

- [54] **METHOD OF TREATING PERIODONTAL DISEASE**
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[51] Int. Cl. **A61k 5/00**
[58] Field of Search **424/49-58, 329**

- [56] **References Cited**
UNITED STATES PATENTS
3,577,490 5/1971 Welsh et al. 424/53
3,591,675 7/1971 Brilliant 424/54
3,590,121 6/1971 Schiff et al. 424/50

- OTHER PUBLICATIONS**
Journal of the American Dental Association, Vol. 78,

pages 347-348, Feb. 1969.
Gross et al., Oral Surg., Vol. 31, pages 32-38, Jan. 1971.

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[57] **ABSTRACT**

Self-administerable method of treating periodontal disease by providing a dilute aqueous benzalkonium chloride solution, pumping the solution through an orifice to provide a pulsating jet stream that is capable of penetrating directly into the periodontal pockets associated with periodontal disease, and applying the jet stream to diseased gingival tissue and into the periodontal pockets.

3 Claims, No Drawings

METHOD OF TREATING PERIODONTAL DISEASE

The present invention relates to a method of treating diseases which affect the supporting tissues of the teeth, and more particularly to a method of treating periodontitis.

Periodontitis, or pyorrhea, is a disease affecting the supporting tissues of the teeth including the gingiva, the membrane lining the sockets in which the teeth lie, and the bones surrounding the teeth. The disease may initially be associated with conditions of constant irritation of the gingiva by dental calculus, food impaction, poor dental restorations, traumatic occlusion, or chemical irritants.

When normal, the gums are pink and resilient, and heal promptly when injured. The gums, however, may be seriously harmed by deposits of dental calculus (tartar), a combination of minerals and bacteria found in the mouth. The bacteria associated with tartar can secrete enzymes and endotoxins which can irritate the gums and cause an inflammatory gingivitis. As the gums become increasingly irritated by this process they have a tendency to bleed, lose their toughness and resiliency, and separate from the teeth, leaving periodontal pockets in which debris, secretions, more bacteria and toxins further accumulate. It is also possible for food to accumulate in these pockets, thereby providing nourishment for increased growth of bacteria and production of endotoxins and destructive enzymes. The pus that forms in this process is capable of destroying gum and bone tissue. A variety of bacteria are generally found to be present during the active stages of periodontal disease. Such organisms as streptococci, staphylococci, pneumococci, etc. are usually present, and are found in the purulent discharge as well as in the involved tissue, and may be absorbed into the general system through the lymphatics or venous blood stream.

The progression of the pyorrheic process usually begins with gingivitis, initiating at the margins of the gums, in which the gingiva become more tender and sensitive, and appear flabby, inflamed and swollen. Periodontal pockets become apparent, and infection takes place in these pockets. Because the periodontal pockets cannot be cleaned by brushing or the use of dental floss, infection becomes progressive and constant. A purulent or toxic discharge is common from the affected tissues, with which may be associated an abnormal taste and odor in the mouth.

The periodontal disease may gradually involve the deeper periodontal tissues until all the supporting tissues of the teeth, including bone, are affected. When the pyorrheic process has proceeded to the stage of destruction of the periodontal tissues, the teeth become loosened, and are usually lost in the more advanced stages of the disease. An additional adverse effect on the general well being of the affected individual is the potential for absorption of a considerable amount of toxic purulent or bacterial matter into the general circulation.

Although pyorrhea is generally considered curable in the early stages, when treated by a dentist, the most effective conventional treatment has been preventive, involving strict oral hygiene and periodic dental prophylaxis. Methods of treatment of persons who are already affected by the disease include regular calculus removal by the dentist, grinding off of rough dental surfaces, surgical removal of diseased gingival tissue, and

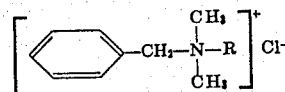
opening and trimming of periodontal gingival pockets.

