EFFECT OF MOBILE PHONE USE WITH AND WITHOUT EARPHONES ON SALIVARY NICKEL ION RELEASE FROM FIXED ORTHODONTIC APPLIANCES – A CROSS OVER TRIAL

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BRANCH – V

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THE TAMILNADU DR. M.G.R MEDICAL UNIVERSITY

CHENNAI – 600 032

2015 – 2018

CERTIFICATE

This is to certify that **DR.AJMA AISHA ALI**, Post Graduate student **(2015 – 2018)** in the Department of Orthodontics and Dentofacial Orthopaedics, Branch V, Tamil Nadu Government Dental College and Hospital, Chennai – 600 003, has done this dissertation titled **"EFFECT OF MOBILE PHONE USE WITH AND WITHOUT EARPHONES ON SALIVARY NICKEL ION RELEASE FROM FIXED ORTHODONTIC APPLIANCES – A CROSS OVER TRIAL"** under my direct guidance and supervision for the partial fulfillment of the M.D.S degree examination in May 2018 as per the regulations laid down by The Tamil Nadu Dr. M.G.R. Medical University, Chennai -600 032 for **M.D.S., Orthodontics and Dentofacial Orthopaedics (Branch – V)** degree examination.

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<u>DECLARATION</u>

I, **Dr.Ajma Aisha Ali**, do hereby declare that the dissertation titled **“Effect Of Mobile Phone Use With And Without Earphones On Salivary Nickel Ion Release From Fixed Orthodontic Appliances – A Cross Over Trial”** was done in the Department of Orthodontics and Dentofacial Orthopaedics, Tamil Nadu Government Dental College & Hospital, Chennai 600 003. I have utilized the facilities provided in the Government Dental College for the study in partial fulfillment of the requirements for the degree of Master of Dental Surgery in the specialty of Orthodontics and Dentofacial Orthopaedics (Branch V) during the course period **2015-2018** under the conceptualization and guidance of my dissertation guide **Professor Dr. B. BALASHANMUGAM, M.D.S.**

I declare that no part of the dissertation will be utilized for gaining financial assistance for research or other promotions without obtaining prior permission from The Tamil Nadu Government Dental College & Hospital.

I also declare that no part of this work will be published either in the print or electronic media except with those who have been actively involved in this dissertation work and I firmly affirm that the right to preserve or publish this work rests solely with the prior permission of the Principal, Tamil Nadu Government Dental College & Hospital, Chennai 600 003, but with the vested right that I shall be cited as the author(s).

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I express my gratitude to my friends and colleagues for their valuable help and suggestions throughout this study.

TRIPARTITE AGREEMENT

This agreement herein after the "Agreement" is entered into on this day............... January 2018 between the Tamil Nadu Government Dental College and Hospital represented by its Principal having address at Tamil Nadu Government Dental College and Hospital, Chennai-03, (hereafter referred to as the 'college')

Dr. AJMA AISHA ALI aged 31 years currently studying **M.D.S (Orthodontics)** in Tamil Nadu Government Dental College and Hospital (hereinafter referred to as the 'PG/Research student and Principal investigator')

And

Dr. B. BALASHANMUGAM, M.D.S., aged 46 years working as Professor in the Department of Orthodontics and Dentofacial Orthopaedics, at the college, having residence address at 8-B, Crescent Road, Shenoy Nagar, Chennai - 600030, Tamil Nadu (hereinafter referred to as the 'Co - investigator')

And

Whereas the 'PG/Research student as part of her curriculum undertakes to research on **"EFFECT OF MOBILE PHONE USE WITH AND WITHOUT EARPHONES ON SALIVARY NICKEL ION RELEASE FROM FIXED ORTHODONTIC APPLIANCES – A CROSS OVER TRIAL"** for which purpose the Co – investigator and the college shall provide the requisite infrastructure based on availability and also provide facility to the PG student as to the extent possible as a Principal Investigator.

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7. The Co investigator shall suitably guide the student research right from selection of the research topic and area till its completion. However, the selection and conduct of research topic and area of research by the student researcher under guidance from the Co investigator shall be subject to the prior approval, recommendations and comments of the Ethical Committee of the college constituted for this purpose.

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10. In witness whereof, the parties herein above mentioned have on this the day month and year herein above mentioned set their hands to this agreement in the presence of the following two witnesses.

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Principal **PG Student**

Witnesses **Student Guide**

1.

2.

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CERTIFICATE – II

This is to certify that this dissertation work titled **"EFFECT OF MOBILE PHONE USE WITH AND WITHOUT EARPHONES ON SALIVARY NICKEL ION RELEASE FROM FIXED ORTHODONTIC APPLIANCES – A CROSS OVER TRIAL"** of the candidate **Dr. AJMA AISHA ALI** with Registration Number **______________** for the award of **MASTER OF DENTAL SURGERY** in the branch of **ORTHODONTICS (BRANCH V)**. I personally verified the urkund.com website for the purpose of plagiarism check. I found that the uploaded thesis file contains from introduction to conclusion pages and result shows **06 (Six only)** percentage of plagiarism in the dissertation.

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LIST OF ABBREVIATIONS

WHO	WORLD HEALTH ORGANISATION
Ni	NICKEL
Cr	CHROMIUM
Ti	TITANIUM
SS	STAINLESS STEEL
DNA	DEOXYRIBONUCLEIC ACID
SGOT	SERUM GLUTAMIC OXALOACETIC TRANSAMINASE
SGPT	SERUM GLUTAMIC PYRUVIC TRANSAMINASE
Mn	MANGANESE
Cu	COPPER
Fe	IRON
He	HELIUM
Ne	NEON
NaF	SODIUM FLUORIDE
MBT	MCLAUGHLIN BENNETT TREVISI
HANT	HEAT ACTIVATED NICKEL TITANIUM
ICP-OES	INDUCTIVELY COUPLED PLASMA OPTICAL EMISSION SPECTROMERY
ICP-AES	INDUCTIVELY COUPLED PLASMA ATOMIC EMISSION SPECTROMERY
ICP-MS	INDUCTIVELY COUPLED PLASMA MASS SPECTROMERY
GCF	GINGIVAL CREVICULAR FLUID

EMR	ELECTROMAGNETIC RADIATION
RF	RADIOFREQUENCY
GSM	GLOBAL SYSTEM FOR MOBILE
AMPS	ADVANCED MOBILE PHONE SERVICE
SAR	SPECIFIC ABSORPTION RATE
HFK	HANDS FREE KIT
ICNIRP	INTERNATIONAL COMMISSION ON NON IONIZING RADIATION PROTECTION
RFER	RADIOFREQUENCY ELECTROMAGNETIC RADIATION

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Introduction

INTRODUCTION

Mobile phone is considered as one of the greatest inventions of the 20th century. Ever since the first mobile phones appeared in the market in the 1980s, their growth has been exponential. From 1990 to 2011, the worldwide mobile phone subscription has grown over 5.6 billion with a global penetration of about 70% [1] reaching even the bottom of the economic pyramid. Today, cell phones have become an easy to use, affordable and comfortable gadget.

Due to the enormous increase in their usage throughout the world, the effect of cell phone radiation on human health has been an area of recent interest. Mobile phones emit electromagnetic radiation in the microwave range which may be harmful to human health.[2] In 2011, the WHO stated that mobile phone use may possibly represent a long-term health risk[3] and classified it in category 2B of the "possibly carcinogenic" substances.[4,5]

The demand for orthodontic treatment has been rising with the improvement in the health expectations of the people. The number of children, adolescents and adults seeking orthodontic therapy has increased considerably in the last 20 years [5], probably due to its significant impact on the psychosocial aspect of the patients' life, increased dental awareness and better acceptance of fixed orthodontic appliances.[6]

A typical fixed orthodontic appliance system includes brackets, bands, arch wires and other auxiliaries made of stainless steel alloy which contains approximately 8-12 % Ni and nickel titanium alloy with Ni content over 50%.

Various factors such as salivary conditions, temperature, pH variations, mechanical loads, microbiological and enzymatic activity, physical and chemical properties of food and oral health conditions provide an environment for the corrosion of orthodontic appliances [7,8] and may lead to the release of metal ions such as Ni [9] and Cr [10,11] into the saliva.

Ni complexes, especially in the form of arsenides and sulphides have been found to be carcinogenic, allergenic and mutating substances even at nontoxic concentrations.[12] Ni is also a common metal that can cause allergic contact dermatitis more than any other metal.[11]

Researches in both human and animal studies have confirmed that mobile phones cause significant increases in salivary oxidative stress, salivary flow, total proteins and albumin and a decrease in amylase activity.[13,14] A positive dose dependent response trend between parotid gland tumour and mobile phone usage has also been found.[15]

It has been reported that mobile phone usage has a time-dependent influence on the concentration of nickel in the saliva of patients with orthodontic appliances.[16]

Based on the proximity of mobile phones to the oral cavity, during the conversation period and the presence of the metallic orthodontic appliances in the mouth, there might be a serious risk of exposure of these appliances to the radiofrequency electromagnetic radiations emitted by the mobile phones, leading to the release of toxic corrosion products into the saliva.[16]

The Swiss Federation of Public Health has reported that there is an 8-22 times reduction in the mobile phone radiation to the head when used with earphones.[17]

No previous study has so far evaluated the possible efficacy of earphones in reducing the release of nickel ions from fixed orthodontic appliances when exposed to radiofrequency electromagnetic fields emitted by mobile phones.

The aim of this study was hence to evaluate the effect of mobile phone use with and without earphones on salivary nickel ion release from fixed orthodontic appliances.

Aims and Objectives

AIMS AND OBJECTIVES

AIM OF THE STUDY

To evaluate the effect of exposure to radiofrequency electromagnetic fields emitted by mobile phones when used with and without earphones on the level of nickel in saliva.

OBJECTIVES

1. To evaluate the effect of exposure to radiofrequency electromagnetic fields emitted by mobile phones on the level of nickel in saliva.

2. To evaluate the effect of exposure to mobile phone radiation when used with earphones on the level of nickel in saliva.

3. To evaluate the efficacy of earphones in reducing the release of nickel ions from fixed orthodontic appliances when exposed to radiofrequency electromagnetic fields emitted by mobile phones.

4. To evaluate the effect of different times of exposure to the radiofrequency electromagnetic radiation on the concentration of nickel in saliva.

Review of Literature

REVIEW OF LITERATURE

STUDIES ON THE HARMFUL EFFECTS OF NICKEL

Peltonen L [18] in 1979 studied the incidence of nickel sensitivity in population above the age of 10 through epicutaneous tests with 5% nickel. Nickel sensitivity was observed in 4.5% of the subjects (44 cases of 980 tested subjects), 8% of the female subjects and 0.8% of the male subjects.

Emmett EA et al [19] in 1988 studied twelve subjects sensitive to nickel who underwent patch testing with serial dilutions of nickel sulfate in petrolatum and in water. They found that the provocation threshold varied from 5.2 mg (2.5%) to 0.47 microgram (0.01%) when tested in petrolatum. The provocation threshold was higher with aqueous solutions. The lowest provocation threshold in a statistically significant number of individuals was 1.5 micrograms. Also nickel bioavailability from dermatitis-inducing earrings and a necklace was determined by immersing them in plasma, normal saline solution, and synthetic sweat at different pH values over 7 days. Nickel leaching under these conditions exceeded the provocation threshold 1.4- to 93-fold depending on the object and solution. The study showed that plasma was the most effective solution for removing available nickel from earrings, a possible explanation for the frequent induction of sensitization by ear piercing.

van Loon et al [20] in 1988 in an in vivo study compared the contact allergic stomatitis-inducing capacity of nickel, nickel-containing dental alloys and a non-corrosive precious metal. Fifteen patients with a positive allergic skin reaction to nickel were divided into 3 groups viz Group A patients were fitted with an intraoral corrosion-resistant nickel-chromium Alloy A; Group B patients received a more corrosion prone nickel-chromium Alloy B and Group C patients with strongly corroding pure nickel. A corrosion resistant pure palladium foil was placed on the contralateral side. On immunohistological examination of the oral mucosa, the results showed that only at the pure nickel site the number of Langerhans cells and helper/inducer T-lymphocytes increased significantly in the connective tissue of the oral mucosa. The authors concluded that neither clinically nor immunohistologically is the presence of high percentages of nickel in the nickel-containing dental alloys necessarily associated with allergic contact stomatitis in nickel-allergic patients.

