An Evaluation of the Fit of Metal-Ceramic Restorations Made with an Autoclaved Silicone-Based Impression Material

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Abstract

Aim: To demonstrate the clinical feasibility of autoclaving certain silicone impression materials in order to avoid potential cross-contamination during handling, transport, and subsequent processing.

Background: Semicritical devices are recommended to be treated at least with high-level disinfectants or actually steam sterilized at 134°C. To date dental impressions have been disinfected rather than sterilized, so the question remains should they be sterilized before being sent to the dental laboratory?

Case Descriptions: Two identical impressions per case were made of metal-ceramic crown and fixed partial denture preparations on the same patient using addition type polyvinyl siloxane (PVS) impression materials (AFFINIS®, Coltene/Whaledent AG, 9450 Altstätten, Switzerland) in different trays. The first impression (IMPx1) was cleaned and treated with an intermediate-level disinfectant (FD 322—Fast Disinfection Spray, Dürr Dental, 74321 Bietigheim-Bissingen, Germany). The second impression (IMPx2) was cleaned, treated with an intermediate-level disinfectant as with IMPx1, subjected to a computer tomography (CT) scan with a dimensional resolution of ±10 µm, steam sterilized, and then subjected to a second CT scan. The dimensional changes of the second impression after steam sterilization were calculated by comparing the overlay of the two CT scans and expressed by color coding of the impression graphics. After the second scan, the impression was sent to a dental laboratory to fabricate a metal-ceramic crown or metal-ceramic fixed partial denture restoration to the one produced from the first impression (IMPx1) subjected only to disinfection. This process was repeated for four clinical cases.

Conclusion: Impressions made with AFFINIS® silicone impression materials in a rigid reinforced polycarbonate impression tray or in a metal dual-arch tray can be autoclaved. The overall dimensional stability of the impressions and the quality of single crowns and small fixed partial dentures made using IMPx2 was not compromised. The maximum dimensional differences at the preparations of the nonautoclaved and the autoclaved impressions...
were found to be within acceptable limits of about 50–100 µm.

Clinical Significance: Steam sterilization of AFFINIS® impressions is possible without adversely affecting dimensional change. In addition, clinicians can clearly indicate to the dental practice and laboratory personnel that sterilization of the impressions has been performed, cross-contamination is unlikely, and the impressions present no apparent health hazard during transport and subsequent processing.

Keywords: Autoclave, case report, dimensional stability, disinfection, impression material, impression tray, PVS, silicone, steam, sterilization.

Disclosure: Dr. Kollefrath is head of Research and Development, Elastomers at Coltène/Whaledent AG, Altstätten, Switzerland, the manufacturer of the impression material evaluated in this report.


Introduction

Disinfection and sterilization of instrumentation in dental offices are well-established procedures. The pathways of cross-contamination and potential transfer of infectious diseases from patients to dental professionals and vice versa are well known.1 According to Kugel et al.1 however, there is a lack of awareness and communication when items are transferred from the dental practice to the dental laboratory. For instance, the Robert Koch-Institute, which is recognized as the Centralized Federal Institution responsible for disease control and prevention in Germany, recommends that all dental appliances be treated as if they were contaminated.1,4

The items to be treated are classified as critical (penetrating soft tissue or bone), semicritical (in contact with mucous membranes, blood, saliva, or wound exudates), or noncritical (in contact with intact skin).1,4 Semicritical devices are recommended to be sterilized at least with high-level disinfectants or, better, steam sterilized at 134°C (273°F) for at least an 18-minute holding time.1,5,6 This categorization could include dental impressions to be sent to a dental laboratory. However, there are some common problems with both chemical disinfection and sterilization procedures. The results vary depending on the material to be disinfected, the type of contaminants, the disinfectant itself, and the methods used.5,7,8 Often microbial contamination is still present after a general disinfection treatment.9 Access to microbes in some materials and items cannot always be assured. In such instances, recontamination is possible under certain circumstances.10 Chemical sterilants like ethylene oxide (EO), peracetic acid, and glutaraldehyde are partly difficult to handle and often aggressive.11,12 In addition, chemical sterilization usually takes longer (up to 12 hours), and no wrapping of the items during treatment is possible to avoid subsequent recontamination.12 Consequently, Jamani and colleagues6 considered chemical sterilization as inadequate for the dental practice. There is also the potential problem for repeated exposure to “sublethal concentrations of biocides [that] can develop . . . resistance to those agents.”12

A literature search in PubMed (http://www.ncbi.nlm.nih.gov/pubmed/) [cited 2009 Mar 2] returned 90 hits for the phrase “impression AND material AND disinfect*,” 23 hits for “impression AND material AND steril*,” but only two hits for “impression AND material AND autoclav*,”13 which suggests the lack of reporting in this area. Several reports found that only a portion of all patient-derived items like dentures, impressions, or gypsum casts sent to dental laboratories are disinfected successfully and an even smaller percentage are sterilized before leaving the dental practice.14-22 Dental impressions are particularly rated as problematic, regardless of whether or not they consist of obviously sensitive and difficult to treat materials like alginates, or materials such as polyethers or addition silicones.15,23 Moreover there is no general consensus about the necessity16,21 and method12,24 of disinfection or sterilization of dental impressions. However, the standard recommendation is to subject dental impressions to an intermediate-level disinfectant prior to pouring a cast or sending that impression to a dental laboratory.
Case Descriptions

Impressions and restorations were made involving four different patients at four dental practices. The two cases presented in detail below involved the use of a heavy body/light body combination. The remaining two cases involved the fabrication of a two-step impression technique of the two maxillary central incisors and a metal-ceramic crown from a one-step impression using the putty/regular body combination.