However, conventional methods of treatment are not entirely satisfactory, and periodontitis continues to be a principal dental disease and a major cause of the loss of teeth. A relatively simple method for treating periodontitis which would be effective in controlling the disease would be very desirable. In addition, such a method which could be employed by individual patients in self-medication on a regular basis would be most desirable.

Accordingly, it is a principal object of the present invention to provide a self-administerable method which is effective for the treatment of periodontal disease.

Generally, the present invention is directed to a method for treating periodontal disease, which method may be self-administered by an individual affected by the disease. The method comprises providing a dilute aqueous solution of benzalkonium chloride, and pumping the dilute solution through an orifice to provide a pulsating jet stream of the solution which is capable of penetrating directly into the periodontal pockets associated with periodontal disease. In the treatment method, the pulsating jet stream of aqueous benzalkonium chloride solution thus provided is applied to the diseased gingival tissues and into the periodontal pockets.

Benzalkonium chloride is a cationic surfactant having antiseptic properties. When applied in the form of a dilute aqueous solution to the gingival tissues by means of a pulsating jet stream of the solution in accordance with the method of the present invention, benzalkonium chloride has proved to be an effective medicant for controlling periodontal disease. Commercial pharmaceutical benzalkonium chloride, which is suitable for use in the present invention, is a mixture of alkyl dimethylbenzylammonium chlorides of the general formula



where R is an alkyl group having from about 8 to about 18 carbon atoms.

Benzalkonium chloride is commercially available in concentrated solution form, for example containing between about 15 and about 20 percent by weight benzalkonium chloride based on the weight of the solution. Such concentrated solutions may be conveniently diluted to provide the dilute aqueous benzalkonium chloride solutions which are used in the method of the present invention.

The benzalkonium chloride used for treatment of periodontal disease by the method of the present invention is employed in a dilute aqueous solution which is suitable for oral application. Generally, the dilute aqueous solution will contain between about 0.005 and about 0.1 percent by weight of benzalkonium chloride, based on the weight of the solution. A preferred range of dilutions is between about 0.02 and about 0.06 percent by weight of benzalkonium chloride based on the weight of the solution. Furthermore, the benzalkonium chloride solution should be substantially free of anionic

surfactants, and other material such as nitrate ions, which interfere with the solubility of the benzalkonium chloride.

The aqueous solution may, however, include additional materials which do not interfere with the medicinal action of the benzalkonium chloride. For example, a commercial product designed to facilitate the self-administration of the method of the present invention by persons affected by periodontal disease might comprise a concentrated benzalkonium chloride solution with instructions for its proper dilution and use. Such a solution concentrate would also include suitable flavoring materials to render the benzalkonium chloride solution more palatable and might also include other materials having a medicinal effect.

In the treatment of periodontal disease in accordance with the method of the present invention, a jet stream of the dilute benzalkonium chloride solution is provided for application of the medication to the gingival tissues. The jet stream is provided by pumping the dilute benzalkonium chloride solution through an orifice to provide a jet stream of the solution which is capable of penetrating directly into the periodontal pockets associated with periodontal disease.

In this regard, the jet stream provided should have characteristics such that upon application of the jet stream to the affected tissues, the aqueous solution of the jet stream will be forced into the periodontal pockets, thus providing forced fluid access for delivering the aqueous benzalkonium chloride solution into these pockets. Although jet streams of other characteristics may be capable of penetrating into periodontal pockets, it is generally satisfactory to pump the solution through a suitable orifice in order to provide a jet stream of the solution having a diameter of from about 0.3 mm. to about 1.0 mm. and an average rate of flow of between about 250 cc/min. and about 600 cc/min. Furthermore, it is particularly preferred and/or essential that the jet stream of benzalkonium solution be a pulsating jet stream such as provided by periodically varying the pumping rate and/or pressure so that the rate and force of delivery of the treatment solution to the affected tissues will vary rapidly with time. The jet stream should pulsate with a frequency of between about 20 cycles per second and about 200 cycles per second. Furthermore, the relative amplitude of pulsation should be large, and in this regard it is desirable that during the intervals between pulse peaks, which interval is ordinarily between about 20 percent and 40 percent of the pulse cycle time, that the flow of the jet stream be completely or almost completely interrupted.

