

Ⅲ. 研究成果の刊行に関する資料①

一覧表

(別添5)

研究成果の刊行に関する一覧表

雑誌

| 発表者氏名 | 論文タイトル名 | 発表誌名 | 巻号 | ページ | 出版年 |
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Ⅲ. 研究成果の刊行に関する資料②

セラミックス, 48(10):819-823 (2013)

ISO/TC 150/SC 7 の現状と課題

Current Activity of ISO/TC 150/SC 7 "Tissue-engineered Medical Products" and Tasks for Its Future
Key-words: ISO, Tissue-engineered medical products, Standardization

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1. はじめに

ISO (International Organization for Standardization: 国際標準化機構) はさまざまな分野における国際標準化活動、すなわち国際的に使用される規格類の作成を行う非政府機関であり、その対象は多岐にわたる。医療機器分野もその対象であり、ISO で作成された国際規格は我が国における医療機器の許認可に係る認証・承認基準や各種ガイドラインにも利用されてきているため、医療機器の規制、開発双方の関係者にとってそれらの作成に積極的に関わって行くことが非常に重要となってきている。

医療機器分野のうち、「外科用インプラント」については TC (Technical Committee: 技術委員会) 150 における対象となっている。TC 150 直下に「再生医療機器」を扱う分科委員会 (Sub Committee: SC) 7 が日本提案により設立されたのは 2007 年のことである。ISO のルールでは、新規 TC や SC が設立された場合、その設立提案国が事務局に相当する幹事国となり、その運営の担う事務局長に相当する国際幹事を出さなければならないことになっている。よって、SC 7 設立に伴い、日本から国際幹事を出さなければならないことになった。それまで一切 TC 150 とは縁のなかった筆者であるが、図らずも当時の上司の推薦により SC 設立当初からその責を担うこととなった。もちろん、当初は具体的な幹事業務内容も全く分からなかったため、日本規格協会担当者や国内委員会委員、さらには TC 150 の幹事国業務を行っているドイツ規格協会 (DIN) 所属の TC 150 国際幹事らから多大な助力をいただいた結果、第 1 回会議を 2007 年 9 月に天津で開催することができた。それ以降も、毎年 1 回の会議開催およびその準備作業を含め、何とか国際幹事業務をこなしている。本稿では、本稿では、国際幹事業務を通して得た話題も含め TC 150/SC 7 における国際標準化活動

の概要を紹介させていただく。

2. ISO/TC 150/SC 7 の設立

上述した通り、ISO/TC 150 は「外科用インプラント」を対象とした TC であり、その設立は 1971 年、幹事国はドイツが担当している。体内に植え込んで用いる医療機器 (人工骨、人工心臓、人工血管等) やその材料を対象とした国際標準規格の作成が主な活動であり、現在に至るまで外科用インプラントに関連した国際規格を作成するための活発な討議を行ってきた。近年はインターネットの発達に伴い、メールベース、あるいはネット会議等を利用して活発な意見交換が頻繁に行われるようになったものの、基本は年一回の、TC 総会、SC およびワーキンググループ (WG) 会議の一斉開催による face to face の意見交換である。本質的には規格作成における科学的根拠が重要な場合でも各国の規制状況等に応じた擦り合わせが必要となることがあるため、直接会議で顔を合わせての議論やその議論で培った人脈が標準規格作成作業においても重要である現状に変わりはないと思われる。ただ、ISO 中央事務局がインターネットを利用したインフラを整えてきていることから、過去においては財政上の問題等から会議参加が困難であった国々もさまざまな情報を容易かつ即時に入手できるようになり、規格作成時に行われる要所要所の投票時に積極的にコメントを行う等、その国の実状に応じた形で規格作成に参加できるようになってきている。条件を整えばインターネットによる Web 会議も行うことができるようになったが、ネット環境が不十分な場合もありうるため、ごく限られたメンバー間での打ち合わせ程度のものが現実的である。余談になるが、筆者が 2011 年にブラジルで行われた SC 7 会議に参加できなくなったため、急遽、ネットを利用してブラジルで行われる SC 7 会議での討議に参加できるよう Web 会議を企画した。その際、会議に参加できない米国、英国のメンバーも参加を表明したため 4 ヶ国を結んでの Web 会議を試みたが、会場のネット環境が脆弱だったこと、会場のネット回線管理者がポルトガル語しか喋れない人物だったため不具合に対応できずに会場との接続ができなくなってしまい、あえなく Web 会議は頓挫した。Web 会議を行うにあたっては、実際の会議とは別に、時差およびネット環境を考慮した上で行う必要性を感じた出来事であった。

当初、TC 150 には再生医療分野に関する国際規格作成作業を議論する WG 11「再生医療機器」が 2001 年に設立されていた。ISO で標準化文書を作成するた

めには、具体的な内容を伴った新規提案を行い、賛成多数、5ヶ国以上の積極的参加 (エキスパートと呼ばれる専門家) を WG での作業に参加させること。国数は当時の規定) により、その作業がスタートする。その後、要所要所で投票作業があり、それらすべてで成立要件を満たすこと、ようやく標準化文書が ISO より発行されて日の目を見るのであるが、逆に言えば、それらの投票で否決されてしまうと、結局日の目を見ないまま廃案となることもある。事実、WG 11 では、convenor と呼ばれる WG 議長が「再生医療を用いた医療機器 (再生医療機器) の一般的要求事項」に関する国際規格文書作成を提案し、その作業スタート要件は満たしたものの、その後、committee draft (CD) と呼ばれる段階から先に進むための CD 投票をクリアできず廃案となってしまった。そこで、CD から先に進まなかった原因は積極的に参加する国が少なかったことが一因であり、再生医療機器の国際規格作成作業を活性化するためにはこの分野を扱う WG を SC へと発展させることが一つの方法であると考えた日本が、2005 年に行われた WG 11 から発展させた新規 SC の設立を提案することになった。提案に対する 1 回目の投票では反対多数のため設立は否決されたものの、2006 年の WG 11 ウィーン会議での討議を経て行われた 2 回目の投票で投票過半数の賛成を得たことにより 2007 年に TC 150 の下に SC 7 "Tissue-engineered medical products (再生医療機器)" が新規設立されることになった。

3. 現在までの SC 7 活動内容

SC 7 設立に関する投票が 2 回行われたのにはいくつかの理由が考えられるが、WG 11 時代の資料を見ると、最も大きな理由は他の TC、具体的には TC

194「医療機器の生物学的評価」と内容が重複するのではないかという懸念だったようである。TC 194 は医療機器の生物学的安全性評価に関する考え方とその手法に関する標準化を行っており、医療機器の有効性に関しては実質上その業務外となっている。また、その時点では再生医療機器を対象とはしておらず、再生医療機器の標準化作業は TC 194 の業務内容と重複していなかった。しかしながら、TC 194 の名称に「生物学的評価」とあることから、1 回目の投票時には再生医療に関する技術は本質的に「生物学的評価」であるから TC 194 での業務対象ではないかというコメントが数多く投じられた。上述した通り、その当時、TC 194 で再生医療技術は対象外だったが、これらのコメントを考慮した結果、2 回目の投票時には、作業の重複を避けるため SC 7 の対象を主に再生医療機器に関する一般的要求事項と有効性に関するものが強調された。つまり、再生医療機器の「生物学的安全性」は SC 7 では扱わないことを強調したわけである。その結果、2 回目の投票は賛成多数となり、SC 7 が設立されることになった。

SC 7 初代議長となったアラバマ大学の Jack Lemons 教授は、文書作成提案の意欲を示していた人物が 4 名いたことを鑑み、また SC 7 の活動を活発化する目的で、これらの人物をそれぞれ convenor とする WG を 3 つ設立する判断を、2007 年に天津で行われた第 1 回 SC 7 会議で行った (4 名のうち 2 名が日本人であったこと、各々の提案が骨関連組織のものであったことからそのうち 1 名を convenor とすることとなり、設立された WG は 3 つになった)。なお、2013 年現在に至るまで、この SC 7 構成は変わっていない (図 1)。実は、この行為は ISO のルールに反するものである。ISO のルールブックに相当する ISO Directives には、新規文書

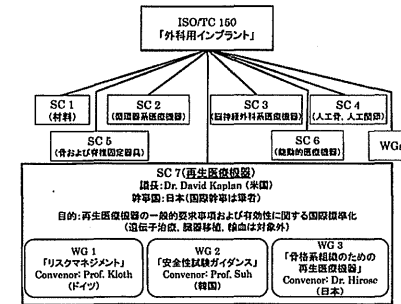


図 1 TC 150 および TC 150/SC 7 の構成

提案が成立後、その議論を行うWGを設立するという主旨の文章が書かれている。よって、SC7においてWGは存在するものの、正式に議論すべき文書がないという奇妙な事態を引き起こした。これは、上述したように文書作成に意欲を示した人物が複数いたことから、彼らをconvenerとしてその意欲を引き出すとともに責任を負わせれば積極的に活動するであろうから、結果として、彼らが考えている新規提案文書がスムーズに成立するであろうというLemons教授の目論見もあったと思われる。

ところが、事態は全く予想外の方向に動いてしまった。初会議時に設立したWGの2つが、当初の合意に反して生物学的安全性に関連した文書を提案してきたのである。この結果、SC7には混乱が生じ、その対応策を練るためTC194との調整を行うことになった。調整の結果、TC194にあるSC1「組織由来製品の安全性」であれば、再生医療機器の生物学的安全性に関する国際規格の作成が可能であろうということになり、それらの提案はTC194/SC1に移すことが双方の議長および国際幹事の間で合意された。しかしながら、その後、TC194/SC1内部での調整が行われた結果、TC150/SC7/WG1での提案のみがTC194/SC1に移されることになった。なお、その提案はISO13022“Medical products containing viable human cells—Application of risk management and requirements for processing practices”として昨年発行された。現在、WG1の活動は欧州における再生医療機器の現状についての情報提供のみに留まっている。

一方、TC150/SC7/WG2で提案されていた文書は2つあったが、それを整理する形で“Tissue-engineered medical products—Guidance on human and animal cell-based implants—General requirements”として新規提案することとなり、その提案は採択され作業が始まった。しかしながら、提案者が各国から寄せられるコメントに対応しきれなかった結果、照会段階(Draft International Standard: DIS)に進むためのCD投票を2回否決され、そのまま時間切れで取り下げられることになった。当該文書は再生医療機器の標準規格作成における包括的な基本文書となりうるためその作成は必須であり、再度その作業を新規提案段階から進めるために、TC150/SC7の現議長(二代目)である米国食品医薬品局(FDA: Food and Drug Administration)のDavid Kaplan博士が文書編集を行っている。

