Prospective, Randomized, Open-Label, Pilot Clinical Trial Comparing the Effects of Dexamethasone Coadministered with Diclofenac Potassium or Acetaminophen and Diclofenac Potassium Monotherapy After Third-Molar Extraction in Adults

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ABSTRACT

**Background:** Patients who experience pain, swelling, and trismus after third-molar extraction are reported to experience a 3-fold higher rate of adverse effects (AEs) on quality of life compared with those who are asymptomatic after this surgery. Therefore, investigators emphasize the necessity for better control of this triad of sequelae. Steroids can reduce the risk for physiologic processes of inflammation, thereby suppressing the development of inflammation.

**Objective:** The aim of this study was to compare the effects of dexamethasone 8 mg IM and diclofenac potassium (K) 50 mg PO, dexamethasone 8 mg IM and acetaminophen 1000 mg PO, and monotherapy with diclofenac K 50 mg PO on postoperative pain, swelling, and trismus after surgical removal of third molars.

**Methods:** This prospective, randomized, open-label pilot study was conducted at the Department of Oral and Maxillofacial Surgery, Lagos University Teaching Hospital, Lagos, Nigeria. Patients were randomly allocated to 1 of 3 treatment groups: concomitant treatment with dexamethasone 8 mg IM and diclofenac K 50 mg PO or acetaminophen 1000 mg PO, or monotherapy with diclofenac K 50 mg PO. Overall analgesic efficacy of the drug combinations was assessed for 7 days postoperatively using a 4-point categorical pain-intensity rating scale (0 = no pain; 1 = mild pain; 2 = moderate pain; and 3 = severe pain).

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Facial swelling was measured in 1 dimension on days 1, 2, and 7 after surgery using a tape measure placed from the tip of the tragus, to gnion, to the tip of the contralateral tragus, and trismus was assessed using interincisal mouth-opening ability, measured using a vernier-calibrated caliper on postoperative days 1, 2, and 7. Tolerability was assessed using direct questioning of the patients at follow-up visits.

**Results:** A total of 150 patients (50 per treatment group) were included in the analysis (76 women, 74 men; mean [SD] age, 26.8 [5.04] years [range, 18–45 years]; 100% Nigerian). The proportion of patients reporting no pain on the pain-intensity rating scale was significantly higher in the group receiving dexamethasone and diclofenac K compared with that in the groups receiving dexamethasone and acetaminophen or diclofenac K monotherapy (44% vs 22% and 24%, respectively; both, P < 0.05). Facial swelling was significantly less with dexamethasone and diclofenac K or dexamethasone and acetaminophen compared with diclofenac K alone (day 1: P = 0.013 and P = 0.011, respectively; day 2: P = 0.002 and P = 0.004, respectively). However, trismus relief was statistically similar between the 3 treatment groups on postoperative days 1 and 2. No AEs or complications were recorded.

**Conclusion:** In this open-label pilot study, concomitant treatment with dexamethasone and diclofenac K provided significant relief of postsurgical pain and swelling compared with dexamethasone and acetaminophen or monotherapy with diclofenac K after third-molar extraction in these patients. *(Curr Ther Res Clin Exp. 2006;67:229–240)* Copyright © 2006 Excerpta Medica, Inc.

**Key words:** dexamethasone, diclofenac potassium, acetaminophen, third-molar extraction.

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**INTRODUCTION**

Surgical removal of impacted third molars is a common outpatient procedure in oral surgery.¹ It has been documented that extraction of impacted teeth results in severe postoperative pain, swelling, and trismus in most cases.² Patients who experience these sequelae are reported to have a 3-fold higher rate of adverse effects (AEs) on quality of life compared with patients who do not.² Pharmacologically controlling the extent of the inflammatory process can decrease the intensity of this triad of sequelae of tissue trauma.³⁻⁵ Oral surgeons have traditionally prescribed corticosteroids, NSAIDs, and narcotic analgesics to manage these 3 sequelae.³

