Efficacy of different concentrations of antiseptics to control bacterial contamination of dental implants: a randomized clinical trial.

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Purpose: *To assess the efficacy of a filling and antiseptic ointment in the control of microbial contamination of dental implants inter-connections spaces.* ***Material and Methods:*** *Different concentrations of the components of the ointment were prepared and applied to the cover screw before it was screwed into the implant in 82 implants, installed in 20 patients. The implants were divided into five groups, with an average of four patients per group, but regardless of choice, some patients belonged to two or more groups. Four groups of implants with n = 16, numbered from 01 to 04, were used as a test group, each receiving a different concentration of the ointment, applied to the cover screw. A group with n = 18 implants, numbered as group 05, was used as a control and the cover screw was installed without the antiseptic. The amount of the applied ointment was sufficient to induce its overflow, ensuring that there were no empty spaces within the connection. Patients were followed during the period of osseointegration, looking for signs or symptoms of peri-implant inflammation, such as pain, discomfort, peri-implant erythema, edema, abscess and malodor.* ***Results:*** *Group 01 presented a case with erythema and edema. Group 02 also presented a case in which the patient reported pain around the implant. Group 03 showed no change in any implant and group 04 presented two implants with peri-implant erythema. The control group (05) presented some type of alteration in 13 implants, such as discomfort, pain, malodor, inflammation, abscess and fistula.* ***Conclusions:*** *The formulation was effective in controlling contamination of the implants during the osseointegration period.*

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The contamination of the internal spaces of the dental implants, during the waiting time of osseointegration, is a clinical inconvenience that frequently occurs.[1,2] As a consequence, mucositis and peri-implantitis may impair implant conditions even before exposure to the oral cavity.[3]

Controlling or eliminating this problem can be a real contribution to the clinical practice of dental implants.

Attempts have been made with different physical devices and chemical agents to eliminate or reduce bacteria in this environment. The chemical agents, antibiotics

and antiseptics, used up to now, such as chlorhexidine, H_2O_2, sodium hypochlorite, ampicillin, terramycin, metronidazole, etc., have proved to be effective, but only for a short time.[4] This condition is due to its short period of pharmaceutical action or the short period of on-site stay.

Other antiseptics with long-acting action and proven efficacy in humans can not remain stable within the implant under these conditions for a long period of time because they are eliminated or inactivated within a few hours.

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A formulation was created based on the properties of iodoform, such as the longtime of pharmaceutical action, long history of use in humans, with high antimicrobial efficacy and low side effects and in the pharmaceutical properties of Calendula officinalis.[5-8]

The vehicles used were safe and capable of maintaining the antiseptic over a long period within the body without interfering with its pharmaceutical effects.[9-13]

The formulation was capable to remain within the implants, occupying the spaces between the components, for the time needed. The substances of the vehicles were a combination of fatty acid esters which resulted in a dense and stable ointment.

The aim of this work was to clinically test the long-term efficacy of this antiseptic and filling ointment applied to the internal environment of the dental implant to control bacterial contamination of the spaces between the implant and the cover screw

Material and Methods

Different concentrations of the components of the ointment were prepared and applied to the cover screw before it was screwed into the implant in 82 implants, installed in 20 patients. The implants were divided into five groups, with an average of four patients per group, but regardless of choice, some patients belonged to two or more groups. Four groups of implants with n = 16, numbered from 01 to 04, were used as a test group, each receiving a different concentration of the ointment, applied to the cover screw. A group with n = 18 implants, numbered as group 05, was used as a control and the cover screw was installed without the antiseptic (Table 01). The amount of the applied ointment was sufficient to induce its overflow, ensuring that there were no empty spaces within the connection.

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Group 01	Group 02	Group 03	Group 04	Group 05
Iodoform 12.0%	Iodoform 8.0%	Iodoform 4.0%	Iodoform 2.0%	none
Calendulla 4.0%	Calendulla 2.0%	Calendulla 1.0%	Calendulla 0.5%	none

Tabela 01- Distribution of the different concentrations in the groups.

	Group 01	Group 02	Group 03	Group 04	Group 05
Pain		01			07
Erythema	01			02	06
Edema	01				06
Abscess					05
Total	01	01	00	02	13

Tabela 02- Signals and Symptoms distribution among the groups.

Patients were followed during the period of osseointegration, looking for signs or symptoms of peri-implant inflammation, such as pain, discomfort, peri-implant erythema, edema, abscess and malodor.

Results

Group 01 presented a case with erythema and edema. Group 02 also presented a case in which the patient reported pain around the implant. Group 03 showed no change in any implant and group 04 presented two implants with peri-implant erythema. The control group (05) presented some type of alteration in 13 implants, such as discomfort, pain, malodor, inflammation, abscess and fistula (Table 02). All implants that presented abscess and fistula, also had pain in the mucosa adjacent to the implants. The intensity of the pain was different in each case.

Discussion

Attempts have been made to control bacterial contamination of the internal environment of dental implants and their components, but so far no reliable evidence has been presented in the literature showing that any product has been consistently successful in this process.[2,14-20.]

Most of these products used, such as hydrogen peroxide, antibiotics or antiseptics, do not have long-term pharmacological activity to control microorganisms during the period of osseointegration, let alone over the

time of use in the prostheses.

The purpose of this investigation was to evaluate the efficacy of a new ointment formulation in the control of bacterial contamination of the internal gaps in dental implant connections, using different concentrations of antiseptics in a randomized clinical trial.

The study included 82 implants, installed in 20 patients, followed for six months during the waiting period for osseointegration of the implants, when they were submerged and covered by the oral mucosa.

The patients included were treated by professionals experienced in oral surgery and prosthodontics. The implants were placed in accordance with the general guidelines for implant placement, and surgical procedures and patient follow-up were similar for all individuals. There was uniformity in the study sample since the implants were placed within the same parameters of diagnosis, planning, and surgical conditions.

Among the limitations of the study were the small sample size, the lack of suitable controls, and the lack of a better objective evaluation parameters.

The test groups showed satisfactory results compared to the control group.

The results show that the pharmacological action of the ointment remained independent of the concentration of the antiseptic.

In the highest concentration, group 01, there was a case of edema and erythema. Pain was present once in group 02 and erythema also once in group 04. These occurrences were possibly due to the failure in the application of the ointment. It must completely fill in the spaces between the connections and empty spaces should not remain. Gaps must be completely eliminated so that the bacteria do not penetrate the internal spaces of the implants. The control group showed that almost all implants were contaminated. There was a big difference between the test and control groups, which shows that the use of the ointment, in any concentration of antiseptics, was effective in controlling the bacterial contamination of the implants.

Other clinical tests should be carried out and the results compared, in order to establish better evidences

Conclusions

The tested ointment was effective in controlling the internal contamination of the implants during the osseointegration period, reducing undesirable events

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