Denkhaus E. and Salnikow K. [21] **in 2002** reported that although nickel allergy in the form of contact dermatitis is the most common and well-known reaction, it can lead to lung fibrosis, cardiovascular and kidney diseases and cancers especially lung and nasal cancers.

Grimsrud et al [22] **in 2002** examined dose-related associations between lung cancer and cumulative exposure to four forms of nickel: water-soluble, sulfidic, oxidic and metallic. The authors found that nickel exposures were moderately to highly correlated. A clear dose-related effect was seen for water-soluble nickel. A general rise in risk from other types of nickel could not be excluded, but no further dose dependent increase was seen. The study suggested an important role of water-soluble nickel species in nickel-related cancer.

Counts AL et al [23] **in 2002** presented a case report in which nickel sensitivity of the oral mucosa was demonstrated during the use of a transpalatal arch appliance in 11-year old patient who presented for orthodontic treatment. 8 months into treatment, the gingiva of the right posterior segment began to hypertrophy, particularly around the bands of the right first molar and premolar. A patch test of 5% nickel sulfate indicated a positive reaction to nickel. The treatment was finished without the use of nickel titanium wires and the mucosa reaction resolved. The authors concluded that while nickel sensitivity may not present an extreme medical risk, the orthodontist must be aware of the problem and the likelihood of treating patients with this condition and that the reaction may vary from patient to patient.

Ramadan AA [10] in 2004 studied the influence of chromium and nickel concentrations in saliva and their effects on gingival tissues during orthodontic treatment. The results showed that after 3 months, 20% of females and 10% of males in this study showed allergic reaction in the form of gingivitis. This reaction disappeared 1 month after appliance removal.

Eliades T et al [24] in 2004 characterized the substances released from orthodontic brackets and nickel-titanium wires and assessed the cytotoxicity of the ions released from these orthodontic alloys. Two full sets of stainless steel brackets and 2 groups NiTi arch wires were immersed in 0.9% saline solution for a month and the ionic content was analysed with inductively coupled plasma-atomic emission spectroscopy. Human periodontal ligament fibroblasts and gingival fibroblasts were exposed to various concentrations of the two immersion media. The results indicated no ionic release for the nickel-titanium alloy aging solution, whereas measurable nickel and traces of chromium were found in the SS bracket-aging medium. Neither orthodontic materials-derived media had any effect on the survival and DNA synthesis of either cells.

Kerusuo and Dahl [25] in 2007 assessed adverse patient reactions during orthodontic treatment with nickel-containing appliances via questionnaires mailed to orthodontists. They were asked to assess the number of patients with adverse reactions retrospectively. They were also asked to describe the reactions, the appliances used, and any implications on treatment. The authors found that at least one adverse patient reaction during treatment was reported by forty-six percent of the orthodontists with almost half of the reactions having treatment implications.

Das et al [26] in 2008 discussed on the haematotoxic, immunotoxic, neurotoxic, genotoxic, reproductive toxic, pulmonary toxic, nephrotoxic, hepatotoxic effects and carcinogenicity of nickel. The authors reported that nickel exposure lead to modifications of DNA bases, enhancement of lipid peroxidation, alteration of calcium and sulfhydryl homeostasis by free radical formation in various human and animal tissues and that the primary route for nickel toxicity is depletion of glutathione and bonding to sulfhydryl groups of proteins.

Noble J et al [27] in 2008 described two cases where nickel allergy was discovered in orthodontic patients. The first patient, a 31-year-old female, reported with swollen, numb lips three days following the insertion of a NiTi arch wire. The patient reported resolution of symptoms within five hours of removal of the NiTi arch wire. Further investigation indicated that while contact with the nickel-containing alloy initiated the patient's symptoms, the nickel was not leached out under laboratory test conditions. The second case was of a 15-year-old female with oropharyngeal itching, sandpaper-like roughness, bumps, burning and strong discomfort which had persisted for six months. Once the NiTi arch wires were replaced with stainless steel the symptoms resolved within two weeks.

Natarajan M et al [28] in 2011 evaluated the genotoxic damage in the oral mucosal cells of 20 patients wearing fixed appliance and the nickel and chromium ion contents in these cells. Oral mucosal smears were studied at debonding and 30 days after debonding. Their results showed that the mean micronuclei frequency was significantly higher in the treated group than in the control group at debonding; the difference was smaller and not statistically significant 30 days after debonding. No correlation could be established between micronuclei frequency and metal ion content. This study concluded that orthodontic appliances release metal ions in quantities sufficient to induce localized genotoxic effects, but these changes revert on appliance removal.

Hafez et al [29] in 2011 tested the biocompatibility (cytotoxic and genotoxic effects on human tissues) of fixed orthodontic appliances in 28 treated subjects. Four combinations of brackets and arch wires were tested viz group 1 (stainless steel brackets and stainless steel wires), group 2 (stainless steel brackets and nickel-titanium wires), group 3 (titanium brackets and stainless steel wires), group 4 (titanium brackets and nickel-titanium wires). Buccal mucosa cell samples were collected before treatment and 3 and 6 months after appliance placement. The cells were then processed for cytotoxicity, genotoxicity, and nickel and chromium contents. The study revealed that there was a reduction in cellular viability, an induction of DNA damage and an increase in the nickel and chromium contents of the buccal mucosa cells with the use of fixed orthodontic appliances. Compared to the control group, these changes were not evident at 6 months, possibly indicating tolerance for or repair of the cells and the DNA.

Pillai AR et al [30] in 2013 determined the cytotoxic effects of the nickel released from the stainless steel brackets on gingival fibroblast using MTT and comet assay. This study concluded that nickel solution at minimal concentration of 1.18 μg could damage human gingival fibroblast and the nickel released from the different brands of the brackets are not uniform.

Satija A et al [31] in 2014 evaluated the Ni and Cr ion concentrations in salivary and serum samples from patients treated with fixed orthodontic appliances and their possible effects on liver enzymes. While significant increase occurred in the Ni and Cr ion concentrations in the serum at 4 weeks, the ions reached their highest levels in saliva at 1 week. Mean liver function enzymes SGOT and SGPT were also significantly increased at 4 weeks.

Zdrojewicz Z et al [32] in 2016 reported that the harmful effects of nickel include genotoxicity, haematotoxicity, teratogenicity, immunotoxicity and carcinogenicity. The study reported that the population of people allergic to nickel is growing, and that it occurs more often in women.

STUDIES ON NICKEL RELEASE FROM ORTHODONTIC APPLIANCES

Park and Shearer [33] in 1983 studied the release of nickel and chromium ions from ten simulated orthodontic appliances. The appliances were each placed in separate solutions of 100 ml. 0.05 % sodium chloride at 37^{o}C. On days 3, 6, 9, and 12, a 4ml sample of the solution in each bottle was removed for subsequent nickel and chromium analyses and an equivalent amount of fresh 0.05 % sodium chloride was added back to each bottle. At the end of the 12-day experiment, the rust-coloured precipitates in the experimental sample bottles were collected and levels of nickel and chromium were analysed by atomic absorption spectrophotometry. The results showed a total cumulative release of soluble nickel of 121ug and chromium of 40ug. The study indicated that nickel was released primarily as a soluble compound, while chromium was released primarily in an insoluble form.

Gursoy, Acar, Sesen [34] in 2005 measured the amounts of metal released from simulated fixed orthodontic appliances. Sixty simulated fixed orthodontic appliances manufactured in different ways were divided into four groups: new brackets and new arch wires (group 1 controls), new brackets and recycled arch wires (group 2), recycled brackets and new arch wires (group 3) and recycled brackets and recycled arch wires (group 4). The appliances were soaked in artificial saliva of pH 7 at 37°C for 45 days and artificial saliva sample was then collected for analysis. Concentrations of Ni, Cr, Fe, Mn, Cu, and Ti ions were measured by atomic absorption spectrometry. The study revealed that group 4 released higher amounts of Cr, Fe, and Ti than any of the other three combinations; Ni release was similar in groups 1 and 2 and in groups 2, 3, and 4; the amounts of Cu, Cr, and Ti ions released from groups 3 and 4 were significantly greater than the amounts released from the other two combinations.

Amini et al [35] in 2008 compared the concentration of nickel, chromium and cobalt in oral mucosa cells of 60 patients with and without fixed orthodontic appliances using atomic absorption spectrophotometry. No significant differences in chromium and cobalt content of oral mucosa cells were found between the test and control samples. The nickel content in mucosa samples was however significantly higher in orthodontic patients compared with the controls. The mean levels of nickel in control and orthodontic patient group were 12.26 and 21.74 ng/ml respectively.

Souza and Menezes [36] in 2008 evaluated the in vivo release of nickel, chromium and iron ions into saliva of 30 volunteers wearing removable appliances bonded with 3 different brands of metallic brackets viz 3M/Unitek, American Orthodontics and Dentaurum. The appliances were worn for 60 days, and saliva samples were collected at the following time points: T1, before placement of the appliance; T2, after 10 minutes; T3, 24 hours; T4, 7 days; T5, 30 days; and T6, 60 days after insertion of the removable appliance. Saliva samples were analysed for nickel, chromium and iron by atomic absorption spectrophotometry. The results indicated an increase in nickel and chromium ions immediately after placement of the appliance (T2), but this was statistically significant only for groups B and C. There was no increase in iron levels. There were no significant differences in the nickel, chromium and iron levels released by the three groups of appliances at all study periods.

Kuhta et al [37] in 2009 examined the effects of three different parameters pH value, type of arch wire, and length of immersion on release of metal ions from orthodontic appliances. Simulated fixed orthodontic appliances with three types of arch wires viz; stainless steel, nickel titanium and thermo NiTi were immersed in artificial saliva of different pH values (6.75, 0.15 and 3.5 0.15) during a 28-day period. The quantity of metal ions was determined with the use of a high-resolution mass spectrophotometer. The results showed the release of six different metal ions was observed: titanium, chromium, nickel, iron, copper, and zinc with maximum release of copper and the least releases of titanium at each time point and for every arch wire used. Results also showed that the change in pH had a very strong effect (up to 100-fold) on the release of ions and that the release of ions was dependent on wire composition, but it was not proportional to the content of metal in the wire. The largest number of ions was released during the first week of appliance immersion.

Petoumenou et al [38] in 2009 studied the saliva samples of 18 orthodontic patients using mass spectrometry to assess the level of nickel before orthodontic treatment, after banding and bonding, 2 weeks later, before placement of NiTi archwires, 4 weeks and 8 weeks after wire placement. The study showed that leaching of nickel ions occurred after banding and bonding and after archwire placement. This effect was found to decrease after 10 weeks.

Sfondrini MF et al [39] in 2010 conducted an in vitro study to compare the nickel released from 3 kinds of orthodontic brackets: new conventional stainless steel, recycled stainless steel, and nickel-free brackets. Samples were immersed in artificial saliva at various acidities (pH 4.2, 6.5, 7.6) over an extended time interval (0.25, 1, 24, 48, and 120 hours). The amount of nickel released was determined by using an atomic absorption spectrophotometer and an inductively coupled plasma atomic emission spectrometer. The recycled brackets released the most nickel (74.02 +/- 170.29 microg per gram); the new stainless steel brackets released 7.14 +/- 20.83 microg per gram. The nickel-free brackets released the least nickel (0.03 +/- 0.06 microg per gram). All the differences among the groups were statistically significant. The 2 experiments performed at pH 4.2 showed the highest nickel release; it was lower at pH 6.5 and 7.6.

Lee et al [40] in 2010 studied the corrosion resistance of different NiTi arch wires in fluoride-containing oral environment. The study showed that increasing the NaF concentration in artificial saliva resulted in a decrease in corrosion resistance of all test NiTi arch wires. The presence of fluoride, especially at a 0.5% NaF concentration, in artificial saliva was deleterious to the corrosion resistance of the test NiTi arch wires.