It should be noted that when a course of treatment of periodontal disease is commenced, that the gums may be capable of tolerating the application of only a relatively weak jet stream of the treatment solution. As improvement progresses pursuant to the course of treatment, the gums are increasingly capable of tolerating more intense and forceful jet streams of the treatment solution. Accordingly, the appropriate jet stream characteristics may be adjusted depending upon the stage of the periodontal disease, and more forceful jet streams may be applied as the patient's condition improves.

A suitable jet stream of treatment solution may be provided by conventional dental irrigating devices, such as those manufactured under the trade name Wa-

ter-Pic, which are capable of ejecting pulsating jet streams of the treatment solution which are satisfactory for use in the present method. By employing such a commercially available dental irrigating device, treatment for periodontal disease according to the present invention may be conveniently self-administered on a regular basis.

In accordance with the present method, the dilute aqueous benzalkonium chloride solution is applied by directing the pulsating jet stream of the solution against the diseased gingival tissues and into the periodontal pockets. The application of the jet stream solution into the periodontal pockets is readily accomplished by directing the stream toward the interdental spaces and along the inner and outer margins between the teeth and gums of both the upper and lower jaw, at an angle inclined toward the roots of the teeth. Playing the stream along these areas in a slow sweeping motion is a convenient and practical method of applying the medication to these regions.

In addition to the importance of the aqueous benzalkonium solution itself being substantially free of anionic surfactants and other materials which interfere with its solubility, it is also important that the teeth and gums be substantially free of anionic surfactants and other materials. For example, if the teeth have been previously brushed with a cleanser, toothpaste or powder, the mouth should be thoroughly rinsed prior to treatment with the benzalkonium chloride solution.

Since the method may be self-administered by the patient, it may be periodically repeated in a relatively frequent manner. It is desirable that the procedure be repeated at least daily, and it is particularly preferred that the procedure be repeated after each meal and before retiring to sleep.

By applying the benzalkonium chloride solution by means of an irrigation device capable of providing a pulsating jet stream of the treatment solution, it is found that the cleansing, fat emulsifying, bacteriocidal and bacteriostatic properties of the benzalkonium chloride solution are all utilized in combination and to fullest advantage toward the control and relief of the periodontal disease. The affected tissues, and particularly the periodontal pockets, are effectively cleansed of debris, including food, purulent discharges and other toxic matter, bacteria, and tissue debris, and a residue of bacteriocidal and bacteriostatic medication is left in place. Furthermore, it is believed that the medication is forced deep into normally inaccessible gingival and periodontal pockets which harbor the destructive infection in periodontal disease and which if not treated would perpetuate the progression of the pyorrheic process. By this means, infection in these pockets can be reduced, with consequent reduction in gingival swelling and spontaneous recession of the gum margins to permit better drainage of purulent secretions.

The method of the present invention has been applied in a number of cases of patients affected by various stages of periodontal disease. The treatment procedure for these patients was as follows:

A dilute solution of benzalkonium chloride was prepared by placing 5 drops of USP Refined 17 percent benzalkonium chloride Concentrate into the receptacle of a commercial irrigating device (such as a Water-Pic or similar device) and then filling the receptacle to its capacity of approximately 840 cc. with warm water. Thus a dilute solution of approximately 1/2500

strength, or 0.04 percent by weight benzalkonium chloride was provided in the receptacle of the irrigating device. The dilute solution of benzalkonium chloride was then applied as a daily treatment regimen to the gingival tissues. If the teeth had been previously brushed with a cleanser, toothpaste or powder, the mouth was thoroughly rinsed of such materials prior to irrigation with the benzalkonium chloride solution. After such rinsing, if necessary, the pulsating jet stream of diluted solution provided by the operation of the irrigating device was directed laterally at a 45° angle toward the roots of the teeth along the inner and outer tooth-gum margins of the upper and lower jaws until approximately half the solution had been used. The stream was then directed vertically against the opposing surfaces of the teeth and their interdental spaces for three or four slow sweeps. Finally, the stream was again directed laterally at a 45° angle against the tooth-gum margins until the remainder of the solution was used.

