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IONTOPHORETIC TOOTHBRUSH

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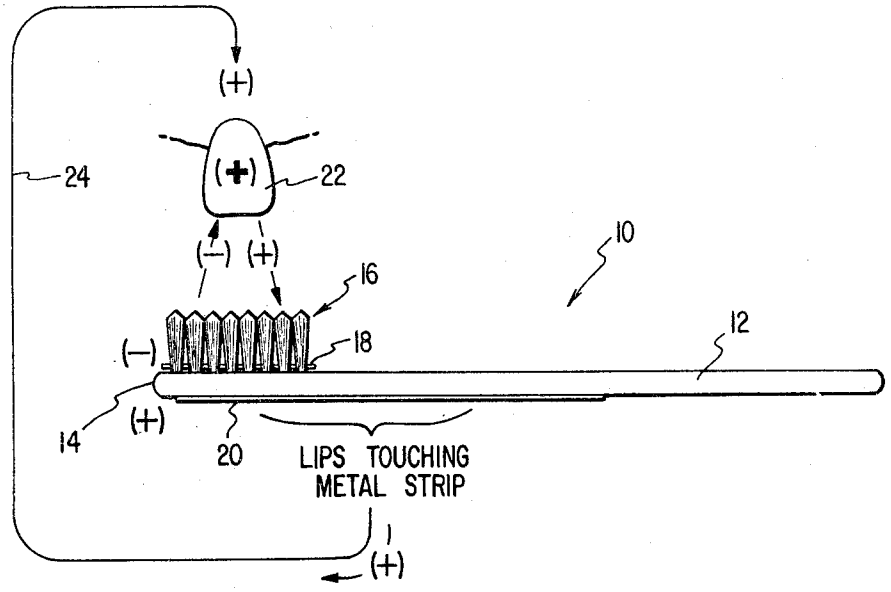

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IONTOPHORETIC TOOTHBRUSH

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ABSTRACT OF THE DISCLOSURE

A system including a brush, such as a toothbrush, having electrodes of different metals thereon which can be utilized in combination with solutions of medicaments to provide an electrical current for use in the introduction of ions of the medicament, such as fluoride ions, into body tissues, e.g. tooth enamel, by iontophoresis.

The use of certain fluoride compounds as additives to drinking water or for topical application on the teeth, e.g. by incorporating such compounds as stannous fluoride in toothpaste, to prevent tooth decay is well known. The success of fluoride compounds as caries preventive agents has been tacitly assumed to be related to the uptake of fluoride ions by sound tooth enamel. Physiochemical studies, however, indicate that the enamel pore wall is negatively charged and acts as an ionic sieve, facilitating the penetration of positively charged ions and resisting the penetration of negatively charged ions. Thus, the penetration of fluoride ions which are strongly negative is normally resisted by the enamel and the fluoride ions which remain on the surface of the enamel are readily washed off.

Recently studies have indicated that the effectiveness of fluoride ions should be increased if the naturally occurring negative charge of the enamel is reversed to become positive, since the amount and depth of penetration by the negative fluoride ions are facilitated. The process of influencing ionic motion known as iontophoresis has been suggested as a way to facilitate the amount and depth of penetration of the fluoride ions. Iontophoresis is the introduction by means of an electric current of ions of soluble salts into the tissues of the body for therapeutic purposes and has been in use some fifty or more years. In the case of anti-caries therapy with fluoride ion, increased penetration of the enamel by fluoride ions is obtained by the use of iontophoresis.

An iontophoresis toothbrush is presently marketed which includes an electric circuit having a dry cell arranged in the handle to provide the current, see U. S. Pat. 2,834,344 to Kanai. This arrangement is disadvantageous, however, since it requires a wet hand to grip the handle and the dry cell limits the design of the brush, makes it bulky, adds to its cost and increases maintenance since it must be periodically replaced. Additionally, the circuit which extends through the arm and head is substantially longer than through the lips as in this invention and persons using the brush can experience headaches.