WG3では、始めから照準を有効性評価技術に絞り込み、セラミックスや高分子を利した骨関連組織再生技術に関する国際規格の作成を行おうとしているが、

その専門性が災いして提案成立に必要なExpert数が確保できない状況が続いている。Expertとは新規提案規格を作成するにあたってその作業に協力する専門家のことであり、新規提案投票時にその作成作業に積極的に関与することを表明した国から推薦される。現行のISOルールでは、SC7で新規提案が成立するためには4ヶ国以上からExpertが推薦されなければならない。しかしながら、(独)産業技術総合研究所の廣瀬博士が提案された“Tissue-engineered medical products—Evaluation of in vivo bone formation in porous materials”および東大の牛田教授が提案された“Tissue-engineered medical products—Quantification of sulphated glycosaminoglycans (sGAG) for evaluation of chondrogenesis”のいずれもが3度の新規提案を行ったにも関わらず、その都度expertが必要数を満たさないためPreliminary work item (PWI)という正式提案採択前の予備段階に留まっている。前者の案件は、再生医療の担体となりうるporous ceramicsも対象とした骨再生評価技術の規格化を提案したものであるため、この規格が成立すれば再生医療に利用できるセラミックス関連国際規格が目の見えることになる。そうすれば、セラミックスを用いた再生医療研究成果のアウトプット先としてISO規格も存在することを読者の皆様にも明示することができるのだが、皮肉にも、投票のたびに文書原案が整っていくにも関わらず、未だその正式な提案採択には至っていない。現在、上記とは別のセラミックス関連新規国際規格作成提案が投票中であり、事前の球出し段階では各国から非常に好意的に受け止められたためその採択が期待されている。その提案内容に関しては、この後の項で提案者である(独)物質・材料研究機構の菊池博士が説明されているのでそちらを一読していただきたい。なお、セラミックスとは関連がないものの、日本から行われたMRIを利用した再生軟骨組織の異質性評価技術に関するTechnical report (TR: 技術報告書)といい、ISOから発行されるものの規格ではない)作成提案が2010年に採択されている。こちらのほうは、WG3での作成作業を経て先日行われた最終投票で過半数以上の賛成を得たため、その発行が認められた。この9月に行われるロンドン会議で審議を経て、適切な修正を行ったものが今年度中には発行される予定である。TRは国際規格ではなく参考文献的扱いとなるため、その発行に至るまでの条件は国際規格よりも緩いものの、SC7設立7年目にしてようやく正式な文書が発行されることになる。

昨年度末、中国とブラジルがSC7の活動に参加す

ることを表明し、SC7の活動に参加するメンバー(P-member)は13ヶ国となった。ちなみに、活動に興味はあるが積極的に参加しないO-memberという立場も存在し、現在、SC7には3ヶ国のO-memberが存在する。P-memberの増加は、今後の規格作成新規提案の成否にも関わるので、その数が増えたことは喜ばしい限りである。各々のメンバー構成については、ISOのホームページを参照していただきたい。

(http://www.iso.org/iso/home/standards_development/list_of_iso_technical_committees/iso_technical_committee.htm?commid=546151)

4. SC7における課題

再生医療機器に関する国際規格作成作業を活性化する目的で、その作業が行われていたTC150/WG11をSCレベルに発展させたものの、実際の参加国は非常に少なくなってしまった。これは、現在も再生医療機器の産業化に取り組んでいる国は少なく、製品の数もわずかしか増えていない現状を反映しているようである。事実、我が国でも、現在販売されている再生医療製品は2品目である。まず、この状況を打破するためには、より多くの製品が販売されるようになることが必要である。他力本願となってしまいが、まずは、より多くの国々が再生医療分野の開発研究に取り組んでいくことを望みたい。

各国における規制の枠組みが、大きく異なっていることも障壁となっている。例えば、EUでは、再生医療製品はすべて先端医薬品として欧州医薬品庁(EMA: European Medicines Agency)による審査が行われることになっている。そのため、EMA本部がある英国はSC7における国際標準化に否定的である。SC7としては規制に利用可能な技術の標準化を考えているため、規制当局にその理解を得る必要がある。この点に関しては、日本でも現在大きな流れが生じている。我が国の成長戦略の柱の一つとして再生医療が挙げられているが、その早期実現化を目指すため先の国会では議員立法により「再生医療基本法」が成立したことは、メディアにも大きく取り上げられたため、読者の多くがご存知のことと思う。また、厚生労働省から先の国会に提出された「再生医療安全推進法」および薬事法改正が次の国会で成立するものと思われるが、これらが成立すると再生医療製品は、従来と異なり、今後は医薬品・医療機器と別枠で規制されるようになる(参考までであるが、上述した我が国の再生医療製品2品目は「医療機器」として承認されている)。この改正内容によっては、幹事国であるにも関わらず我が国の

SC7に対するスタンスを変更しなければならない可能性がある。今後、政府および厚生労働省が掲げる再生医療技術の国際戦略がどのような形になるのかが極めて重要であるので注視して行かなければならない。

会議の運営という面では、SC7初会議時、WG11からの持ち越し議題を取り扱うことに意欲を示した人物がいたため、ISOのルールを無視する形で先にWGを設立したことが一つ反省点となっている。本来は新規提案が採択された後、それを討議するためのWGが設立されるのであるが、予めWGを設立したために、提案者がその提案を成立、発行させるための積極性を失っていると感じられるケースがあった。また、WG単位で成立前の新規提案を討議してしまうため、その討議への参加者が限られてしまうという現象も生じてしまった。結果として、これらがSC7での国際標準化作業が進まなくなった一因となったと考えている。これらの反省は今後の作業に生かさなければならぬ。

Expert不足に悩まされるのは、最先端分野特有の課題である。今まで、研究者個別のアプローチが行われていたものの、正式にExpertとなるためには各国のISO登録代表機関、日本であれば日本工業標準調査会から正式に推薦される必要があり、個別にアプローチした研究者がその団体とコンタクトできない等の問題があった。今後は、それらの団体への直接的なアプローチや関連学会との連携構築、さらには再生医療分野の研究者に対して彼らの持つ技術の国際標準化による利益・不利益に関する啓蒙を行うことで潜在的に存在するExpert候補を掘り出していくこと等が今後のSC7活動活性化の鍵になるであろう。

5. おわりに

これまでのTC150/SC7国際幹事としての活動を元へ、TC150/SC7の歴史、活動内容および今後の課題を紹介していただいたが、ISO活動を通して感じたことをもう一点述べさせていただく。

このような国際会議においては当然英語による討論が行われるのであるが、ご存知の通り、日本人は英語による討論を苦手とする傾向にある。理想をいえば、英語に極めて堪能でかつ専門知識の豊富な人物を日本代表として議論に参加させたいところであるが、なかなかそのような人物をスカウトすることはできない。そこで、流暢ではなくても英語での議論が可能な人物に議論を託すことになることが多くある。残念なことに、国際会議においては所謂「阿吽の呼吸」的なものは通用せず、思うところがあれば必ず発言しなければ

自分たちの主張は取り上げられない、にも関わらず、どうしても流暢な英語で表現したくなるのであろうか、ある程度の英語力が有るのに発言すべき時に発言できない日本人がよく見受けられる。それに対して、おおよそ「流暢」とはほど遠い non-native English speaker であっても、必死で大きな声を上げて発言する方々もよく見受けられる。このような方々の意見はたどたどしい英語であってもその意図を native speaker がフォローしてくれるので、意図は出席メンバーに通じ、その発言が採択されることが多い。要するに、国際会議では「言ったもの勝ち」なのである。幸い、TC 150/SC 7に参加している国内メンバーは「大きな声」の持ち主が多いため日本の意見は考慮されているが、必ずしも国際会議のすべてにおいて「大きな声」の日本人が参加している訳ではない。黙って会議に参加しているだけでは、主張がない国だと判断されると同時に他の出席者からの信用も得られない。特に、自己主張がはっきりしている諸外国のメンバーが参加する国際会議では「沈黙」は美德ではなく、むしろ国益を妨げる「害」であることを賢明な読者の方々は容易にご理解

いただけるであろう（ご経験済みかもしれないが）、どのような国際会議であっても有意義な情報収集は他国から信用される信頼関係の構築が重要となるので、少なくとも己の英語力を気にせず大きな声で理論的、建設的な発言を行い、会議を活発かつ有意義なものとしていただきたい。ただし、客観的に見てその発言が利己的であれば逆効果になるので、その点はくれぐれもご注意ください。

筆者紹介



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Ⅲ. 研究成果の刊行に関する資料③

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Magnetic fields from electric toothbrushes promote corrosion in orthodontic stainless steel appliances but not in titanium appliances

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Electric toothbrushes are widely used, and their electric motors have been reported to produce low-frequency electromagnetic fields that induced electric currents in metallic objects worn by the users. In this study, we showed that electric toothbrushes generated low-frequency magnetic fields (MFs) and induced electric currents in orthodontic appliances in artificial saliva (AS), which accelerated corrosion in stainless steel (SUS) appliances, but not in titanium (Ti) appliances; the corrosion was evaluated by using an inductively coupled plasma-optical emission spectrometer and a three-dimensional laser confocal microscope. The pH of AS used for appliance immersion did not change during or after MF exposure. These results suggested that MF-induced currents from electric toothbrushes could erode SUS appliances, but not Ti appliances, because of their high corrosion potentials. Further studies are required to clarify the mechanisms of metallic corrosion by induced currents in dental fields, which may trigger metal allergies in patients.

Keywords: Low-frequency magnetic field, Induced current, Metallic elution, Surface roughness

INTRODUCTION

Electric toothbrushes are widely used for their convenience. However, they have also been reported to produce low-frequency electromagnetic fields, which could cause problems, e.g. interference with pacemakers^{1,2}. In low-frequency magnetic fields (MFs), the strength of the induced electric current is thought to be more important than the strength of the MF itself in affecting the health of living bodies³. Many home electrical appliances generate low-frequency MFs that could induce electric currents in the human body and within any metallic objects or devices worn in or on the body^{4,5}. Previous reports showed that MFs from electric toothbrushes could induce alternating electric currents in metallic dental appliances and teeth^{6,7}. Electric currents in oral appliances, e.g. galvanic currents, could cause discomfort for the user and corrosion of metallic dental appliances^{7,8}. Induced currents by electric toothbrushes were also thought to cause some problems in the oral condition of patients. However, the currents induced by the toothbrushes are unlike galvanic currents⁹. Galvanic currents, which are direct currents, exhibited high voltages (several tens to hundreds of mV) with low currents (several tens to hundreds of nA), whereas the electric currents induced by electric toothbrushes were of the order of μA to mA with a voltage range of μV to mV⁹. These findings

seemed to indicate that the galvanic currents were one of the causes of metal corrosion, whereas the electric currents induced in dental appliances should not be a direct cause of metal corrosion. However, there were some reports about metallic corrosion caused by induced alternating current (AC). Rapid geomagnetic variation was known to induce electric currents in power lines and pipelines, which could lead to the destruction of power transmission systems and the corrosion of pipelines¹⁰. In stray-current corrosion caused by alternating currents, the induced current occurred in embedded metal objects parallel to high voltage AC power lines or to the transportation routes of alternating current electric railways, which caused corrosion of the embedded metal objects¹⁰. We show here that the currents induced in metallic dental appliances by MF exposure from electric toothbrushes corroded stainless steel appliances but not titanium appliances.

MATERIALS AND METHODS

Materials

Five identical electric toothbrushes (Philips Sonicare HX9340/02, Philips Oral Healthcare Inc., Bothell, WA, USA, all from Lot no. 59 114303 1 881934202461), acting as the magnetic field (MF) sources, were prepared for this investigation based on the results of previous reports^{5,6}.

We also prepared three orthodontic wire materials (SUS304, Suzuki stainless steel wire, Mitsuba Ortho

Supply Inc., Tokyo, Japan; β -titanium (β -Ti, Ti-11.5Mo-6Zr-4.5Sn)¹¹, Bentalloy, Rocky Mountain Morita Inc., Tokyo, Japan; and nickel-titanium (NiTi), Sentalloy, Tomy International Inc., Tokyo, Japan). The cross-sectional sizes of these wires were approximately 0.43×0.64 mm (0.017×0.025 inches). Stainless steel (SUS) orthodontic brackets (SUS304, SuperMesh Bracket medium twin bondable for mandible incisors, Tomy International Inc., Tokyo, Japan) were also prepared. Because each SUS orthodontic bracket was 0.068±0.001 g ($n=5$) when weighed with an electronic balance (Mettler type AE240-S, Siber Inc., Zurich, Switzerland) with readability of 0.01 mg placed on a suitable mounting (Vibro-Absorbing Mount VAM-I, Murakami Koki Inc., Osaka, Japan), the SUS wire length was determined to be 3.0 cm by having the same weight as the brackets (0.068±0.001 g, $n=5$). Based on these results, the wires made from the other materials were used in 3.0 cm lengths (β -Ti wire: 0.046±0.002 g; NiTi wire: 0.053±0.001 g; $n=5$). Each orthodontic wire was tied to the brackets with elastomeric modules (polyurethane elastic ligature tie, Shofu Inc., Tokyo, Japan). The solution used for immersion was Fusayama-

Meyer artificial saliva (AS), with content as follows: 0.4 g of KCl, 0.4 g of NaCl, 0.795 g of $\text{CaCl}_2 \cdot 2\text{H}_2\text{O}$, 0.78 g of $\text{NaH}_2\text{PO}_4 \cdot 2\text{H}_2\text{O}$, 0.005 g of $\text{Na}_2\text{S} \cdot 9\text{H}_2\text{O}$, and 1 g of NH_4CONH_2 (all reagents were purchased from Wako Pure Chemical Industries Inc., Tokyo, Japan) in 1 L of deionized distilled water (DDW), with pH of 5.3¹².

