EFFECT OF MOBILE PHONE WITH AND WITHOUT EARPHONES USAGE ON METAL ION RELEASE FROM FIXED ORTHODONTIC APPLIANCES.

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CERTIFICATE

This is to certify that DR T.BALAVIGNESH, Post graduate student (2015-2018) in the Department of Orthodontics and Dentofacial Orthopedics, Adhiparasakthi Dental College and Hospital, Melmaruvathur – 603319, has done this dissertation titled **"EFFECT OF MOBILE PHONE WITH AND WITHOUT EARPHONES USAGE ON METAL ION RELEASE FROM FIXED ORTHODONTIC APPLIANCES"** under our direct guidance and supervision in partial fulfillment of the regulations laid down by The Tamilnadu Dr .M.G.R Medical University, Chennai – 600032 for MDS; (Branch V) Department of Orthodontics& dentofacial Orthopedics Degree Examination.

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DECLARATION

TITLE OF THE DISSERTATION	"**Effect of mobile phone with and without earphones usage on metal ion release from fixed orthodontic appliances**"
PLACE OF THE STUDY	Adhiparasakthi Dental College and Hospital, Melmaruvathur – 603319
DURATION OF THE COURSE	3 years
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I hereby declare that no part of the dissertation will be utilized for gaining financial assistance or any promotion without obtaining prior permission of the Principal, Adhiparasakthi Dental College and Hospital, Melmaruvathur – 603319. In addition, I declare that no part of this work will be published either in print or in electronic media without the guides who has been actively involved in dissertation. The author has the right to reserve for publish work solely with the permission of the Principal, Adhiparasakthi Dental College and Hospital, Melmaruvathur – 603319

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ABSTRACT

AIM:

The aim of the study is to validate the hypothesis whether there is a significant variation in nickel ion release from fixed orthodontic appliance among the patients using hand held mobile phones and patients using mobile earphones.

MATERIALS AND METHODS:

A total of 60 healthy patients, who were undergoing fixed orthodontic treatment in the Department of Orthodontics and Dentofacial Orthopedics, Adhiparasakthi Dental College and Hospital, Melmaruvathur, Chennai, India and all these patients were bonded and banded and all of them are class I malocclusion with bimaxillary protrusion and their salivary samples were collected in their regular check up after two months and 7^{th} day,14^{th} day and 21^{st} day salivary nickel level were evaluated based on their usage of mobile phones with earphones and without earphones.

RESULTS:

Based on the statistics results, the mean of nickel release in the patients using mobile phone without earphones were significantly higher than the patients using mobile phone with earphones in both the males and females.

CONCLUSION:

By our study we concluded that usage of mobile phones with earphones have an significant reduced effects on metal ion release from fixed orthodontic appliance when compare to usage of mobile phones without earphones.

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LIST OF ABBREVIATIONS

RFER	-	**Radio Frequency Emitted Radiation.**
SAR	-	**Specific Absorption Rate**
RF	-	**Radio Frequency**
RV	-	**Radio waves**
MV	-	**Microwaves**
ELF	-	**Electromagnetic Fields**
MPH	-	**Handheld Mobile Phones**
Ni	-	**Nickel**
Ci	-	**Chromium**
MN	-	**Micronucleus**
CA	-	**Comet Assay**
DNA	-	**Deoxyribo Nucleic Acid**
IgA	-	**Immunoglobulin A**
SEM	-	**Scanning Electron Microscopy**
ICP-MS	-	**Inductively Coupled Plasma- Mass Spectrometry**
NITI	-	**Nickel Titanium**
SS	-	**Stainless Steel**

INTRODUCTION

Modern dental appliances are generally made of three main groups of materials, e.g. metals, resins and ceramics. Because they are intended to perform life-long in contact with the tissues of the oral cavity they are included in the group of biomaterials and considered, from a legal point of view, medical devices.

Most of the orthodontic Biomaterials are not inert, rather induces an interaction with the biological environment. This interaction will influence the material quality and also have side effects for the patients. The extent of the effect will determine the biocompatibility and safety of the material.

Metal is the considerable part of every orthodontic armamentarium. Earlier orthodontics used gold, platinum, titanium and silver alloy. The ductility, malleability and physical properties of those alloys made it inappropriate for complex machining for various orthodontic mechanics. To overcome these difficulties, stainless steel gained popularity in1932 in the field of orthodontics [2]. The austenitic stainless steel used in orthodontic brackets, bands and wires contains 18% of chromium and 8% nickel [1]. Intra oral fixed orthodontic appliance are mostly made up of alloys containing nickel, cobalt and chromium in different percentage [1,2].

The oral environment is particularly ideal for the biodegradation of metal because of its thermal, microbiological and enzymatic properties [2,9]. Several studies have investigated whether orthodontic appliances releases metal ions, through emission of electro galvanic currents with saliva as the medium or through continuous erosion overtime [8,10].

Nickel is the most common cause of metal induced allergic contact dermatitis in human beings and produces more allergic reaction than all other metals followed by chromium [19,39]. Nickel allergy was estimated as 16.9% in males and 28% in females [75]. Orthodontic appliances were reported to release 22-40 μg /day of nickel and 36 μg /day of chromium [38,60] .Nickel release from orthodontic appliance is far below the average nickel daily dietary intake. The content of nickel in body fluids (saliva, urine, blood) was shown to be increased in patient undergoing orthodontic treatment [31,32,].

The use of various combination of metal alloys for prolonged duration in orthodontic patients warrants special consideration regarding biocompatibility. The oral cavity is a complete corrosion cell with many factors enhance biodegradation of orthodontic appliance. The inherent heterogeneity of each metal alloy, force and function between wires and brackets, together with various chemical introduced into oral cavity, the fluctuation in pH , enzymatic and microbial activity influence the metal ion release from orthodontic brackets. Many in-vivo and in-vitro studies documenting the corrosion of orthodontic appliance and release of metal ions is indisputable [12,16,20,29]. It has been reported that metal ions are taken by the adjacent tissues, Predisposes toxic, allergic, mutagenic or carcinogenic effects. Albeit et al found out that the release of nickel ions from orthodontic appliance has shown to increase epithelial proliferation and an initiating factor for gingival overgrowth [48].

In the modern society the ever increasing psychological and physical stress associated with daily activities must also be considered. It affects the composition of saliva and pH of saliva which favours the nickel release from orthodontic appliance [36]. Over the past few years the use of mobile phones have become a kind of addiction indeed. It is almost impossible to imagine a life without a mobile phone. Many teenagers are of analytical about being always available and becomes extremely uneasy, if unable to contact their friends countless time every day.

The number of mobile phone users in the world is expected to pass the 5 billion mark by 2019. The mobile technology has emerged into our world and has caused many changes in our lifestyle. Statistics shows that 79% of US population and 90% of European and Asians teens own a mobile phone. Mobile phones has caused concern because of possible adverse effects from exposure of Radio Frequency Emitted Radiation (RFER) emitted by the device which operates as a receiver and a transmitter. Its operation is based on electromagnetic waves especially RF waves and microwaves.

Sadetzki et al examined the correlation between parotid gland and mobile phone usage and he found there is a dose dependent response. Thus the RFER emitted from mobile phones may influence the amount of nickel release from fixed orthodontic appliances [67].

Therefore our study was aimed to validate the hypothesis whether there is a significant variation in nickel ion release from fixed orthodontic appliance among patients using hand held mobile phones and patient using mobile ear phones.

AIM AND OBJECTIVES

Aim:

The aim of the study is to validate the hypothesis whether there is a significant variation in nickel ion release from fixed orthodontic appliance among the patients using hand held mobile phones and patients using mobile earphones.

Objective:

- To evaluate the effect of usage of mobile phones with and without earphones on nickel ion release in Male patients undergoing fixed orthodontic appliance therapy.
- To evaluate the effect of usage of mobile phones with and without earphones on nickel ion release in Females patients undergoing fixed orthodontic appliance therapy.
- To compare the effects among the individual group.
- To compare the effects between the two groups.

REVIEW OF LITERATURE

Greig in 1983[26], investigated several case reports of allergic reactions to nickel plated parts of a cervical headgear; hence the skin reactions may be avoided by covering exposed metal with varnish or non-allergenic strapping.

Park HY and Shearer TR (1983)[3] evaluated quantitative amounts of nickel and chromium released from simulated orthodontic appliances and they found that 40 µg nickel and 36 µg chromium released per day for a simulated full-mouth appliance. They concluded that these values are well below the normal daily intake of these two metals and may not be of clinical significance in most patients. However, the clinician should be aware that the release of the metal ions may cause a local hypersensitivity reaction at oral soft-tissue sites.

Vreeburg KJJ et al (1984)[4] studied the reaction of Ni-Cr compounds administered orally to either hypersensitivity or tolerance. They orally exposed guinea pigs to nickel and chromium. They concluded that individuals who are not hypersensitive to nickel or chromium may become tolerant to these metals as a result of the presence of these metals in their mouths.

Staerkjaer L and Menne T (1990)[19] investigated whether nickel sensitive persons are at greater risk of developing discomfort in the oral cavity during orthodontic treatment. Their study on 1085 girls treated by intraoral orthodontic appliances did not reveal any instance of intraoral nickel allergic reaction. Thus they concluded that nickel sensitive persons are not at greater risk of developing discomfort in the oral cavity when wearing an intraoral orthodontic appliance.

