

TITLE

TREATMENT FOR PERIODONTAL DISEASE

FIELD OF THE INVENTION

5 The field of the invention relates to preparation and formulation used in the dental field.

In particular, the invention relates to preparations and formulations used in the field of dental surgery.

DESCRIPTION OF THE PRIOR ART

10 Root canal surgery is often seen as a rather dramatic step due to a number of factors such as the complexity of the surgery and the belief amongst many of the associated negative side effects.

One of the major drawbacks with the current methodology associated with root canal surgery is that the antibiotic paste currently in use, Ledermix, results in unsightly staining of the teeth of the patient.

15 The active antibiotic ingredient in Ledermix is demeclocycline hydrochloride, a tetracycline antibacterial. It has been shown that in practice when Ledermix paste is applied apical to the cemento-enamel junction and then exposed to sunlight an unsightly brown staining is produced. This staining can be minimised by placing the Ledermix paste below the gingival margin so as
20 reduce exposure to sunlight and also ensuring that the Ledermix paste is not left on any of the walls of the access cavities.

However, it is not always possible to restrict the placement of Ledermix in such a manner and thus it is inevitable that some of the paste is exposed to sunlight, resulting in staining of the teeth.

25 As such, the teeth of the effected patient often require cleaning, which can be considerable expensive and inconvenient. Added to the root canal surgery itself, the end result is one that takes a substantial amount of time. The

associated economic impact on the patient is evident as is the general hesitation by others to undergo what may be a necessary surgery to avoid more dire consequences at a later stage due to infection of the root canal area.

OBJECT OF THE INVENTION

5 It is an object of the present invention to provide an acceptable dental paste formulation that is able to function effectively as an antibiotic without staining the enamel of the tooth that it is applied to.

It is a further object of the invention to provide an acceptable dental paste formulation that permeates bone/dentin greater than dental pastes of the prior art.
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It is an object of the present invention to overcome, or at least substantially ameliorate, the disadvantages and shortcomings of the prior art.

Other objects and advantages of the present invention will become apparent from the following description, taking in connection with the accompanying drawings, wherein, by way of illustration and example, an embodiment of the present invention is disclosed.
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SUMMARY OF THE INVENTION

According to the present invention, although this should not be seen as limiting the invention in any way, there is provided a dental paste including a therapeutically effective amount of clindamycin and a pharmaceutically acceptable carrier for inserting into an evacuated root canal area, such that when in use the dental paste, when exposed to sunlight, does not stain tooth enamel.
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In preference, the therapeutically effective amount of clindamycin is between 3-6% w/w.
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In preference, the therapeutically effective amount of clindamycin is 5% w/w.

In preference, the dental paste further includes at least one additive or preservative.

In preference, the dental paste further includes at least one corticosteroid.

In preference, the at least one additive or preservative includes polyethylene glycol.

A further form of the invention can be said to exist in a composition including a therapeutically effective amount of clindamycin and a pharmaceutically acceptable carrier for oral application, when used as a dental paste in the treatment of bacterial infections in the tooth.

10 A further form of the invention can be said to exist in the method of treating or reducing the risk of microbial infection in a root canal providing the step of inserting into an evacuated root canal area a therapeutically effective amount of clindamycin and a pharmaceutically acceptable carrier for oral application.

DETAILED DESCRIPTION OF THE INVENTION

15 The microbiological flora found in the root canal is quite diverse and dentoalveolar infection is characterised in that the infection is usually polymicrobial with a mixture of some three to four different species. Monomicrobial infection is highly unusual and strict anaerobes are the predominant organisms.

Bacteria commonly isolated from dentoalveolar abscesses.
Facultative anaerobes
Streptococcus milleri
Streptococcus sanguis
Actinomyces spp.
Obligate anaerobes

Peptostreptococcus spp.

