Cervitec® Gel

Scientific documentation
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1. Introduction

Oral health implies well-being, freedom of pain, physical integrity and social acceptance. A variety of studies show that oral health and quality of life are closely connected. For example, an epidemiological investigation conducted among 2050 people between the ages of 16 and 79 in Germany revealed a connection between “not being comfortable” and poor oral health [1]. Other studies show that social behaviour changes with the onset of toothache [2]. Furthermore, the presence of caries in children correlates with negative self-perception and perception by others [3; 4].

Poor oral health is generally associated with oral microorganisms. The infected dental hard tissue causes caries and endodontic problems. Moreover, incipient caries can cause the loss of dental restorations. The infected soft tissue may lead to periodontitis, gingival inflammation, halitosis or denture stomatitis.

Crowded teeth or brackets and bands make cleaning measures difficult and therefore promote the accumulation of pathogenic organisms. These problem areas in the mouth require special protection, for example, with Cervitec Gel. The time-tested ingredient chlorhexidine (CHX) reduces the growth of harmful bacteria and yeast. Therefore, less plaque forms on the teeth and dental restorations and the inflammation of gum tissue subsides. The tissue is able to recover and bacterial growth on restorations is reduced.

In addition to the antibacterial chlorhexidine, Cervitec Gel contains fluoride. This ingredient promotes remineralization and protects the teeth from caries. Therefore, Cervitec Gel can be used to replace toothpaste to brush teeth in the evening, for example. The fact that users of the product do not have to change their daily routine increases their compliance. Furthermore, studies have shown that CHX and fluoride together are more effective against oral microorganisms than if they are used on their own [5-7]. Therefore, Cervitec offers both effective antimicrobial action and protection against caries.

Cervitec Gel can
- be used with interdental brushes for cleaning the spaces between the teeth and fixed restorations (e.g. crowns, bridges and implants)
- be applied with a toothbrush (e.g. by patients with high bacteria counts or orthodontic appliances)
- be applied directly on the gums, oral mucous membrane or tongue and on the inner aspects of removable restorations
- be applied with a tray
2. **Composition**

**Composition in wt.%:**

<table>
<thead>
<tr>
<th>Component</th>
<th>wt.%</th>
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<tbody>
<tr>
<td>Water, hydroxyethyl cellulose, Laureth 23</td>
<td>99.5</td>
</tr>
<tr>
<td>Sodium fluoride (900 ppm fluoride)</td>
<td>0.2</td>
</tr>
<tr>
<td>Chlorhexidine digluconate (0.11% chlorhexidine as free base)</td>
<td>0.2</td>
</tr>
<tr>
<td>Peppermint oil and sodium saccharin</td>
<td>0.1</td>
</tr>
</tbody>
</table>

**Physical values:**

<table>
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<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH value</td>
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</tr>
<tr>
<td>Density [g/cm³]</td>
<td>0.99 – 1.01</td>
</tr>
</tbody>
</table>
3. **In vitro investigations**

3.1 **Fluoride release**

**Objective:** Evaluation of the fluoride released from Cervitec Gel compared with other oral health care products

**Investigator:** Ivoclar Vivadent R&D, Schaan, Liechtenstein

**Method:** The fluoride released from different toothpastes in water was determined by means of an ion selective electrode. For this purpose, the gels were covered with deionized water at room temperature. After 0.5, 1, 2, 5 and 10 min, the fluoride content was measured in the supernatant.

**Results:** The total amount of fluoride in Cervitec Gel was shown to be available within only one minute. The other products released fluoride more slowly. The rate correlated with the solubility of the products (Fig. 1).

![Figure 1: Fluoride release rate of various fluoride toothpastes and of Cervitec Gel. Various toothpastes / gels were covered with deionized water and the fluoride content was measured in the supernatant with an ion selective electrode after 0.5, 1, 2, 5 and 10 min. Cervitec Gel showed the fastest release of fluoride.](image-url)
3.2 Viscosity

Investigator: Ivoclar Vivadent R&D, Schaan, Liechtenstein

Method: The viscosity was determined by means of the CVO rheometer at 23.0 °C, gap 70 µm, measuring system CP 2.5°/20 mm, shear rate 1 to 100 s\(^{-1}\).

Results: Cervitec Gel is shear thinning, i.e. the viscosity increases immediately (in contrast to thixotropic gels) once the shear stress is discontinued.

In comparison to other oral health care preparations, Cervitec Gel shows a low viscosity (Fig. 2). As a result, it can be evenly distributed on the mucous membrane or the denture. This consistency is ideal for use with interdental brushes. Nevertheless, the gel exhibits sufficient stability for application with regular toothbrushes.