For exposure of the orthodontic appliances to the MFs of the electric toothbrushes, we created five experimental sets for the five prepared electric toothbrushes (Fig. 1). We created acrylic stages, plaster tube racks and silicon toothbrush racks with the same shapes and sizes by using silicon counter-dies. Turntables (battery type turntable, MM Kobo Inc., Shizuoka, Japan) driven by a single AAA battery were used for the rotation of the electric toothbrushes at 5×10^{-2} Hz (3 rpm). The electromagnetic fields from the turntables could not be detected at the positions of the orthodontic appliances (data not shown here).

Measurement of MFs generated by electric toothbrushes

The MFs produced by the electric toothbrushes and their frequencies were detected and evaluated using a spectrum analyzer (SPECTRAN NF-5035, Aaronia AB

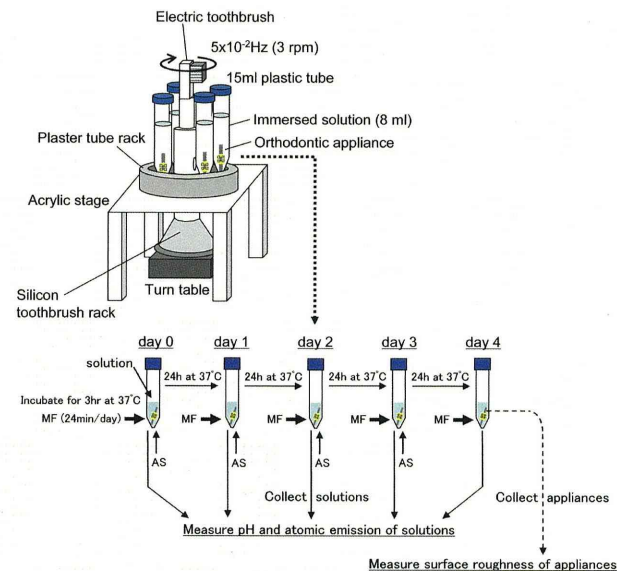


Fig. 1 Schematic representation and time schedules of experiments for exposure of orthodontic appliances to MFs.

Color figures can be viewed in the online issue, which is available at J-STAGE.

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Inc., Euscheid, Germany)^{6,9}. We estimated the MFs within the 1-2000 Hz frequency range, in keeping with the preliminary study and with the previous literature, which stated that this was the appropriate range to monitor^{2,5,9}. The MFs were estimated at 2 cm distances from the front, back, and right and left sides of activated or inactive electric toothbrushes⁹.

Measurement of electric currents induced in dental appliances by electric toothbrushes

The electric currents induced in dental appliances were estimated using a digital multimeter (7351 A/E, ADC Corporation, Tokyo, Japan) in AC+DC mode (*i.e.* voltage=(ACV²+DCV²)^{1/2}, and current=(ACI²+DCI²)^{1/2}). Because the electric current induced by electric toothbrushes was ostensibly known to be alternating current from the results of previous studies¹⁰, its value when measured in the AC+DC mode was practically identical to that in the AC mode. The induced electric current was estimated for a distance of 2 cm between the front of the toothbrush and the appliance immersed in AS in plastic culture dishes. We also estimated the electric current induced between only the connecting anode and the cathode in the AS (*i.e.* with no orthodontic appliance), and confirmed that no electricity was detected from electric toothbrushes at a distance of 2 cm (data not shown here). The induced electric voltages and currents in the appliance that were estimated in this study are shown in Fig. 2.

MF exposure of orthodontic wires combined with orthodontic brackets immersed in AS

For exposure of orthodontic appliances to the MFs from electric toothbrushes, four specimens immersed in 8 mL of AS solutions in 15 mL plastic tubes were set in the plaster tube racks on each acrylic stage. Each electric toothbrush was set in the silicon toothbrush racks on the electric turntable (Fig. 1). During exposure to the MFs from the electric toothbrushes, the turntables were

rotated at 5×10⁻² Hz. The specimens were exposed to the MF from each electric toothbrush for 24 min/day, and a total of 120 min exposure from the five toothbrushes (24 min each) was accomplished by five day exposures for each specimen. In a questionnaire survey of the tooth brushing habits of 1,200 Japanese people (600 males and 600 females, aged from teens to sixties), 52.5% of respondents cleaned their teeth twice a day, and 48% of them had brushing times of 1-3 min¹⁰. From these reports, the average Japanese person's brushing time for one month was estimated to be 120 min (2 min×2 times/day×30 days). We thus deduced that the exposure time of specimens to MFs from the electric toothbrushes was a total of 120 min, *e.g.* 24 min/day×5 times (4 days).

Measurement of pH of AS after immersion of orthodontic appliances

Immersion solutions containing metal appliances that had been exposed to MFs from electric toothbrushes and that had been incubated at 37°C in air were collected (Fig. 1), and their pH values were measured with a pH meter (F-12, Horiba Inc., Kyoto, Japan). Before the measurements were taken, the pH meter was calibrated using three types of standard pH solution, *e.g.* pH4, 7 and 10 solutions (MJ-PH4, MJ-PH7, MJ-PH10, Sato Shouji Inc., Kanagawa, Japan).

Detection of metallic elution from orthodontic appliances using the inductively coupled plasma-optical emission spectrometer (ICP-OES)

ICP-OES measurements (ICP-OES model iCAP 6300 Duo, Thermo Fisher Scientific, Waltham, MA, USA) for specimens collected as shown in Fig. 3 were taken. Briefly, AS solutions containing metal appliances were incubated at 37°C for 3 h (day 0) or for 24 h (days 1-4) in air, and exposed to the MF for 24 min. After that, the solutions were collected for the ICP-OES measurements. The ICP-OES instrument was optimized before the

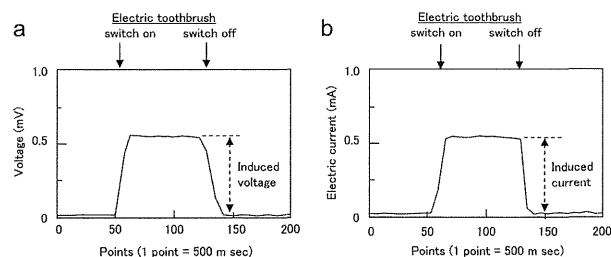


Fig. 2 Electric current induced in orthodontic appliance immersed in AS by the Sonicare HX9340/02 at a distance of 2 cm between the electric toothbrush and the appliance. a. Induced voltage; b. induced current.

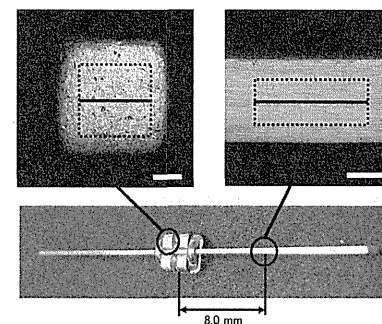


Fig. 3 Measurement area and lines of brackets and wires for surface roughness measurement by 3D laser confocal microscope.

Upper left: 3D laser confocal micrograph of wing of orthodontic bracket; upper right: 3D laser confocal micrograph of SUS wire at a distance of 8.0 mm from the center of the bracket; and lower: photograph of orthodontic appliance (bracket+3 cm of wire+elastomeric module) used in this study. The area surrounded by the dotted line was the measurement area, and the horizontal solid line was the measurement line for evaluation of the surface roughness of the appliance. White lines in the micrographs represented 100 μ m.

measurement process by using standard solutions of Cr, Fe, Ni, Sn and Ti normally used in atomic absorption spectrometry (Kanto Chemical Co. Ltd., Tokyo, Japan), and was operated according to the manufacturers' instructions. The spectrometer was used with the following parameters: radiofrequency (RF) power of 1.15 kW, frequency of 27.12 MHz, a demountable quartz torch containing Ar/Ar/Ar, plasma gas (Ar) flow of 16.5 L/min⁻¹, auxiliary gas (Ar) flow of 0.5 L/min⁻¹, nebulizer pressure of 0.15 MPa, a glass spray chamber according to the method of Scott (cyclone chamber, Fisher Scientific Inc., Waltham, MA, USA), with a sample pump flow rate of 1.8 mL/min⁻¹, an integration time (45 s), replication capability (5 times), and the wavelength range of a monochromator (166-847 nm). First, standard curves for the AS, with or without Cr, Fe, Ni, Sn and Ti, were created, and then each of the detection limits (3.3 σ /slope) and determination limits (10.2 σ /slope) were obtained (Table 1)¹⁹. The elution volumes of the metallic ions in the immersion solutions were shown as concentrations (ppb/ppm), so that these values could be converted to the eluted metal weight (μ g) for easier understanding (Table 1). Selected metal ions were measured at wavelengths of 205.552 nm for Cr, 239.562 nm for Fe, 216.556 nm for Ni, 189.989 nm for

Table 1 Detection and determination limits at each detection wavelength for each element in AS by ICP-OES

| | Detection wavelength (nm) | Detection limit (μ g) | Determination limit (μ g) |
|----|---------------------------|----------------------------|--------------------------------|
| Cr | 205.552 | 0.011 | 0.047 |
| Fe | 239.562 | 0.017 | 0.071 |
| Ni | 216.556 | 0.028 | 0.118 |
| Sn | 189.989 | 0.033 | 0.141 |
| Ti | 308.802 | 0.006 | 0.026 |

Sn and 308.802 nm for Ti from the results of each standard curve (Table 1). The metallic elution values were shown as converted values (\geq determination limit), + (detection values \leq values < determination limit) or - (<detection limit) (Tables 2, 3). All reagents used were of analytical and spectral purity grade.

Detection of surface roughness of orthodontic appliances by three-dimensional laser confocal microscope

The surface roughnesses of the appliances were measured using a 3D laser confocal microscope (LEXT OLS4000, Olympus Inc., Tokyo, Japan) and estimated as Ra (the arithmetic average of the absolute value, $Ra = n^{-1} \sum |Y_i|$ ($i=1-n$))¹⁰, Rz (the highest peaks (Rp) and lowest valleys (Rv) over the entire sampling length, $Rz = Rp + Rv$), and Sa (the arithmetic average of the 3D roughness (areal roughness)) by the Lext software package (Olympus Inc.) on a workstation computer (MB-P5300X-WS, Mouse Computer Inc., Tokyo, Japan). Preparation of the specimens for surface roughness estimation was performed as follows: 1) discard immersion AS; 2) wash appliances twice with distilled water (DW); 3) ultrasonicate appliances in DW for 15 min twice; 4) wash appliances twice with DW; and 5) dry the appliances in air. Estimation of the surface roughness was performed about the labial surfaces of the wires at a distance of 8 mm from the horizontal central point of the brackets (the 500 μ m mesiodistal line of the center of the wires), and the 200×500 μ m area of the wire surfaces), and the labial flat part of the wing surfaces of the bracket (the 500 μ m mesiodistal line, and the 500×500 μ m area of the flat surfaces) (Fig. 3).