Danaei et al [41] in 2011 studied the quantity of metal ion release from orthodontic brackets when stored in different mouthwashes viz Oral B, chlorhexidine and Persica mouthwashes and deionized water which were incubated at 37^{o}C for 45 days. Inductively coupled plasma spectrometer was used to measure the levels of nickel, chromium, iron, copper and manganese ions. The highest ion release was seen in deionized water. Comparatively higher ion release was found with chlorhexidine mouthwash. The study concluded that for orthodontic patients with stainless steel brackets Oral B and Persica mouthwashes might be better options than chlorhexidine when ion release is taken into consideration.

Amini et al [42] in 2011 compared the salivary metal ion content in 28 subjects with fixed orthodontic appliances with that of their siblings of the same gender. Saliva sample analysis using atomic absorption spectrometry showed that the mean salivary nickel and chromium levels were higher in the study group, the difference of nickel level being statistically significant.

Bengleil MS et al [43] in 2013 compared the level of nickel released into the saliva of 18 patients undergoing treatment with two of the commonly used fixed orthodontic appliances viz conventional bracket system and nickel-free premium bracket system. Results obtained from the first group with conventional bracket system demonstrated that there was an increase in the level of nickel 4 weeks after initial arch wire application which reduced to the pre-treatment level 8 weeks later. Concentrations of nickel released in samples obtained from this group were then almost similar over the period of study.

Talic NF et al [44] in 2013 measured the amount of nickel and chromium ions in the saliva of 40 Saudi patients with fixed orthodontic appliances at different periods of orthodontic treatment from the first month to 32 months into treatment. Saliva samples were analysed using Inductive Coupled Plasma/Mass Spectrometry and Inductively Coupled Plasma Optical Emission Spectroscopy to measure Ni and Cr levels, respectively. The results showed that the highest level of Ni occurred after 20 months of treatment, whereas the highest level of Cr occurred after 4 months of treatment.

Guo Y et al [45] in 2014 quantitatively evaluated the urinary nickel levels in adolescents in the initial period of orthodontic fixed treatment. It was found that urinary levels of youngsters began to increase after the appliance placement. When the dynamic metabolic balance between absorption and elimination of nickel was achieved, the urinary concentrations seem to become relatively stable.

Mikulewicza M et al [46] in 2014 evaluated the release of metal ions from fixed orthodontic appliances in an invitro study. A new system for in vitro testing of dental materials was constructed and consisted of a thermostatic glass reactor that enabled immersion of the studied material. Experimental conditions reflected the human oral cavity, with a temperature of $37^{o}C$ and a saliva flow rate of 0.5 mL/min. Simulated stainless steel fixed orthodontic appliance was then evaluated. Sampling was performed at several time points during the 28-day study and the metal ion concentration was determined by inductively coupled plasma optical emission spectrometry. The total mass of released metal ions from the appliance were recorded to be 18.7 mg of nickel, 5.47 mg of chromium, 31.3 mg copper and these were far below the human toxic dose.

Ahmad S [47] in 2014 studied the effects of thermocycling on nickel release from 40 orthodontic arch wires stored in artificial saliva with different pH values. Forty new wire pieces were selected. Each wire piece was placed in a special capillary Pyrex tube filled with artificial saliva, immersed in deionized water at 37 °C. The samples were divided into four groups of ten. Group I received no treatment; group II was subjected to thermocycling. The pH of storage in groups III and IV was reduced to 4.5, group IV was subjected to thermocycling. The study showed that maximum Ni was released under acidic pH in the thermocycled group (group 4) followed by groups 2, 3, and 1. The study indicated that even though pH had some influence on Ni release, thermocycling was clearly the dominant factor.

Neamah Z [48] in 2014 conducted a study to test the hypothesis that there is no difference in salivary metal ion content between 50 subjects with fixed orthodontic appliances and their same-gender sister or brother without any orthodontic appliance who were used as controls. Stimulated saliva samples were collected from patients, before insertion, 1 month, 2 months and 6 months after insertion of the appliance and analysed for nickel, chromium, by electrothermal atomic absorption spectrophotometry. The results showed that the mean salivary nickel content in subjects with a fixed orthodontic appliance was significantly more than the control group. The mean salivary chromium ion level in the study group was also more than the control group but the difference was statistically insignificant. This study concluded that the nickel and chromium ion concentrations increased immediately after placement of the appliance in the mouth and that there were no significant differences in the nickel and chromium levels released by the appliances at different study periods.

Senkutvan et al [49] in 2014 compared the amount and rate of nickel on release form nickel titanium archwires, stainless steel arch wires, copper NiTi archwires and ion implanted NiTi archwires on the 7th, 14th and 21st day of immersion in artificial saliva using atomic adsorption spectrometer. The results showed that the levels of nickel leached reached the maximium on the 7th day after which it declined. The highest nickel release was from the untreated NiTi wire, followed by copper NiTi archwires, ion implanted NiTi and stainless steel wires. At all times the nickel released was well below that ingested with a normal daily diet.

Arab S et al [50] in 2015 conducted an in vivo study to evaluate the effect of length of immersion on the release of nickel and chromium ions from stainless steel, NiTi and HANT arch wires by immersing 15 numbers of each type of wire in 50 ml of distilled water and incubating at 37ºC for 28 days. The samples were incubated for another 28 days in new distilled water. After each 28-day time span, the concentrations of nickel and chromium were measured using an atomic absorption spectrophotometer. The results showed that the greatest amount of nickel and chromium ions at both 28 days periods was released from stainless steel wires. The lowest amount of nickel was released from NiTi while HANT arch wires released the lowest amount of chromium. Nickel ion release decreased overtime while the chromium release increased.

Nayak RS et al [51] in 2015 evaluated the release of nickel and chromium ions in 30 orthodontic patients undergoing treatment with 0.022″ MBT mechanotherapy using Inductively Coupled Plasma-Mass Spectrometer by collecting saliva samples prior to commencement of treatment, after initial aligning wires and after 10-12 months of treatment. The results showed significant increase in nickel and chromium ion concentration after the initial alignment phase. The ionic concentration at the end of 10-12 months of treatment showed a statistically significant increase for chromium and a statistically insignificant decrease in nickel ion concentration. A positive correlation for an increase in nickel concentration was seen after alignment, but not at the end of 10-12 months. A positive correlation was seen for an increase in chromium ion concentration at both time intervals.

Dwivedi A et al [52] in 2015 compared the compared the level of nickel and chromium in the saliva of 13 patients undergoing fixed orthodontic treatment at different time periods. The saliva samples were taken at different time periods that is: Group 1 (before appliance placement), Group II, III, and IV (after 1-week, 1-month, and 3 months of appliance placement respectively). The level of ions was determined using graphite furnace atomic absorption spectrophotometry. The results showed that the level of nickel and chromium in saliva was highest in Group II and lowest in Groups I for both the ions. On comparison among different groups, the results were found to be statistically significant among all the groups (<0.001) except between Group III and Group IV. They found that the release of nickel and chromium was maximum at 1-week and then the level gradually declined. They concluded that these values were well below the toxic dose of these ions but should be viewed with caution in subjects with Ni hypersensitivity.

Mikulewicz et al [53] in 2015 evaluated the metal ion accumulation in hair of patients undergoing orthodontic treatment with fixed appliances in time. Hair sampling of 47 patients was performed at the beginning and in the 4th, 8th and12th month of the treatment. The content of metals (Cr, Ni, Fe) in hair was analysed by ICP– OES. They found that the peak release of Cr and Fe occurred after 4 months of the treatment, and the peak release of Ni gradually increased throughout the whole year of the therapy. The differences were statistically significant for Cr. For Ni and Fe, they were not statistically significant.

Heravi et al [54] in 2015 evaluated and compared the corrosion resistance of three commercially available NiTi archwires exposed to 0.05 wt% and 0.2 wt% fluoride mouthwashes. The results showed that while all the wires were passive in artificial saliva, with the addition of fluoride ions to the solution, a decrease in the archwires' corrosion resistance was noticed which was in direct proportion to the increase in fluoride concentration. The authors concluded that NiTi wires experienced deterioration of their corrosion properties under the effect of fluoride but not as much as the stainless steel archwires.

Azizi et al [55] in 2016 evaluated the amount of nickel and titanium ions released from two wires with different shapes and similar surface area. Forty round NiTi arch wires and 40 rectangular NiTi arch wires were immersed in artificial saliva for 21 days at 37^{o}C. Inductively coupled plasma atomic emission spectrometry (ICP-AES) was used to measure the amount of ions released at 1 h, 24 h, 1 week, and 3 weeks. Their results indicated that the amount of nickel and titanium concentrations was significantly higher in the rectangular wire group and that the most significant release of all metals was measured after the first hour of immersion. The authors conclude that the release of metal ions was influenced by the shape of the wire and increase of time.

Kumar V et al [56] in 2016 conducted a study to evaluate the release of nickel and chromium in human saliva during fixed orthodontic treatment. Saliva samples of 10 patients with fixed orthodontic appliances were collected at three stages viz before bonding, 10 days after bonding and after 1 month of bonding. They analysed these samples for nickel and chromium content using inductively coupled plasma optical emission spectrometry. Their results showed that while the nickel content showed a gradual increase in the first 10 days, it declined thereafter. Chromium showed a gradual increase and was statistically significant on the 30th day.

Hussain HD et al [57] in 2016 evaluated the nickel release from stainless steel and nickel titanium arch wires in artificial saliva over three months with the use of simulated fixed orthodontic appliances. Five groups of ten samples each were made: group A was the control group without arch wires, groups B and C contained stainless steel arch wires from American Orthodontics and Dentaurum respectively, groups D and E contained NiTi arch wires from American Orthodontics and copper NiTi from Ormco respectively. The amount of nickel released from the appliances into the artificial saliva were measured after 1 day, 7 days, 1 month, 2 months and 3 months. Their results indicated that the release of nickel was seen in all groups up to the end of first month. The highest amount of nickel was released from nickel titanium arch wires, but the quantity of nickel released from neither NiTi nor stainless steel arch wires were significant. The rate of nickel released was high within the first week and continued up to the first month after which the nickel content was stable in all the groups.

Bhasin V et al [58] in 2017 evaluated nickel and chromium levels in the GCF during fixed orthodontic treatment. Three samples were taken from the GCF of the 30 patients at baseline (pre-treatment), 1 month after the start of orthodontic treatment and 6 months after the commencement of orthodontic treatment using standardized cellulose acetate absorbent strip. The specimens were analysed using atomic absorption spectrophotometry. The results showed that the levels of nickel and chromium might show considerable elevation in the GCF with time along with an increase in the severity of inflammation in the gingival health in patients undergoing fixed orthodontic treatment.

STUDIES ON HARMFUL EFFECTS OF MOBILE PHONES

Monfrecola G et al [59] in 2003 assessed the effects of non-ionizing EMR emitted by cellular phones on cutaneous blood flow in 30 healthy volunteers using a laser Doppler He-Ne flowmeter. Statistically significant increase in cutaneous microflow to the ear skin on the side where the mobile phone was held was seen.

Straume et al [60] in 2005 used infrared camera techniques to assess the contribution of thermal insulation of the phone, heating of the mobile phone due to its electrical power dissipation, and radio frequency (RF) exposure to the increase in skin temperature resulting from the use of one GSM 900 phone. The changes in temperature after 15 and 30 minutes of mobile phone use were calculated on the exposed side of the head relative to the unexposed side. The study found that insulation and the electrical power dissipation led to statistically significant rises in the skin temperature, while the RF exposure did not.

Anderson and Rowley [61] in 2006 measured the maximum temperature rises on the side of the face after 6 minutes of continuous mobile phone operation using two models of AMPS analog phones and three early model GSM digital phones operating in the 900 MHz band. The authors found that for the GSM phones the highest recorded temperature rise difference was 2.3°C and for the AMPS phones it was 4.5°C, both at locations on the cheek which may be due to the maximum average operating power of AMPS (600 mW) versus GSM 900 (250 mW). Temperature changes at a consistent location on the cheek for an AMPS phone that was inoperative (−0.7 °C), transmitting at full power (+2.6 °C) and in stand-by mode (+2.0 °C) were also compared. The results suggested that direct RF heating of the skin only contributes a small part of the temperature rise and that most is due to heat conduction from the handset.