Gjerdet NR et al 1991[20], studied nickel and iron in saliva of patients with fixed orthodontic appliances. Saliva was obtained from patients receiving treatment with fixed orthodontic appliances. No statistically significant differences were found either in the concentrations or in absolute masses of nickel or iron in samples taken without appliances and in those obtained when the appliances had been in the mouth for at least 3 weeks. For samples taken immediately after placement of the appliance, there was a significant increase in both concentrations and masses of nickel and iron. Thus it seems, that there is a high initial release of metals, and the effect diminishes with time.

Grimsdottir MR et al (1992)[18] analyzed the nickel and chromium content in different types of metal appliances/devices used in orthodontics and evaluated the nickel and chromium release stored in physiologic saline. These appliance included face bows, brackets, bands and arch wires. They concluded (i) the release of nickel and chromium seemed to be related to the composition and the manufacturing of the appliances rather than directly related to the actual nickel and chromium content (ii) appliances like the face bow with silver or gold solders showed enhanced release of nickel and chromium, (iii) alloys containing titanium released little nickel when tested under static conditions.

Barrett RD et al (1993)[21] compared in vitro corrosion rate of a standard orthodontic appliance consisting of bands, brackets, and both stainless steel and nickel-titanium arch wires. The corrosion products analyzed were nickel and chromium. Evaluation was conducted with the appliances immersed for 4 weeks in a prepared artificial saliva medium at 37° C. They concluded that orthodontic appliances release measurable amounts of nickel and chromium when placed in an artificial saliva medium. The rate of release of nickel and chromium diminishes with time. The release rates of nickel and chromium from stainless steel or nickel-titanium arch wires were not significantly different. The release rate for nickel averaged 37 times greater than that for chromium.

Bishara SE et al (1993)[9] determined whether orthodontic patients accumulate measurable concentrations of the nickel in their blood during their initial course of orthodontic therapy. They concluded orthodontic therapy using appliances made of alloys containing nickel-titanium did not result in a significant increase in the blood levels of nickel.

Bass JK et al (1993)[22] determined if standard orthodontic therapy can sensitize patients to nickel and also assessed gingival response to nickel-containing orthodontic appliances in patients who are nickel sensitive before treatment, in twenty nine random patients. Their result showed a 17.2% prevalence rate of nickel sensitivity and they concluded that prevalence of nickel allergy is higher in females than males. Nickel-containing orthodontic appliances had little or no effect on the gingival and oral health of the patient and orthodontic treatment may induce nickel sensitivity.

Kerosuo K et al (1995)[23] investigated the amount nickel and chromium release from different types of orthodontic appliance, especially from a fixed orthodontic appliance in a simulated oral environment under both static and dynamic test condition. Their result indicated that dynamic conditions could alter the corrosion behaviour of orthodontic alloys. They concluded that there was a significantly detectable release of nickel and to minor extent chromium in different stainless steel orthodontic appliance in vitro. The amount of nickel release increased during functional stress.

Oller AR et al (1996)[24] gathered and reviewed the most pertinent epidemiological data available to understand the carcinogenic potential of various Ni compounds. They concluded that nickel subsulfide is likely to be carcinogenic where as nickel sulfate hexahydrate, by itself, is not likely to be carcinogenic to humans. Green nickel oxide was carcinogenic to animals and humans only at high temperature and high doses.

Kerosuo H et al (1996)[25] investigated the prevalence of nickel hypersensitivity in 700 Finnish adolescents in relation to sex, the onset, duration, and type of orthodontic treatment, in relation to age at which ears were pierced. All the patients underwent patch testing. The results suggested that orthodontic treatment did not increase the risk for nickel hypersensitivity, although orthodontic treatment with metallic appliances before sensitization to nickel (ear piercing) may even reduce nickel hypersensitivity.

Kerosuo H et al (1997)[27] investigated the nickel and chromium concentration of saliva in patients with different fixed orthodontic appliances. Their study included 47 patients from whom they collected saliva at different time interval. Their results showed large variation in the concentrations of both nickel and chromium in saliva. However they concluded that orthodontic appliances did not affect significantly the nickel and chromium concentration of saliva during the first month of treatment.

Janson GRP et al (1998)[28] determined the prevalence of nickel hypersensitivity in young subjects without previous orthodontic treatment, currently undergoing orthodontic treatment with fixed stainless steel appliances, and previously treated with orthodontic fixed stainless steel appliances and also compare the prevalence of nickel hypersensitivity in the three aforementioned groups to evaluate the possibility that stainless steel orthodontic appliances induce a hypersensitivity reaction to nickel. They concluded that orthodontic treatment with conventional stainless steel alloys did not induce a nickel hypersensitive reaction. There was a sexual dimorphism for the hypersensitivity reaction to nickel and the frequency in females was four times that of males. There was an association between personal history of allergic reaction to metals and use of metallic objects in contact with the skin with hypersensitivity to nickel. Previous family history of allergy, blood group, presence of restorations, number of restored teeth, age, lower 3 × 3 retainer, and the elapsed time after appliance removal did not characterize the nickel hypersensitive subject.

Vijay K Biswa, and V Surendra Shetty in 1998[34], indicated that a decrease in pH increased the release of nickel and chromium concentration, while an increase in pH decreased the release. Artificial saliva was made for each pH value i.e.5, 6,7,8. However, it was noted that the obtained release of nickel and chromium are less than 5-10% of the reported average daily intake for nickel and chromium.

Kim H and Johnson JW (1999)[29] studied the corrosion potential of various commercially available orthodontic wire alloys and determined whether epoxy or nitrite coating could inhibit corrosion of the wire. The authors concluded that titanium wires were safer to use in corrosive environment and it was unlikely to release metal ions when used intraorally, so it could be used in patient with nickel hypersensitivity. Further if nickel titanium was to be used, epoxy-coating would protect it from the environment, thus lowering the corrosive potential and subsequent release of nickel.

Jia W et al (1999)[30] studied the amount of nickel released from three types of nickel containing arch wires into a synthetic saliva in-vitro, and evaluated whether there is cytotoxic in human PBMC. The results obtained was the maximum amount of nickel released from all tested arch wire was 700 times lower than concentration necessary to induce cytotoxic effect in human PBMCs.

Wataha JC et al (1999)[33] selected an *in vitro* cell-culture system to evaluate several alloys containing nickel, used in biomedical applications, for the releae nickel containing alloy of either IL-1β or TNF-α from monocytes or expression of ICAMs on endothelial cells. Their results showed only pure Ni had statistically significant cytotoxic effect as assessed by succinic dehydrogenase (SDH) activity after 72 h of exposure. The authors concluded that, there was no *in vitro* evidence that found that Ni-containing biomedical alloys could directly induce the intercellular adhesion molecule (ICAM-1) on endothelial cells.

Kocadereli I et al (2000)[13] determined the alterations in the chromium and nickel concentrations in the saliva of orthodontic patients treated with fixed orthodontic appliances. The authors found no significant differences between the control group and the samples obtained after insertion of the appliances. The results of the study suggested that fixed orthodontic appliances did not significantly affect nickel and chromium concentrations of saliva during the first 2 months of treatment.

Hwang C J et al (2001)[34] measured the metal release in artificial saliva for a period of 3 months. The study included 320 prepared simulated orthodontic appliances .All the 320 samples were divided into 4 groups according to the manufacturer and the type of ligated wires. They conclude that the daily amount of chromium and nickel released was insignificant when compared with the daily dietary intake of these metals.

Agaoglu G et al (2001)[8] evaluated the concentrations of nickel and chromium ions in salivary and serum samples from patients treated with fixed orthodontic appliances. They concluded that fixed orthodontic appliances release measurable amount of nickel and chromium when placed in the mouth, but this increase did not reach toxic levels for nickel and chromium in the saliva and serum.

Eliades T et al (2002)[35] addressed the critical issues of corrosion potential and nickel leaching from alloys by investigating the effect of intraoral conditions on the surface reactivity of the materials. This review was presented with the methods for studying its release, hypersensitivity in orthodontic patients induced by nickel and its biological effects.

Faccioni F et al (2003)[11] conducted in-vivo study to evaluate the biocompatibility of fixed orthodontic appliances, evaluating the presence of metal ions in oral mucosa cells, their cytotoxicity, and their possible genotoxic effects. The results indicated that nickel and cobalt concentrations were 3.4-fold and 2.8-fold higher, respectively, in the patients than in the controls. The biologic effects, evaluated by alkaline comet assay, indicated that both metals induced DNA damage.

Rahilly G & Price N (2003)[36] discussed the diagnosis of nickel allergy in orthodontics and describes alternative products that were nickel free or have a very low nickel content, which would be appropriate to use in patients diagnosed with a nickel allergy. They quoted that stainless steel orthodontic wires, brackets, and auxiliaries appeared to be safe. However, high content nickel-titanium wires should be avoided in nickel sensitive patients, as nickel free alternatives were available and should be considered for these patients.

Marigo M et al (2003)[37] developed a new approach to test the impact of nickel antigen on in vitro cell-proliferation assay, to identify adverse reactions to casting alloys among orthodontic patients. Cell- proliferation assay in vitro was used as the basic methodology to assess the influence of such variables as source of nickel antigen, type of serum used to supplement the culture medium, and number of cells in the culture.