Experimental conditions, data and statistical analysis

All experiments were performed in the laboratory, which was maintained at a temperature of 22±1°C. Data were obtained from each experiment, and six data out of a total of eight data were used, which meant that the maximum and minimum data were removed. These six data were calculated and represented as means±standard deviations. The data were analyzed by Mann-Whitney's U test to determine which of the differences were statistically significant.

Table 2 Elution amount of each element (μg) from the appliances (bracket+wire+elastomeric module) to AS

| | SUS | | β -Ti | | Ni-Ti | |
|----|------------------|-------------------|--------------------|---------------------|--------------------|---------------------|
| | MF (-) | MF (+) | MF (-) | MF (+) | MF (-) | MF (+) |
| Cr | - | + | - | + | - | + |
| Fe | 0.20 \pm 0.012 | 1.39 \pm 0.067* | 0.12 \pm 0.011** | 0.80 \pm 0.044*** | 0.11 \pm 0.014** | 0.70 \pm 0.067*** |
| Ni | - | + | - | + | - | + |
| Sn | na | na | - | - | na | na |
| Ti | na | na | - | - | - | - |

$n=6$ for each experimental condition. SUS: stainless steel wire; β -Ti: β -titanium wire; NiTi: nickel titanium wire; MF: magnetic field; +: detection values \leq values < determination limit; -: values < detection limit; and na: not available. Data were analyzed by Mann-Whitney's U test to define the differences that were statistically significant. Superscript asterisks denote statistically significant differences ($p < 0.05$) within each appliance compared to *MF(-), and within each MF exposure compared to **SUS and *** β -Ti.

Table 3 Elution amount of each element (μg) from the brackets to AS

| | MF (-) | MF (+) |
|----|------------------|-------------------|
| Cr | - | + |
| Fe | 0.11 \pm 0.018 | 0.71 \pm 0.082* |
| Ni | - | + |
| Sn | - | - |
| Ti | - | - |

$n=6$ for each experimental condition. MF: magnetic field; +: detection values \leq values < determination limit; and -: values < detection limit. Data were analyzed by Mann-Whitney's U test to define the differences that were statistically significant. Superscript asterisks denote statistically significant differences ($p < 0.05$) within each row compared to *MF(-).

RESULTS

Electric current induced in orthodontic appliances by low-frequency MFs from electric toothbrushes

In this study, electric toothbrushes acting as MF sources were set on a turntable rotating at 5×10^{-2} Hz, so that the appliances were exposed to the MFs from every side of the toothbrushes (Fig. 1). First, the MFs from the front, right, left and back sides of the toothbrushes were estimated. Typical MF profiles from every side of the toothbrushes exhibited the same pattern; however the ranking order of these fields was: right > left > back > front side (Fig. 4).

The results for the currents induced in appliances with a distance of 2 cm between the front of the toothbrush and the appliance immersed in AS in plastic culture dishes are shown in Fig. 5. The voltage and current in each appliance that faced toward the electric

toothbrush, which was switched off, when immersed in AS were 0.02 \pm 0.01 mV and 0.02 \pm 0.01 mA in the SUS wire+SUS bracket, 0.02 \pm 0.01 mV and 0.03 \pm 0.02 mA in the β -Ti wire+SUS bracket, and 0.02 \pm 0.01 mV and 0.03 \pm 0.01 mA in the NiTi wire+SUS bracket, respectively. The induced voltages among the SUS, β -Ti and NiTi wire groups exhibited almost the same values; however, the currents were dramatically different between the SUS and titanium groups. The ranking order of the induced currents is for SUS brackets with wires composed of NiTi > β -Ti > SUS, as shown in Fig. 5.

Measurement of pH of AS after immersion of orthodontic appliances

The pH changes in the immersion AS samples are shown in Fig. 6. The pH of incubated AS samples containing appliances showed lower values than that of AS without appliances. No pH differences between the non MF-exposed and MF-exposed groups were observed.

Metallic elution from orthodontic appliances by MF exposure from electric toothbrushes

First, the standard curves of AS with and without metallic elements, e.g. Cr, Fe, Ni, Sn and Ti, were created, and then the detection limit, the determination limit and the appropriate wavelength for the detection of each element were obtained (Table 1). The elution volumes of the metallic ions in AS were shown as concentrations (ppb/ppm), so that these values could be converted into eluted metal weight/appliance (μg) for easier understanding (Table 1). Fe was detected in AS with no MF exposure for each combination (Table 2). In the titanium wires combined with the SUS brackets, the elution amounts of Fe were approximately half that of the SUS wires with the SUS bracket group in both the MF-exposed and unexposed groups. Elution of the elements in the SUS brackets without any wires was also investigated (Table 3). The Fe elution amounts in the bracket-only group were approximately half the values for the SUS wires with SUS brackets group

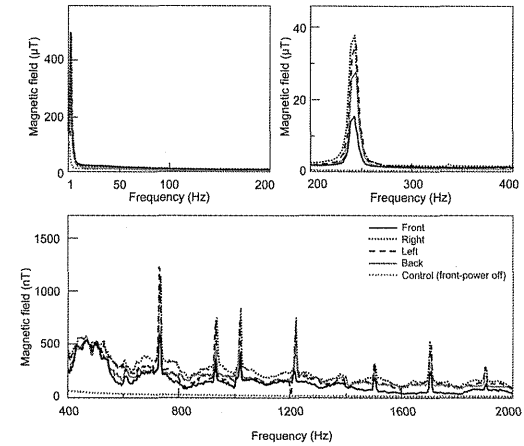


Fig. 4 Low-frequency MFs produced by the electric toothbrush. MFs (1–2,000 Hz) produced by the Sonicare HX9340/02 were estimated at a distance of 2 cm between the electric toothbrush and the front/right/left/back sides of the appliance with a spectrum analyzer.

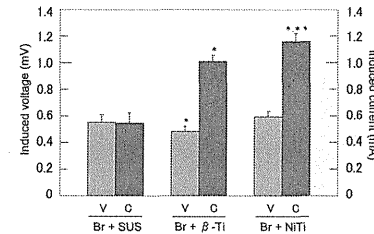


Fig. 5 Electric voltage and current induced in orthodontic appliances immersed in AS by electric toothbrushes. $n=6$ for each experimental condition. Br: bracket; SUS: stainless steel wire; β -Ti: β -titanium wire; NiTi: nickel-titanium wire; V: induced voltage; and C: induced current. The data were analyzed by Mann-Whitney's U test to define the differences that were statistically significant. Asterisks denote the statistically significant differences ($p < 0.05$) within the induced voltages or current compared to *Br+SUS wire and **Br+ β -Ti wire.

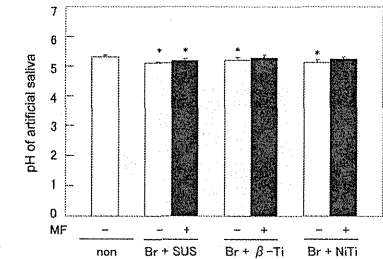


Fig. 6 pH changes in AS used to immerse the appliances, with or without exposure to MFs from electric toothbrushes. $n=6$ for each experimental condition. non: artificial saliva with no appliances; Br: bracket; SUS: stainless steel wire; β -Ti: β -titanium wire; NiTi: nickel-titanium wire; and MF: magnetic field. The data were analyzed by Mann-Whitney's U test to define the differences that were statistically significant. Asterisks denote the statistically significant differences ($p < 0.05$) within the groups with appliances compared to *non; **Br+SUS; ***Br+ β -Ti; and within each appliance when compared to ****MF(-).

in both the MF-exposed and the unexposed groups. The Fe elution amount in the bracket-only group also showed almost the same values as those of the titanium wires with SUS brackets groups in both the MF-exposed and unexposed groups (Tables 2 and 3). MF exposure dramatically increased Fe elution from the appliances (Table 2). Cr and Ni were also detected in the MF-exposed groups for each appliance. Ti could not be detected after MF exposure of the groups of titanium wires with SUS brackets (Table 2).

Surface roughness of orthodontic appliances caused by exposure to MFs from electric toothbrushes
The 3D laser confocal micrographs of the surfaces of the wires and the brackets in each combination were

represented in Figs. 7 and 8. The surface roughnesses of the appliances as measured and calculated by the 3D laser confocal microscope as Ra (arithmetic average of the absolute value), Rz (highest peaks and lowest valleys over the entire sampling length), and Sa (the arithmetic average of the 3D roughness) are shown in Fig. 9. These results revealed that MF exposure made the surfaces of the SUS wires and the SUS brackets uneven; however, little or no effect was observed from the MF exposure of the surfaces of the titanium wires (Fig. 9). In the micrographs, the surfaces of the intact appliances were seen not to be entirely smooth, so that the surface changes and roughness caused by MF exposure were difficult to judge, especially in the titanium wires (Figs. 7 and 8).

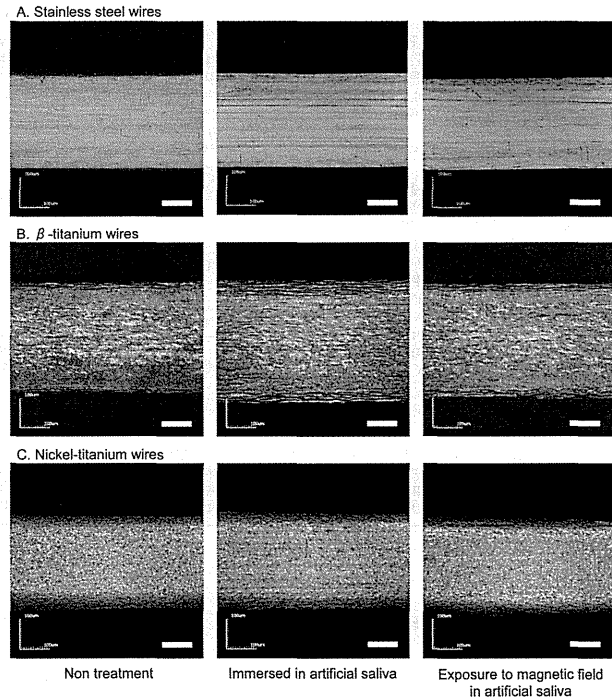


Fig. 7 3D laser confocal micrographs of the wire surfaces immersed in AS with or without exposure to the MFs from electric toothbrushes ($\times 20$). White lines in the micrographs represented 100 μm .

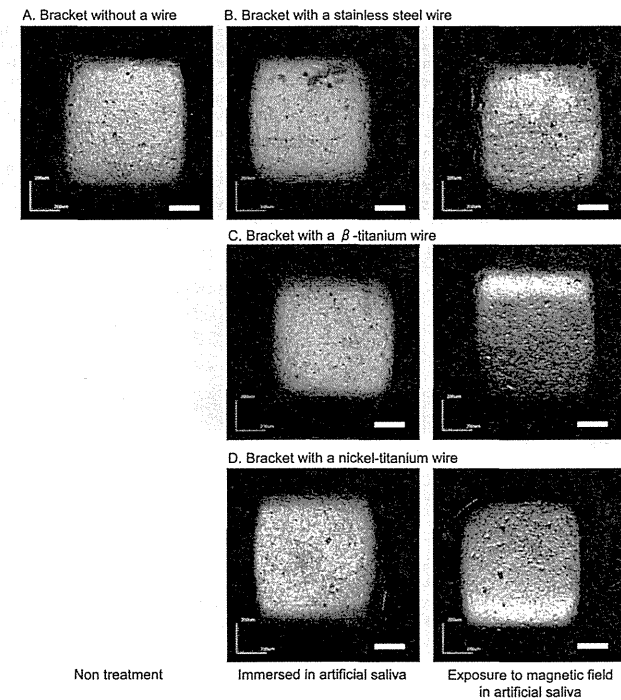


Fig. 8 3D laser confocal micrographs of the bracket surfaces immersed in AS with or without exposure to the MFs from electric toothbrushes ($\times 10$). White lines in the micrographs represented 200 μm .