Generally, the progression of the pyorrheic process in these patients was slowed, and the well-being of the gingival tissue was improved as observed by more normal color, firmer soft tissue and less bleeding. Furthermore, the active inflammation and infectious processes were diminished, and the general well-being of the patients was improved because of less absorption of purulent and toxic matter into the general circulation.

Such beneficial results became substantially apparent in some patients after only 5 days of treatment, while the general period of treatment for providing improvement was about 7 to 14 days. The same treatment is then continued as described in order to maintain the state of improvement already achieved.

During the course of treatment of 28 patients with the dilute benzalkonium chloride solution, the following results have been observed:

Response	Excellent	Good	Fair	Poor
Reduction in swelling of gums	28			
Reduction in depth of periodontal pockets	26	1	1	
Diminution of purulent discharge	27			1
Reduction of gum bleeding	24	2	2	
Removal of abnormal mouth odor	28			
Increase in toughness of gums	28			
Improvement in color of gums	27		1	
Less sensitivity and tenderness of gums	26	1	1	

While the method of the invention has been described with respect to dilute aqueous solutions of benzalkonium chloride, which have been found to be particularly effective in the treatment of periodontal disease when employed in accordance with the techniques described hereinabove, solutions of certain other surface active and/or antiseptic compounds particularly of the cationic, nitrogen-based type having antiseptic properties, may be suggested to those skilled in the art

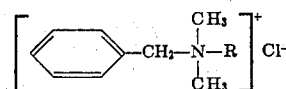
in view of the present disclosure. Examples of such compounds, with a trademark under which they are sold indicated parenthetically where appropriate, are as follows:

Sodium lauryl sulfate
Sodium Ethasulfate (Tergemist)
Cetyl pyridinium chloride (Ceepryn)
Triclobisium (Triburon)
Thonzonium Bromide (Thonzide)
Domiphen Bromide (Bradosol)
Imidecyl Iodine (Amphodyne)
Cetalkonium Chloride (Zettyn)
Centrimonium Chloride
Denatonium Benzoate (Bitrex)
Tyrothricin; Polmyxin
Chlorhexidine Chloride (Hibitane)
Tyloxapol (Superinone W R 1339)
Betadine

Various of the features of the present invention are set forth in the following claims:

What is claimed is:

1. A self-administerable method for the treatment and control of periodontal disease, comprising providing a dilute aqueous solution of benzalkonium chloride containing between about 0.005 and about 0.1 percent by weight of benzalkonium chloride of the formula



where R is an alkyl group of between about 8 and about 18 carbon atoms, pumping said dilute aqueous solution through an orifice to provide a pulsating jet stream of said aqueous solution which is capable of penetrating directly into the periodontal pockets associated with periodontal disease, said jet stream having a diameter of from about 0.3mm to about 1.0mm and having an average rate of flow of from about 250 cc/min. to about 600 cc/min. and applying said pulsating jet stream of dilute aqueous benzalkonium chloride solution along the teeth-gum margins at an angle inclined towards the roots of the teeth against the diseased gingival tissues and into the periodontal pockets of an individual affected by periodontal disease so as to cleanse the diseased tissues and pockets and to provide a medicinal residue of said benzalkonium chloride.

2. A method in accordance with claim 1 wherein said aqueous solution contains between about 0.02 and about 0.06 weight percent benzalkonium chloride, based on the weight of said solution.

3. A process in accordance with claim 1 wherein said applying of said jet stream is carried out daily for a period of at least about 7 days.

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