Porphyromonas gingivalis

Prevotella intermedia

Prevotella melaninogenica

Fusobacterium nucleatum

To cure an infection of the root canal a pulpectomy is required, often referred to as a "root canal" in which the unhealthy tooth is cut open or access is gained into by widening of an already existing cavity to provide access to the internal infected pulp, which is subsequently removed by scraping out of the root canals.

- 5 The now empty or excavated root canal is then filled with the paste of the following formulation (weight/weight):

Ingredients	% Weight
1. Sterile water	28.0%
2. Calcium Chloride - BP	2.1%
3. Peg 400 - BP	33.9% approx
4. Peg 4000 -BP	3.9% approx
5. Triethanolamine –BP	0.4%
6. Clindamycin – BP	5.0%
7. Triamcinolone – BP	1.0%
8. Germaben 2E – BP	3.0%
9. Sodium Bisulphite –BP	0.4%
10. EDTA – disodium salt –BP	3.6%

11. Zinc Oxide –BP	13.2%
12. Silicon Dioxide	5.5%
	100.00%

It is during the stage of cleaning up the root that a dental paste is placed into the vacant area in order to thoroughly and efficiently destroy any remaining bacteria so as to prevent any subsequent infection. The paste is then left in the patients tooth for a period of time and then removed prior to filling with a suitable inter material.

Clindamycin has been used in the treatment of dental abscesses for over fifteen years, primarily as an oral pharmaceutical tooth root infection. The use of current dental pastes which all include the tetracycline antibacterial demeclocycline, which, upon exposure to sunlight results in unsightly staining of teeth enamel. The use of the paste of the current invention, which includes the antibacterial clindamycin, provides an equal, if not greater, antibacterial effect to that of currently used pastes and has the important advantage of not being susceptible to light in that it does not cause unsightly staining of the tooth enamel.

In addition, clindamycin has the added therapeutic advantage of having a higher bone/dentin permeability factor than that of demeclocycline and therefore is able to act on bacteria deeper in the root canal as well as providing greater efficacy.

This then represents a significant advancement in the root canal treatment and therapy that provides significant advantageous to both the patient and practitioner.

In addition, due to the fact that clindamycin is UV stable and exposure to UV light will not result in staining of the patients teeth as such there is no need for the dentist to apply the paste only below the gingival margin and extra paste can be applied when necessary to the walls of the access cavities so as to

ensure complete and thorough treatment. This then of course has a flow-on effect to the patient in that more efficient treatment is provided without any of the drawbacks of the currently used containing pastes.

Although the invention has been herein shown and described in what is
5 conceived to be the most practical and preferred embodiment, it is recognized that departures can be made within the scope of the invention, which is not to be limited to the details described herein but it is to be accorded the full scope of the appended claims so as to embrace any and all equivalent methods and formulations.

CLAIMS

1. A dental paste including a therapeutically effective amount of clindamycin and a pharmaceutically acceptable carrier for insertion into an evacuated dental root canal area, such that when in use the dental paste, when
5 exposed to sunlight, does not stain tooth enamel.
2. The dental paste of claim 1, wherein the therapeutically effective amount of clindamycin is between 3-6% w/w.
3. The dental paste of claim 2, wherein the therapeutically effective amount of clindamycin is 5% w/w.
- 10 4. The dental paste of claim 3, further including at least one additive or preservative.
5. The dental paste of claim 4, further including at least one corticosteroid.
6. The dental paste of claim 5, wherein the at least one additive or preservative includes polyethylene glycol.
- 15 7. A composition including a therapeutically effective amount of clindamycin and a pharmaceutically acceptable carrier for inserting into an evacuated dental root canal area, when used as a dental paste in the treatment of bacterial infections in the tooth.
8. A method of treating or reducing the risk of microbial infection in a dental
20 root canal providing the step of inserting into an evacuated root canal area a therapeutically effective amount of clindamycin and a pharmaceutically acceptable carrier for oral application.
9. A dental paste for treatment of bacterial infections within the dental root of a patient's tooth as substantially described herein with reference to the
25 accompanying description.