DISCUSSION

There has been considerable recent interest in the effects of electromagnetic fields, such as those near electrical transmission lines, on human health, and the International Agency for Research on Cancer (IARC), the International Commission on Non-Ionizing Radiation Protection (ICNIRP) and the World Health Organization (WHO) have each established guidelines and criteria outlining the roles and risks of MFs in carcinogenesis¹⁶⁻¹⁸. Previous studies have demonstrated that alternating electric currents can be induced not only in fixed dental appliances (including orthodontic appliances), but also in human teeth by electromagnetic fields generated by electric toothbrushes and curing lights^{8,9}. Galvanic corrosion caused by weak galvanic

currents, which are direct currents, can occur in various combinations of dental materials, and can cause various human health problems, including metal allergies and poisoning^{7,8}. Some reports have also described metallic corrosion caused by electromagnetic field-induced AC^{15,16}. Alternating electric currents induced in dental appliances by electromagnetic fields may therefore also affect the corrosion of these appliances.

The MFs from the front, right, left and back sides of toothbrushes were found to have the same profiles in five identical electric toothbrushes with the same lot number. The MFs from every side of these toothbrushes showed the same patterns with the ranked order of right>left>back>front side (Fig. 4). These differences in MFs may be caused by the structure, including the electrical circuits, of the electric toothbrush. Induced

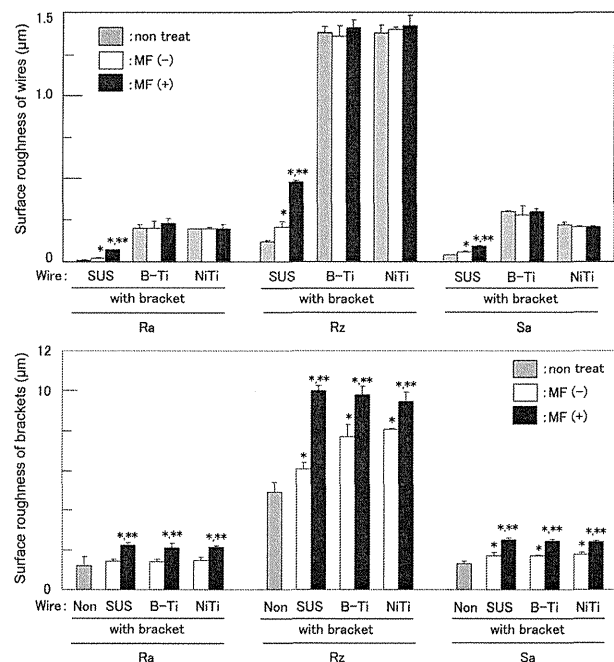


Fig. 9 Surface roughnesses of brackets and wires immersed in AS with or without exposure to MFs from electric toothbrushes. $n=6$ for each experimental condition. Br: bracket; SUS: stainless steel; β -Ti: β -titanium; NiTi: nickel-titanium; and MF: magnetic field. Ra represents the arithmetic average of the absolute value, Rz represents the highest peaks and lowest valleys over the entire sampling length, and Sa represents the arithmetic average of the 3D roughness (areal roughness). The data were analyzed by Mann-Whitney's U test to define the differences that were statistically significant. Asterisks denote the statistically significant differences ($p < 0.05$) within each measurement item of each appliance group when compared to *non, and **MF(-).

currents in appliances in AS when exposed to the above MFs were detected (Fig. 5). The induced voltages among the SUS, β -Ti and NiTi wire groups had almost the same values; however, the current showed dramatic differences between the SUS and titanium wire groups (Fig. 5). These values were not in proportion to their electrical resistivity, which were 70–80 Ω m for SUS304 and 80–100 Ω m for NiTi. One of the reasons for this phenomenon might be the combination of the NiTi wire with the SUS bracket. From the measured results for the induced voltage and current in each appliance in

AS when facing an electric toothbrush that is switched off, the galvanic current between SUS and NiTi, which could not be detected, must have no relationship to this phenomenon.

Metallic elution from orthodontic appliances under MF exposure from electric toothbrushes was detected by the ICP-OES. The obtained element concentrations in the AS (ppb/ppm) were converted into eluted metal weight/appliance (μ g) for easier understanding (Table 1). From the results of the standard curves for AS with or without additional elements, the detection

limit (3.38/slope), the determination limit ($10/\sqrt{28}$ /slope) and the appropriate wavelength were obtained for each element (Table 1). An approximately seven-fold increased concentration of Fe was detected in AS after MF exposure for each combination when compared to each of the no-MF-exposure group (Table 2). In each MF exposure group, Cr and Ni were also detected, with values that varied between the detection values and the determination limit. In titanium wires combined with SUS brackets, the Fe elution amount was approximately half that of the SUS wires with SUS bracket group in both the MF-exposed and non-MF-exposed groups, which almost matched the values of the bracket-only group. These results suggested that the Ni eluted by MF exposure could be derived from the SUS brackets, but not from the NiTi wires (Tables 2 and 3). In titanium wires combined with the SUS brackets in AS under MF exposure, Ti and Sn could not be detected, indicating a strong resistance against corrosion by electric current for the titanium alloy in comparison to SUS.

The surface roughness of each wire and bracket measured by the 3D laser confocal microscope as Ra, Rz and Sa supported the metallic elution measurement results (Fig. 9). MF exposure made the surfaces of the SUS wires and SUS brackets uneven; however, little or no effects of MF exposure on the surfaces of the titanium wires could be found (Fig. 9). As the surfaces of the intact appliances were not completely smooth, the surface changes caused by MF exposure were difficult to see, but the roughness, including corrosion pits, could be found by detailed observation (Figs. 7 and 8). These changes are likely to be caused by the small amount of metallic elution, which was approximately 1/1000 of the weight of the appliances (Tables 2 and 3).

In contrast to the evidence of the surface roughness for the occurrence of metallic elution, no pH differences were observed between the non-MF-exposed and MF-exposed groups (Fig. 6). The pH values were lowered by the immersion of each of the appliances; however, these pH values, which did not reach the depassivation pH, could not have eroded these alloys^{19,20}. These results suggested that pH changes in the AS have no relation to the MF-induced SUS corrosion.

In this study, we have shown that the low-frequency MFs induced by electric toothbrushes promote the corrosion of orthodontic SUS appliances without pH changes by inducing electric currents through an evaluation of the metallic elution when the appliances are immersed in AS, and from the roughness of the metal surfaces. These results suggested the possibility that low-frequency MFs around the oral cavity that originated from electronic equipment such as electric toothbrushes induce electric currents in intraorally installed metals (especially in SUS), prostheses and appliances, and promote metallic elution which is likely to be one of the causes of metallic allergies. We must be careful when using electric toothbrushes, especially when metal prostheses and/or appliances are worn in our mouths. However, it is very difficult to protect ourselves from low-frequency MFs because they can

pass through human tissues and most other materials, including glass, plastics, metals and concrete²¹. The only viable way to limit exposure to low-frequency electromagnetic fields is thought to be the elimination of their generation by home electrical appliances and dental devices. Further studies are necessary to clarify exactly how they affect human oral health, and whether countermeasures, including standardization, can be developed to negate their effects.

CONCLUSION

We examined the possibility of metallic corrosion caused by exposure to the MFs from electric toothbrushes *via* induced currents. The results obtained in this study are as follows:

1. Exposure of orthodontic appliances to MFs from electric toothbrushes induced currents in the appliances when they were immersed in AS.
2. SUS appliances were corroded by exposure to the MFs from electric toothbrushes.
3. Metal elution caused by exposure to the MFs from electric toothbrushes could not be detected in two types of titanium wire.
4. The pH values of the solutions used for the immersion, with or without MF exposure, exhibited no statistical significance.

We concluded that corrosion of SUS appliances, but not titanium appliances, occurred under exposure to MFs from electric toothbrushes *via* induced currents, but not through pH changes.

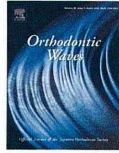
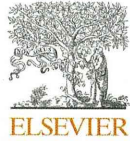
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Ⅲ. 研究成果の刊行に関する資料④

Orthod Waves, 72:959-969 (2013)



Research paper

Electric current induced in teeth by electromagnetic fields from electric toothbrushes and curing lights

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ABSTRACT

Purpose: The purpose of this study was to examine the electric current induced in teeth and tooth-bonded brackets by electromagnetic fields from electric toothbrushes and the curing lights used for photo-activating light-cured resins.

Materials and methods: Curing lights-generated low-frequency magnetic fields (1–2000 Hz) were measured with a spectrum analyzer. Temperature changes induced in the enamel and pulpal dentin surface of extracted upper premolar teeth (with or without a stainless steel or zirconia bracket) by electric toothbrushes and curing lights were estimated using an infrared thermometer. Electric current induced in these extracted teeth by electric appliances was estimated using a digital multimeter.

Results: Curing lights generated low-frequency magnetic fields. Irradiation of the tooth surface by curing lights elevated the temperature of the enamel and pulpal dentin surfaces, but there were no differences between curing lights. About electric current induced in extracted teeth (with or without a bracket) by electric toothbrushes and curing lights, the highest current was induced in teeth to which a zirconia bracket was bonded, whereas the lowest current was in unmodified teeth. Intermediate currents were generated in teeth bonded to stainless steel brackets.

Conclusion: The low-frequency magnetic fields induced by electric toothbrushes and light curing units induce electric current in tooth tissue, irrespective of whether these teeth are bonded to stainless steel or zirconia brackets.

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1. Introduction

The role of low-frequency electromagnetic fields in carcinogenesis, especially the development of leukemia and central nervous system tumors, has been well-documented [1–6]. The International Agency for Research on Cancer (IARC), the International Commission on Non-Ionizing Radiation

Protection (ICNIRP) and the World Health Organization (WHO) have all defined the roles and risks of magnetic fields in carcinogenesis [7–9]. Previous study has demonstrated that electric current can be induced in fixed dental appliances (including orthodontic appliances) by electromagnetic fields generated by electric toothbrushes [10]. Galvanic corrosion caused by weak galvanic currents can occur in various combinations of dental materials [11,12] and causes various

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human health problems including metal allergy and poisoning. Electric current induced in dental appliances by electromagnetic fields may therefore also influence human health [10].

Many electric home appliances and dental devices generate magnetic fields [13,14]. In this study, we first estimated the low-frequency magnetic fields (1–2000 Hz) generated by three commercially available light units used for curing photo-activated resins. We then examined whether magnetic fields from these and electric toothbrushes induced electric current and thermal elevation in teeth bonded (or not) to a stainless steel (SUS) or zirconia (ZrO₂) bracket. We show here that these devices do induce electric current in tooth tissue without thermal changes, irrespective of whether these teeth are bonded to SUS or ZrO₂ brackets, which may cause pain and discomfort and therefore represents a significant health risk.

2. Materials and methods

2.1. Materials

The five electric toothbrushes used in this study were: Braun Oral-B (P&G Inc., Ohio, USA); GC PRINIA Slim (GC Inc., Tokyo, Japan, but produced by Panasonic Inc., Osaka, Japan), Lion Vibracare Dental ExSystema (Lion Inc., Tokyo, Japan, but produced by OMRON Inc., Kyoto, Japan), Philips Sonicare HX6100 (Royale Philips Electronics Inc., Amsterdam, The Netherlands), and Philips Sonicare HX9100 (Philips Oral Healthcare Inc., WA, USA). Three curing lights were used: Lightel-II (Morita Inc., Tokyo, Japan), OPTILUX500 (Kerr Inc., WA, USA), and G-Light Prima (GC Inc., Tokyo, Japan).