It is also known that iontophoresis can be used to introduce ions of other soluble medicaments into the body tissues such as fingernails and skin. For example, the penetration of pharmagel into the nail in the treatment of brittle nails can be facilitated by iontophoresis. Also, the use of sulfacetamide in gum infections and the use of selenium compounds in scalp treatments for dandruff causing organisms can be assisted. The apparatus and system of this invention is suitable for these uses, and others, although hereinbelow for simplicity it will be described with reference to the penetration of tooth enamel by fluoride ions.

In general this invention is directed to a self-energizing iontophoresis apparatus for introducing ions into the body tissues which generally comprises a brush having a handle

made of an electrical non-conductor carrying a plurality of bristles and two dissimilar metal pieces. The two metal pieces are arranged so that they do not touch and one metal piece is arranged so that it does not contact the body tissue during use of the brush. The other metal piece is affixed in such a position on the brush handle that it contacts the body tissues, e.g. the lips adjacent the teeth which are to be treated by iontophoresis.

It is known that dissimilar metals when placed in an electrolyte exhibit an electrical potential therebetween. The Electromotive Force Series of Elements is a compilation of the electrode potentials of various metals utilizing a standard hydrogen reference electrode. In the system of this invention, a solution containing the ions to be introduced into the body tissues, e.g. a saliva solution of tooth cleansers containing a fluoride salt, forms an electrolyte, and since the human body is electrically conductive, when the brush is used with the solution, an electrical circuit is closed through the two metal pieces, the body and the saliva solution through which circuit flows a current generated by the difference in potentials of the two metals. The direction of current flow in the circuit is controlled by choosing the particular metals. If the metal piece touching the body has a higher potential than the other metal piece, a positive charge will be applied to the body tissues at the electrolyte. This system is desirable when the ions to be introduced into the body tissues, such as fluoride ions, sulfacetamide, etc., have a negative charge, since the positively charged tissue attracts the negatively charged ions facilitating penetration of the tissues by the ions. Reversing the position of the metals reverses the flow of current and applies a negative charge to the body tissues at the electrolyte. Utilizing this system with positively charged therapeutically active ions such as those found in anesthetics, zinc sulfate, streptomycin HCl, epinephrine HCl, copper sulfate, etc. facilitates their penetration. It is apparent that if both metal pieces touched the body, a short circuit occurs between the two points of contact rather than at the desired area of treatment so this is avoided.

The two dissimilar metals in this invention are selected from the Electromotive Force Series of Metals to provide a cell voltage and generate a current sufficient to place a charge on the body tissues, e.g. a positive charge on the teeth having sufficient strength to attract the desired ions and increase the penetration thereof into the body tissues. Generally, the cell voltage will be between about 0.3 v. and 2 v., preferably about 0.5 to about 1 v. and the current strength between about 20 and 2000 microamps, preferably about 40 to 600 microamps. The current should generally not exceed about 2000 microamps due to physical discomfort such as tingling of the tissues, sore fillings and headaches which can develop with higher currents. The current flow is affected not only by the particular metal combination, but also by the relative surface areas of the two metals in contact with the ionic solution of the medicament, the particular medicament and concentration of ions, etc. Suitable sizes of the electrodes vary over a wide range and are limited only by brush size. In general, the greater the area of the more positive metal piece exposed to the ionic solution, the larger the current generated. Also, the size of the negative, or less positive, metal piece will affect the life of the brush since it is used up to provide the electron flow. In either case only a small portion of the metal piece need touch the body tissue. The ionic solution should generally be either acidic or basic and, preferably will have a pH below about 5 or above about pH 8.