Acar GO et al [62] in 2009 investigated the possible thermal effects of microwaves from mobile phones on facial nerves and surrounding soft tissue on 12 rabbits. The results showed that the average temperature of the surrounding soft tissues was 0.39 K higher than the pre-exposure values during the exposure and immediately after turning off the mobile phone. The temperature returned to normal levels 25 minutes after the exposure, which was statistically significant. The authors concluded that temporary facial nerve dysfunction may be caused by the radiation emitted by the mobile phone which may be due to the temporary increase in temperature of the soft tissue around the facial nerve.

STUDIES ON EFFECT OF MOBILE PHONES ON SALIVARY GLANDS

Sadetzki et al [15] in 2008 assessed the association between cellular phone use and development of parotid gland tumours. They found a positive dose-response and suggested an association between cellular phone use and parotid gland tumours.

Goldwein and Aframian [63] in 2009 evaluated whether handheld mobile phone use induced physiologic changes in the adjacent parotid gland located on the dominant side, in terms of secretion rates and protein levels in the secreted saliva. A significantly higher saliva secretion rate and lower total protein concentration was noticed in the dominant side compared with that in the non-dominant side. The authors concluded that parotid glands adjacent to handheld mobile phones respond by elevated salivary rates and decreased protein secretion reflecting the continuous insult to the glands.

Bhargava et al [64] in 2012 observed the functional and volumetric changes in parotid glands associated with mobile phone use. Unstimulated parotid salivary flow rate in 142 individuals was measured bilaterally using a modified Schirmer test and the subjects were then divided into 2 groups of heavy users and control subjects. Parotid gland volume was evaluated bilaterally using ultrasosnography. The authors found a significant increase in salivary flow rate in addition to increased blood flow rate and parotid gland volume on the side where mobile phones were frequently placed in the heavy user group.

Hamzany et al [13] in 2013 compared salivary outcomes (secretion, oxidative damage indices, flow rate, and composition) between mobile phone users and nonusers. This study reported a significant increase in all salivary oxidative stress indices and salivary flow rate in mobile phone users. However, the total protein, albumin, and amylase activity were decreased in mobile phone users.

Hashemipour MS et al [65] in 2014 evaluated the effect of mobile phone use on parotid gland salivary concentrations of protein, amylase, lipase, immunoglobulin A, lysozyme, lactoferrin, peroxidase and C-reactive protein from parotid glands of 86 healthy volunteers. The study revealed that salivary flow rate and parotid gland salivary concentrations of protein were significantly higher on the dominant. There was a decrease in concentrations of amylase, lipase, lysozyme, lactoferrin and peroxidase.

Gupta et al [66] in 2016 studied the influence of using mobile phone on parotid gland salivary flow rate and lipid peroxidation levels in 200 individuals. The results showed that parotid salivation on the dominant side was increased when compared with the nondominant side. There was no significant effect of talking time on the levels of salivary lipid peroxidation.

STUDIES ON EFFECT OF MOBILE PHONE ON ORTHODONTIC ARCH WIRES

Ionescu IC and Ionescu E [67] in 2012 tested the effect of electromagnetic waves generated by mobile phones on orthodontic arch wires and the potential effects on saliva. The average pH values in the presence of electromagnetic fields generated by mobile phones were measured in patients undergoing fixed orthodontic treatment with NiTi wires/NiTi brackets and NiTi wires/ceramic brackets appliances. In addition, the change in salivary pH due to mobile phone radiation exposure was studied in non-orthodontic subjects. This study found that when mobile phone was used (cell phone/no wire or brackets case), the average pH value decreased to 6.88 from 7.02. When the mobile phone was used in combination with NiTi wires and ceramic brackets, the average pH value decreased to 6.81. In the presence of NiTi wires/NiTi brackets the average pH value decreased even further to 6.73.

Saghiri et al [16] in 2015 evaluated the effect of exposure to radiofrequency electromagnetic fields emitted by mobile phones on the level of nickel in saliva in fifty healthy patients with fixed orthodontic appliances. The participants were asked not to use their cell phones for a week, and their saliva samples were taken at the end of the week. The patients recorded their time of mobile phone usage during the next week and returned for a second saliva collection. The results showed significant increase in the level of nickel in the experimental group compared to the control group. This study concluded that mobile phone usage has a time-dependent influence on the concentration of nickel in the saliva of patients with orthodontic appliances.

Nanjannawar et al [68] in 2017 assessed the level of nickel ions in saliva and pH of saliva in mobile phone users undergoing fixed orthodontic treatment. 42 healthy patients with fixed orthodontic appliance in mouth for a duration of six to nine months were selected for the study. They were divided into experimental group (n=21) consisting of mobile phone users and control group (n=21) of non-mobile phone users. Saliva samples were collected from both the groups and nickel ion levels were measured using inductively coupled plasma-mass spectroscopy. The pH values were also assessed for both groups using pH meter. The results showed that pH levels were reduced, and the nickel ion levels were higher in the experimental group compared to the control group. The results were however non-significant.

STUDIES ON EFFICACY OF EARPHONES IN REDUCING MOBILE PHONE RADIATION

Bit-Babik et al [17] in 2003 conducted a study to estimate the SAR in the human head and body due to radiofrequency radiation exposure from handheld mobile phones with hands-free accessories. The authors used two different models, a simple and a realistic one to represent the user's body and a lossy homogeneous dielectric sphere of diameter 16 cm to represent the head. Using a Motorola GSM phone and an associated earpiece, the radiation exposure of the head region alone and the whole phantom was tested. This study found that the SAR near the ear where the earpiece was located was low compared to the peak SAR produced by the phone, the global peak SAR is not located near the ear with the earpiece accessory and that the presence of torso attenuates the field from the earpiece accessory, resulting in a lower SAR compared to that measured without the torso.

Kuhn S et al [69] in 2009 did a study in which the radiation emission from mobile phones when used with wireless and wired hands-free kits (HFK) was evaluated to determine the extent to which the use of wired and wireless HFK can reduce human exposure. In experimentally validated simulations of a wired HFK and a mobile phone operating on anatomical whole-body models were also performed. The authors found that the maximum spatial peak SAR in the head when using wired HFK was more than five times lower than ICNIRP limits and that a wired HFK considerably reduces the exposure of the entire head region compared to mobile phones operated at the head. Wired HFK may cause a localized increase of the exposure in the region of the ear inside the head under worst-case conditions. Wireless HFK exhibited a low but constant exposure.

Materials & Methods

MATERIALS AND METHODS

SELECTION OF PATIENTS

Inclusion criteria:

1. Patients who have been undergoing fixed orthodontic treatment for at least 2 months and no more than 4 months.
2. Patients with permanent dentition aged between 15 and 20 years of both genders.
3. Patients with good general health.

Exclusion criteria

1. Patients with systemic illness or medication intake.
2. Patients who smoke or consume alcohol.
3. Patients with metallic restorations in mouth.
4. Patients with poor oral health or open untreated caries lesions or gingival inflammation.
5. Patients unwilling to participate in the study.

MATERIALS

1. Stainless Steel Brackets MBT.022 Slot (3M Gemini)
2. Nickel Titanium and Stainless Steel Arch wires (3M Unitek)
3. Transpalatal arch and lingual arch (19 gauge Stainless Steel wire)
4. Etching Agent (EAZETCH)
5. Primer (3M Unitek)
6. Adhesive Resin (Transbond XT 3M Unitek)
7. Mobile phones with RFER within the normal range of 800 to 2200 MHz and SAR value of or below 1.6W/Kg
8. Wired earphones

METHODOLOGY

Study design and setting

A short term interventional follow up study done in the outpatient section of Department of Orthodontics and Dentofacial Orthopaedics, Tamil Nadu Government Dental College and Hospital, Chennai in collaboration with Chennai Mettex Lab Private Limited, Guindy, Chennai.

Type of study: Cross over trial

Type of sampling: Simple Random sampling

Study population

20 subjects who were undergoing orthodontic treatment with fixed appliance mechanotherapy, were selected from the post graduate clinic of Department of Orthodontics and Dentofacial Orthopaedics, Tamil Nadu Government Dental College and Hospital, Chennai according to the inclusion and exclusion criteria for this study. The study procedure was then explained, and an informed consent was signed from the patient &/or the parents.

All patients were bonded with MBT 022 slot stainless steel brackets, had either 0.016 stainless steel or 0.016 nickel titanium archwires and transpalatal and lingual arches fabricated in 19-gauge stainless steel wire.

During the regular check-ups, the patients were asked to refrain from cell phone use for 1 week and saliva samples were collected from them at the end of the week. The patients were then divided into 2 subgroups of 10 subjects each viz:

o **Subgroup A**: Group using mobile phones placed directly against the ear during the second week.

o **Subgroup B**: Group using mobile phones only with earphones during the second week.

The patients were instructed to calculate the number of minutes that they use their cell phones for speaking during the second week of the study.

At the end of the second week the saliva samples were collected again. During the third week of the study, the participants were once more asked to refrain from cell phone use and the saliva samples collected. In the fourth week of the study participants of Subgroup A and Subgroup B were exchanged. They were then instructed to use their cell phones (with and without earphones) for the same number of minutes that they had used in the second week of the study. At the end of the fourth week the final saliva samples were collected to check the nickel level.

Samples taken at the end of week 1 and week 3 were considered the control group. Those collected at the end of week 2 and week 4 were considered the experimental group.

The patients were instructed to abstain from eating seafood and canned food, drinking hot tea and coffee and were told to avoid brushing their teeth and rinsing their mouth with fluoridated products during the study period. They were also advised to use their mobile phones only for making and receiving calls during the study.

Collection of saliva samples

At the end of the first, second, third and fourth weeks, saliva samples were collected. The participants were called on the specified days to collect midmorning saliva samples.

The patients were asked to rinse their mouth with deionized water for 30 seconds before the sample collection. They were instructed to collect approximately 15ml unstimulated salvia into sterile nickel-free, 20-mL plastic containers by direct spitting. (Fig 3)

Storage and transport of saliva samples

All the samples were stored at -20^{0}C and were then transported to the laboratory in a coolant box. (Fig 4, Fig 5)

Processing of samples

The samples once transported to the laboratory were first brought to room temperature. 15ml of each saliva sample was taken in 50ml centrifugal tube and 1ml of concentrate nitric acid and 0.25ml of internal standard rhodium (1ppm) were added. The volume of this mixture was made up to 25ml using deionized water. The solution was then vigorously mixed for 1 minute and subjected to inductively coupled plasma-mass spectrometry to measure the amount of nickel. (Fig 6, Fig 7, Fig 8)

ANALYSIS OF DATA

The data were analysed using SPSS (IBM SPSS Statistics for Windows, Version 22.0, Armonk, NY: IBM Corp. Released 2013).