For experiments investigating the surface temperature and induction of electric current, 129 human maxillary premolar teeth were collected following extraction from patients undergoing orthodontic treatment. Soft tissue was removed and the teeth were cleaned with tooth brushes and immersed in physiological salt solution (Otsuka normal saline (0.9% (154 mM) NaCl solution), Otsuka Pharmaceutical Co., Ltd., Tokyo, Japan) in a sealed container until testing. The saline was changed weekly to prevent the growth of bacteria and/or fungi. To qualify for selection, the teeth had to have intact enamel with no cracks and no caries. The brackets used in this study were KBT stainless steel (SUS630) and zirconia (ZrO₂) brackets (Rocky Mountain Morita Inc., Tokyo, Japan) developed by Kameda, T., as the latest modified Begg multibracket system. These brackets had identical shapes and dimensions (width × height × depth: 32 mm × 32 mm × 24 mm) and were bonded to the enamel surface of extracted premolars using adhesive (Light Bond, Reliance Orthodontic Products Inc., IL, USA) according to the manufacturer's instructions.

2.2. Measurement of magnetic fields generated by curing lights

Detection of magnetic fields generated by curing lights and the measurement of their frequencies was achieved using a spectrum analyzer (SPECTRAN NF-5035, Aaronia AB Inc., Euscheid, Germany). Published literature [13,15] and our own preliminary studies showed that the appropriate range

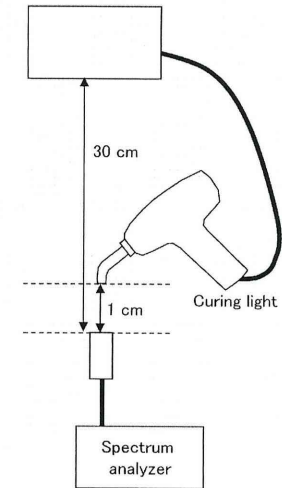


Fig. 1 – Schematic representation of experiments for estimating electromagnetic fields generated by curing lights using a spectrum analyzer.

of magnetic field frequencies to monitor was 1–2000 Hz, because preliminary experiments indicated that all curing lights generated very weak magnetic fields, but not at frequencies above 2000 Hz. Magnetic fields were tested at 1 cm from the tips of the light guides for 40 s (Fig. 1). [13].

2.3. Measurement of temperature changes in enamel and pulpal dentin surfaces

To evaluate temperature changes in the enamel and pulpal dentin surfaces of our sample teeth, we used an infrared thermometer (IT-550S, Horiba Inc., Kyoto, Japan). The palatal half of the premolar crown was dissected to allow estimation of the pulpal dentin surface temperature (Fig. 2). Literature suggests that the emissivity of enamel and dentin is 0.91 [16,17], so this value was used to calibrate our infrared thermometer prior to temperature measurement.

2.4. Measurement of electric current in tooth tissue

Electric current induced in the tooth tissue was estimated using a digital multimeter (7351 A/E, ADC Corporation, Tokyo, Japan) in AC + DC mode (i.e. voltage = $(ACV^2 + DCV^2)^{1/2}$ and current = $(ACI^2 + DCI^2)^{1/2}$). The positions of the electrodes and stimulating device (i.e. electric toothbrush/curing light) relative to the teeth are shown in Fig. 1. The mesial and distal sides of each tooth were drilled down to dentin using diamond points in an air turbine. Silver electrodes were then set into

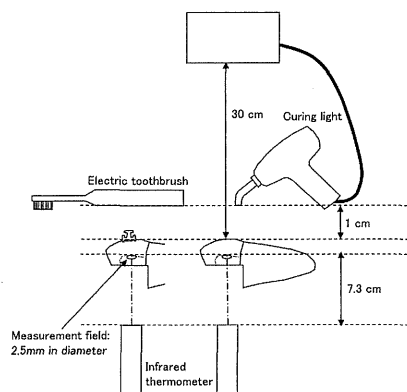


Fig. 2 – Schematic representation of experiments for estimating temperature of pulpal dentin of tooth after exposure of magnetic fields from electric toothbrushes and irradiation of curing lights.

this exposed dentin. Induced electric current was estimated with a separation of 1, 3 or 5 cm between the front of the toothbrush and the enamel surface (Fig. 3A) or with a 1-cm separation between the tip of the curing unit light guide and the enamel surface of a tooth in an acrylic jig (Fig. 3B). We also estimated the electric current induced between the anode and cathode in the absence of a tooth and confirmed that no electricity was detected from electric toothbrushes and curing lights at a distance of 1, 3 or 5 cm. Electric voltage and current were estimated as shown in Fig. 4.

2.5. Experimental conditions, data and statistical analysis

All experiments were performed in a laboratory environment maintained at $22 \pm 1^\circ\text{C}$ without magnetic shielding. Each experiment was repeated seven times independently, with the maximum and minimum values in each data set being removed before calculation of mean values. Data are given as the mean \pm standard deviation. The statistical significance of the differences within and between groups was determined with two-way ANOVA Bonferroni's post-test comparing all columns. Statistical significance was accepted at $p < 0.05$.

3. Results

3.1. Low-frequency magnetic fields produced by curing lights

Preliminary experiments indicated that curing lights generated very weak low-frequency magnetic fields. We therefore measured the magnetic fields generated by three different

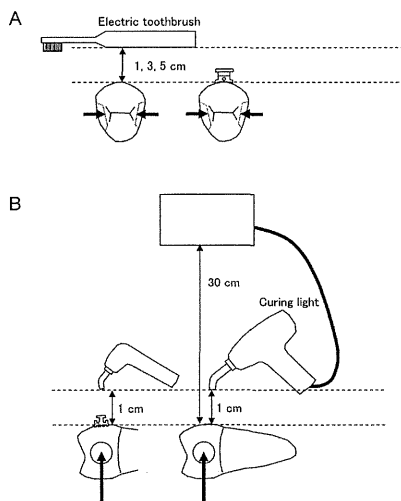


Fig. 3 – Schematic representation of experiments for estimating induced electric currents. (A) Electric toothbrushes. Left; tooth only, right; tooth with a stainless steel or a zirconia bracket. (B) Curing lights. Left upper; a curing light driven by rechargeable battery (with no electric wire), left lower; tooth with stainless steel or zirconia bracket, right upper; a curing light consisted of a handpiece and a control box with an electric wire. Arrows indicate the positions of electrodes for estimation of voltage and current by a digital multimeter.

curing lights (Lightel-II, OPTILUX500 and G-Light Prima) at 1-2000 Hz (Fig. 5).

A common profile of the magnetic field generated by Lightel-II and G-Light Prima curing units was typified by a weak magnetic field with no peaks (Fig. 5A and C). In contrast, the OPTILUX500 unit generated many strong peaks at 50-2000 Hz (Fig. 5B).

3.2. Temperature changes in enamel and pulpal surfaces

We used an infrared thermometer to estimate the temperature changes induced by electric toothbrushes and light curing units in the enamel and pulpal dentin surfaces of teeth bonded (or not) to a stainless steel or zirconia bracket. A 1-min exposure to the magnetic field generated by the electric toothbrushes did not alter the tooth surface temperature in either the presence or absence of a bracket (Table 1). Curing lights are known to have an elevated temperature at the tips of their light guides and this is transferred to the exposed enamel surface [18,19]. Indeed, temperature in both enamel and pulpal

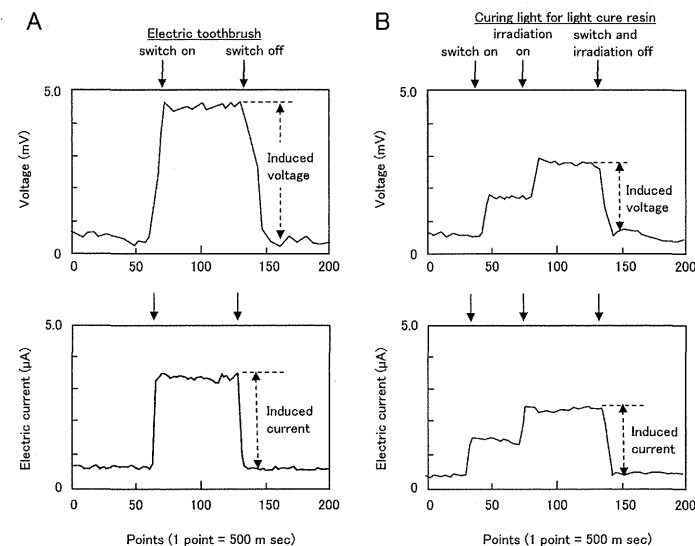


Fig. 4 – Electric current induced in tooth with a zirconia bracket. (A) Electric current induced by Philips Sonicare HX9100 at a distance of 1 cm between the electric toothbrush and the enamel surface. (B) Electric current induced by OPTILUX500 at a distance of 1 cm between the tip of light guide of a curing light and the enamel surface.

dentin surfaces was elevated by a 20-s exposure to the curing light. However, no statistically significant difference between the different units was observed (Table 2).

3.3. Electric current induced in teeth by electric toothbrushes and curing lights

The results of our experiments demonstrating the induction of electric current in tooth tissue by electric toothbrushes and curing lights are shown in Tables 3-6. No voltage or current

was induced when the devices were switched off and placed at a distance of 1 cm from the tooth (induced voltage and current were $0 \pm 0 \mu\text{V}$ and $0 \pm 0 \mu\text{A}$, respectively). Current induced by electric toothbrushes was inversely related to the distance between the brush and the tooth (Tables 3 and 4). Current induced by curing lights was detected whenever the curing lights were connected to power, irrespective of whether they were irradiating (Tables 5 and 6), although the current increased when the light was irradiating. Each device stimulated its highest current in teeth with zirconia brackets.

| Table 1 – Temperature increase after exposure of magnetic field from electric toothbrushes. | | | | | | |
|---------------------------------------------------------------------------------------------|------------------------------------------|---------------|---------------|------------------|-------------------------|-------------------------|
| | Surface temperature ($^\circ\text{C}$) | Brown OralB | GC PRINIA | Lion VibrateCare | Philips Sonicare HX6100 | Philips Sonicare HX9100 |
| Tooth | Enamel | 0.0 ± 0.0 | 0.0 ± 0.0 | 0.0 ± 0.0 | 0.0 ± 0.0 | 0.0 ± 0.0 |
| | Pulpal dentin | 0.0 ± 0.0 | 0.0 ± 0.0 | 0.0 ± 0.0 | 0.0 ± 0.0 | 0.0 ± 0.0 |
| Tooth + ZrO ₂ bracket | Enamel | 0.0 ± 0.0 | 0.0 ± 0.0 | 0.0 ± 0.0 | 0.0 ± 0.0 | 0.0 ± 0.0 |
| | Pulpal dentin | 0.0 ± 0.0 | 0.0 ± 0.0 | 0.0 ± 0.0 | 0.0 ± 0.0 | 0.0 ± 0.0 |
| Tooth + SUS bracket | Enamel | 0.0 ± 0.0 | 0.0 ± 0.0 | 0.0 ± 0.0 | 0.0 ± 0.0 | 0.0 ± 0.0 |
| | Pulpal dentin | 0.0 ± 0.0 | 0.0 ± 0.0 | 0.0 ± 0.0 | 0.0 ± 0.0 | 0.0 ± 0.0 |

Tooth tissue (enamel or dentin) was exposed to magnetic field from electric toothbrushes for 1 min and the change in temperature measured using an infrared thermometer with emissivity of enamel and dentin fixed at 0.91. Experiments were repeated five times independently.