In general, any metal combination which exhibits the desired EMF and generates the desired current can be used in this invention. Since the apparatus is designed

for use on human tissue, however, non-toxic materials are used. Suitable metals include generally those above copper in the electromotive series, such as iron, tin, nickel, zinc, magnesium, aluminum, etc., as well as non-toxic compounds such as oxides of these materials and hereinafter when metals are referred to it is intended to include such compounds. Carbon, e.g. in the form of graphite, and silver can also be used. Also, when selecting metals for toothbrushes, it is desirable to use metals having an EMF above the constituents of dental filings in the electromotive series since otherwise use of the toothbrush would cause deterioration of the filings. Desirable metal combinations are tin-zinc, tin-magnesium, tin-aluminum, zinc-silver, copper-zinc, silver-magnesium, etc. Although described as strips, or pieces, the metals can be present in various forms such as a powder embedded in the bristles of the brush or in the back surface of the brush handle, as well as actual strips or foils affixed to the brush, and the terms "strips" and "pieces" are intended to encompass such forms.

Referring now to the attached drawing, the sole figure therein illustrates an embodiment of the apparatus in accordance with this invention which is in the form of a toothbrush. In this figure, the toothbrush, generally designated as **10**, includes bristles **16** and a body having a handle portion **12** and a head portion **14** of conventional construction. Two dissimilar metal pieces **18** and **20** are affixed to head **14** by conventional means. As affixed, the metal pieces do not touch and only piece **20** will touch the body tissues, e.g., the lips, when the brush is used. If desired, piece **20** can extend rearward on handle **12** to where it touches the hand. The signs (−) and (+) are intended to show that metal piece **20** has a higher, more positive, electrode potential than does metal piece **18**. With this arrangement a positive charge will be applied to the teeth, represented by tooth **22** by an electrical circuit, depicted by line **24**, established through metal piece **20** and the body which is closed to metal piece **18** when the two metal pieces **18** and **20** contact the saliva in the mouth. The saliva becomes the medium in which ions commence their selective movement. Negative ions flow toward the now positively charged teeth **22** and positive ions to the negatively charged area at bristles **16** as shown by the positively and negatively marked arrows.

The following examples serve to further illustrate this invention.

EXAMPLE I

Tin and magnesium foils were fastened to a toothbrush head. The tin foils used had areas of 600 sq. mm., 150 sq. mm. and 75 sq. mm. and the magnesium foil an area of about 30 sq. mm. Approximately ⅓ inch of dentifrice was applied to a wetted brush and the toothbrush heads were dipped in a slurry of toothpaste containing equal parts of water and toothpaste. Current readings were taken at room temperature as the toothbrush was moved in the slurry in a circuit formed by connecting the metal pieces. The electrical potential reached 1.08 volt. Table I sets forth the current flow obtained using the tin foils with several commercial dentifrices.

TABLE I

Dentifrice	600 sq. mm. (ma.)	150 sq. mm. (μa.)	75 sq. mm. (μa.)
Amm-i-dent, a sodium fluoride [1]	1	250	200
Oral B Special, a stannous fluoride [2]	1	350	200
Crest, a stannous fluoride [3]	1.0	420	420
Fact [4]	2	700	600
Cue [5]	1.2	200	180

[1] Containing toothpaste (about 0.2%), pH 7.4.
[2] Containing toothpaste (about 0.4%), pH 9.1.
[3] Containing toothpaste (about 0.4%), pH 5.6.
[4] A stannous fluoride containing toothpaste (about 0.4%), pH 4.6.
[5] A stannous fluoride containing toothpaste (about 0.4%), pH 4.5.

EXAMPLE II

Using three brushes having, respectively, tin areas of 75 sq. mm., 135 sq. mm. and 850 sq. mm., and each

having a zinc area 30 sq. mm. in a slurry of equal parts of toothpaste and water in a procedure similar to Example I, the following readings were obtained.

TABLE II

Brand of toothpaste	Tin (microamps) 850 sq. mm.	135 sq. mm.	75 sq. mm.
Amm-i-dent fluoride	145	56	66
Oral B (fluoride)	82	58	28
Fact (fluoride)	148	95	100
Crest (fluoride)	75	80	72
Cue (fluoride)	114	70	84

The following readings of Table III were obtained using the brushes in the mouth with the participant brushing sufficiently to create a foam.