COLOUR PLATES

Fig 1. ARMAMENTARIUM

Fig 2. MOBILE PHONES WITH EARPHONES

Fig 3. COLLECTION OF UNSTIMULATED SALIVA

Fig.4 SALIVA SAMPLES

Fig 5. COOLANT BOX USED TO TRANSPORT SALIVA SAMPLES

Fig.6 PROCESSING OF SALIVA SAMPLES

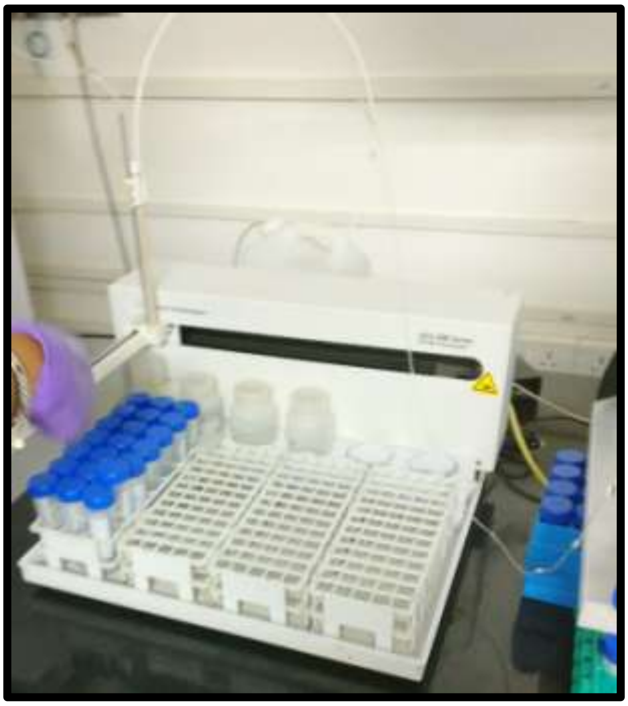


Fig.7 INDUCTIVELY COUPLED PLASMA MASS SPECTROMETRY

Fig.8 ANALYSIS OF SALIVA SAMPLES FOR ASSESSMENT OF NICKEL ION LEVELS

Results

RESULTS

STATISTICAL ANALYSIS

The data were analysed using SPSS (IBM SPSS Statistics for Windows, Version 22.0, Armonk, NY: IBM Corp. Released 2013). The Normality tests Kolmogorov-Smirnov and Shapiro-Wilks tests results revealed that variables did not follow normal distribution. Therefore, to analyse the data non-parametric tests were applied. To compare variables between Groups, Mann Whitney test was used. Comparison of variables between time points was made using Wilcoxon Signed Rank test. To calculate correlation between variables Spearman Rank Correlation was used. Significance level was fixed as 5% ($p < 0.05$).

RESULTS

The mean value of nickel in the saliva of the patients in Subgroup A at the end of week 1 was found to be 4.94 ng/ml. (Table – 1, Chart - 1)

Subgroup A participants then used mobile phones placed directly against the ear in the second week of the study.

The mean duration of speaking was 56.01 minutes. (Table – 1, Chart - 2)

At the end of week 2, the mean value of nickel was found to be 7.63 ng/ml. (Table – 1, Chart - 1)

Wilcoxon Signed Ranks test was used to compare variables between time points.

The mean of nickel release at the end of week 2 was significantly higher than week 1 ($P = 0.005$). (Table - 2)

The mean percentage increase in Subgroup A patients at the end of week 2 on using the mobile phone directly against the ear for a mean duration of 56.1 minutes was 87.11%. (Table – 3, Chart - 3)

The mean value of nickel at the end of week 3 was 7.52 ng/ml. (Table – 1, Chart - 1).

After the cross over, in the fourth week, the patients in Subgroup A were asked to use mobile phones only with earphones for the same mean duration of 56.1 minutes.

The mean value of nickel at the end of week 4 was found to be 8.29 ng/ml. (Table – 1, Chart - 1).

The mean of nickel release at the end week 4 was higher than week 3 (P = 0.037). (Table - 2)

However, the mean percentage increase in Subgroup A patients at the end of week 4 on using mobile phones with earphones for the mean duration of 56.1 minutes was only 3.98 %. (Table –3, Chart - 4)

This increase of 3.98% in week 4 was much less compared to the increase of 87.11 % when these patients had used mobile phones placed directly against the ear in week 2. (Table – 3, Chart – 3, Chart - 4)

The mean value of nickel in the saliva of the patients in Subgroup B at the end of week 1 was found to be 5.75 ng/ml. (Table – 1, Chart - 1)

Subgroup B participants then used mobile phones with earphones in the second week of the study.

The mean duration of speaking was 73.7 minutes. (Table – 1, Chart - 2)

At the end of week 2, the mean value of nickel was found to be 6.58 ng/ml. (Table – 1, Chart - 1)

Wilcoxon Signed Ranks test was used to compare variables between time points.

Although the mean of nickel release at the end of week 2 was higher than week 1, this increase was not significant (P = 0.139). (Table - 2)

The mean percentage increase in Subgroup B patients at the end of week 2 on using the mobile phone with earphones for the mean duration of 73.7 minutes was only 33.79 %. (Table – 3, Chart - 3)

The mean value of nickel at the end of week 3 in Subgroup B was 6.11 ng/ml. (Table – 1, Chart - 1).

After the cross over, in the fourth week, the patients in Subgroup B were asked to use mobile phones directly placed against the ear for the same duration of 73.7 minutes as they had used in week 2.

The mean value of nickel at the end of week 4 was found to be 9.27 ng/ml. (Table – 1, Chart - 1).

There was a significant increase in the mean of nickel release at the end week 4 in Subgroup B compared to week 3 (P = 0.005). (Table - 2)

The mean percentage increase in Subgroup B patients at the end of week 4 on using mobile phones placed directly against the ear for the mean duration of 73.7 minutes was 107 %. (Table – 3, Chart - 4)

This increase of 107 % in the nickel level was much higher when compared to the increase of 33.79 % when these patients had used mobile phones with earphones in week 2. (Table – 3, Chart – 3, Chart - 4)

Intergroup comparison

Mann-Whitney Test to compare variables between the subgroups.

The participants of Subgroup A had used mobile phones directly placed on the ear for a mean duration of 56.1 minutes in the second week and mean percentage increase of 87.11%. (Table – 1, Table – 3, Chart – 2, Chart - 3)

The participants of Subgroup B used mobile phones only with ear phones in the second week. Even though these patients used this for a mean duration of 73.7 minutes, the mean percentage increase in nickel level was only 33.8%. (Table – 1, Table – 3, Chart - 3)

Mann Whitney test shows that this difference in the percentage increase of nickel between the two subgroups in week 2 is statistically significant (P = 0.034). (Table - 4)

When Subgroup A patients used mobile phones with earphones in week 4 for the same mean duration of 56.1 minutes, the mean percentage increase in nickel level was only 3.98% (Table – 1, Table – 3, Chart – 2, Chart - 3)

Subgroup B patients on using mobile phones placed directly against the ear for the mean duration of 73.7 minutes in week 4 showed an increase of 107 % in the nickel level. (Table – 1, Table – 3, Chart – 2, Chart - 3)

Mann Whitney test shows that this difference in the percentage increase of nickel between the two subgroups in week 4 is again statistically significant (P = 0.001). (Table - 4)

Spearman's rank correlation test showed that a positive correlation was found between the duration of mobile phone use and the nickel release. This correlation was statistically significant in week 4 of this study (P = 0.008).

TABLE – 1: Means, medians, standard deviations, 1st quartile and third quartile of measured concentrations of nickel in saliva and duration of mobile phone use.

		Group	
		Subgroup A	Subgroup B
Ni (ng/ml): Week 1	N	10	10
	Mean	4.94	5.75
	Std. Dev.	5.32	5.31
	Median	2.90	4.20
	1st Quartile	1.10	1.13
	3rd Quartile	8.31	9.80
Ni (ng/ml): Week 2	N	10	10
	Mean	7.63	6.58
	Std. Dev.	6.21	5.41
	Median	6.54	4.23
	1st Quartile	2.01	2.64
	3rd Quartile	13.99	11.96
Ni (ng/ml): Week 3	N	10	10
	Mean	7.52	6.11
	Std. Dev.	6.31	5.09
	Median	6.25	4.14
	1st Quartile	1.87	1.93
	3rd Quartile	13.91	10.50
Ni (ng/ml): Week 4	N	10	10
	Mean	8.29	9.27
	Std. Dev.	6.97	5.62
	Median	7.54	6.97
	1st Quartile	1.22	4.66
	3rd Quartile	15.93	13.89
Duration (min)	N	10	10
	Mean	56.01	73.66
	Std. Dev.	29.45	17.55
	Median	57.38	76.00
	1st Quartile	30.00	69.00
	3rd Quartile	71.00	83.00

Table– 2: Wilcoxon Signed - Rank Test to compare nickel levels between time points.

Group	Time points	p-Value
Subgroup A	Ni (ng/ml): Week 2 - Ni (ng/ml): Week 1	0.005
	Ni (ng/ml): Week 3 - Ni (ng/ml): Week 1	0.005
	Ni (ng/ml): Week 4 - Ni (ng/ml): Week 1	0.005
	Ni (ng/ml): Week 3 - Ni (ng/ml): Week 2	0.169
	Ni (ng/ml): Week 4 - Ni (ng/ml): Week 2	0.074
	Ni (ng/ml): Week 4 - Ni (ng/ml): Week 3	0.037
Subgroup B	Ni (ng/ml): Week 2 - Ni (ng/ml): Week 1	0.139
	Ni (ng/ml): Week 3 - Ni (ng/ml): Week 1	0.508
	Ni (ng/ml): Week 4 - Ni (ng/ml): Week 1	0.005
	Ni (ng/ml): Week 3 - Ni (ng/ml): Week 2	0.011
	Ni (ng/ml): Week 4 - Ni (ng/ml): Week 2	0.005
	Ni (ng/ml): Week 4 - Ni (ng/ml): Week 3	0.005

TABLE – 3: Percentage change in the nickel levels of Subgroup A and Subgroup B in week 2 and week 4

		Group	
		Subgroup A	Subgroup B
Percentage change in Ni at 2nd Week	N	10	10
	Mean	87.11	33.79
	Std. Dev.	60.89	80.66
	Median	69.89	16.69
	1st Quartile	36.36	-2.29
	3rd Quartile	145.45	64.00
Percentage change in Ni at 4th Week	N	10	10
	Mean	3.98	107.00
	Std. Dev.	28.03	110.81
	Median	13.70	44.44
	1st Quartile	-21.79	32.48

TABLE – 4: Mann-Whitney U Test to compare percentage change in nickel levels between Subgroup A and Subgroup B.

Variables	P-Value
Percentage change in Ni at 2^{nd} Week from 1^{st} week	0.034
Percentage change in Ni at 4^{th} Week from 3^{rd} week	0.001

TABLE – 5: Spearman's rank correlation test – Overall

		Ni (ng/ml): Week 1	Ni (ng/ml): Week 2	Ni (ng/ml): Week 3	Ni (ng/ml): Week 4	Duration (min)
Ni (ng/ml): Week 1	Correlation		0.910	0.895	0.928	0.378
	P-Value		<0.001	<0.001	<0.001	0.101
Ni (ng/ml): Week 2	Correlation	0.910		0.991	0.949	0.411
	P-Value	<0.001		<0.001	<0.001	0.072
Ni (ng/ml): Week 3	Correlation	0.895	0.991		0.938	0.400
	P-Value	<0.001	<0.001		<0.001	0.081
Ni (ng/ml): Week 4	Correlation	0.928	0.949	0.938		0.573
	P-Value	<0.001	<0.001	<0.001		0.008
Duration (min)	Correlation	0.378	0.411	0.400	0.573	
	P-Value	0.101	0.072	0.081	0.008	
	N	20	20	20	20	20