One technique for reducing the postoperative inflammatory process is the administration of corticosteroids,⁴ such as cortisol and the synthetic analogue of cortisol, which have been found to suppress the physiologic processes of local heat, redness, swelling, and tenderness that characterize inflammation.⁴ Although both short-term and single-dose corticosteroid treatment have been found effective in reducing postoperative inflammation,⁵,⁶ many clinicians are reluctant to use corticosteroids in conjunction with oral surgery because of
concerns about possible AEs, primarily infection and adrenal suppression, even though the latter has been found to occur only with long-term administration. The corticosteroid dexamethasone, one of the potent synthetic analogues of cortisol, has predominantly anti-inflammatory effects. Its main clinical application is as a steroidal anti-inflammatory agent, with effects on metabolism, water and electrolyte balance, negative feedback on the hypothalamus and pituitary, and anti-inflammatory and immunosuppressive effects.

Another technique is the administration of NSAIDs, which block the arachidonic acid cascade, thereby inhibiting the activity of the cyclooxygenase (COX) enzyme system, which, in turn, reduces the biosynthesis of the prostaglandins (e.g., PGF₂₅, PG₂) that play a major role in causing pain, inflammation, and fever. When NSAIDs are administered before surgery, their absorption and distribution can occur before the initiation of tissue trauma, the ensuing synthesis of prostaglandins, and the subsequent inflammatory response. NSAIDs have been found to be particularly effective in combating postoperative pain, including pain after oral surgery. Diclofenac potassium (K), a potent NSAID, has been shown to be useful in controlling pain after the removal of third molars. Like other NSAIDs, diclofenac inhibits COX activity by reducing the production of prostaglandins in tissue. However, diclofenac has been associated with gastric erosion and prolonged bleeding time. Thus, it is preferable to avoid prescribing diclofenac in patients with current or a history of peptic ulceration, and to discontinue treatment with the drug if gastrointestinal lesions develop.

Although the usual approach in studies of the analgesic effects of NSAIDs has been to compare the effects of ≥2 NSAIDs, based on a MEDLINE search (key terms: clinical trials, third molar, surgery, and adverse effects; years: 1982–2000), many studies have compared the efficacy of NSAIDs with that of acetaminophen. Analysis of the results showed no statistical differences between the active-treatment groups and NSAIDs and acetaminophen. Seymour et al found that single-dose ketoprofen (12.5 and 25 mg) and acetaminophen were effective in treating pain after third-molar extraction. Acetaminophen has analgesic and antipyretic effects similar to aspirin. However, it has only weak anti-inflammatory effects and is thought to have a generally poor ability to inhibit the activity of the COX enzyme system in the presence of high concentrations of peroxidases, as are found at sites of inflammation.

The addition of dexamethasone, a synthetic adrenocortical steroid, to a regimen containing diclofenac K or acetaminophen might have additive anti-inflammatory effects, thereby reducing the inflammatory exudates, with resultant further reduction in edema and pain, after third-molar extraction. However, data comparing the effects of dexamethasone coadministered with diclofenac K or acetaminophen and diclofenac K monotherapy are lacking, and this was the reason for our study.

This study assessed the effects of combination treatment with dexamethasone and diclofenac K or acetaminophen with those of diclofenac K alone on postoperative pain, swelling, and trismus after surgical removal of third molars.
PATIENTS AND METHODS
This prospective, randomized, open-label pilot study was conducted at the Department of Oral and Maxillofacial Surgery, Lagos University Teaching Hospital, Lagos, Nigeria. The study protocol was approved by the research and ethics committee of the hospital. The study was conducted in accordance with the principles of the Guideline for Good Clinical Practice and Declaration of Helsinki of the World Medical Association and its amendments.

Inclusion and Exclusion Criteria
Patients between 18 and 45 years of age presenting in 2003–2004 to the Oral and Maxillofacial Surgery Clinic at the Lagos University Teaching Hospital and scheduled for surgical removal of a unilateral or bilateral bone-impacted mandibular third molar under local anesthesia were included. Before the study, full medical history was obtained from all patients.