![Figure 2: Viscosity of Cervitec Gel compared with that of other oral care preparations.](image)

The viscosity of various oral care preparations was determined with the CVO rheometer at 23.0 °C, shear rate of 1 to 100 s\(^{-1}\). Cervitec Gel showed the lowest viscosity.
### 3.3 Antimicrobial effect

**Objective:** The objective of this examination was to evaluate the antimicrobial effect of Cervitec Gel on various oral microorganisms.

**Investigator:** Ivoclar Vivadent R&D, Schaan, Liechtenstein

**Method:** The antimicrobial effect of various tooth care preparations on *Actinomyces naeslundii*, *Streptococcus mutans*, *Streptococcus sobrinus*, *Streptococcus gordonii*, *Lactobacillus casei*, *Lactobacillus rhamnosus*, *Lactobacillus acidophilus* and *Candida albicans* was tested in a classical inhibition zone assay.

**Results:** Cervitec Gel showed similar efficacy against cariogenic streptococci as gels containing 0.56% of free CHX base. Growth inhibition of the remaining microorganisms was comparable for Cervitec Gel and other gels with the same CHX content. *Actinomyces naeslundii* showed the highest sensitivity towards the tested formulations, while the yeast *Candida albicans* demonstrated the lowest sensitivity (Fig. 3). Cervitec Gel was also shown to inhibit the growth of *S. aureus*, which often causes inflammations around implants (periimplantitis) (see Scientific Documentation Cervitec Liquid).

![Antimicrobial Effect Chart](image)

**Figure 3:** Antimicrobial effect of Cervitec Gel compared to that of other CHX gels. The antimicrobial effect on various oral microorganisms (*A. naeslundii*, *S. mutans*, *S. sobrinus*, *S. gordonii*, *L. casei*, *L. rhamnosus*, *L. acidophilus* and *C. albicans*) was determined in inhibition zone assays.

Modified after Bolis *et al.*, 2008 [7]
The difference between the nominal CHX concentration and the concentration of CHX free base is important for the evaluation of CHX preparations, since only the free-base form has an antibacterial effect. Cervitec Gel, which is composed of 0.2% chlorhexidine digluconate, contains 0.1% CHX free base. Chlorhexamed, which is composed of 1% chlorhexidine gluconate, contains 0.56% CHX free base. The examination of the relationship between the concentration of CHX free base and the antibacterial effect of various CHX preparations on S. mutans revealed that highly concentrated products (Chlorhexamed, Corsodyl) create only minimally larger inhibition zones than products containing a concentration of five times less CHX free base (Fig. 4). As a result, the antimicrobial effect of Cervitec Gel containing 0.1% CHX was found to be comparable to that of highly concentrated CHX gels [7].

Figure 4: Antimicrobial effect in relation to the concentration of CHX free base. The graph shows the concentration of chlorhexidine free base (bars) of various CHX preparations and the effectiveness of these products against S. mutans in inhibition zone assays (inhibition zone, diamonds). Despite low concentrations of CHX free base, preparations containing 0.1% CHX, and Cervitec Gel in particular, were shown to have a comparable antimicrobial effect against S. mutans to products containing 0.2% CHX with a concentration of 0.56% CHX free base.

Changed according to Bolis et al., 2008 [7].
3.4 **Compatibility with denture materials**

**Objective:** The objective of this study was to examine the influence of Cervitec Gel on the colour of denture base resins.

**Investigator:** Ivoclar Vivadent R&D, Schaan, Liechtenstein

**Method:** A Dynstate disc (64 x 3.8 x 36 mm) was fabricated for each of the following denture base resins according to the standard methods stipulated in the different Instructions for Use: Ivocap High Impact (heat-curing polymer, injection system), ProBase Cold (self-curing polymer), ProBase Hot (heat-curing polymer) and ProBase High Impact (heat-curing polymer, impact resistant). One side of these discs was ground with sand paper (1000 grit) to 3.3 ± 0.1 mm and polished with aluminium oxide on a polishing wheel. Five samples of equal size were cut diagonally from these discs. They were labelled and subsequently immersed in Cervitec Gel for 7 weeks at 37°C and 1 week at 60°C. A sample immersed in water served as the control. After the immersion period, the samples were visually inspected.

**Results:** No difference was observed between any of the denture base resins immersed in the gel and the samples immersed in water. Cervitec Gel did not influence the colour of any of the materials (Fig. 5).