CHARTS

CHART – 1: Mean nickel levels in Subgroup A and Subgroup B from week 1 to week 4

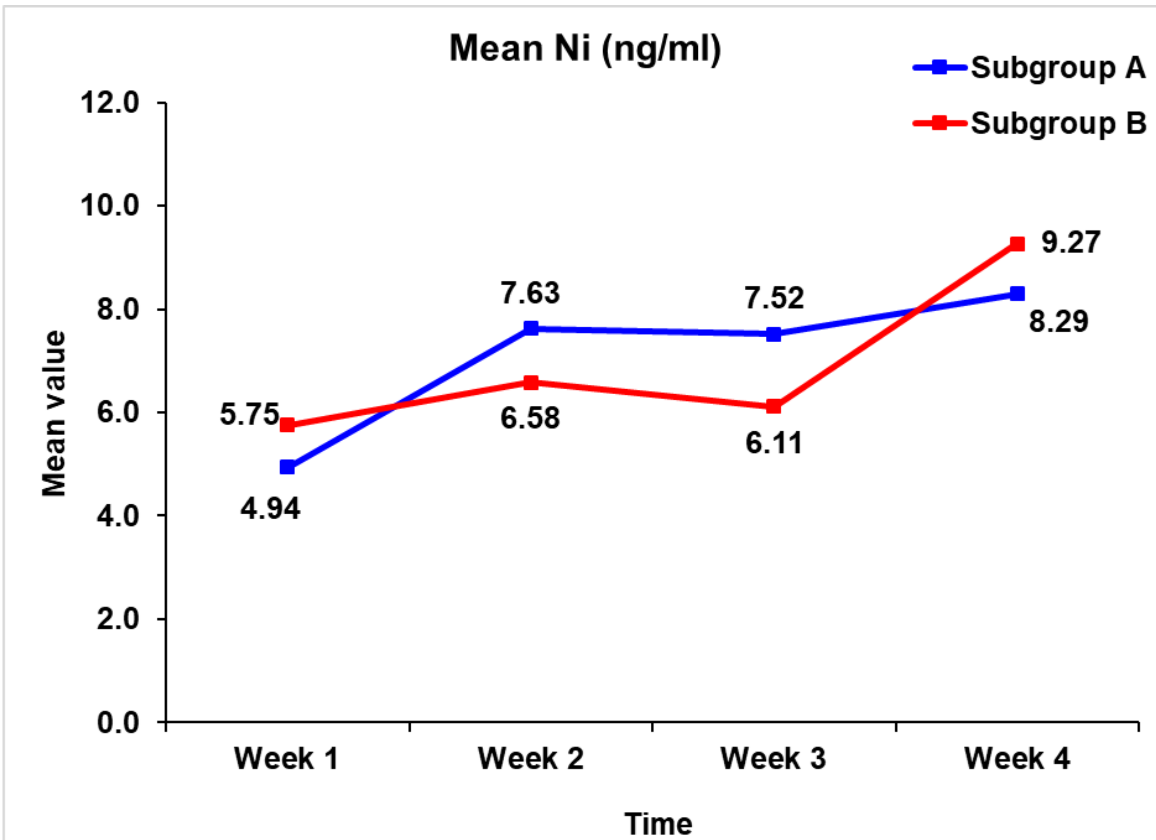


CHART – 2: Mean duration of mobile phone use in Subgroup A and Subgroup B

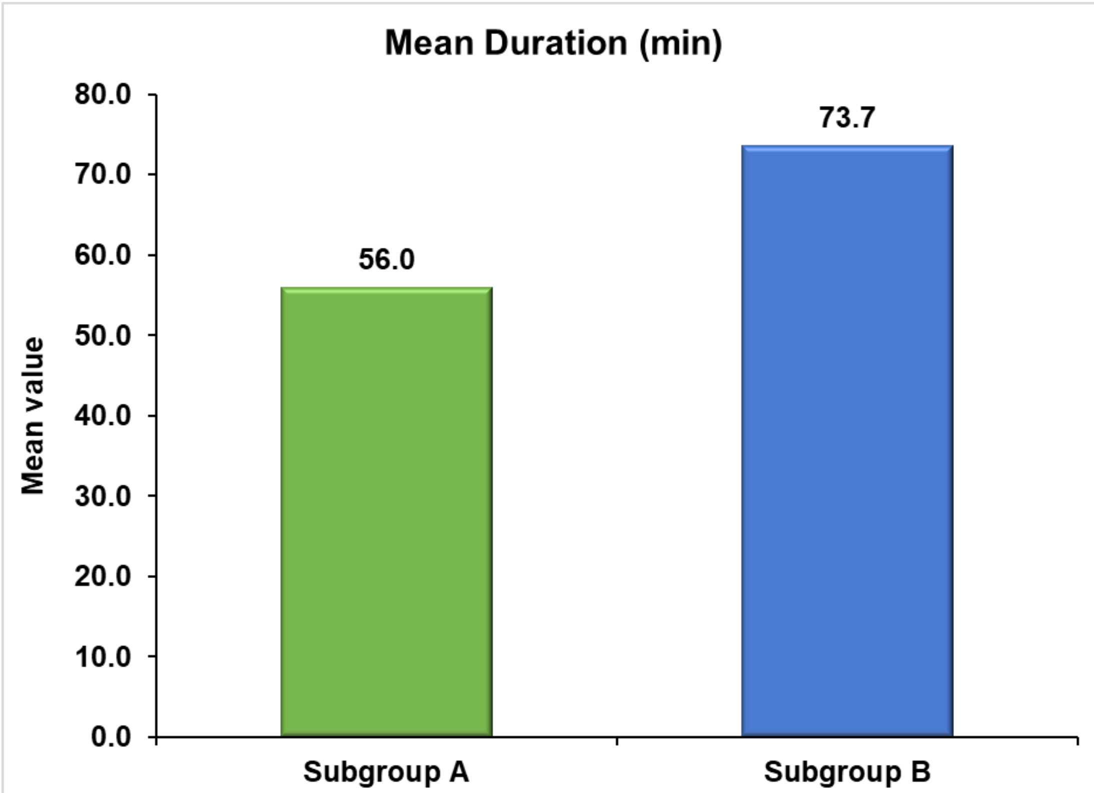
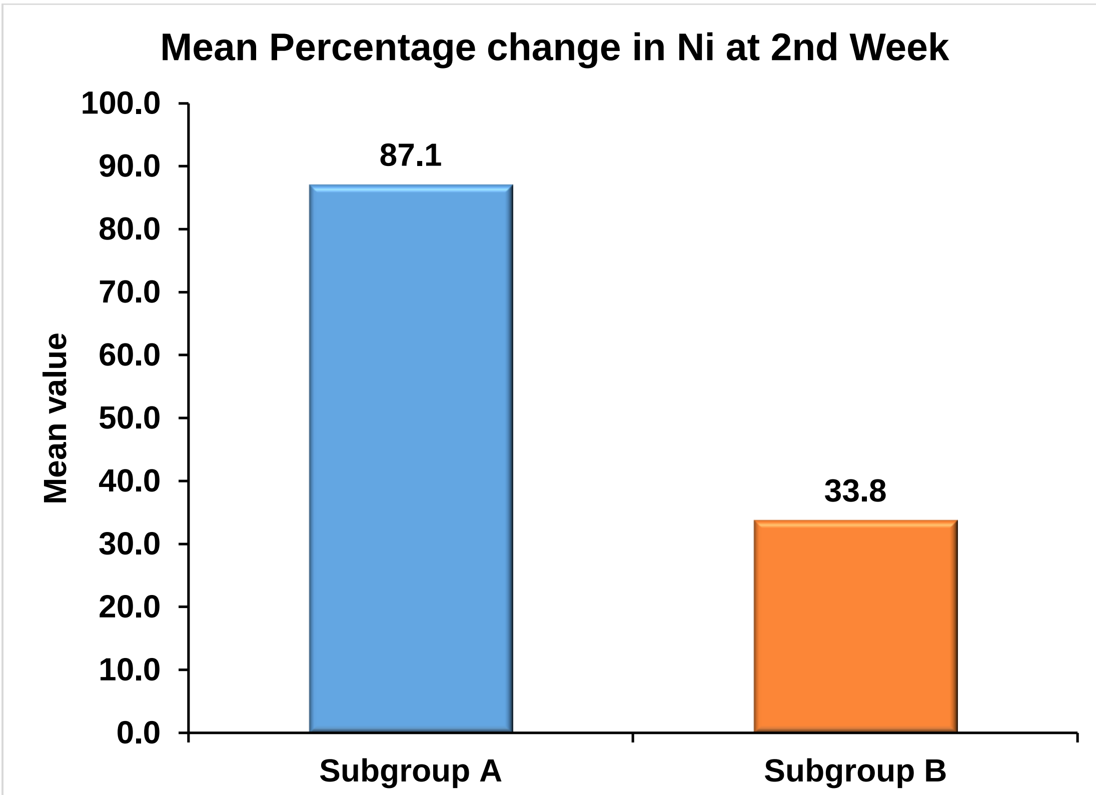
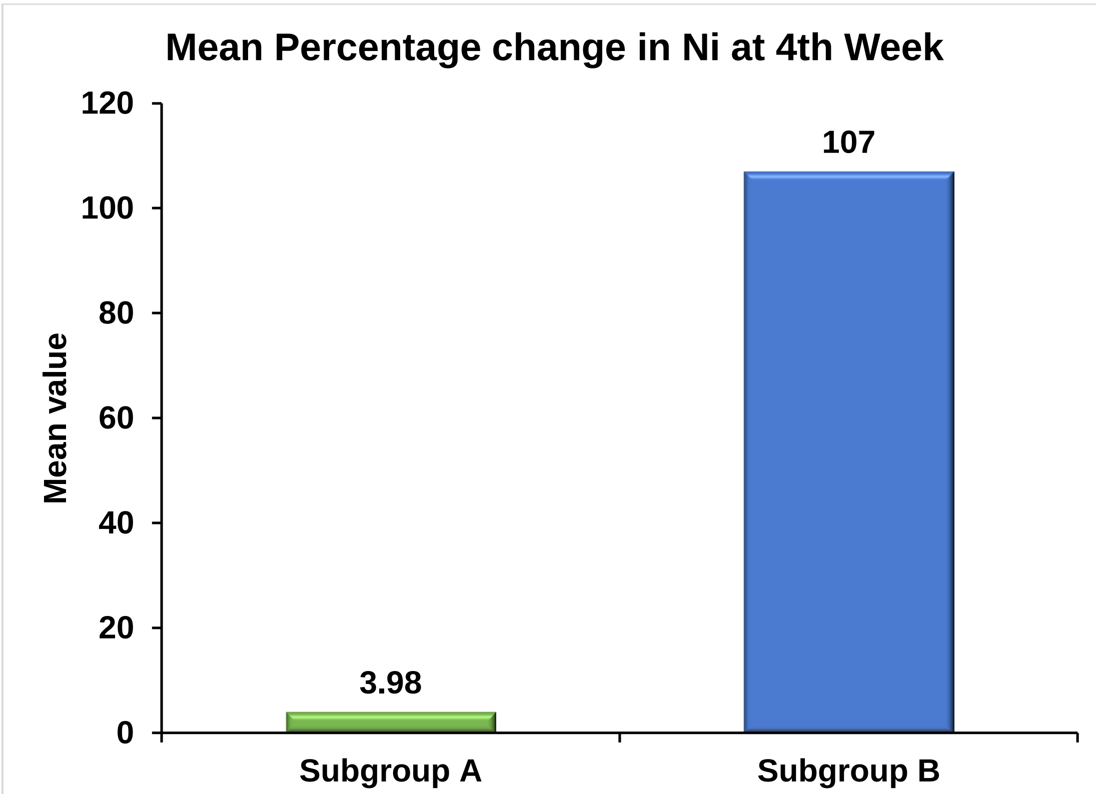


CHART – 3: Mean percentage change in nickel level in Subgroup A and Subgroup B at week 2.



C**HART – 4:** Mean percentage change in nickel level in Subgroup A and Subgroup B at week 4.



Discussion

DISCUSSION

The mouth is an aggressive environment with a salinity approaching that of sea water.[70] It is continuously bathed in saliva which is a complex mixture of electrolytes and a variety of organic substances. [71]

Modern orthodontics uses a wide range of appliances to bring about the desired degree of tooth movement. A typical fixed orthodontic armamentarium consists of brackets, arch wires, tubes and other auxiliaries most of which are made up of alloys like stainless steel, nickel titanium, beta titanium and cobalt chromium.

The use of these various combinations of metal alloys in the oral cavity warrants special attention regarding their biocompatibility, taking into consideration the extended duration that they are to remain in the mouth.[72]

Literature is replete with many invitro and in vivo studies documenting the corrosion of orthodontic appliances and the release of harmful metal ions, the major concern among which is nickel.

With saliva acting as a suitable electrolytic medium, the fluctuations in the oral pH and temperature, microbial and enzymatic activities and the presence of various chemicals in food and drink, all behave as corrosion conductors. [24]

Although previous research has shown that the amounts of nickel released from orthodontic appliances fall below the recommended daily dietary intake,[33, 35, 50, 56] this might be false assurance of safety since chronic low levels of metal ions can alter cellular morphology, metabolism and produce genetic instability.[73-78]

The nickel ions released may be deposited in different tissues at different levels, [35, 78] and might serve as a chronic risk factor to physical health and may adversely affect the biological functions of the whole organism.