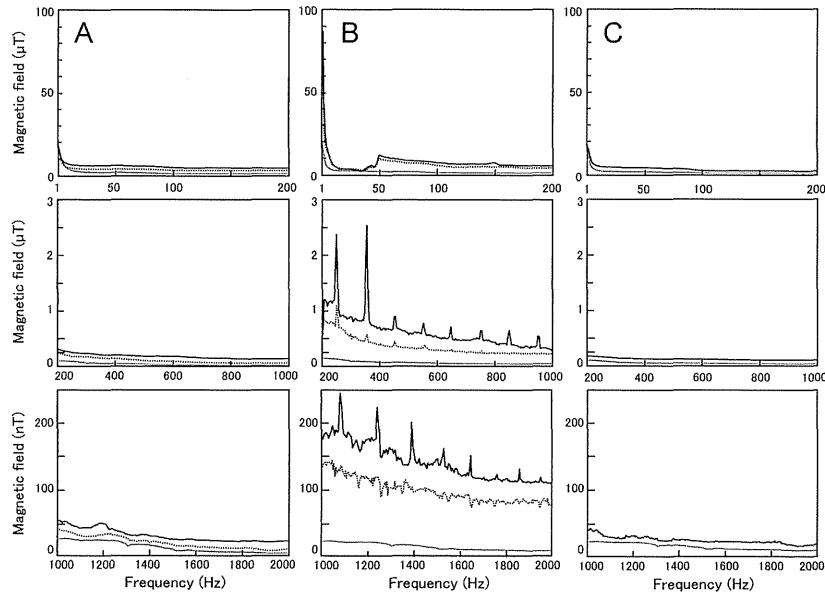


Fig. 5 – Low frequency magnetic fields produced by curing lights for light curing resin. (A) Lightel-II; (B) OPTILUX500; (C) G-Light Prima. Black line indicates the magnetic fields by curing lights under irradiation. The dotted line indicates magnetic fields by curing lights switched on with no irradiation. The gray line denotes magnetic fields measured by curing lights switched off.

The current in teeth with stainless steel brackets was somewhat lower, but still higher than in teeth with no brackets (Tables 3-6).

We also measured, under identical conditions, the current induced in the stainless steel and zirconia brackets

themselves. Current was detected in the stainless steel brackets, but not in the zirconia ones. Furthermore, the teeth exposed only to bonding adhesive (no bracket) experienced similar currents to those in teeth with no adhesive. Finally, in teeth bonded to an acrylic bracket (of the same shape and size

Table 2 – Temperature increase after irradiation by curing light units.

| Surface | temperature (°C) | LIGHTEL-II | OPTILUX500 | G-Light Prima |
|--------------------------|------------------|------------|------------|---------------|
| | | Enamel | 1.8±0.1 | 1.7±0.2 |
| Pulpal dentin | 1.0±0.2 | 1.0±0.2 | 1.0±0.1 | |
| Tooth + Enamel | 1.7±0.2 | 1.7±0.1 | 1.6±0.1 | |
| ZrO ₂ bracket | Pulpal dentin | 1.0±0.1 | 1.0±0.1 | 0.9±0.2 |
| Tooth + Enamel | 1.7±0.1 | 1.7±0.1 | 1.6±0.2 | |
| SUS bracket | Pulpal dentin | 1.0±0.2 | 1.0±0.1 | 0.9±0.1 |

NS NS NS NS NS

Tooth tissue (enamel or dentin) was exposed to irradiation by light curing units for 20 s and the change in temperature measured using an infrared thermometer with emissivity of enamel and dentin fixed at 0.91. Experiments were repeated five times independently. NS denotes no statistically significant difference, as determined by one-way ANOVA followed by Dunnett's post-test ($P < 0.05$), $n = 5$.

Table 3 – Electric voltage induced in tooth tissue by various electric toothbrushes.

| A. Induced voltage | | | | | | |
|----------------------------------|---------------|-------------|------------------------|------------------------|----------------------------|------------------------------|
| Induced voltage (mV) | Distance (cm) | Brown OralB | GC PRINIA | Lion VibratCare | Philips Sonicare HX6100 | Philips Sonicare HX9100 |
| Tooth | 1 | 1.7 ± 0.1 | 1.5 ± 0.1 | 1.6 ± 0.1 | 2.3 ± 0.1 ^{a,b,c} | 2.7 ± 0.2 ^{a,b,c,d} |
| | 3 | 1.5 ± 0.1 | 1.0 ± 0.2 ^a | 1.3 ± 0.1 | 1.6 ± 0.1 ^{b,c} | 2.1 ± 0.2 ^{a,b,c,d} |
| | 5 | 1.0 ± 0.1 | 0.6 ± 0.1 ^a | 1.0 ± 0.1 ^b | 1.0 ± 0.1 ^b | 1.3 ± 0.2 ^b |
| Tooth + ZrO ₂ bracket | 1 | 2.5 ± 0.1 | 2.1 ± 0.1 ^a | 2.6 ± 0.2 ^b | 3.7 ± 0.3 ^{a,b,c} | 4.3 ± 0.2 ^{a,b,c,d} |
| | 3 | 1.9 ± 0.1 | 1.6 ± 0.1 ^a | 2.2 ± 0.2 ^b | 2.4 ± 0.3 ^{a,b} | 2.7 ± 0.3 ^b |
| | 5 | 1.5 ± 0.1 | 1.0 ± 0.2 ^a | 1.7 ± 0.1 ^b | 1.7 ± 0.2 ^b | 1.9 ± 0.3 ^b |
| Tooth + SUS bracket | 1 | 2.2 ± 0.1 | 1.8 ± 0.1 ^a | 1.8 ± 0.2 | 2.2 ± 0.2 ^b | 2.7 ± 0.2 ^{a,b,c,d} |
| | 3 | 1.4 ± 0.1 | 1.4 ± 0.1 | 1.4 ± 0.1 | 1.5 ± 0.2 | 1.6 ± 0.2 |
| | 5 | 1.0 ± 0.1 | 0.8 ± 0.2 | 1.2 ± 0.1 ^b | 0.8 ± 0.2 | 1.1 ± 0.2 |

| B. Induced voltage: distances vs bracket materials | | | |
|----------------------------------------------------|-------------------------|--------------------------|----------------------------|
| Induced voltage (mV) | 1 cm | 3 cm | 5 cm |
| Tooth | 1.9 ± 0.3 | 1.5 ± 0.1 ^a | 1.0 ± 0.1 ^{a,b} |
| Tooth + ZrO ₂ bracket | 3.0 ± 0.7 [*] | 2.2 ± 0.2 ^{a*} | 1.6 ± 0.1 ^{a,b*} |
| Tooth + SUS bracket | 2.1 ± 0.1 ^{**} | 1.5 ± 0.1 ^{a**} | 1.0 ± 0.1 ^{a,b**} |

| C. Induced voltage: electric toothbrushes vs distances | | | | | |
|--------------------------------------------------------|-------------------------|----------------------------|--------------------------|----------------------------|------------------------------|
| Induced voltage (mV) | Brown OralB | GC PRINIA | Lion VibratCare | Philips Sonicare HX6100 | Philips Sonicare HX9100 |
| 1 cm | 2.1 ± 0.1 | 1.8 ± 0.1 ^a | 2.0 ± 0.2 ^b | 2.7 ± 0.5 ^{a,b,c} | 3.2 ± 0.6 ^{a,b,c,d} |
| 3 cm | 1.6 ± 0.1 | 1.3 ± 0.1 ^a | 1.6 ± 0.2 ^{b*} | 1.9 ± 0.2 ^{a,b*} | 2.1 ± 0.3 ^{a,b,c*} |
| 5 cm | 1.2 ± 0.1 ^{b*} | 0.8 ± 0.1 ^{a,b**} | 1.3 ± 0.1 ^{b**} | 1.2 ± 0.2 ^{b,c**} | 1.4 ± 0.2 ^{b,c**} |

$n = 5$ for each experimental condition.
 $n = 25$ for each experimental condition.
 $n = 15$ for each experimental condition.
 Data were analyzed by two-way ANOVA with Bonferroni's post-test to define which differences were statistically significant. Superscript letters denote statistically significant differences ($p < 0.05$). (A) Within each row compared to (a) Braun OralB; (b) GC Prinia; (c) Lion VibratCare; (d) Philips Sonicare HX6100, (B) within each row compared to (a) 1 cm; (b) 3 cm, and within each column compared to 'tooth', 'tooth + ZrO₂ bracket', (C) within each row, compared to (a) Braun OralB; (b) GC Prinia; (c) Lion VibratCare; (d) Philips Sonicare HX6100, and within each column compared to '1 cm', '3 cm'.

as the steel and zirconia ones), the induced current was similar to that in teeth that had not been bonded to any bracket.

4. Discussion

There has been much recent interest in the effect of electromagnetic fields (such as those near electricity transmission lines) on human health, especially their potential to effect the development of leukemia and central nervous system tumors. An elevated risk of leukemia following exposure to electromagnetic fields has been demonstrated [1,2], and the IARC, the ICNIRP and the WHO have each established guidelines and criteria outlining the roles and risks of magnetic fields in carcinogenesis [7-9]. However, other reports have found no significant correlation between exposure to electromagnetic fields and leukemia [3,4]. Results from studies into the correlation between electromagnetic fields and the risk of central nervous system tumors are also equivocal [2,4]. These findings about the risks of electromagnetic fields on leukemia and central nervous system tumors should be depended on the exposure conditions, e.g. intensity and exposure time, of electromagnetic fields [5,6].

In this study, we observed weak magnetic field with no peaks when using the Lightel-II and G-Light Prima curing units, but with many strong peaks between 50 and 2000 Hz when using the OPTILUX500 unit (Fig. 5). This might be due to its electricity consumption of the power and the light unit, e.g. OPTILUX500; 200 W (halogen light unit), Lightel-II; 120 W (halogen light unit), G-Light Prima; 10 W (LED light unit). Compared with the magnitude of magnetic fields induced by electric toothbrushes in our previous report [10], the fields generated here were very weak. However, in terms of influencing the health of an organism, the strength of the electric current is more important than that of the low-frequency magnetic field itself [20]. Many dental devices and electric home appliances generate low-frequency magnetic fields [10,13] that could induce electric current in the human body and within metallic objects such as dental appliances or devices worn in or on the body [15]. Electric current in oral and dental appliances (i.e. galvanic current) is known to induce pain, discomfort and corrosion of metallic dental appliances [13,14]. We have shown here (Tables 3 and 4) that such currents in teeth can be generated by electric toothbrushes and curing lights. Electrical conductivity can be influenced by the temperature of an object. However, we found that although the curing lights elevated the tooth surface temperature slightly (Table 4), there was no thermal effect

Table 4 – Electric current induced in tooth tissue by various electric toothbrushes.