![Figure 5: Colour stability of denture base resins after exposure to Cervitec Gel.](image)

Samples of various denture base resins (Ivocap High Impact, ProBase Cold, ProBase High Impact, ProBase Hot) were immersed in Cervitec Gel or water for 7 weeks at 37°C and 1 week at 60°C. Photographs of the resin specimens are shown. No difference was detected in the colour stability of the specimens immersed in water and the ones immersed in Cervitec Gel.
3.5 **Compatibility with titanium surfaces**

**Objective:** Scientists in various laboratories have observed that titanium, which is often used to fabricate dental implants, corrodes in the presence of fluoride, especially under acidic conditions [15-17]. The objective of the study was to find out if fluoride-containing gels, such as Fluor Protector Gel, Cervitec Gel and Elmex Gelée, are capable of corroding titanium surfaces.

<table>
<thead>
<tr>
<th>Product name</th>
<th>Fluoride concentration according to the manufacturer's information/ ppm</th>
<th>pH</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluor Protector Gel</td>
<td>1450</td>
<td>7.3</td>
<td>Ivoclar Vivadent AG</td>
</tr>
<tr>
<td>Cervitec Gel</td>
<td>900</td>
<td>5.7 – 6.3</td>
<td>Ivoclar Vivadent AG</td>
</tr>
<tr>
<td>Elmex Gelée</td>
<td>12500</td>
<td>4.8*</td>
<td>GABA</td>
</tr>
</tbody>
</table>

*10% in water, information provided by the manufacturer

**Table 1: Overview of the fluoridated dental care products investigated**

**Investigator:** Ivoclar Vivadent R&D, Schaan, Liechtenstein

**Method:** Titanium discs were ground, polished, rinsed with demineralized water and cleaned with ethanol in an ultrasound bath. The test materials were applied to the titanium surfaces with a plastic spatula and evenly distributed with a microbrush. The specimens were stored at 37°C for 24 hours and 168 hours (7 days).

**Results:** Figure 6 shows the titanium surfaces after the treatment with the different fluoride gels. The surfaces of the specimens conditioned with Fluor Protector Gel and Cervitec Gel do not show any changes compared with the untreated surfaces of the controls. However, Elmex Gelée has left clear traces of corrosion. A titanium abutment treated with Elmex Gelée for 24 hours also showed signs of corrosion.
Figure 6: Corrosion of titanium surfaces following exposure to fluoride.
Titanium discs were treated with Fluor Protector Gel, Cervitec Gel or Elmex Gelée for 24 hours and 7 days. Subsequently, the surfaces were analyzed under the scanning electron microscope. The specimens conditioned with Fluor Protector Gel and Cervitec Gel did not demonstrate any changes. However, Elmex Gelée was shown to corrode the titanium samples. Furthermore, a titanium abutment (Straumann RC) treated with Elmex Gelée also showed signs of corrosion after 24 hours.
4. Clinical experiences

4.1 Use in interdental areas (Prof. Dr Birkhed, Göteborg, Sweden)

Objective: This study compared the clinical effect of the daily application of Cervitec Gel with an interdental brush to that of a placebo gel without CHX and fluoride.

Investigators: Mari Svensson, Stefan Renvert, Downen Birkhed, Kristianstad University and Göteborg University, Sweden

Study design: Randomized, placebo-controlled, double-blind study in cross-over design with 15 patients. The placebo gel did not contain fluoride or chlorhexidine. The gels were applied by means of interdental brushes once daily over a period of 3 weeks. Changes of the mutans streptococci and the total bacteria count in saliva and plaque, as well as the following clinical parameters were examined: plaque index, gingival fluid flow rate, bleeding index and pocket depth.

Results: The microbiological analysis showed a significant reduction of mutans streptococci in saliva and plaque (Figs. 7 and 8). However, no significant reduction of mutans streptococci was observed for the placebo.

Both gel preparations improved the following clinical parameters: plaque index (Fig. 9), bleeding index (Fig. 10), pocket depth (Fig. 12). The gingival fluid flow rate improved significantly only if the active gel (containing CHX and fluoride) was used (Fig. 11).

![Image](data:image/png;base64,iVBORw0KGgoAAAANSUhEUgAAAAEAAAABCAQAAAC1HAwCAAAAC0lEQVR42mP8/A8wBwAAwIAAgAAAAABAAAHfAAAAAHbAAAAAHfAAAAAHbAAAAAHbAAAAAHfAAAAAHbAAAAAHfAAAAAHbAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHfAAAAAHf
Figure 8: Number of mutans streptococci in plaque before and after the treatment with Cervitec Gel or a placebo. Cervitec Gel or a placebo gel was applied with an interdental brush once daily for a period of 3 weeks. The mutans streptococcus count was established at the beginning of the study (baseline) and after 21 days. Cervitec Gel was shown to significantly reduce the number of bacteria in plaque. Only a slight effect was observed for the placebo group.