Eliades T et al (2003)[38] assessed qualitatively and quantitatively the salivary metal content of orthodontic patient. This study included 17 subject and their result showed no statistically significant differences found among groups with respect to metal concentrations. The range of salivary metal level found did not exceed those of daily intake through food and air.

Huang HH, et al (2003)[40], the author concluded that the manufacturer, pH value, and immersion period, had a significant statistical influence on the release of Ni and Ti ions. The amount of Ni ions released in all test solutions was well below the critical value necessary to induce allergy and below daily dietary intake level. The amount of Ti ions released in pH>/=3.75 solution was mostly not detectable, representing that the TiO_2 film on NiTi wires exhibited a good protection against corrosion. Pre-existed surface defects on NiTi wires might be the preferred locations for corrosion. The NiTi wire with the highest release amount of metal ions had the maximal increase in surface roughness after immersion test, while a rougher surface did not correspond to a higher metal ion release.

Fiorenzo faccioni, Paola .F, et al (2003)[11] concluded that nickel and cobalt concentrations were 3.4 fold and 2.8 fold higher in patients than in controls; cellular viability was significantly lower in the patients than in the controls but there was a significant negative correlation with metal levels. The biologic effects, evaluated by alkaline cornet assay indicated that both metals induced DNA damage (more cells with cornets and apoptotic cells) and there were significant positive correlations between (1) cobalt levels and the number of cornets and apoptotic cells (2) nickel cells and number of cornet cells and (3) cobalt levels and cornet tails.

C G Matasa et al (2003)[50], Instead, of using various method to test amount leached in-vitro he did an simple, do-it-yourself test was proposed. The appliances presumed to endanger the health of the patient are immersed, along with known samples (controls), in a solution recommended by ISO for the accelerated corrosion of stainless steel alloys for dental castings. To allow detection, the solution is added with reagents specific for nickel or iron and then gelled. After a few hours, the degree of attack and the nickel and iron releases can be inferred from the size of the colored spots generated around the immersed attachments. Hence concluded that the method has been successfully applied to wires, brackets, and expansion screws, detecting the attachments that have a greater likelihood of harming the patient.

Kalimo K et al (2004)[39] studied nickel sensitization among university students exposured to orthodontic treatment. One hundred and fifty-three randomly selected university students visiting the Finnish Student Health Service in Turku in 1997–98 participated. One hundred and twenty-one were females and 32 were males with a mean age of 22 years. Result showed 21 of 44 of the students with pierced skin displayed a positive skin patch test to nickel with no differences regarding timing of orthodontic treatment. Fifteen were with non-permanent appliances, and five of eight females with skin piercing had developed nickel allergy. All seven males without skin piercing were patch test negative.

Huang TH et al (2004)[40] compared the metal ion release from new and recycled orthodontic metal brackets following immersion on artificial saliva under controlled conditions of PH over an extended time interval. The authors have investigated four different types of brackets Unitek DynaLock twin-torque brackets, Tomy metal base brackets, Ormco standard edgewise bracket and Dentaurum Rickett bracket. Their results showed that metallic brackets immersed in a PH -4 solutions released more ions than those immersed in buffered artificial saliva solution at PH- 7. The release of metal ion increased with long-term immersion of the brackets, with Ni being the most predominant metal ion released. The highest level of Cu ion release was found with the Dentaurum brackets following immersion for 48 weeks. They concluded that metal brackets used in orthodontic appliance would corrode in an acid or neutral environment after long-term use.

Leite LP and Bell RA (2004)[41] reviewed the implications of latex- and metal-based allergens and provided suggestions for management of such reactions in the orthodontic office. They concluded that metal based orthodontic appliances did not increase the risk for nickel hypersensitivity to patients.

Theodore Eliades, et al (2004)[15]**,** in this in- vitro study, the ions released from stainless steel and NiTi orthodontic alloys were found to have no measurable effect in viability and physiology of PDL and gingival fibroblasts.10% of males in this study showed allergic reaction in the form of gingivitis.

Gursoy S et al (2004)[13] determined and compared the levels of Ni, Cr, Mn, Cu, Ti, and Fe released from four bracket-arch wire combinations. The author divided 60 appliance into four equal groups ,new brackets and new arch wires (group 1), 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). They concluded that the recycled brackets–recycled arch wires appliances 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 the amounts of Cu, Cr, and Ti ions released from the recycled brackets–new arch wires (group 3) and recycled brackets–recycled arch wires (group 4) appliances were significantly greater than the amounts released from the other two combinations.

Arndt M et al (2005)[44] determined the nickel ion release of NiTi wires simulating the intraoral environment in a nearly realistic manner and compared the results with reference wires made of stainless steel, cobalt chromium and titanium molybdenum. Nickel titanium seems to be a biocompatible material and is applicable for orthodontic treatment. The authors concluded that even under mechanical and thermal loading the nickel release was far below than the daily dietary intake level. The release of nickel could be reduced if the surface nickel concentration was in the same range as in the bulk of the super elastic material. The presence of aluminium on the surface seemed to have negative influence on nickel ion release as well, while nickel substitution by copper was neutral.

Kasacka I et al (2006)[45] assessed the changes in salivary cells of allergic patients treated with fixed orthodontic appliances conducted on the non-stimulated saliva obtained from 39 subjects. The results showed that the number and the morphology of salivary cells in allergic patients altered in response to ions released from dental alloys. Thus, saliva could be used as diagnostic material.

Fors R and Persson M (2006)[10] compared the nickel content in the saliva and the dental bio film in young patients with and without orthodontic appliances. The possible influence of dietary intake of nickel on recorded nickel levels was examined. A significantly higher content of nickel was found in the plaque and the filter-retained fraction of whole saliva of patients with orthodontic appliances compared with non orthodontic patients. Moreover, in orthodontic patients, significantly higher nickel content was found in plaque from metal surfaces (band and brackets) than from enamel surfaces.

Pantuzo MCG et al (2007)[46] compared the cutaneous sensitivity provoked by conventional metallic brackets to that brackets with low concentrations of nickel, also known as nickel-free brackets in 58 orthodontic patients out of 400 patient undergoing orthodontic treatment. A significant positive association was found between patients sensitive to nickel and a history of contact allergy, and it was therefore important to elicit this fact when taking a patient's medical history. The nickel-free test specimens provoked a significantly smaller allergic reaction in only 31% of the patients, sensitive to nickel. The allergenic potential of other metals such as chrome and cobalt should be emphasised, and a response to them occurring simultaneously with a response to nickel should be considered since they are all constituents of orthodontic accessories.

Menezes LM et al (2007)[47] evaluated systemic changes in nickel levels after the placement of fixed orthodontic appliance in 21 patients. Their results showed statistically significant difference in the amount of nickel excreted that was observed before and after placement of the appliances, and they concluded that nickel increased significantly in patients' urine 2 months after the placement of fixed orthodontic appliances. The biologic effect of a systemic increase in urinary nickel was unknown.

Gursoy UK et al (2007)[48] determined the amount of nickel accumulation in gingival tissues with or without gingival overgrowth within the orthodontic patients Their results indicated low-dose continuing nickel release from orthodontic appliances might have been the initiating factor for gingival overgrowth, as it had the capability of increasing epithelial cell proliferation.

de Souza RM and de Menezes LM(2008)[49] investigated the ion release associated with the biodegradation process of three brands of metallic brackets manufactured with different types of steel and techniques. This study was conducted using removable appliances with bonded brackets. These appliances were worn for 60 days. They concluded that there was a large variability among individuals in the concentrations of nickel, chromium, and iron ions in saliva. There was an increase in nickel and chromium ions immediately after placement of the appliance in the mouth. There was no alteration in iron levels after placement of the appliance. There were no significant differences among the nickel, chromium, and iron levels released by the three groups at all study periods.

Amini F et al (2008)[50] compared the content of nickel, chromium and cobalt in oral mucosa cells in young patients with and without orthodontic appliances. Totally 60 subjects were included in this study out which 30 were orthodontic patients and the other 30 were the control group. Their results showed a mean level 12.26 ng/ml of nickel in the control group and 21.74 ng⁄ml in the test group. The authors concluded that there was no difference in the concentration of chromium and cobalt in oral mucosa cells of patients with or without fixed appliances.

House K et al (2008)[12] reviewed the potential mechanical, clinical, and health implications of orthodontic corrosion. The authors concluded that metal ions were released during orthodontic treatment, but the level was far lower than that ingested in a routine daily diet. Some patients demonstrated nickel hypersensitivity when exposed to nickel-containing alloys; previous nickel sensitivity, and the patient's age were the best indicators. There were even indications that orthodontic treatment could improve the immune system's tolerance to nickel in sensitive people. There was significantly higher concentration of nickel found in buccal mucosa cells of patients wearing fixed orthodontic appliances.

Pazzini CA et al (2008)[51] determined the prevalence of nickel allergy in a population of orthodontic patients and longitudinally compared the periodontal status of these patients to a group of nonallergic patients. Ninety-six individuals about to begin orthodontic treatment prior to the placement of the appliances, all participants received prophylaxis with a bicarbonate spray as well as orientation on oral hygiene. Their results showed 17.2% prevalence of nickel allergy, in that 94% occurred in female patients and 6% in male patients. They concluded that the cumulative effect of nickel throughout orthodontic treatment and was associated with clinically significant periodontal abnormalities.