| A. Induced current | | | | | | |
|----------------------------------|---------------|-------------|-----------|------------------|------------------------------|------------------------------|
| Induced current (µA) | Distance (cm) | Brown OralB | GC PRINIA | Lion VibrateCare | Philips Sonicare HX6100 | Philips Sonicare HX9100 |
| Tooth | 1 | 1.5 ± 0.2 | 1.3 ± 0.1 | 1.6 ± 0.1 | 2.0 ± 0.2 ^{a,b,c} | 2.0 ± 0.2 ^{a,b,c} |
| | 3 | 0.9 ± 0.1 | 0.9 ± 0.2 | 1.2 ± 0.1 | 1.4 ± 0.1 ^{a,b} | 1.5 ± 0.2 ^{a,b} |
| | 5 | 0.7 ± 0.1 | 0.6 ± 0.1 | 0.7 ± 0.1 | 1.0 ± 0.2 ^b | 0.9 ± 0.3 |
| Tooth + ZrO ₂ bracket | 1 | 2.0 ± 0.1 | 1.7 ± 0.2 | 2.3 ± 0.2 | 2.4 ± 0.2 ^{a,b} | 2.5 ± 0.2 ^{a,b} |
| | 3 | 1.5 ± 0.1 | 1.3 ± 0.1 | 1.8 ± 0.3 | 1.9 ± 0.2 ^{a,b} | 2.0 ± 0.2 ^{a,b} |
| | 5 | 1.0 ± 0.2 | 0.7 ± 0.1 | 1.0 ± 0.1 | 1.5 ± 0.1 ^{a,b,c,d} | 1.5 ± 0.1 ^{a,b,c,d} |
| Tooth + SUS bracket | 1 | 1.8 ± 0.1 | 1.5 ± 0.1 | 1.7 ± 0.1 | 2.2 ± 0.2 ^{a,b,c} | 2.1 ± 0.3 ^{b,c} |
| | 3 | 1.3 ± 0.1 | 1.2 ± 0.2 | 1.3 ± 0.3 | 1.5 ± 0.1 | 1.6 ± 0.2 ^b |
| | 5 | 0.9 ± 0.3 | 0.8 ± 0.2 | 0.9 ± 0.1 | 1.1 ± 0.2 | 1.1 ± 0.3 |

| B. Induced current: distances vs bracket materials | | | |
|----------------------------------------------------|------------------------|--------------------------|--------------------------|
| Induced current (µA) | 1 cm | 3 cm | 5 cm |
| Tooth | 1.7 ± 0.1 | 1.2 ± 0.1 ^a | 0.8 ± 0.1 ^{a,b} |
| Tooth + ZrO ₂ bracket | 2.2 ± 0.1 ^a | 1.7 ± 0.1 ^{a,c} | 1.0 ± 0.1 ^{a,b} |
| Tooth + SUS bracket | 1.9 ± 0.1 ^a | 1.4 ± 0.1 ^{a,c} | 0.9 ± 0.1 ^{a,b} |

| C. Induced current: electric toothbrush vs distances | | | | | |
|------------------------------------------------------|------------------------|------------------------|------------------------|----------------------------|----------------------------|
| Induced current (µA) | Brown OralB | GC PRINIA | Lion VibrateCare | Philips Sonicare HX6100 | Philips Sonicare HX9100 |
| 1 cm | 1.8 ± 0.1 | 1.5 ± 0.1 ^a | 1.9 ± 0.1 ^b | 2.2 ± 0.1 ^{a,b,c} | 2.2 ± 0.1 ^{a,b,c} |
| 3 cm | 1.2 ± 0.1 ^a | 1.1 ± 0.1 ^a | 1.4 ± 0.1 ^b | 1.6 ± 0.1 ^{a,b} | 1.7 ± 0.1 ^{a,b,c} |
| 5 cm | 0.8 ± 0.1 ^a | 0.7 ± 0.1 ^a | 0.9 ± 0.1 ^a | 1.0 ± 0.1 ^{a,b,c} | 1.2 ± 0.1 ^{a,b,c} |

n = 5 for each experimental condition.
n = 25 for each experimental condition.
n = 15 for each experimental condition.
Data were analyzed by two-way ANOVA with Bonferroni's post-test to define which differences were statistically significant. Superscript letters denote statistically significant differences (p < 0.05). (A) Within each row compared to (a) Braun OralB; (b) GC Prinia; (c) Lion VibrateCare; (d) Philips Sonicare HX6100, (B) within each row compared to (a) 1 cm; (b) 3 cm, and within each column compared to 'tooth'; 'tooth + ZrO₂ bracket', (C) within each row compared to (a) Braun OralB; (b) GC Prinia; (c) Lion VibrateCare; (d) Philips Sonicare HX6100, and within each column compared to 1 cm, 3 cm.

associated with electric toothbrushes (Tables 1 and 3). In addition, temperature of enamel surface was higher than that of pulpal dentin in the curing light group (Table 2). These results suggested that magnetic field-induced current in teeth generated by these devices did not play important roles in temperature elevation of tooth surface. We concluded that thermal changes in the tooth or dental appliance induced by devices emitting a low-frequency magnetic field are negligible, and that induction heating of the tooth is unlikely to be sufficient to cause significant adverse effects.

Electric current induced in tooth tissue by electric toothbrushes was inversely related to the distance between the brush and the tooth (Table 3A and B), consistent with findings in our previous study [10]. However, we found that the voltages induced in the tooth were higher (10²-10³ µV) than those measured previously in dental appliances (10¹-10² µV) [10]. In contrast, the current induced by electric toothbrushes in our study were lower (~10¹ µA) than those measured previously in dental appliances (10²-10³ µA) [8]. This difference could relate to disparities in the electrical resistivity of tooth tissue (~10³ Ω m) and metal (stainless steel = ~10⁻⁸ Ω m) [21,22]. When tooth surfaces were irradiated by curing lights, the current induced was greater than when the (powered) unit was held in proximity to the tooth but without irradiating, consistent with our magnetic field findings (Table 4A and B). The rank orders in which electric toothbrushes generated electric voltage and

current in tooth tissue are: Sonicare HX9100 > Sonicare HX6100 > VibrateCare ≥ OralB > PRINIA (voltage) and Sonicare HX9100 ≥ Sonicare HX6100 > VibrateCare ≥ OralB ≥ PRINIA (current). These orders were almost identical to our previous results demonstrating magnetic field generation by these devices [10]. The rank orders in which curing light units generated electric voltage and current in tooth tissue were: OPTILUX500 > Lightel-II > G-Light Prima (voltage) and OPTILUX500 ≈ Lightel-II > G-Light Prima (current), consistent with our results here describing magnetic field generation by these units (Fig. 5). These orders were almost identical to the results demonstrating magnetic field generation by these devices and their electricity consumption of the power unit (Fig. 5).

We predicted that the rank order in which currents could be induced in different materials would be tooth + stainless steel bracket > tooth + zirconia bracket ≈ tooth, based on their electrical resistivity (tooth, 10³ Ω m; stainless steel, 10⁻⁸ Ω m; ZrO₂, 10¹⁰-10¹² Ω cm; resin (acrylic), 10¹³-10¹⁴ Ω m) [23,24]. However, we found that the actual rank order was tooth + zirconia bracket > tooth + stainless steel bracket > tooth. The reason for this unexpected result is unclear. The presence of adhesive appears not to be a factor because the induced current was comparable with and without adhesive (no bracket). The resistivity of bracket materials also appears to be insignificant because the current was greater in teeth attached to ZrO₂ or stainless steel brackets than in teeth

Table 5 – Electric voltage induced in teeth by light curing units used for photo-activating light-cured resins.

| A. Induced voltage | | | | | |
|----------------------------------|---------------|-------------------------|----------------------|------------------------|--------------------------|
| Induced voltage (mV) | Distance (cm) | Irradiation (switch:ON) | Lightel-II by Morita | OPTILUX500 by KERR | G-Light Prima by GC |
| Tooth only | 1 | No | 0.8 ± 0.1 | 1.3 ± 0.1 ^a | 0.0 ± 0.0 ^{a,b} |
| | 1 | Yes | 1.5 ± 0.1 | 1.5 ± 0.1 ^a | 0.3 ± 0.1 ^{a,b} |
| Tooth + ZrO ₂ bracket | 1 | No | 0.8 ± 0.1 | 1.3 ± 0.1 ^a | 0.0 ± 0.0 ^{a,b} |
| | 1 | Yes | 1.5 ± 0.1 | 2.4 ± 0.1 ^a | 0.6 ± 0.1 ^{a,b} |
| Tooth + SUS bracket | 1 | No | 1.0 ± 0.1 | 1.2 ± 0.2 | 0.0 ± 0.0 ^{a,b} |
| | 1 | Yes | 1.3 ± 0.2 | 2.0 ± 0.2 ^a | 0.4 ± 0.1 ^{a,b} |

| B. Induced voltage: irradiation vs bracket materials | | |
|------------------------------------------------------|-----------------|------------------------|
| Induced voltage (mV) | Irradiation-off | Irradiation-on |
| Tooth | 0.7 ± 0.3 | 0.9 ± 0.3 |
| Tooth + ZrO ₂ bracket | 0.7 ± 0.3 | 1.5 ± 0.6 ^a |
| Tooth + SUS bracket | 0.8 ± 0.1 | 1.2 ± 0.5 |

| C. Induced voltage: curing light units vs irradiation | | | |
|-------------------------------------------------------|------------------------|------------------------|--------------------------|
| Induced voltage (mV) | Lightel-II by Morita | OPTILUX500 by KERR | G-Light Prima By GC |
| Irradiation-off | 0.9 ± 0.1 | 1.3 ± 0.1 ^a | 0.0 ± 0.0 ^{a,b} |
| Irradiation-on | 1.3 ± 0.1 ^a | 2.0 ± 0.2 ^a | 0.4 ± 0.1 ^{a,b} |

n = 5 for each experimental condition.
n = 15 for each experimental condition.
n = 15 for each experimental condition.
Data were analyzed by two-way ANOVA with Bonferroni's post-test to define which differences were statistically significant. Superscript letters denote statistically significant differences (p < 0.05). (A) Within each row compared to (a) Lightel-II; (b) OPTILUX500, (B) within each row compared to a) irradiation-off, and within each column compared to 'tooth'; 'tooth + ZrO₂ bracket', (C) within each row compared to (a) Lightel-II; (b) OPTILUX500, and within each column compared to 'irradiation-off.'

Table 6 – Electric current induced in teeth by light curing units used for photo-activating light-cured resins.

| A. Induced current | | | | | |
|----------------------------------|---------------|--------------------------|----------------------|--------------------|--------------------------|
| Induced current (µA) | Distance (cm) | Irradiation (switch: ON) | Lightel-II by Morita | OPTILUX500 by KERR | G-Light Prima by GC |
| Tooth only | 1 | No | 1.0 ± 0.1 | 1.1 ± 0.2 | 0.0 ± 0.0 ^{a,b} |
| | 1 | Yes | 1.3 ± 0.2 | 1.4 ± 0.2 | 0.4 ± 0.2 ^{a,b} |
| Tooth + ZrO ₂ bracket | 1 | No | 1.2 ± 0.2 | 1.2 ± 0.2 | 0.0 ± 0.0 ^{a,b} |
| | 1 | Yes | 1.8 ± 0.1 | 2.2 ± 0.3 | 0.9 ± 0.1 ^{a,b} |
| Tooth + SUS bracket | 1 | No | 1.2 ± 0.2 | 1.2 ± 0.2 | 0.0 ± 0.0 ^{a,b} |
| | 1 | Yes | 1.5 ± 0.2 | 1.8 ± 0.2 | 0.7 ± 0.2 ^{a,b} |

| B. Induced current: irradiation vs bracket materials | | |
|------------------------------------------------------|-----------------|------------------------|
| Induced current (µA) | Irradiation-off | Irradiation-on |
| Tooth | 0.7 ± 0.3 | 1.0 ± 0.2 |
| Tooth + ZrO ₂ bracket | 0.8 ± 0.4 | 1.7 ± 0.4 ^a |
| Tooth + SUS bracket | 0.8 ± 0.4 | 1.4 ± 0.3 |

| C. Induced current: curing light units vs irradiation | | | |
|-------------------------------------------------------|------------------------|------------------------|--------------------------|
| Induced current (µA) | Lightel-II by Morita | OPTILUX500 by KERR | G-Light Prima by GC |
| Irradiation-off | 1.1 ± 0.1 | 1.2 ± 0.1 | 0.0 ± 0.0 ^{a,b} |
| Irradiation-on | 1.6 ± 0.1 ^a | 1.8 ± 0.2 ^a | 0.7 ± 0.1 ^{a,b} |

n = 5 for each experimental condition.
n = 15 for each experimental condition.
n = 15 for each experimental condition.
Data were analyzed by two-way ANOVA with Bonferroni's post-test to define which differences were statistically significant. Superscript letters denote statistically significant differences (p < 0.05). (A) Within each row compared to (a) Lightel-II; (b) OPTILUX500, (B) within each row compared to a) irradiation-off, and within each column compared to 'tooth'; 'tooth + ZrO₂ bracket', (C) within each row compared to (a) Lightel-II; (b) OPTILUX500, and within each column compared to 'irradiation-off.'