Figure 9: Plaque index before and after the treatment with Cervitec Gel or a placebo. Cervitec Gel or a placebo gel was applied with an interdental brush once daily for a period of 3 weeks. The plaque index was established at the beginning of the study (baseline) and after 21 days. Cervitec Gel significantly reduced the plaque index, while the placebo had a somewhat weaker effect.
Figure 10: Bleeding index before and after the treatment with Cervitec Gel or a placebo. Cervitec Gel or a placebo gel was applied with an interdental brush once daily for a period of 3 weeks. The bleeding index was established at the beginning of the study (baseline) and after 21 days. Cervitec Gel and the placebo reduced the bleeding index to the same extent.

Figure 11: Gingival fluid flow rate before and after the treatment with Cervitec Gel or a placebo. Cervitec Gel or a placebo gel was applied with an interdental brush once daily for a period of 3 weeks. The gingival fluid flow rate was established at the beginning of the study (baseline) and after 21 days. Cervitec Gel was shown to reduce the gingival fluid flow rate. This parameter remained unchanged after the treatment with the placebo.
Figure 12: Pocket depth before and after the treatment with Cervitec Gel or a placebo. Cervitec Gel or a placebo gel was applied once daily with an interdental brush for a period of 3 weeks. The pocket depth was established at the beginning of the study (baseline) and after 21 days. Cervitec Gel and the placebo reduced the pocket depth to the same extent.

Conclusion: Daily cleaning of the interdental areas resulted in the improvement of the plaque index, the bleeding index and the probing depth of pockets. In addition, the gingival fluid flow rate improved following the treatment with the gel containing the active ingredients. A reduction in the number of mutans streptococci in saliva and plaque was also observed with Cervitec Gel. As a result, the caries risk may decline.

4.2 Use in orthodontic treatment (Prof. Dr Kneist, Jena, Germany)

Objective: The objective of this study was to examine the caries-preventive effect of Cervitec Gel in patients undergoing orthodontic treatment with fixed orthodontic appliances. Patients with fixed orthodontic appliances are classified as caries risk patients. The artificially created retention surfaces provided by the orthodontic appliances offer additional niches in the oral cavity in which mutans streptococcus bacteria can multiply.

Investigator: Prof. Dr S. Kneist, S. Püstow, U. Langbein, Biological Laboratory and Polyclinic for Orthodontics, Dental School Friedrich-Schiller University of Jena, Germany.

Study design: A total of 42 patients participated in the two-arm, randomized, controlled, single-blind clinical study. The members of the control group (n=21) cleaned their teeth with Elmex® anti-caries toothpaste in the morning and in the evening. In an 8-week cycle, the members of the test group cleaned their teeth with Cervitec Gel for two weeks and with their regular toothpaste for 6 weeks. Over a period of one year, the approximal plaque index (API), the papillary bleeding index (PBI),
the salivary bacteria count and tooth discolouration were checked every 2 months.

**Results:**

The oral hygiene of the test group members improved after using Cervitec Gel. Furthermore, the number of patients with extremely high *S. mutans* counts (10^6 to 10^8 *S. mutans* per ml saliva) in the test group dropped from 48% to 10%. In the control group, however, more than half of the patients exhibited high bacteria counts (Fig. 13).

![Graph showing reduction in high bacteria counts](image)

**Figure 13:** Reduction of high bacteria counts in orthodontic patients (*S. mutans*) by using Cervitec Gel during a specific treatment cycle. The members of the control group of orthodontic patients with multi-bracket appliances brushed their teeth twice a day with a conventional fluoridated toothpaste, while the members of the test group brushed their teeth with Cervitec Gel for 2 weeks and a conventional toothpaste for 6 weeks in an 8-week cycle. The number of *S. mutans* was determined with CRT bacteria. The graph shows the frequency of patients with very high bacteria counts (>10^6 bacteria per ml saliva). The cycle involving 2 weeks of using Cervitec Gel and 6 weeks of using a regular toothpaste shown in the graph resulted in a significant and rapid decrease in the number of patients with high bacteria counts in the first 2 weeks and a gradual increase during the time that the regular toothpaste was used. A longer treatment period is shown for the control group to take into account the natural fluctuations. Most of the members of the control group (>50%) were observed to have and retain high germ counts. However, Cervitec Gel was found to significantly lower the germ counts in the test group (only 10% still had high germ counts).