Patients with renal or hepatic disease; blood dyscrasia; history or presence of gastric ulcers; cardiovascular disease; known hypersensitivity, allergy, or history of idiosyncratic reaction, to any of the study medications; and/or who were pregnant or breastfeeding were excluded from the study. Patients who had received analgesics or anti-inflammatory drugs within 24 hours before surgery were also excluded from the study. Patients with pain and/or other inflammatory symptoms (e.g., swelling, hyperemia, decreased mouth-opening due to trismus) at the time of surgery were excluded.

The study protocol was explained to the patients in detail, after which written, informed consent was obtained.

Study Drug Administration
Patients were randomly allocated to 1 of 3 treatment groups, as follows. Color codes were placed in sealed envelopes. The color code selected by the patient represented the treatment group into which he or she was allocated. Interpretation of the color codes was disclosed only to the surgeon on completion of the study. This method of randomization has not been validated. One group was assigned to receive concomitant treatment with dexamethasone 8 mg IM and diclofenac K 50 mg PO. Another group of patients was concomitantly administered dexamethasone 8 mg PO and acetaminophen 1000 mg PO, and a third group comprised patients administered diclofenac K 50 mg PO. Dexamethasone was administered 30 minutes before and 6 and 12 hours after surgery. Diclofenac K was administered 30 minutes before and BID for 5 days after surgery. Acetaminophen was administered 30 minutes before and TID for 5 days after surgery. During the hospital stay, all study medications were administered by a nurse. Compliance was assessed using a pill count for medications administered after hospital discharge.

Patients were instructed to request additional analgesia in the event of an aggravated pain episode during the study. The use of additional analgesia was considered a withdrawal criterion a priori, and these patients were excluded from the data analysis.
Surgical Procedures

The degree of surgical difficulty was assessed using Winter's and Terence Ward lines and Pell-Gregory criteria. Oral antibiotics (500 mg ampicillin/cloxacillin and 400 mg metronidazole) were administered to all patients 30 minutes before surgery. After surgery, patients received a 5-day antibiotic regimen (500-mg ampicillin/cloxacillin every 6 hours and 400 mg metronidazole every 8 hours).

After adequate elevation and reflection of the buccal mucoperiosteal flap with the patient under local anesthesia (2% lignocaine hydrochloride with adrenaline 1:100,000), surgical extraction of the third molar was carried out using the buccal guttering technique. Tooth removal was followed by meticulous irrigation of the surgical area with isotonic saline (0.9%). The 3-sided mucoperiosteal flap was repositioned and sutured. A single surgeon (B.O.B.) performed all of the surgical procedures.

Efficacy Assessments

Pain Intensity

Preoperative pain intensity was assessed using a 4-point Likert-type categorical rating scale (0 = no pain [no discomfort]; 1 = mild [almost unnoticeable]; 2 = moderate [noticeable, but patient can still engage in activities of daily living (ADLs)]; and 3 = severe [very noticeable and disrupts ADLs]). Pain intensity was recorded in a pain-assessment diary by the surgeon once daily during the first 2 days after surgery, and by the patient once daily for the remaining 5 days of observation. Before patients were discharged, the surgeon ensured they were thoroughly instructed on how to complete the pain self-assessment diary and when and how to self-administer medications.

Facial Swelling

Assessment of facial swelling resulting from surgical procedures has proved problematic because swelling involves a 3-dimensional volumetric change at the tissue and cellular levels. Several methods are used to assess facial swelling. These include photographic analysis, modified face bowl, linear measurements, and subjective assessment. No technique has been proven more accurate than others in analyzing facial swelling. We used a tape measure (Superior tailoring rule, Butterfly, Shanghai, China) to assess facial swelling in 1 dimension: from the tip of tragus of the left ear, to the gonion, to the tip of tragus of the right ear. The mean of 3 measurements was used. The same tape measure was used in all patients. Facial width was measured just before surgery (baseline) and on postoperative days 1, 2, and 7, and facial swelling was expressed as the percentage increase from baseline in facial width.

Trismus

A vernier-calibrated sliding caliper placed on the incisal edge of the maxillary and mandibular central incisors was used to record maximum interincisal
mouth-opening. The mean of 3 measurements was used. Mouth-opening was assessed just before surgery and on days 1, 2, and 7 after surgery. Postoperative trismus was expressed as the percentage decrease from baseline in mouth-opening.