Singh DP et al (2008)[15]evaluated the changes in the salivary nickel and chromium concentration in orthodontic patients over a period of time. 10 patient who were about to undergo orthodontic treatment were included in this study. The fixed orthodontic appliances consisted of an average of 4 bands and 16 brackets. They concluded that there was a statistically significant difference in salivary nickel and chromium when measured at baseline, 1 week and 3 weeks after insertion fixed orthodontic appliances. The highest release of both metals was noted in the first week and then decreased in the third week. The concentrations of both elements in the post appliance insertion period were higher than the baseline levels.

Westphalen GH et al (2008)[52] determined the genotoxicity induced by metals from orthodontic appliances, by employing both the micronucleus (MN) and the comet assay (CA) in a group of twenty healthy patients undergoing orthodontic treatment. Primary DNA damage level, as assessed by the CA, was low either before the beginning or 10 days after the placement of orthodontic appliance and did not change significantly between these time points. MN assay was found to be more sensitive than CA.

Sfondrini MF et al (2008)[54] evaluated and compared the amounts of chromium released from three different kinds of metallic orthodontic brackets: new conventional stainless steel brackets, recycled stainless steel brackets, and nickel-free (Ni-free) brackets in vitro. Their study included 360 new conventional Victory stainless steel brackets, 360 recycled Victory stainless steel brackets and 360 Sprint Ni-free brackets. The results showed that greatest amount of chromium was released from new stainless steel brackets (0.52 ± 1.083µg/g), whereas the recycled brackets released 0.27 ±0.38 µg/g and the smallest release was measured with Ni-free brackets (0.21 ±0.51 µg/g). The greatest chromium release was measured at acidic pH (pH 4.2). Chromium release from all types of brackets tested was very low when compared with daily dietary intake.

Luft S et al (2009)[16] determined corrosive processes on classical and self-ligating orthodontic brackets by a static immersion test combined with the analysis of the nickel ion release, and a potentio-dynamic electrochemical test using scanning electron microscopy (SEM) before and after electrochemical exposure. The nickel ion release into artificial saliva was measured by inductively coupled mass spectrometry (ICP-MS). Nine commercially available brackets were used in this study. The measured nickel release was far below the daily dietary intake level for all tested bracket systems. A static immersion test combined with the nickel ion release measurement seemed to deliver information of high relevance for clinical application and biocompatibility.

Kuhta M et al (2009)[55] determined the types and quantities of metal ions released from three types of arch wires of different composition and mechanical properties in solutions of different pH values and also evaluated the change in pH and time of exposure on release of metal ions from these alloys. The arch wires used were nickel-titanium (NiTi), thermo NiTi, and stainless steel (SS). Statistically significant stimulation of ion released at lower pH. Release of metal ions was influenced by the composition of the orthodontic arch wire, but this was not proportional to the content of metal in the wire. Quantities of all released ions were below toxic levels and did not exceed the daily dietary intake, but these levels were sufficient to cause an allergic reaction because of the high potential of released elements.

Kolokitha OE and Chatzistavrou E (2009)[55] reported a severe reaction to nickel-containing orthodontic appliances in an adult 27-year-old female patient, which occurred after the surgical exposure of her impacted teeth. The patient presented an allergic reaction to nickel-containing orthodontic brackets only after the surgical exposure of the impacted teeth, which acted as an injury; the bonding of the metal buttons caused the contact with the allergen. No signs of allergy were seen before surgical exposure, although the patient was in orthodontic treatment with metal brackets, bands, and NiTi arch wires.

de Menezes LM et al (2010)[58] reviewed the release of ions from metallic orthodontic appliances. The authors concluded that several questions remain unanswered concerning the biological effect of a systemic increase in nickel levels. There was a lack of information on abnormal accumulation of nickel in specific tissues of the body. The increase of nickel in the patients, despite the low amounts in the composition of orthodontic appliances, was not easily explained. The differences in the changes of excretion of these metal ions might be due to differences in corrosion processes, solubility coefficients, or excretion mechanisms. Although increases in metal ion levels had been detected in some studies after placement of orthodontic appliances, the levels were not sufficient to cause alarm.

O Goldwein et al (2010) [11] A significantly higher saliva secretion rate was noticed in the dominant MPH side compared with that in the non-dominant side. Lower total protein concentration was obtained in the dominant compared with the non-dominant MPH side among the right dominant MPH users. Parotid glands adjacent to handheld MPH in use respond by elevated salivary rates and decreased protein secretion reflecting the continuous insult to the glands. This phenomenon should be revealed to the worldwide population and further exploration by means of large-scale longitudinal studies is warranted.

Mikulewicz et al (2011)[60] investigated metal toxicity of stainless steel orthodontic appliances both in-vitro and in-vivo. The authors assessed chemical composition of brackets, bands, and wires using X-ray microanalysis. They concluded that the use of fixed orthodontic appliances made of stainless steel could be a source of risk exposure to nickel. The coefficients α, β and γ showed the elements which were dissolved to the highest extent and that their release was not proportional to their content in an alloy.

Hafez H S et al (2011)[61] undertook a longitudinal study on the biocompatibility of fixed orthodontic appliances. They concluded that the buccal mucosa cells of patients treated with fixed orthodontic appliances for 6 months showed significant increases in nickel and chromium content, with a significant decreases in viability and damage to the DNA. The compared result with control group showed significant changes in cellular chromium content and DNA damage at 3 months. This may imply recovery from the initial insult by cellular and DNA tolerance or repair. Stainless steel brackets with stainless steel arch wires showed the least biologic damage, whereas the titanium brackets with nickel-titanium arch wires produced the greatest cytotoxicity and genotoxicity.

Sahoo N et al (2011)[62] evaluated and compared the salivary levels of nickel and chromium before and 1, 7, and 30 days after placement of conventional and self-ligating appliance systems and they had found that the amount of nickel and chromium released into saliva from conventional and self-ligating brackets progressively increased from days 1 to 7 and then decreased at day 30. Nickel release was less and chromium release was greater in the conventional bracket group. They concluded that the conventional and the self-ligating brackets did not seem to affect significantly the nickel and chromium concentrations in saliva during the first month of treatment.

IONUȚ-CORNEL IONESCU et al (2012)[63] stated that there is a direct correlation between the amount of metal in the oral cavity and the temporary decrease of pH in the presence of mobile phones.

They shown that the effects of Radio Frequency (RF) microwave and consequently ELF electromagnetic fields may represent a risks and partially affect the orthodontic treatment.

Stuti Bhargava et al (2012)[16] its is an in vitro study that he took 142 individuals and divided into 2 groups of heavy users and control subjects using a modified schirmer test. And stated that a significant increased in saliva flow rate along with increased blood flow rate and volume of the parotid gland of the slide where mobile phones are frequently placed was observed in the heavy user group.

Yaniv Hamzany et al (2013) [66] in this article they compared the salivary outcomes (secretion, oxidative damage indices, flow rate, and composition) between mobile phone users and nonusers. They reported there was significant increase in all salivary oxidative stress indices studied in mobile phone users. Salivary flow, total protein, albumin, and amylase activity were decreased in mobile phone users. These observations lead to the hypothesis that the use of mobile phones may cause oxidative stress and modify salivary function.

ARBABI-KALATI et al (2014)[65] this author concluded Speaking on the mobile phone over an hour will decrease total antioxidant capacity of saliva and salivary IgA levels more than those speaking less than 20 minutes; this may increase the risk of inflammatory diseases or mouth cancer in the people. It is suggested that future studies be conducted with larger sample size examining the antioxidant system separately.

Namrata Adhauliya et al (2015) [68] this author Concluded that in most studies, no statistically significant changes were recorded in oral mucosal cells and Short-term usage could not be associated with an increased risk of developing salivary gland tumors and Most studies demonstrated a significant increase in salivary flow rate and volume of salivary glands as well as an increase in oxidative stress.

Mohammad Ali Saghiri et al (2015) [67] from the outcomes of this study, it can be concluded that mobile phone radiation, regardless of the type of phone, can influence the concentration of nickel in saliva in a time-dependent manner. In addition, this adverse effect of radiation on the release of nickel was more prominent in women because of longer usage times. Future large-scale studies, which should include more parameters such as the effects on the parotid glands or the saliva fl ow rate, are needed.

Jatin Gupta et al (2016) [69] This study was conducted on 200 healthy male and female individuals aged 18-30 years with a history of handheld mobile phone use ≥ 3 years. Group I (50 male, 50 female participants) was the heavy-user group, who used handheld mobile phone ≥ 2 hours daily on average. Group II, the control group, (50 male, 50 female participants) participants used mobile phone < 2 hours daily. Unstimulated parotid saliva flow rate from parotid glands on both sides was measured by Modified Schirmer test. Lipid peroxidation levels were biochemically analysed using calorimetric methods. Group I showed more significant rate of parotid salivation on the dominant side compared with the non-dominant side in contrast to Group II, whereas no significance was observed in antioxidant levels. These observations lead to the hypothesis that the use of mobile phones may modify salivary gland function.

Neda Babaee et al (2016)[71] The relationship between the dominant phone conversation side and parotid amylase activity was not statistically significant but the correlation between prevailing chewing side and amylase activity was statistically significant (p=0.001). This author Concluded Handheld mobile phone was not effective on parotid amylase enzyme activity whereas chewing was effective on parotid amylase enzyme activity.

