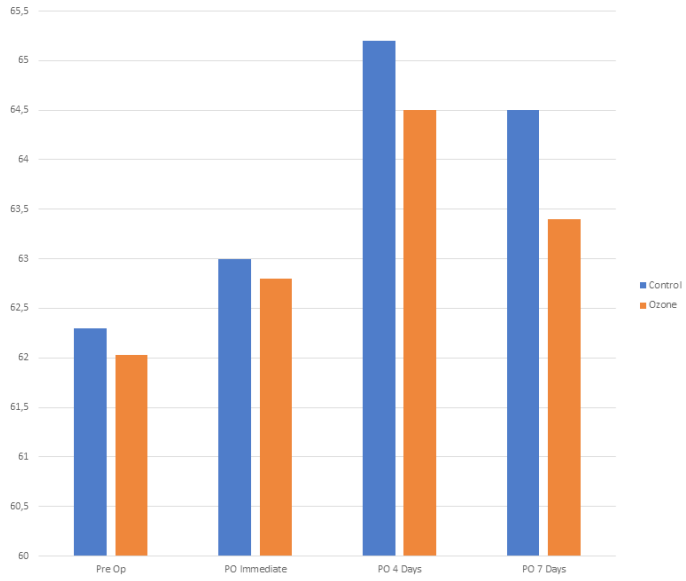

Figure 5: Edema Assessment: Tragus – Angle (mm).

Discussion

Third molar extraction is a procedure frequently performed by dental surgeons, in which a known triad of post-operative symptoms such as pain, oedema and trismus commonly occur, which can affect the patients' quality of life. However, the literature has shown that ozone therapy is a safe treatment method with great applicability that have been reported due to its different forms of presentation (gas, oil, gel,…), thus allowing its use for therapeutic purposes. Therefore, ozone therapy is a beneficial option by the dental surgeon for reducing

pain and complications intra- and post-operatively [17,18].

In the study by Naik, et al. [5], ozone in the gel form was applied to the alveolus after the surgery twice a day for three days, presenting statistical differences regarding pain. The gel form was obtained by mixing oxidised oil with 0.25 parts of ozone and 99.75 parts of oxygen. On the other hand, in the study by Kazancioglu, et al. [1], ozone gas was applied to the region of the masseter muscle insertion at concentrations ranging from 10 to 100 mg/ml immediately and 1, 3, 5 and 7 days after the surgery, achieving better results regarding pain and reducing the number of analgesics. In our study, ozone was also used in gas form at the concentration of 50 mg/ml by using 20-ml syringes with ozonised gas, which was immediately applied to the masseter muscle and alveolus after the surgery, with no statistical difference in the variables assessed. Considering these findings, although ozone gel is more difficult to obtain and associated with higher costs, this formulation exhibits greater stability than the direct application of ozone gas, as employed in the present study. This increased stability may account for the superior clinical outcomes reported with ozone gel when compared with ozone gas administration.

Articles like those by Kazancioglu, et al. [11] report that there was a post-operative improvement in 60 patients who underwent third molar extraction and received ozone therapy extra-orally in the masseter muscle insertion at concentrations ranging from 1o to 100 mg/ml. In our study, the same concentration was used, but ozone was applied intra-orally. As a result, the authors observed that the ozone group had a decrease in both pain and amount of analgesic medications, which differed from our findings. Nevertheless, they found no significant difference between the groups regarding oedema and mouth opening in the post-operative period, a finding similar to ours. Although the extraoral approach is technically more invasive and may be associated with greater discomfort for the patient, it may represent a more effective alternative to the intraoral approach in terms of postoperative pain control

Considering that the amount of oedema is directly related to the extension of tissue injury after the removal of impacted third molars and that pain is a subjective experience influenced by age, gender and level of anxiety, including the difficulty of this surgical procedure, our study sought for standardisation by using a split-mouth, single-blind design in which only one operator was involved and Pell & Gregory classification was used [13] in order to maintain the reliability of the results. However, we observed higher values for oedema in the ozone group immediately after the surgery and either no statistical difference was found on the fourth and seventh days between placebo and ozone groups. Sivalingam, et al. [3] evaluated 33 patients submitted to extraction of impacted lower third molars by analysing the study (ozone therapy) and control groups, in which the former had the alveoli irrigated with ozonised water after tooth avulsion, as in our study, and the patients were also post-operatively evaluated on days 1, 3 and 7. As a result, the study group showed an improvement in the mouth opening, used less analgesic medications and had less oedema, thus corroborating the study by Kazancioglu, et al. [1] in relation to the lower amount of analgesic medications. But their results differed from ours regarding trismus and oedema, as our study showed no statistical differences between the groups assessed.

Contra-indications for the application of ozone are the following: presence of auto-immune disorders, hyperthyroidism, ozone allergy, myasthenia and myocardial infarction [3]. However, according to Song et al. [8], ozone has good effects on the cicatrisation of wounds due to elevated levels of oxygen, glucose and ATP in ischemic tissues, thus promoting angiogenesis and regeneration of tissues, increasing the production of anti-oxidant enzymes and inducing the production of growth factors. In view of this, it is pertinent to state that no post-operative complication was observed in none of the surgical procedures performed during our study period.

Therefore, is it necessary to carry out further research to achieve a treatment protocol in order to confirm or not the successful use of ozone to reduce pain, oedema and trismus after a third molar extraction.

Based on the findings of the present study and in comparison, with the available literature, submucosal administration of ozone gas at a concentration of 50 mg/ml did not result in significant improvements in postoperative pain, mouth opening, or facial swelling. Therefore, alternative ozone delivery modalities, such as ozone gel, ozonized oil, or extraoral ozone application, may be preferable to the technique employed in the present study, given their potentially greater clinical efficacy.

Ethics Approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The study was approved by Research Ethics Committee of the São Paulo State University (UNESP) Institute of Science and Technology according to protocol number CAAE 79322424.4.0000.0077.

Conflict of Interest

All authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest or non-financial interest in the subject matter or materials discussed in this manuscript.

Author Contributions

FRLS – Conception, Design, Supervision; RSA – Data Collection and Processing, MBM – Analysis and Interpretation, Writing; FWR – Analysis and Interpretation; MMA – Critical Review; RDN – Critical Review.

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