**Tolerability**
Patients were specifically questioned about AEs by the surgeon at follow-up appointments. Follow-up appointments were scheduled for once daily in the morning on postoperative days 1 to 5.

**Statistical Analysis**
The required sample size (50 patients per group) to determine significant between-group differences in mean postoperative pain-intensity score, facial swelling, and maximum interincisal mouth-opening was calculated using a previously validated formula. Descriptive statistics, 1-way analysis of variance, the t test, and the \( \chi^2 \) test were used to compare facial swelling, pain intensity, and mouth-opening. Data were analyzed using SPSS version 11.5 (SPSS Inc., Chicago, Illinois). Statistical significance was set at \( P < 0.05 \).

**RESULTS**

**Study Population**
A total of 155 patients were originally recruited. Alveolar osteitis developed in 3 patients (2 women, 1 man) 2 days after surgery, and severe pain requiring use of additional analgesics developed in 2 patients (acetaminophen group) on postoperative day 1; these patients were excluded from the final analysis. Thus, 150 patients were included in the data analysis (76 women, 74 men; mean [SD] age, 26.8 [5.04] years [range, 18–45 years]; 100% Nigerians; 50 patients per group). The male-to-female ratio was 1:1.02. The radiographic analysis of the types of impactions showed that mesioangular impaction constituted 79 (52.7%) cases, followed by distoangular impaction in 30 (20.0%) (Table I). The mean total operation time was 39.4 minutes, while the mean bone operating time was 17.10 minutes. No statistically significant differences were observed in the mean total operation time between the 3 groups.

**Efficacy**

**Pain Intensity**
The proportion of patients reporting no pain on postoperative day 1 was significantly greater in the group receiving concomitant treatment with dexamethasone and diclofenac K compared with those receiving dexamethasone and acetaminophen or diclofenac K monotherapy (both, \( P < 0.05 \)) (Table II). Rates of mild to moderate and severe pain were statistically similar between the 3 treatment groups. By the third day after surgical extraction, no detectable differences in pain intensity were observed between the 3 groups.
Table I. Baseline characteristics of the study patients.*†

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Dexamethasone and Diclofenac K (n = 50)</th>
<th>Dexamethasone and Acetaminophen (n = 50)</th>
<th>Diclofenac K (n = 50)</th>
<th>All Patients (N = 150)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>25.6 (4.8)</td>
<td>27.6 (5.3)</td>
<td>27.2 (5.1)</td>
<td>26.8 (5.04)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>17–46</td>
<td>16–47</td>
<td>19–44</td>
<td>18–45</td>
</tr>
<tr>
<td>Range</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex, no. (%)</td>
<td>25 (56)</td>
<td>28 (56)</td>
<td>24 (48)</td>
<td>74 (49)</td>
</tr>
<tr>
<td>Male</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>22 (44)</td>
<td>22 (44)</td>
<td>26 (52)</td>
<td>76 (51)</td>
</tr>
<tr>
<td>Nigerian race, no. (%)</td>
<td>50 (100)</td>
<td>50 (100)</td>
<td>50 (100)</td>
<td>150 (100)</td>
</tr>
<tr>
<td>Impaction type, no. (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mesioangular</td>
<td>28 (56)</td>
<td>25 (50)</td>
<td>26 (52)</td>
<td>79 (53)</td>
</tr>
<tr>
<td>Distoangular</td>
<td>12 (24)</td>
<td>10 (20)</td>
<td>8 (16)</td>
<td>30 (20)</td>
</tr>
<tr>
<td>Horizontal</td>
<td>6 (12)</td>
<td>7 (14)</td>
<td>10 (20)</td>
<td>23 (15)</td>
</tr>
<tr>
<td>Vertical</td>
<td>4 (8)</td>
<td>8 (16)</td>
<td>6 (12)</td>
<td>18 (12)</td>
</tr>
<tr>
<td>Duration of surgery, mean (SD), min</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bone</td>
<td>20.78 (9.69)</td>
<td>13.08 (7.53)</td>
<td>17.44 (10.69)</td>
<td>17.10 (9.86)</td>
</tr>
<tr>
<td>Total</td>
<td>41.30 (12.65)</td>
<td>38.48 (13.44)</td>
<td>38.26 (14.71)</td>
<td>39.35 (13.61)</td>
</tr>
</tbody>
</table>

K = potassium.
*No significant between-group differences were found.
†Although some patients underwent extraction of >1 tooth, only 1 tooth per patient was included in the analysis.