Nanjannawar L G et al (2017) [72] stated that though the pH levels were reduced and the nickel ion levels were higher in the experimental group compared to the control group, the results were non-significant and Concluded Mobile phone usage may affect the pH of saliva and results in increased release of nickel ions in saliva of patients with fixed orthodontic appliances in the oral cavity.

MATERIALS AND METHODS

A total of 60 healthy patients, who were undergoing fixed orthodontic treatment in the Department of Orthodontics and Dentofacial Orthopedics, Adhiparasakthi Dental College and Hospital, Melmaruvathur, Chennai, India were selected for this study. Sample size was determined using G Power 3.0.10. Effect size of 0.891 was calculated using data from a similar previous study by Saghiri MA et al [65].

Ethical clearance was obtained from the Research Review Committee Written consent was obtained from the patients to participate in this study by providing them information about the purpose of the study

Inclusion criteria:

i. Patients (both male & female) in the age group of 18- 25 years.

ii. Angles class I malocclusion with Bimaxillary protrusion which needs therapeutic extraction of all first premolars.

iii. Mobile phone usage should be minimum of 30 minutes per day.

Exclusion criteria:

i. Patients with systemic diseases or medication intake.
ii. Patients who smoke or consume alcohol.
iii. Patients with any metallic restoration such as amalgam or fixed prosthesis.
iv. Patient with missing or extracted tooth – except third molars.
v. Unwilling patients.
vi. Menstruating women.

All those patients who satisfied both inclusion and exclusion criteria were bonded with 0.022'' Equilibrium 2 MBT (DENTARUM) (figure:1) and Transbond XT (figure:2) Prescription brackets. After initial levelling and aligning all these patients were upgraded to 0.016 Ni-Ti (3M UNITEX ORTHOFORM III ARCH) in the both upper and lower arches. And each tooth were secured with 3M UNITEX clear modules (figure:3) and they were divided into two groups of 30 each based on their sex. A total of sixty patients were interviewed regarding their duration of mobile phone usage. Group I: 30 Male patients and Group II: 30 Female patients were selected.

In regular check-up after two month patients saliva samples were collected on the 7th day in both groups and sent to laboratory for estimation of amount of nickel present in saliva and the patients recalled after one week with regular use of mobile phones and the saliva samples were again collected on the 14th day to estimate the amount of nickel present in saliva (figure:4,5).

For the next visit, patients were strictly instructed to use their mobile phones with earphones for one week and the saliva samples were collected at the end of 21st day and sent for salivary nickel evaluation. A chronometer was given to the patients to calculate how many minutes they used their cell phones during the experiment. At the end of second week saliva samples were collected, and the sexes, ages and cell phone usage times were also recorded.

Salivary Sample collection:

All these patients were instructed not to drink hot tea or coffee for three days prior to saliva collection appointment. They were also asked not to use any fluoridated products such as toothpastes or mouth rinses for three nights before visit. Before the collection of saliva from patients, they were asked not to eat and drink an hour before collection. In order to overcome diurnal variations, all samples were collected in the morning between 9 am and 11 am. Unstimulated saliva samples were collected by spitting method in sterile containers. For this, the subjects were asked to collect their saliva in nickel free, 20 ml plastic containers for two minutes and then it was taken (figure:4,5). Saliva samples were isolated and kept at -20^{0}C and transferred to laboratory for analysis. Inductively coupled plasma-mass spectrometry were used to measure the nickel ion levels in the saliva samples (figure:6).

Figure: 1 Dentarum 0.022” MBT prescription bracket

Figure: 2 3M Transbond XT bonding kit

Figure: 3 Armamentarium used for individual patients.

Figure: 4 Initial Sample collection from 20 healthy patients

Figure: 5 Unstimulated salivary sample of 53 healthy patients.

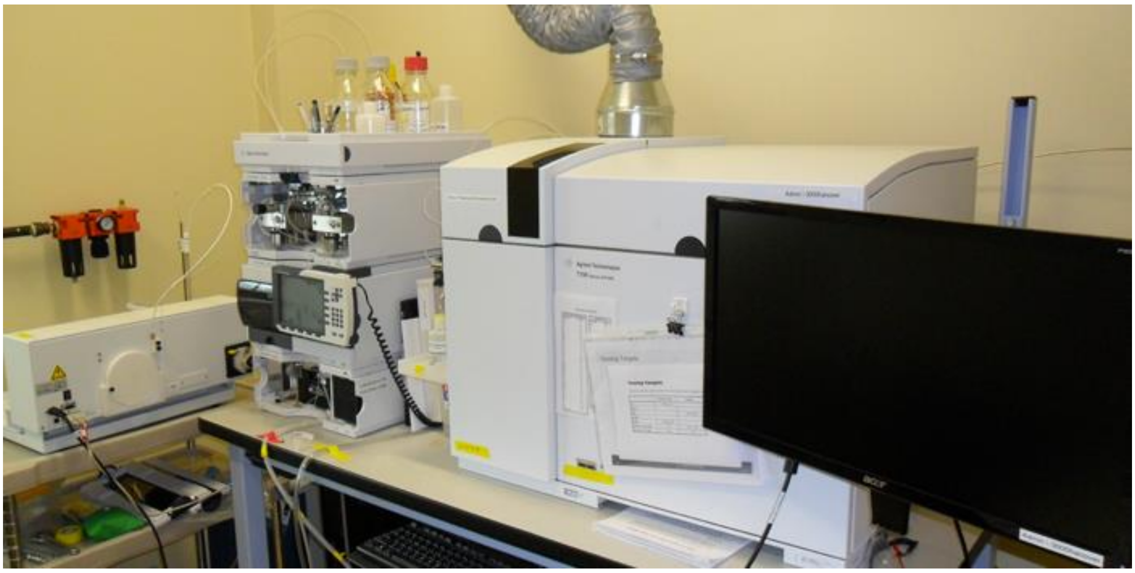

Figure: 6 Inductively coupled plasma-mass spectrometry (ICP-MS)

RESULTS

S.No	Initial sample 7th day	without earphone14th day	with earphone 21st day
1	0.79	3.58	3.38
2	1.56	7.73	5.03
3	3.2	4.39	4.04
4	0.40	3.26	-
5	0.98	5.15	3.24
6	0.49	8.55	8.33
7	2.85	5.91	4.40
8	0.36	5.78	5.03
9	0.97	3.18	2.23
10	0.35	4.14	3.78
11	2.68	3.74	3.33
12	0.70	3.92	3.78
13	0.40	-	-
14	0.52	6.32	4.24
15	0.32	7.67	5.77
16	2.21	10.32	8.23
17	0.47	5.47	4.97
18	3.25	-	-
19	0.91	8.37	5.95
20	0.67	5.79	4.84
21	3.45	9.38	7.29
22	0.45	6.34	5.11
23	0.69	7.27	5.69
24	1.82	5.82	4.34
25	0.77	6.96	4.92
26	0.89	4.55	4.10
27	1.23	5.79	3.76
28	0.66	3.56	2.96
29	0.39	6.73	-
30	0.47	7.76	6.13

Table: 1 Salivary Nickel ion levels for Group. I (30 male patients).

S.No	Initial sample 7th day	Without earphones 14th day	with earphones 21st day
1	1.34	3.79	2.54
2	1.14	5.59	3.89
3	1.45	4.25	3.19
4	0.44	4.19	3.28
5	0.75	3.11	2.28
6	2.35	4.34	3.28
7	3.16	4.93	3.39
8	2.45	3.93	-
9	0.57	5.73	4.24
10	0.74	4.43	2.21
11	0.93	5.81	3.72
12	1.17	6.73	4.93
13	1.49	7.54	5.27
14	0.69	5.93	3.32
15	3.76	10.73	8.45
16	5.23	11.51	8.37
17	4.44	9.77	7.63
18	0.32	5.12	3.93
19	0.23	6.21	4.50
20	0.29	4.73	-
21	2.83	3.35	3.19
22	3.64	5.17	4.83
23	1.71	6.73	5.21
24	0.53	5.43	4.84
25	1.93	4.97	4.03
26	0.76	-	-
27	1.32	6.34	4.83
28	2.36	6.98	5.06
29	0.98	3.75	2.48
30	1.78	4.29	3.04

Table: 2 Salivary Nickel ion levels for Group. II (30 female patients)

NOTE:

- All the units are measured in PPb (parts per billion).
- All these patients were used their cell phones at an average of more than half hour per day.

STATISTICS RESULTS:

(If P-Value is <0.05 then statistically significant)

The Normality tests Kolmogorov-Smirnov test results reveal that the variable follows Normal distribution. Therefore, to analyse the data Parametric methods are applied. To compare the mean values between groups independent samples t-test is applied. To compare mean values between time points paired sample t-test is applied. To analyse the data SPSS (IBM SPSS Statistics for Windows, Version 22.0, Armonk, NY: IBM Corp. Released 2013) is used. Significance level is fixed as 5% ($\alpha = 0.05$).