Whilst nickel allergy in the form of contact dermatitis is the most common reaction, it can lead to other potentially serious conditions like lung fibrosis, lung and nasal cancers, cardiovascular and renal diseases.[21]

It has been found that nickel is a genotoxic, hematotoxic, teratogenic, immunotoxic, nephrotoxic, neurotoxic and carcinogenic metal. [33, 26]

Nickel levels as low as 2.5ng/ml has been reported to cause chemotaxis of leukocytes and stimulation of neutrophils to become aspherical. [34, 37, 39]

There is thus growing concern about the impending effects of the release of nickel ions from orthodontic appliances.

In 2015, Sahgiri et al [16] evaluated the effects of mobile phone use on metal ion release from fixed orthodontic appliances. Their study showed that mobile phone usage has a time dependent influence on the concentration of nickel in the saliva of orthodontic patients.

Taking into consideration the fact that mobile phone has become an indispensable part of communication worldwide and that both children and adults are active cell phone users with hours spend on speaking and texting, there is increasing concern on the mobile phone radiation leading to the release of nickel ions in fixed orthodontic patients.

In today's world of portable connectivity and multifunctional services, it is impractical and unrealistic to advise orthodontic patients to reduce, let alone, refrain from mobile phone use. It is thus imperative to find a way to reduce the effect of mobile phone radiation on orthodontic appliances and the consequent release of nickel ions.

Ionescu IC and Ionescu E [67] in 2012 reported that a radiofrequency magnetic field can transfer energy by means of electromagnetic induction in the surrounding areas. A radiofrequency alternating current passed through a coil of wire, i.e.; the mobile phone antenna, acts as the transmitter, while a second coil, i.e.; any conducting abject like an orthodontic wire can act as the receiver. Shortly, the current flow through the mobile phone antenna induces a voltage across the ends of the orthodontic wire through electromagnetic induction.

The proximity of the mobile phone to the oral cavity and the metallic appliances there in, is therefore, an important factor and a serious risk in exposure of these appliances to the phones radiation. [67]

Bit-Babek et al [17] in 2003 and Kuhn et al [69] in 2009 reported that a wired hands-free kit when used with mobile phones considerably reduces the exposure of the head region when compared to mobile phones operated directly at the head.

Although these studies have proven that the use of wired earphones considerably reduce the radiation exposure of the head region, no study has yet been reported to have evaluated whether this reduction in radiation exposure can actually reduce the nickel ion release in fixed orthodontic patients if they use mobile phones with headsets or earphones.

The present study was hence undertaken to evaluate the efficiency of ear phones in reducing the release of nickel ions from fixed orthodontic appliances when exposed to radiofrequency electromagnetic radiation emitted by mobile phones.

The anatomic location of the parotid gland, 4-10mm deep under the skin at the anterior border of the external ear makes it vulnerable to be influenced by exposure to the RFER on the side of the head where the mobile phone is held.[16]

Previous researches have confirmed that mobile phone use causes a significant increase in the salivary flow rate, salivary gland volume, salivary oxidative stress, total proteins and albumin and a decrease in the salivary amylase activity. [13,63,64, 66]

In the aggressive oral environment flushed with saliva, the salivary ions and non-electrolytes constantly flow against the wires, brackets and bands. Corrosion process occurs from the progressive dissolution of the surface film of the metallic orthodontic appliances and the release of metal ions directly into the saliva. The galvanic differences between the metal alloys and the physiological fluids in the mouth can also trigger electrochemical reactions which leads to corrosion.[67]

The increased salivary flow rate has a diluting effect on the macromolecules and ions in saliva.[68] Studies have reported that the concentration of salivary calcium, magnesium and phosphorus were lower in mobile phone users. [13] The greater flow rate, in addition to the lower concentration of ionic components in saliva, might thus cause more nickel leaching from the orthodontic appliances. [67]

The results of the present study show that nickel ion concentration in the saliva of patients using mobile phones held directly against the head for one week in both subgroup A (who used it during the second week) and subgroup B (who used it during the fourth week) was significantly higher than the week before when they had refrained from cell phone use.

The mean level of nickel increased from 4.94 ng/ml to 7.63 ng/ml in the saliva of the patients in Subgroup A during the second week with direct mobile phone use for a mean duration of 56.1 minutes. This was a mean percentage increase of 87.11 % and it was found to be statistically significant. (P = 0.005)

In Subgroup B patients, the mean level of salivary nickel increased from 6.11 ng/ml to 9.27 ng/ml during the fourth week when these patients had used mobile phone placed directly against the ear for a mean duration of 73.7 minutes. This was a mean percentage increase of 107 % and it was found to be statistically significant. (P = 0.005)

A positive correlation was found between the duration of mobile phone use and the nickel release. This correlation was statistically significant in week 4 of this study (P = 0.008).

This was in accordance with the study done by Sahgiri et al [16] and Nanjannawar et al [68] who found that mobile phone usage increased the release of nickel ions in saliva of patients with fixed orthodontic appliances.

The measure of the rate at which body tissues absorb radiofrequency electromagnetic radiation is called as the Specific Absorption Rate or SAR. The SAR value of a phone depends on the model of the handset. Different countries have placed radiation exposure limits on the maximum level of SAR for modern handsets.[16] In the US, the Federal Communication Commission has set a maximum SAR limit of 1.6 W/kg, while in Europe this limit is 2W/kg.[13] The

Government of India has made it mandatory that all new designs of mobile handsets shall comply with the SAR values of 1.6W/kg averaged over 1g of human tissue.[79]

All the participants of this study used mobile phones with SAR values below 1.6 W/kg.

An increase in temperature reduces the ability of a material to repasssivate and thereby makes it vulnerable to corrosion. Temperature fluctuations can also affect the nature of the environment by changing the solubility of a constituent that can affect the corrosion behaviour of the material.[80]

The patients in the present study were hence instructed to avoid taking hot tea and coffee and were asked not to smoke during the study.

Corrosion resistance of the arch wires is found to decrease in direct proportion to the increase in the fluoride concentration in the mouth.[54] The participants were therefore advised to avoid using fluoridated toothpastes and mouthwashes during the study period.

Saliva collected by chewing paraffin or gum has a different organic composition compared to unstimulated saliva. In the resting state, about two-third of the volume of whole saliva is produced by the submandibular glands. When the salivary glands are stimulated, the parotids can account for at least half the whole saliva. Thus, stimulation could change the protein composition of saliva. Since nickel rapidly combines with proteins, a change in protein composition of saliva could also affect nickel concentration. This might possibly induce a false negative result.[38] Therefore unstimulated saliva was collected from the participants in this study.

All saliva samples were stored in a freezer at –20 ^{o} C to prevent any opportunity for bacterial growth until they were processed and subjected to nickel content analysis in the laboratory using inductively coupled plasma mass spectrometry.

Inductively coupled plasma mass spectrometry (ICP-MS) is a type of mass spectrometry which can detect metals and several non-metals at concentrations as low as one part in 10^{15} (part per quadrillion, ppq) on non-interfered low-background isotopes. The sample is ionized with inductively coupled plasma and then the ions are separated and quantified using a mass spectrometer. Compared to atomic absorption spectroscopy and inductively coupled plasma atomic emission spectroscopy, which were used in many previous studies, ICP-MS has greater speed, precision, and sensitivity.[51]

Mobile phones are known to generate heat and emit RFER in the form of ionizing electromagnetic radiation in the range of 800 to 2200 MHz.[63, 81] It has been found that an increase in the skin temperature and cutaneous microflow occurs on the side of the head against which the mobile phone is held. This heating of the skin is mostly due to heat conduction and electrical power dissipation from the handset while direct RF heating of the skin contributes only to a small part. [59-62]

The heat generated by the mobile phone when placed against the ear will change the properties, flow rate and the pH of saliva. These changes might increase the corrosion rate of the orthodontic appliances by influencing the passive layer on the metal surface.[67] All these effects might explain the increased release of nickel ions from orthodontic appliances with the use of mobile phones.

Since the mobile phone is held at a distance from the head and the mouth when a hands-free device like an earphone is used, the effect of the radiation emitted by the phone on the oral cavity and hence the salivary glands and orthodontic appliances is greatly reduced. This subsequently leads to a reduction in the action of the heat generated by the mobile phone on the arch wires and salivary glands. Therefore, the effect of increase in salivary flow rate, reduction in pH, the increase in temperature are all avoided to a large extent.

Thus, a comparative reduction in nickel ion release from orthodontic appliances may be expected when an earphone is used.

In the present study it was found that when the patients used earphones with mobile phones instead of directly placing the handset against the face, there was a comparative reduction in the nickel release from the orthodontic appliances into the patients' saliva.

The patients in Subgroup A were asked to use mobile phones only with earphones for the mean duration of 56.1 minutes during week 4 of the study. The mean value of nickel level then increased from 7.52 ng/ml to 8.29 ng/ml in these patients. This was a mean percentage increase of only 3.98% against the 87.11 % increase when these same patients had used mobile phones placed directly against the ears for the same mean duration of 56.1 minutes during week 2.

In like manner, the patients of Subgroup B showed a mean percentage increase of only 33.79 % in the salivary nickel level on using earphones with the mobile phone during week 2 of the study. This was against the mean percentage increase of 107 % when these patients had used mobile phones directly in week 4. Also, the increase in the mean level of nickel in these patients during the direct use of mobile phones in week 4 from 6.11ng/ml to 9.27ng/ml was statistically significant (P = 0.005). On the other hand, although the mean of nickel release at the end of week 2 was higher than week 1, this increase was not statistically significant (P = 0.139).

On intergroup comparison, it was found that Subgroup B patients on using earphones with mobile phones showed less mean percentage increase of salivary nickel content in week 2 compared to Subgroup A patients, even though they had greater mean duration of phone usage. Statistical analysis showed this difference to be significant (P = 0.034)

Likewise, Subgroup A patients also showed lesser increase in mean nickel content on earphone use in week 4 of the study when compared to Subgroup B patients who had then used mobile phones directly placed on the ear. This difference was again statistically significant (P = 0.001)

It may be thus surmised that the use of ear phones helps in reducing the release of nickel ions from fixed orthodontic appliances when exposed to mobile phone radiation.

Summary And Conclusions

SUMMARY AND CONCLUSION

SUMMARY

The present study was done in the of Department of Orthodontics and Dentofacial Orthopaedics, Tamil Nadu Government Dental College and Hospital, Chennai in collaboration with Chennai Mettex Lab Pvt Ltd, Chennai. A total of 30 patients in the age group of 15-20 years of both genders who were undergoing orthodontic treatment with fixed orthodontic appliances were included in the study according to the inclusion and exclusion criteria. Of these 20 patients successfully completed the study. Four patients did not maintain proper records of their mobile phone usage and six patients did not report for the weekly saliva sample collections and were hence excluded. Unstimulated saliva samples of the study population were collected, and nickel ion levels were assessed after use of mobile phones with and without earphones.

The results of the present study showed that

- Mobile phone usage leads to an increase in the release of nickel ions into the saliva of patients with fixed orthodontic appliances.
- There was a comparative reduction in the nickel ion release from the appliance when the patients used earphones with the mobile phones.
- There exists a positive correlation between the duration of mobile phone use and the nickel ion release from fixed orthodontic appliances.

LIMITATIONS OF THE STUDY

- The subjects of this study were not divided based on sex for the analysis of nickel level differences with respect to the speaking time.
- The data were not divided based on the type of arch wire present in the mouth during the study. The participants of this study had either 0.016 round SS wire or 0.016 round NiTi wire during the study period. The same wire was however maintained for each participant throughout the course of the study.
- Although the distance between the mobile phone antenna and the mobile base station can influence the magnitude of radiofrequency electromagnetic radiation emitted from the mobile phone, the controlling of this factor was beyond the scope of this study.