Facial Swelling and Trismus

Table II also shows data concerning facial swelling and maximal mouth-opening on postoperative days 1 and 2. Patients administered dexamethasone and diclofenac K or acetaminophen had significantly less postoperative facial swelling compared with the group receiving diclofenac K monotherapy (day 1: \( P = 0.013 \) and \( P = 0.011 \), respectively; day 2: \( P = 0.002 \) and \( P = 0.004 \), respectively), suggesting that dexamethasone was associated with a significant reduction in facial swelling. No statistically significant differences in trismus were found between the 3 groups on postoperative days 1 and 2. By day 7 after surgical extraction, no detectable differences in facial swelling or trismus were observed between the 3 groups.

Tolerability

No AEs or complications were recorded. Postoperative healing proceeded normally in all patients, and no increased tendency for intraoperative or postoperative bleeding was recorded.
Table II. Pain intensity, facial swelling, and mouth-opening ability at postsurgical days 1 and 2.*

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Dexamethasone and Diclofenac K (n = 50)</th>
<th>Dexamethasone and Acetaminophen (n = 50)</th>
<th>Diclofenac K (n = 50)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day-1 pain intensity, no. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>22 (44)†</td>
<td>11 (22)</td>
<td>12 (24)</td>
</tr>
<tr>
<td>Mild</td>
<td>25 (50)</td>
<td>32 (64)</td>
<td>23 (46)</td>
</tr>
<tr>
<td>Moderate</td>
<td>3 (6)</td>
<td>7 (14)</td>
<td>11 (22)</td>
</tr>
<tr>
<td>Severe</td>
<td>0</td>
<td>0</td>
<td>4 (8)</td>
</tr>
<tr>
<td>Facial swelling, mean (SD), %</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day 1</td>
<td>30.9 (1.6)§</td>
<td>30.9 (1.5)§</td>
<td>31.7 (1.6)</td>
</tr>
<tr>
<td>Day 2</td>
<td>31.0 (1.6)¶</td>
<td>31.2 (1.5)¶</td>
<td>32.0 (1.5)</td>
</tr>
<tr>
<td>Mouth-opening, mean (SD), %</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day 1</td>
<td>36.0 (11.2)</td>
<td>38.8 (12.6)</td>
<td>39.2 (11.3)</td>
</tr>
<tr>
<td>Day 2</td>
<td>38.1 (10.1)</td>
<td>38.1 (10.8)</td>
<td>36.0 (10.0)</td>
</tr>
</tbody>
</table>

K = potassium.

*P values were calculated using the 2-tailed t test.
†P < 0.05 versus dexamethasone and acetaminophen and diclofenac K.
‡P = 0.013 versus diclofenac K.
§P = 0.011 versus diclofenac K.
¶P = 0.002 versus diclofenac K.
‖P = 0.004 versus diclofenac K.

**DISCUSSION**

In this study, the impact of drug combinations on pain, facial swelling, and trismus were assessed. By pharmacologically controlling the extent of the inflammatory process, the intensity of postoperative sequelae, such as pain, swelling, and trismus, may be reduced.4,5 Regardless of drug combination, the pattern of postoperative pain has been reported to increase from postoperative days 1 to 3 and reduce gradually thereafter.22-27 Our findings support this observation. Based on the literature search, many studies have compared the efficacy of NSAIIDs and acetaminophen in controlling pain after oral surgery,6,7,11-15 but none have compared the combination of dexamethasone and diclofenac K or acetaminophen. In the present study, dexamethasone was associated with augmentation of the analgesic potency of diclofenac K, suggesting that additional clinical benefit might be offered by adding dexamethasone to a regimen containing acetaminophen or diclofenac K in the control of pain after third-molar extraction.2,6,16,23,27,28