Variables	Group	N	Mean	Std. Dev	p-Value
Initial sample (ppb)	Group -I	26	1.2504	1.05124	0.165
	Group -II	27	1.7432	1.39836	
without earphones 14th day(ppb)	Group -I	26	6.0716	1.96617	0.596
	Group -II	27	5.7608	2.15047	
with earphones 21st day (ppb)	Group -I	26	4.7776	1.52134	0.320
	Group -II	27	4.3220	1.68193	

Table: 3 Independent samples T-Test to compare mean values between Group I and Group II

Group	Pair	Variables	N	Mean	Std. Dev	p-Value
Group -I	Pair 1	Initial sample (ppb)	26	1.2504	1.05124	**<0.001**
		Without earphones 14th day (ppb)	26	6.0716	1.96617	
	Pair 2	Initial sample (ppb)	26	1.2504	1.05124	**<0.001**
		with earphones 21st day (ppb)	26	4.7776	1.52134	
	Pair 3	without earphones 14th day (ppb)	26	6.0716	1.96617	**<0.001**
		with earphones 21st day (ppb)	26	4.7776	1.52134	

Table:4 Paired sample T-Test to compare mean values between time points in Group-I

Group	Pair	Variables	N	Mean	Std. Dev	p-Value
Group –II	Pair 1	Initial sample 7th day	27	1.7432	1.39836	**<0.001**
		without earphones 14th day	27	5.7608	2.15047	
	Pair 2	Initial sample 7th day	27	1.7432	1.39836	**<0.001**
		with earphones 21st day	27	4.3220	1.68193	
	Pair 3	Without earphones 14th day	27	5.7608	2.15047	**<0.001**
		With earphones 21st day	27	4.3220	1.68193	

Table: 5 Paired sample T-Test to compare mean values between time points in Group-II

CHARTS

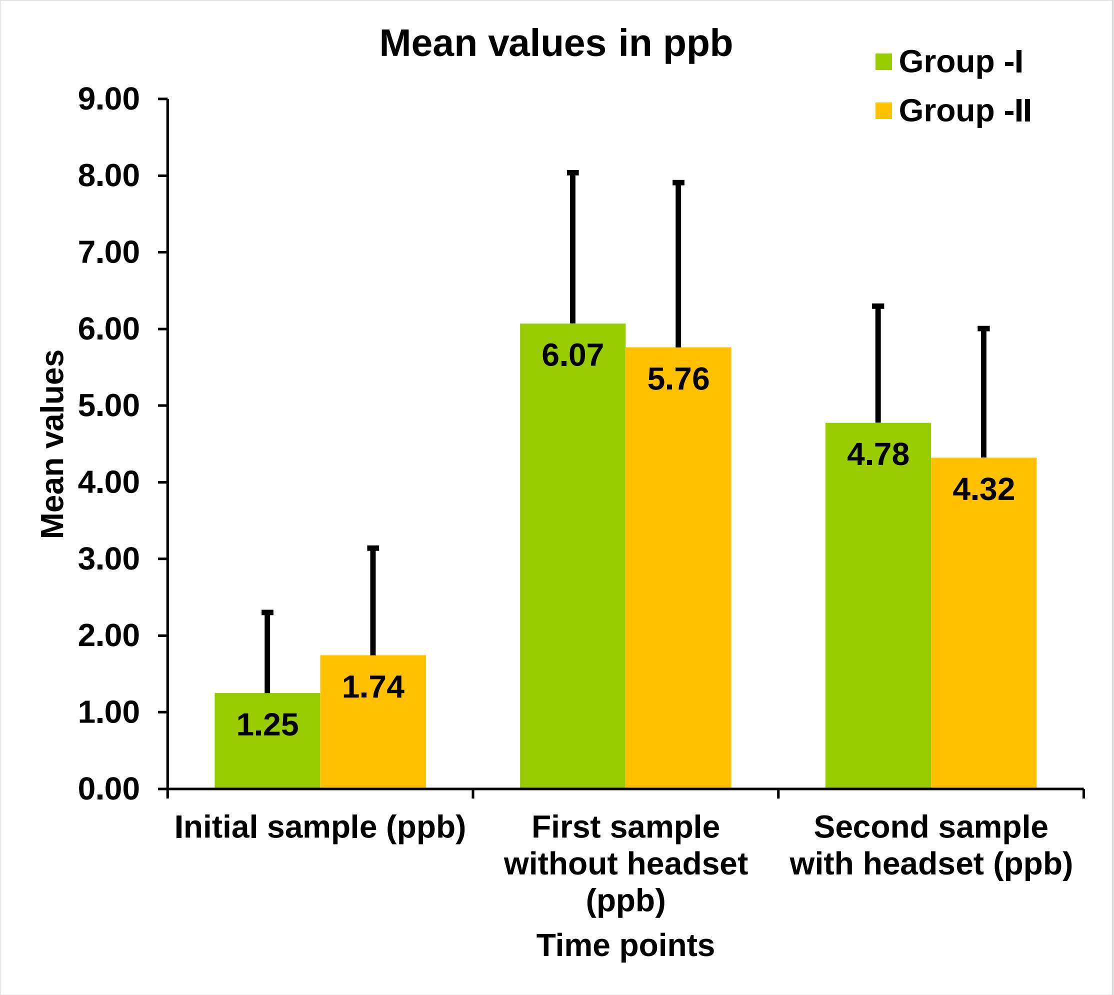

Chart :1 Mean values of Group I and Group II

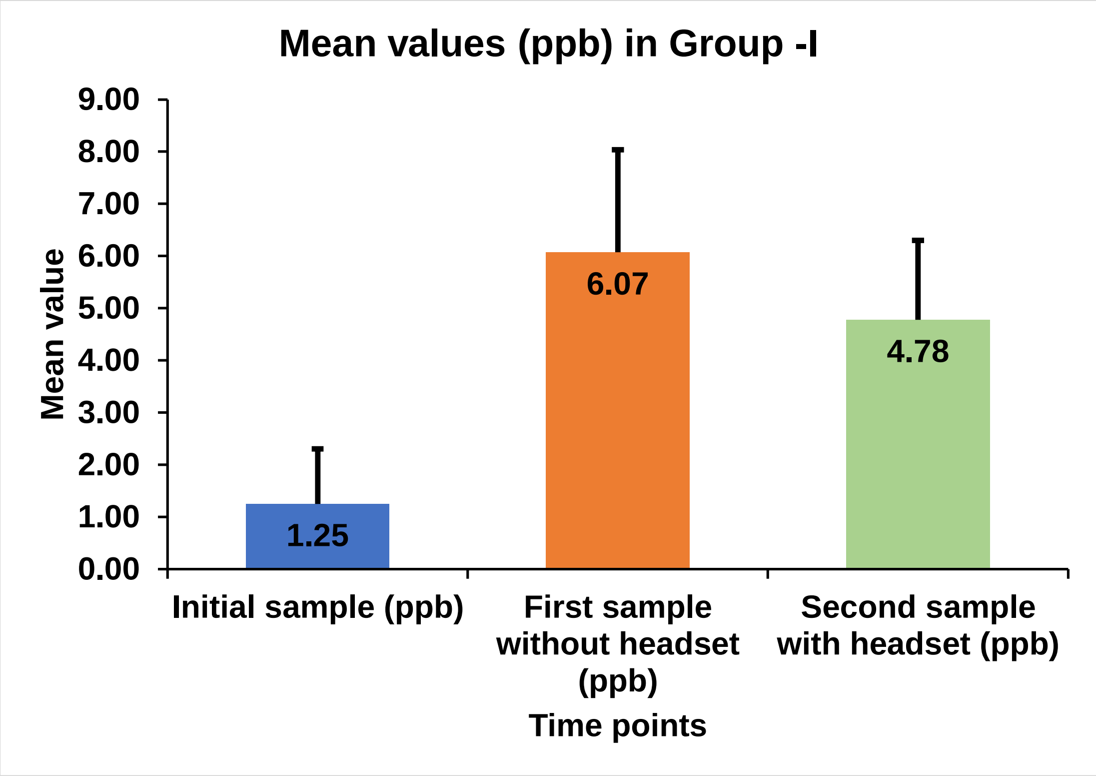

Chart :2 Mean values of Group I.