*Modified according to Kneist et al., 2008*

**Conclusion:** Caries prophylaxis, which is of utmost importance for orthodontic patients, is effectively enhanced by taking advantage of the antibacterial effect of Cervitec Gel [8; 9].
4.3 Use in cases of denture stomatitis – A case report (Ronny Watzke, Ivoclar Vivadent)

Introduction: A 44-year-old patient with a complete denture presented to our clinic with severe general redness of the mucous membrane and papillary hyperplasia of the palate (Fig. 14a). This clinical finding corresponds to type 3 denture stomatitis.

Clinician: Ronny Watzke, Ivoclar Vivadent, Internal Clinic R&D, Schaan, Liechtenstein

Treatment: The patient was informed about oral and denture hygiene measures. He was especially instructed to clean the mucosa with a soft toothbrush on a daily basis and to wear the denture only during the day. Moreover, he was advised in detail on how to clean the denture. The denture had to be stored in a dry place.

As a supportive measure, Cervitec Gel was applied on the affected areas of the oral mucous membrane twice a day. In the mornings, a pea-size amount of Cervitec Gel was applied to the complete upper denture (in the palatal area). Subsequently, the denture was inserted. In the evenings a small amount of Cervitec Gel was applied on the affected areas with a finger.

Result: The general redness of the mucosa was less pronounced after 4 weeks of improved oral and denture hygiene than at the beginning of the treatment. After another 3 weeks and the additional application of Cervitec Gel, the patient was re-examined. At this appointment, the general redness of the mucosa was found to have subsided (see Fig. 14b). In the palatal region, papillary hyperplasia was still diagnosed, which would have to be completely treated by surgical measures. The patient perceived Cervitec Gel to be very pleasant. No side effects were recorded (redness of the mucosa, burning of the mucosa, impaired sense of taste, discoloration, etc.) [10].

Figure 14a: Situation at the first examination. Severe general redness of the mucosa with papillary hyperplasia of the palate is clearly visible.

Figure 14b: Situation after the treatment with Cervitec Gel. After 3 weeks of using Cervitec Gel the general redness of the mucosa has subsided.
4.4 Use in wound healing after surgical interventions – A case report (Ronny Watzke, Ivoclar Vivadent)

Introduction: Teeth 24 to 27 had to be restored in a patient. Tooth 25 was severely damaged.

Clinician: Ronny Watzke, Ivoclar Vivadent, Internal Clinical R&D, Schaan, Liechtenstein

Treatment: After the preparation and provisional restoration (crown) of tooth 25, the tooth was surgically lengthened in order to restore its biological width. The post-operative situation is shown in Figure 15a.

After the surgical procedure, Cervitec Gel was applied to promote wound healing. Subsequently, the patient was instructed to apply Cervitec Gel twice daily. After a week, the gel was applied once daily for another week. After this treatment, the patient was asked to use Cervitec Gel at least once a week.

Result: Figure 15b shows that one day after the surgical intervention, wound healing was already highly satisfactory. When the stitches were removed after 6 days, the tissue was shown to have healed very well (Figure 15c). One month after the surgical crown lengthening procedure, the gingival tissue had completely recovered and the patient was ready for the next stage of the restorative treatment.
5. **Biocompatibility**

The two carrier substances used, hydroxyethyl cellulose and Laureth 23, are common agents in toothpastes. The LD$_{50}$ (rats) value for both substances is >5000 mg/kg. Both substances are not known to have a sensitizing or irritating effect.

Sodium fluoride is toxic with an LD$_{50}$ (rats) of approx. 11 mg/kg bw. The European Cosmetic Directive sets an upper limit of 1500 ppm free fluoride for oral health care products. Cervitec Gel contains 900 ppm fluoride and therefore falls within the directive.

Chlorhexidine digluconate has an LD$_{50}$ (rats) of approx. 2500 mg/kg. The European Cosmetic Directive stipulates an upper limit of 0.3% chlorhexidine free base. Cervitec Gel contains 0.11% chlorhexidine free base and therefore complies with the directive.

Cervitec Gel contains sodium saccharin as the sweetener and natural peppermint oil as the flavourant. Both substances are permitted in the EU as food additives.

6. **Literature**


This documentation contains a survey of internal and external scientific data ("Information"). The documentation and Information have been prepared exclusively for use in-house by Ivoclar Vivadent and for external Ivoclar Vivadent partners. They are not intended to be used for any other purpose. While we believe the Information is current, we have not reviewed all the Information, and we cannot and do not guarantee its accuracy, truthfulness, or reliability. We will not be liable for use of or reliance on any of the Information, even if we have been advised to the contrary. In particular, use of the Information is at your sole risk. It is provided “as-is”, “as available” and without any warranty express or implied, including (without limitation) of merchantability or fitness for a particular purpose.

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