TABLE III

Brand of toothpaste	Tin (microamps) 850 sq. mm.	135 sq. mm.	75 sq. mm.
Amm-i-dent fluoride	150	40	10
Oral B (fluoride)	200	8	8
Fact (fluoride)	180	108	110
Crest (fluoride)	180	26	22
Cue (fluoride)	200	35	32

EXAMPLE III

The amount and depth of penetration of tooth enamel by fluoride ions is improved with the following dentrifrice when using a brush constructed as in Examples I and II.

Dentifrice	
Stannous fluoride	0.40
Calcium pyrophosphate	42.00
Glycerol	25.00
Gum	0.50
Water	32.10
	100.00

Approximate pH 5.0

What is claimed is:

1. An article of manufacture adapted to be held which comprises a bristle carrying and handle means made of electrically non-conductive material, a plurality of bristles carried by said first-mentioned means, first and second metal pieces affixed in open circuit relationship to said first-mentioned means at said bristles, said first and second metal pieces being of dissimilar metals, one of said first and second metal pieces being arranged on said first-mentioned means so that it is adapted to touch the holder during use of the article and the other of said first and second metal pieces being arranged on said first-mentioned means so that it does not normally touch the holder during use of the article, said metal pieces each being arranged with respect to said bristles whereby each will communicate electrically with an electrically conductive liquid carried by said bristles, said dissimilar metals having an electrode potential therebetween on the standard hydrogen reference electrode scale, said electrode potential and the relative sizes of said first and second metal pieces being effective to provide a cell voltage therebetween and generate a current of above 20 microamps when placed in contact with said electrically conductive liquid.

2. The article of claim **1** wherein the metals used as said first and second pieces are each non-toxic to humans.

3. The article of claim **1** wherein the metals used as said first and second pieces are each above copper in the electromotive series.

4. The article of claim **1** wherein the metals used as said first and second pieces and the relative sizes thereof generate a current of below about 2000 microamps when placed in contact with said electrically conductive solution.

5. The article of claim **4** wherein said metal pieces have an electrode potential therebetween of between about 0.3 and 2 volts.

6. The article of claim 1 wherein the metals used as said first and second pieces and the relative sizes thereof generate a current of between about 40 and 600 microamps when placed in contact with said electrically conductive solution.

7. A system for the introduction of medicaments into body tissues of humans by iontophoresis comprising an electrically conductive ionic solution of said medicament arranged on the tissue to be treated, and brush means adapted to be held in contact with said solution at the tissue to be treated comprising bristle carrying and handle means made of electrically non-conductive material, a plurality of bristles carried by said bristle carrying means, first and second metal pieces affixed in open circuit relationship to said bristle carrying means at said bristles, said first and second metal pieces being of dissimilar nontoxic metals having, respectively, a higher and a lower electrode potential on the standard hydrogen reference electrode scale, said metal pieces being arranged with respect to said bristles so that each will communicate electrically with said ionic solution as it is carried by the bristles, one of said first and second metal pieces being arranged one said bristle carrying means so that it is adapted to touch the holder during use of the brush means and the other of said metal pieces being arranged on said bristle carrying means so that it does not normally touch the holder during use of the brush means, said one of the metal pieces having the higher electrode potential when the ions of said medicament have a negative charge and said one of the metal pieces having the lower electrode potential when the ions of said medicament have a positive charge,

the difference between the higher and lower electrode potentials and the relative sizes of said first and second metal pieces being effective to provide a cell voltage therebetween and generate a current in excess of 20 microamps through said solution and the body tissues.

8. The system of claim 7 wherein said ions are negative and the first metal piece is said one metal piece and has the higher electrode potential.

9. The system of claim 8 wherein said ions are fluoride ions, said brush means is a toothbrush and the body tissues touched by said first metal piece are the lips.

10. The article of claim 7 wherein the metals used as said first and second pieces are each above copper in the electromotive series.

11. The article of claim 10 wherein the metals used as said first and second pieces and the relative sizes thereof generate a current of below about 2000 microamps when placed in contact with said electrically conductive solution.

12. The article of claim 11 wherein said metal pieces have an electrode potential therebetween of between about 0.3 and 2 volts.

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