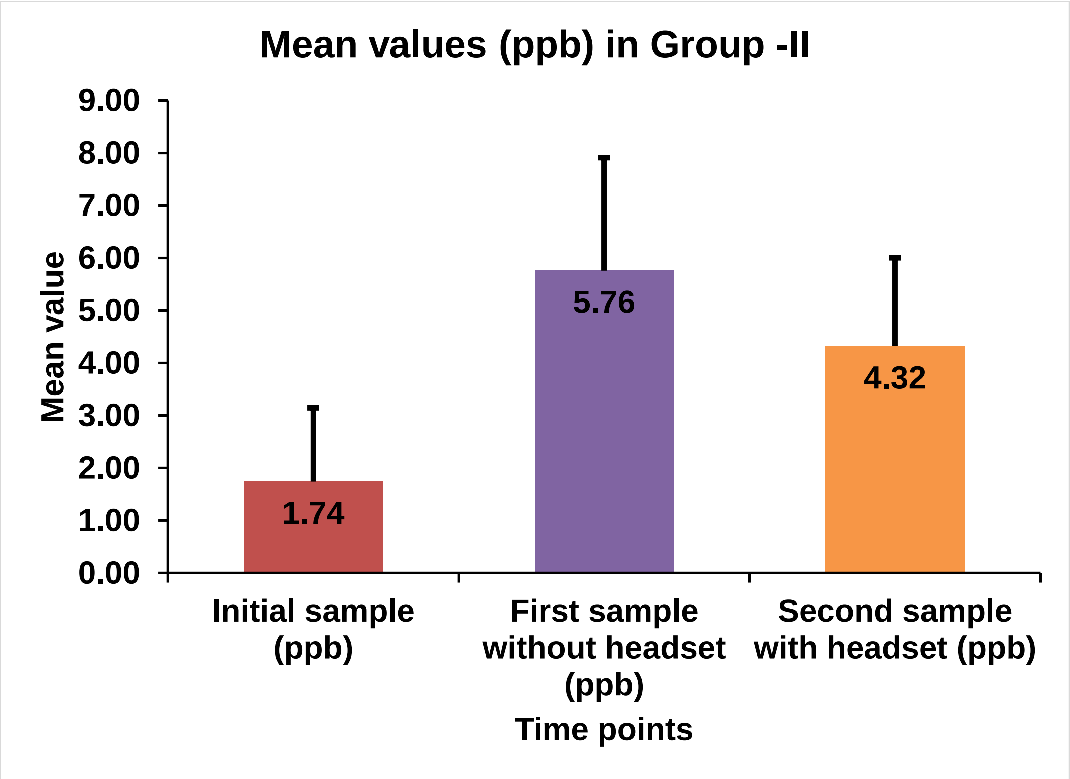

Chart:3 Mean values of Group II

The initial sample collection was done without any sex distribution (N=60) in the analysis of nickel level differences between the patients using mobile phone with headset and patients without headset to assess the overall effect of speaking time. To compare the mean values of nickel release in patients using headset and nonuser independent samples t-test were used and to compare the mean values between time points in group I and group II paired sample t-test were used. The test showed significant difference between the levels of nickel in the patients using headset and nonusers. Means, standard deviations and P values of the measured concentration of nickel are presented in the table. (Table:1, Table:2, Chart:1)

To compare the mean values between time points in Group I paired sample t-test were used and the tests showed significant difference between the levels of nickel in the patients using mobile phone with earphones (t [26] = 4.7776; $P < 0.001$) and without earphones (t [26] = 6.0716; $P < 0.001$).The mean of nickel release in the patients using mobile phone without headset were significantly higher than the patients using mobile phone with headset. (Table:4, Chart:2)

To compare the mean values between time points in Group II paired sample t-test were used and the tests showed significant difference between the levels of nickel in the patients using mobile phone with headset (t [27] = 4.3220; $P < 0.001$) and without headset (t [27] = 5.7608; P <0.001). The mean of nickel release in the patients using mobile phone without headset were significantly higher than the patients using mobile phone with headset. (Table:5, Chart:3)

The independent t test were performed on both sexes in the patients using mobile phone with headset and without headset. No significant difference were found (P >0.05). Sex did not affect the amount of nickel in the 2 groups. The Mann-Whitney test were used to statistically analyse the relationship between sex and nickel the nickel release difference between the patients using mobile phone with headset and without headset. The test showed significant difference between the sex and the nickel concentration (P <0.001). (Table:3 Chart:1)

DISCUSSION

Mobile phone have changed the way we live our life. In the last two decades, scientific research has been focused on the impact of electromagnetic radiation on the living matter in general.

The frequency under which it works ranges from 800 to 2200MHZ. the type of radiation of emitted is a non-ionising and rate of exposure is defined as rate of RF energy absorption in a weight or mass unit of a biologic body. These measured by SAR (specific absorption rate) in watts kg^{-1} or $mkvg^{-1}$. Different handset have different SAR rating. There limits vary according to the country, the federal communication commission has set a maximum limit of 2.0 w per kg. it is therefore expected that level of RFER emitted will correlate with the biological impact induced, which in turn depends on the different mobile phone technologies.

According to the proximity of mobile phones to oral cavity and metallic orthodontic appliance in the mouth, there may be a serious risk in the exposure of these appliance to the mobile phone radiation which may further induces the Nickel ion release.

The oral environment is dynamic where variation of factors including pH, temperature, salivary conditions, mechanical loading and microbiological enzymatic activity, bacterial acidic production affect the corrosion rate of metals. Accordingly when orthodontic appliance are placed in hostile electrolytic environment the degradation of the material by electrochemical attack is evident. The degradation of the orthodontic appliance has been studied extremely by various authors. Allergic reaction to the nickel containing dental alloys has been reported in the several publication.

With the above mentioned information as background, this study throws light on the orthodontist perspective about mobile phone usage on fixed appliances and as the previous study done by saghri et al in 2015 and lalitha girish et al in 2017 stated that there is effect on mobile phone usage in fixed orthodontic appliance by the release of metal ion in an time dependent manner. In that the most common released metal is nickel and chromium and followed by other metals[67,72].

Nickel (Ni) is the most common cause of allergic contact dermatitis, with an estimation of incidence up to 17% in women and 3% in men[73]. The difference in Ni allergy incidence between male and female is related to daily contact to jewellery and especially (ear) piercings in the female population, and is considered the most important cause of Ni sensitization[74,75]. Nevertheless, other important sources of exposure are cosmetics, detergents, coins, the professional environment, and dentistry.

In dentistry, nickel is used in a broad spectrum of applications, but mainly in orthodontics for arch wires, bands, headgear, and brackets. During active orthodontic treatment, those appliances are used for a relatively short period of time with an average of approximately 2 years. Many studies report on the release of nickel from these fixed orthodontic appliances in both static and dynamic conditions[3,11,23,31,59,60].

In 1983, Greig first investigated the several allergic reaction to nickel plated parts of cervical headgear and he avoided the allergy by covering the exposed metals with varnish or non-allergic strapping. In the same year, Park HY and Shearer first evaluated the release of nickel and chromium from stimulated orthodontic appliance but they didn't found any significant results [3].

In 1991 Gjerdet NR et al [20] studied nickel and iron level in saliva of patients with fixed orthodontic appliances and stated that there is a high intial release of metals and the effect diminishes with time. Barrett RD et al [21] in 1993 stated that the average release of nickel was 37% times greater than that of chromium. In 1997 Kerosuo H et al [23,25] investigated salivary nickel and chromium concentration of 47 patients at different time intervals found large variation in the concentration of both nickel and chromium in saliva and he concluded that this concentration did not affect significantly during the first month of treatment.

Kocadereli I et al [14] also stated that the concentration of nickel and chromium in saliva did not affect during the first 2 months. Based on these results our study samples were taken at the period of 4 to 6 months after wearing orthodontic appliances. Goldwein et al the first author who conducted a study about handheld mobile phones (MPH) examined whether the use of MPH influences the parotid gland's two fundamental functions i.e. the rate of saliva secretion and protein concentration in saliva.

Conversely, as per Burlage et al, salivary secretion is regulated by the autonomic parasympathetic and sympathetic nervous system, whereas the parasympathetic pathway induces more waterish saliva and the sympathetic one generates the protein secretory component. Interestingly, in contrast to higher salivary secretion rates in the dominant side, decreased protein concentration were measured from the right dominant MPH side compared with that from the left non-dominant side.

There are two known possible effects of the mobile energy on the human body – thermal and non-thermal. The heating of biological tissue is a result of microwave energy absorption by the water content of the tissues (Hyland, 2000). Moreover, mobile radiation can modify cutaneous blood flow (Monfrecola et al, 2003). Symptoms reported by MPH users include a feeling of warmth on the ear and behind it, and a feeling of burning and tingling on the face (Sandstrom et al,2001).

Monfrecola et al found an elevation in skin due to increased salivary flow from the dominant MPH side because of thermal effect attributed to secretory parenchymal tissue expansion. Where as in 2011 Hafez H S et al concluded that the buccal mucosa cells of patients treated with fixed orthodontic appliance for 6 months showed significant increase and decrease in viability and damage to DNA ,stating that titanium brackets with nickel – titanium arch wires produced the greatest cytotoxicity and genotoxicity.

Ionut et al [63] showed that effect of Radio Frequency (RF) microwave and consequently ELF electromagnetic fields present a risk and partially affect the orthodontic treatment and in 2013 Yaniv Hamzanyet et al compared the salivary outcomes between mobile phone users and nonusers. He stated that salivary flow, total protein, albumin, and amylase activity were decreased in mobile phone users and it also modifies salivary function.

Arbabi-Kalati et al [65] concluded that speaking over the mobile phone more than a hour showed decreased total antioxidant capacity of saliva and increased salivary IgA levels than those who are speaking for less than 20 minutes and this leads to increase risk of inflammatory diseases or mouth cancer. For this reason we made our study samples to use their mobile phones at an average of half hour a day. In 2016 Jatin Gupta stated that the use of mobile phones may modify salivary gland function when used above an average of 2 hours per day .

The physical characteristics of saliva change according to food intake, health, and time of the day. Thus, sampling were done at the same time for all patients to eliminate possible effects. The most important factor in corrosion is the salivary flow rate. An increase in temperature that can affect the resistance to localized corrosion by reducing the ability of the material to repassivate.

Temperature can also affect the nature of the environment by changing the solubility of a constituent that can affect the corrosion behaviour of a material. It was also claimed that when a mobile phone was used, the average pH value decreased, and this decrease was more evident when the patient had fixed orthodontic appliance. Thus, heat generated by the mobile phone will change the properties, flow rate, and pH of saliva; these changes might increase the corrosion rate of orthodontic appliances and influence the passive layer on the metal surface.

Taking all of these effects together, the significant increase of nickel concentration in saliva can be confirmed. But major problem encountered in our study was to recall the whole set of patients at the same time as they had their own personal and professional works. So we made the patients to collect the saliva at the correct time by themselves. And in order to overcome the difficulty in ensuring the patients to use head phones on regular basis we selected the patients who were using headsets in normal routine day to day manner.