CONCLUSION

This short term interventional study has elucidated the efficacy of earphones in reducing the release of nickel ions from fixed orthodontic appliances when exposed to radiofrequency electromagnetic fields emitted by mobile phones. Future research by means of large scale longitudinal studies in this field is essential to further validate the results.

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Annexure: AF 06/004/01.0

INFORMED CONSENT FORM

"Effect of mobile phone use with and without earphones on salivary nickel ion release from fixed orthodontic appliances – A cross over trial"

Participant ID No:

"I have read the foregoing information sheet given to me about the methods and procedures to be followed for the study, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have asked, have been answered to my satisfaction. I consent voluntarily to participate as a participant in this study and understand that I have the right to withdraw from the study at any time without ii in any way affecting my further medical care."

Date Name of the participant Signature/thumb impression of the participant

[The literate witness selected by the participant must sign the informed consent form. The witness should not have any relationship with the research team; If the participant doesn't want to disclose his / her participation details to others, in view of respecting the wishes of the participant, he / she can be allowed to waive from the witness procedure (This is applicable to literate participant ONLY). This

should be documented by the study staff by getting signature from the prospective participant]

I have witnessed the accurate reading of the consent form to the potential participant and the individual has had opportunity to ask questions. I confirm that the individual has given consent freely"

Date Name of the witness Signature of the witness

Date Name of the interviewer Signature of the interviewer

PARTICIPANT INFORMATION SHEET

TITLE OF THE STUDY: "Effect of Mobile Phone Use With And Without Earphones on Salivary Nickel Ion Release from Fixed Orthodontic Appliances – A Cross Over Trial"

Name of the research institution: Tamil Nadu Government Dental College & Hospital

Purpose of the study

- To evaluate the effect of exposure to mobile phone radiation when used with and without earphones on the level of nickel in saliva.

Procedure of the study

- Saliva samples will be collected from the participants of the study after 1 week of refrainment from mobile phone use and the nickel content evaluated.
- The participants will be divided into two groups and saliva samples will again be collected after another week of mobile phone use without earphones in the first group and with earphones in the second group and the nickel content evaluated.
- Saliva samples will be collected for a third time for nickel content evaluation after another week of not using mobile phones.

- Saliva samples will finally be collected at the end of the fourth week after exchanging the participants of the two groups to assess the level of nickel in saliva.
- The participants are instructed to abstain from eating seafood and canned food, drinking hot tea and coffee during the study period.
- The participants are instructed to avoid brushing their teeth and rinsing their mouth with fluoridated products during the study period.
- The participants are advised to use their mobile phones only for making and receiving calls during the study.

Risk of participation

- Patients are selected only according to inclusion and exclusion criteria hence there will be negligible risk.

Benefit of participation: NIL

Confidentiality:

The privacy of the patients in the research will be maintained throughout the study. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

Participant's rights:

Taking part in the study is voluntary. You are free to decide whether to participate in the study or to withdraw at any time. Your decision will not result in any loss of benefits to which you are otherwise entitled.

Compensation: NIL

Contact:

For queries related to the study:

Primary Investigator: Dr. Ajma Aisha Ali

Contact Details: PG Section, Dept Of Orthodontics And Dentofacial Orthopaedics, Tamilnadu Govt Dental College Hospital, Frazer Bridge Road, Chennai-600003.

Phone number: 9645821328

For queries related to the rights as a study participant, please write to:

The Chairperson,

Tamilnadu Govt Dental College & Hospital,

Frazer Bridge Road, Chennai-600003

சுய ஒப்புதல் படிவம்

பெயர் : ஆராய்ச்சி சேர்க்கை எண் :

வயது :

பால் :

ஆராய்ச்சி செய்யப்படும் தலைப்பு

“பல் சீரமைப்பு சிகிச்சைக்காக பயன்படும் உலோக பொத்தான்களிலிருந்து வெளிப்பட்டு உமிழ்நீரில் கலந்திருக்கும் நிக்கல் உலோக துகள்களின் மீது கைப்பேசியை (மொபைல் போன் நேரடியாகவோ அல்லது கேட்பொறி (இயர் போன்) மூலமாக பயன்படுத்துவதால் ஏற்படும் தாக்கத்தினை ஒப்பீடு செய்தல்”

ஆராய்ச்சி நிலையம் : அரசு பல் மருத்துவக் கல்லூரி, சென்னை 600003.

பங்கு பெறுபவரின் பிறந்த தேதி : தேதி : .... மாதம் : .... வருடம் :

இந்த ஆய்வு சம்மந்தமாக நான் மேலே கூறப்பட்ட தகவல் படிவத்தை முழுமையாக படித்துப் பார்த்தேன் என்று உறுதி கூறுகிறேன்.

நான் இது தொடர்பாக அனைத்து கேள்விகளுக்கும் நிறைவான பதில் பெறப்பட்டேன்.

இந்த ஆய்வில் எனது பங்கு தன்னிச்சையானது என்றும், எந்த நேரத்திலும் இந்த ஆய்விலிருந்து சட்ட உரிமைகள் பாதிக்கக்கடாமல் விலகிக் கொள்ள சம்மதிக்கிறேன்.

மருத்துவ ஆய்வு அதிகாரிகள் எனது சிகிச்சை தொடர்பான பதிவேடுகளை பார்வையிடவும் எந்த நேரத்திலும் ஆய்விலிருந்து நான் விலகினாலும் பார்வையிட சம்மதிக்கிறேன். எனது அடையாளக் குறிப்புகள் மூன்றாவது நபருக்கு தெரிவிக்கப்பட மாட்டாது என்று புரிந்து கொண்டேன்.

இந்த ஆய்வு அறிக்கைகளை பயன்படுத்தவும் வெளிடவும் நான் சம்மதிக்கிறேன். ஆய்வாளர்கள் எனது மருத்துவ குறிப்புகளை வெளியிட தடையாக இருக்க மாட்டேன் என உறுதி அளிக்கிறேன்.

பங்கேற்பவரின் கையொப்பம் இடம் ....தேதி ....

கட்டைவிரல் ரேகை :

ஆராய்ச்சி பற்றிய தகவல் படிவம்

மரு. அஜ்மா ஆயிஷா அலி ஆகிய நான் மரு. பாலஷண்முகம் MDS., அவர்களின் வழிநடத்துதலின் கீழ் "பல் சீரமைப்பு சிகிச்சைக்காக பயன்படும் உலோக பொத்தான்களிலிருந்து வெளிப்பட்டு உமிழ்நீரில் கலந்திருக்கும் நிக்கல் உலோக துகர்களின் மீது கைப்பேசியை (மொபைல் போன்) நேரடியாகவோ அல்லது கேட்பொறி (இயர் போன்) மூலமாகவேத பயன்பத்துவதால் ஏற்படும் தாக்கத்தினை ஒப்பீடு செய்தல்" தொடர்பாக ஆய்வு செய்ய உள்ளேன்.

ஆய்வின் நோக்கம் :

பல் சீரமைப்பு சிகிச்சைக்காக பயன்படும் உலோக பொத்தான்களிலிருந்து வெளிப்பட்டு உமிழ்நீரில் கலந்திருக்கும் நிக்கல் உலோக துகள்களின் மீது கைப்பேசியை நேரடியாகவோ அல்லது கேட்பொறி மூலமாகவோ பயன்படுத்துவதால் ஏற்படும் மின்காந்த புலன்களின் தாக்கத்தினை கண்டறிதல்.

செய்முறை :

ஆராய்ச்சிக்காக தேர்ந்தெடுக்கப் பட்டவர்களுக்கு வழக்கம் போலவே பல் சீரமைப்பு சிகிச்சை மேற்கொள்ளப்படும்.

முதல் 7 நாட்கள் கைப்பேசியை முற்றிலும் பயன்படுத்தாமலிருக்க அறிவுறுத்தப்பட்டு அவர்களிடமிருந்து உமிழ்நீர் சோதனை மாதிரி சேகரிக்கப்படும்.

இந்த ஆராய்ச்சியில் தேர்ந்தெடுக்கப்பட்டவர்களை இரண்டு பிரிவினராக பிரித்து, ஒரு பிரிவு

அடுத்த 7 நாட்கள் கைப்பேசியை நேரடியாக பயன்டுத்த அறிவுறுத்தப்பட்டு அவர்களிடமிருந்து உமிழ்நீர் சோதனை மாதிரி சேகரிக்கப்படும்.

இன்னோரு பிரிவினருக்கு அடுத்த 7 நாட்கள் கைப்போசியை கேட்பொறியுடன் (இயர் போன் பயன்படுத்த அறிவுறுத்தப்பட்டு அவர்களிடமிருந்து உமிழ்நீர் சோதனை மாதிரி சேகரிக்கப்படும்.

இதன் பிறகு ஒரு வாரத்திற்கு கைபேசியை பயன்படுத்தாமலும் இன்னொரு பிரிவினர் கேட்பொடிறியுடன் கைபேசியும் பயன்படுத்தமாலும் மூன்றாவது வாரம் கணக்கிடபடுகிறது.

பின்னர் நான்காவது வாரம் பிரிவினர் பயன்படுத்தும் முறை மாற்றப்பட்டு நிக்கல் துகள் அளவு கணக்கிடப்படுகிறது,

ஆராய்ச்சியிக்கு உட்பட்டவர்கள் எந்த வித கடல்சார் உணவுகளையும் மிகவும் சூடான மற்று மிகவும் குளிர்ந்த உணவுகளை சாப்பிட வேண்டாம் என்று அறிவுறுத்தப்பகிறது

ஆராய்ச்யின் போது ஆராய்ச்சில் உப்பட்டவர்கள் பூளுரைட் பல் பேஸ்ட் கொண்டு பல்துலக்க கூடாது.

ஆராய்ச்யின் போது அவர்கன் கைபேசியை அழைப்பு மற்றும் பேசுவதற்கு மட்டும் உபயோக்கிக்க வேண்டும்.

அனைத்து சோதனை மாதிரிகளிலும் உள்ள நிக்கல் துகள்களின் அளவு கணக்கிடப்டும்.

நன்மைகள் :---

இரகசிய நன்மை :

நோயளிகள் பற்றிய குறிப்புகள் ஆராய்ச்சி முடியும்வரை ரகசியமாக பாதுகாக்கப்படும். இந்த ஆராய்ச்சியை வெளியிம்போது நோயாளிகளின் தனிப்பட்ட விவரங்கள் எதுவும் பாதிக்கப்படமாட்டாது.

பங்குபெறுவோரின் உரிமை :

இந்த ஆராய்ச்சியில் பங்கு பெறுவது நோயாளிகளின் தனிப்பட்ட விருப்பம் மேலும் நோயாளிகள் இந்த ஆராய்ச்சியலிருந்து எப்போது வேண்டுமென்றாலும் விலகி கொள்ளலாம். நோயாளிகளின் இந்த முடிவினால் அவருக்கோ அல்லது ஆராய்ச்சியாளருக்கோ எவ்வித பாதிப்பும் கிடையாது.

இந்த ஆராய்ச்சியின் முடிவும் நோயாளிகளுக்கு ஆராய்ச்சி முடியும் தருவாயிலோ அல்லது இடையிலோ தெரிவிக்கப்படும். ஆராய்ச்சியன் பொழுது ஏதும் பின் விளைவுகள் ஏற்பட்டால் அதை சரிசெய்ய தகுந்த உதவிகள் அல்லது தேவையான சிகிச்சைகள் உடனடியாக மேற்கொள்ளப்படும்.

இழப்பீடு : எதுவும் வழங்கப்படமாட்டாது.

ஆய்வு பற்றிய தகவலை பெற
மரு. அஜ்மா ஆயிஷா அலி
மூன்றாம் ஆணடு MDS.,
தமிழ்நாடு பல் மருத்துவ கல்லுரி மற்றும் மருத்துவமணை
சென்னை – 600 003.

செல்பேசி : ....

நோயாளியின் பெயர் கையொப்பம் / கைரேகை
தேதி

ஆராய்ச்சியாளரின் கையொப்பம் / கைரேகை
தேதி