Schultze-Mosgau et al,28 in a prospective, randomized, controlled trial in 40 (33 females, 7 males) patients (age range, 13-26 years) scheduled for third-
molar extraction, found that a combination of ibuprofen and methylprednisolone had good analgesic and anti-inflammatory action. The course of the swelling was assessed ultrasonically using a digital linear scanner, and pain was assessed using a visual analog scale. Results from randomized, controlled trials in adult patients undergoing oral surgery suggest that single-dose administration of a glucocorticoid (methylprednisolone) reduces tissue levels of bradykinin and suppresses circulating levels of cortisol and β-endorphin.28 Bradykinin and kallidin are the 2 kinins that act independently and synergistically with products of arachidonic acid cascade to produce pain and increase vascular permeability.29 Combination treatment with dexamethasone and NSAIDs has been found to have a positive effect on the arachidonic-acid cascade in the control of pain.9,28,29

The 4-point rating scale for pain intensity was used in this study because it is generally easily understood by patients. This method has been reported to be simple to administer, reliable, and valid.6,21

Postsurgical facial edema is difficult to quantify accurately because it requires 3 planes of measurement. Facial swelling is often irregular and can manifest internally or externally. Over the years, numerous researchers have tried various techniques to objectively measure edema.14,16,22,28,29 Most are indirect assessments of the altered contours of the skin surface. Measurement tools mentioned in the literature include visual analog scales, trismus recordings, standardized stereo radiographic or photographic measurements, computed tomography, modified face bow devices, ultrasonography, and facial plethysmographs.14,16,22,28,29 In the present study, a single measurement from the tip of the tragus to gonion to the tip of the contralateral tragus was taken. Cheek swelling after third-molar extraction was diffuse in different planes and difficult to measure accurately. The concomitant administration of dexamethasone and diclofenac K was associated with a significant reduction compared with diclofenac K monotherapy in postoperative facial swelling, suggesting that the efficacy of diclofenac K in the control of postoperative facial swelling is augmented by the addition of dexamethasone. Based on results from previous studies, the reduction, compared with diclofenac K monotherapy, in postoperative facial swelling in patients receiving concomitant therapy with dexamethasone and diclofenac K or acetaminophen was likely due to the anti-inflammatory effect of dexamethasone.27,30–34

In the present study, the independent (t test) analysis did not find any statistically significant differences in trismus between the 3 treatment groups. Although this finding was contrary to previous reports in the literature,22,25,28,34 we observed a positive clinical association between dexamethasone and postoperative recovery of mouth-opening in third-molar extraction.

**Study Limitations**

There are no validated methods for the measurement of facial swelling. The technique adopted for measurement of facial swelling in this study has some
limitations. Facial swelling was measured in 1 dimension only, whereas it should be measured in 3 dimensions. Pain measurement is subjective and depends on the perception and pain threshold of the patient. The randomization method we used has not been validated. In addition, analysis of a third group comparing the effects of concomitant treatment with dexamethasone and acetaminophen with those of monotherapy with acetaminophen would have been beneficial. The objective of the present study was to measure the analgesic efficacy within the stated dosing regimens. We considered that additional analgesics would disrupt the homogeneity of the outcome measures because only 2 of 155 patients required additional analgesics. Excluding 2 patients who required additional analgesia did not seem to bias the results.

CONCLUSIONS
In this small pilot study in patients undergoing third-molar extraction, concomitant administration of dexamethasone and diclofenac K was associated with better control of short-term postoperative pain and edema compared with monotherapy with diclofenac K. The results seem to suggest that the addition of dexamethasone to regimens containing diclofenac K or acetaminophen enhances the analgesic and anti-inflammatory effects of these 2 drugs.

ACKNOWLEDGMENTS
This article is dedicated to the memory of the late Dr. J.O. Osuntola, formerly a fellow of the International College of Oral and Maxillofacial Surgeons. His contributions to the development and growth of the field of oral and maxillofacial surgery in Nigeria are memorable.

REFERENCES

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