The effects of mobile phones in metal ion release is mainly by the emission of EFER and in order to control the exposure of EFER to the patients, in our study we decided to check whether the radiation exposure can be controlled by using earphones. So our investigation was to compare the mobile phone usage effects on fixed orthodontic appliance with and without usage of earphones.

This study was initiated with sample size of 60 healthy patients consist of 30 males and 30 females who were using their mobile phones at an above average of half hour a day and the patients those who were school going students and patients in remote area were excluded. Out of 60 patients, two male & one female patient who didn't report for the next visit, one male & one female patient who forgot to use their earphones while speaking ,one male & one female failed to follow the inclusion criteria were excluded from the study, so finally we collected the samples of fifty three healthy individuals.

Based on time, in our study, one female patient used her mobile phone at an average of 3 hours a day showed high value of nickel content in the saliva and one more female patient who is working in a call centre used her earphone at an average of 8 hours per day shows an high value of nickel content in her saliva. From the collected samples we found out, the duration of mobile phone usage in females were more when compared to males and the nickel content were also more in females than males. Our results were concurrent with the study conducted by Saghiri et al in 2015 [67] who confirmed that the duration of mobile phone usage and metal ion release from fixed orthodontic appliance have a significant effect in time dependent manner.

Based on the statistical results of our study, we confirmed that the effect of mobile phone usage with earphones shows significant decrease in the amount of nickel content in saliva when compared to mobile phone usage without earphones. Further studies are required to find out the ways that can effectively decrease the metal ion release from fixed orthodontic appliance by decreasing the exposure of RFER emitted by the mobile phones. Several studies under process to find out the effect of RFER in the parotid gland as well as salivary flow rate, pH and any other effects in the DNA damage and cancer causing cells.

SUMMARY

The present in vivo study was designed to evaluate the effect of usage of mobile phone with and without headset on metal ion release on fixed orthodontic appliance. The objective of this study was to quantify the results and correlate the findings for clinical significance.

A total of 60 healthy patients, who were undergoing fixed orthodontic treatment in the Department of Orthodontics and Dentofacial Orthopedics, Adhiparasakthi Dental College and Hospital, Melmaruvathur, Chennai, India were selected for this study. Sample size was determined using G Power 3.0.10. Effect size of 0.891 was calculated using data from a similar previous study by Saghiri MA et al.

All the patients were in the age group of 18 to 25 years and had fixed orthodontic appliances in their oral cavity for a duration ranging from two to four months, All these patients were angles class I Malocclusion with bimaxillary proclination and all the four first premolar tooth were extracted and all their first permanent molars were banded and full mouth were bonded with 022’’ slot DENTARUM- MBT Prescription bracet, They were divided into two groups of 25 each based on their sex. A total of fifty patients were interviewed regarding their duration of mobile phone usage. Group A : 25 male patients and Group B : 25 female patients were selected.

In regular check-up after two month patients saliva samples were collected to estimate the amount of nickel present in saliva and the patients recalled after one week without using their headphones and at the end of first week saliva samples were again collected to estimate the amount of nickel present in saliva. For the next visit, patients were instructed to use mobile phones with earphones for one week and the saliva samples were collected at the end of the week. A chronometer was given to the patients to calculate how many minutes they used their cell phones during the experiment. At the end of second week saliva samples were collected, and the sexes, ages and cell phone usage times were also recorded.

The Normality tests Kolmogorov-Smirnov test results reveal that the variable follows Normal distribution. Therefore, to analyse the data Parametric methods are applied. To compare the mean values between groups independent samples t-test is applied. To compare mean values between time points paired sample t-test is applied. To analyse the data SPSS (IBM SPSS Statistics for Windows, Version 22.0, Armonk, NY: IBM Corp. Released 2013) is used. Significance level is fixed as 5% ($\alpha = 0.05$).

The result shows a sharp rise in nickel leach out after one week in all the 50 samples, by using their mobile phones without earphones and there is significant decrease amount of nickel level in the second week in all the patients while they using their mobile phones with earphones.

There was considerable amount of nickel release when compared among the males and females. Maximum release of nickel leach out seen in females when compared with males due to their more usage of mobile phones.

CONCLUSION

Based on the results obtained from this study, it can be concluded that mobile phone radiation can influence the nickel ion release in saliva of patients undergoing fixed orthodontic treatment and regardless of the type of phone, can influence the concentration of nickel in saliva in a time dependent manner. In addition this adverse effect of radiation on the release of nickel were more prominent in women because of longer usage times when compared to males. By our study we concluded that usage of mobile phones with headsets have an significant reduced effects on metal ion release from fixed orthodontic appliance when compare to usage of mobile phones without headsets and we need further more studies regarding the emission of RFER from mobile phones have to controlled and Future large scale studies, which should include more parameters such as the effect on parotid gland or the salivary flow rate, pH level of saliva and taking necessary measures to reduce the radiation effect caused by RFER emitted from mobile phones are needed.

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PARTICIPANT INFORMED CONSENT FORM (PICF)

(English)

Protocol / Study number: _______________________

Participant identification number for this trial: ________________________

The contents of the information sheet dated that was provided have been read carefully by me / explained in detail to me, in a language that I comprehend, and I have fully understood the contents. I confirm that I have had the opportunity to ask questions.

The nature and purpose of the study and its potential risks / benefits and expected duration of the study, and other relevant details of the study have been explained to me in detail. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal right being affected.

I understand that the information collected about me from my participation in this research and sections of any of my medical notes may be looked at by responsible individuals from APDCH. I give permission for these individuals to have access to my records.

I agree to take part in the above study.

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(Signatures / Left Thumb Impression)	Signatures of the Principal Investigator

ஆராய்ச்சியில் பங்கேற்பதற்கு இணக்கம்

தேதி:

நோயாளியின் பெயர் :

வயது / பாலினம் :

புறநோயாளி எண் :

அறுவை சிகிச்சை மருத்துவ நிபுணரின் பெயர் :

சிகிச்சையின் பெயர் :________________________

அளிக்கப்படும் மயக்க மருந்தின் வகை :

எனது தற்போதைய வாய்நலம் குறித்தும், அதற்கு உரிய சிகிச்சை முறைகளையும், மாற்று சிகிச்சை முறைகளையும் மற்றும் சிகிச்சை மேற்கொள்ளாவிடில் ஏற்படும் பின்விளைவுகளையும் பல் மருத்துவர் முழுமையாக என்னிடம் கூறினார். அதற்கான எனது சந்தேகங்களையும் பல் மருத்துவரிடம் கேட்டு தெளிவுபடுத்திகொண்டேன். மேலும் சிகிச்சை முறை, என் சிகிச்சையின் போது தேவைப்படும் மயக்கமருந்துகள் மற்றும் பிறமருந்துகள் செலுத்த சம்மதிக்கின்றேன். நான் மனப்பூர்வமாக எனது சிகிச்சை முறை மற்றும் அதனால் வரும் பின் விளைவுகளையும் ஏற்றுக் கொள்கிறேன் மற்றும் மருத்துவர் கூறும் அறிவுரைகளையும் கடைபிடிப்பேன்.

மேலே சொல்லப்பட்டு இருக்கும் ஆராய்ச்சி ஆய்வில் பங்கேற்பதற்கு மனப்பூர்வமான எனது சம்மதம்.

மேலுள்ள தகவல்கள் உள்ளிட்டு ஆராய்ச்சி ஆய்வானது வாய்வழியாக விளக்கப்பட்டிருக்கிறது மற்றும் பங்கேற்பதற்கு சுயவிருப்பத்தில் இணங்குகிறேன் என்பது இந்த ஆவணத்தில் கையெழுத்திடுவதன் அர்த்தமாகும்.

நோயாளியின் கையொப்பம் அறுவை சிகிச்சை நிபுணரின் கையொப்பம்

PLAGIARISM CERTIFICATE – II

This is to certify that this dissertation work titled **"EFFECT OF MOBILE PHONE WITH AND WITHOUT EARPHONES USAGE ON METAL ION RELEASE FROM FIXED ORTHODONTIC APPLIANCES"** of the candidate **DR.T.BALAVIGNESH** with registration Number **241519452** for the award of Master of Dental Surgery in the branch of Orthodontics and Dentofacial Orthopedics. 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 4% percentage of plagiarism in the dissertation.

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This ethical committee has undergone the research protocol submitted by **T.BALAVIGNESH** Post Graduate Student, Orthodontics and Dentofacial Orthopedics under the title "**EFFECT OF MOBILE PHONE WITH AND WITHOUT EARPHONES USAGE ON METAL ION RELEASE FROM FIXED ORTHODONTIC APPLIANCES",** Reference No: **2015- MD-Br II-MAN-11/APDCH** under the guidance of **DR. V.SUDHAKAR** for consideration of approval to proceed with the study.

This committee has discussed about the material being involved with the study, the qualification of the investigator, the present norms and recommendation from the Clinical Research scientific body and comes to a conclusion that this research protocol fulfils the specific requirements and the committee authorizes the proposal.

Date:

CHAIR PERSON

- Inform IEC/IRB immediately in case of any issue(s) / adverse events.
- Inform IEC/IRB in case of any change of study procedure, site and investigator.
- Annual report to be submitted to IEC/IRB.
- Members of IEC/IRB have right to monitor the trial with prior intimation.