Making Impressions

Two identical impressions per case (IMPx1 and IMPx2, x=number of case) were made using AFFINIS® heavy body and AFFINIS® PRECIOUS light body or AFFINIS® putty soft and AFFINIS® PRECIOUS regular body addition silicone impression material in experimental glass-fiber-reinforced polycarbonate single-use trays with an experimental permanent tray adhesive (XPC, Coltène/Whaledent AG, 9450 Altstätten, Switzerland) or QUAD-TRAY® Xtreme™ Metal Dual Arch Impression Trays (QTX, Clinician’s Choice Dental Products, New Milford, CT 06776, USA) without adhesive (Figure 1).

Attention also should be paid to the fact that the maximum acceptable clinical gap size for crown preparations is not generally defined. In fact, there is a wide spectrum of values influenced on whether or not in vitro or in vivo studies were performed. For example, Boeckler and colleagues reported that published data on acceptable marginal opening varied between 30 µm and 200 µm. Upon examination of crowns placed in vivo, Donath and Roth even found average marginal gaps of more than 600 µm. Gassino and coworkers surmised that “there is no clinical evidence for a reliable criterion” to determine an acceptable fit of prosthetic restorations. The debate over the maximum acceptable gap distance includes a wide range of values from approximately 50 to 120 µm. This demonstrates that there is no consensus about this topic.

Finally, a point often missed in discussions regarding the marginal fit of restorations is the thermal behavior of the materials involved in the reconstruction process. Kim et al. reported that the “dimensional changes averaged by more than 40 µm in the anterior region, but less than 40 µm in the posterior region” when testing five brands of light-bodied addition-reaction silicone impression materials cooled down from 37°C (mouth temperature) to 23°C (room temperature). They noted that the coefficient of thermal expansion was significantly different among certain brands. It is remarkable that these thermal dimensional changes exceed the lower acceptable marginal gaps published by Boeckler et al. just by working with a dental impression at room temperature instead of mouth temperature.

Autoclaving (i.e., steam sterilizing) of dental impression materials is discussed as controversial or posed as a question to be addressed. Funasaka et al. and Millar found autoclaving of some types of addition silicone impression materials to be possible, whereas Holtan et al., Olin et al., and Mandikos did not recommend steam sterilization for the fabrication of prostheses such as crowns and fixed partial dentures. Concerns center not only on changes in the impression material itself but the potential for distortion of the impression tray used during sterilization. Acrylic resin custom trays and prefabricated plastic trays may undergo distortion and water uptake, making rigid metal or ceramic trays preferred if sterilization is selected.

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was sent to the dental laboratory to fabricate an identical restoration for comparison to IMPx1.

**Case #1**

A 55-year-old female patient with her maxillary right first molar, first premolar, and canine prepared for fixed restorations (Figure 5).

Two-step silicone impressions were made as described above using XPC trays, rinsed with water, and disinfected with FD 322—Fast Disinfection Spray. In this case, in addition to the silicone impression IMP11a, a polyether impression, IMP11b, was made using Permadyne™ Penta™ H (3M ESPE AG, 82229 Seefeld, Germany) for reference purposes. The

Figure 2. Protocols used for IMPx1 and IMPx2.

Figure 3. The Metrotom® CT computer tomograph. (Courtesy of Dr. M. Wagener, Carl Zeiss IMT GmbH)

Figure 4. An example of an impression made with the XPC tray and AFFINIS impression material sealed in a pouch and autoclaved.
were noted that were attributed to the somewhat flexible XPC tray.

The cast substructures of the metal-ceramic restorations were fabricated and compared. A very good fit of the metal substructures made from a cast produced from the autoclaved IMP12 impression was noted when these units were tried in the mouth (Figure 7).

Regarding the fit, there were no apparent differences detectable by the dentists between the restorations made from the spray disinfected conventional IMP11a (silicone), the monophase impression IMP11b (polyether), and the autoclaved two-step silicone impression IMP12 (silicone). Both frameworks were judged to have acceptable fit on the gypsum model as well as in the mouth. (Figure 8)

**Case #2**
A 52-year-old female patient required a metal-ceramic crown on the mandibular left second premolar (Figure 9).
Autoclaving nonaqueous elastomeric impressions provides the dentist and dental technician with an effective means to eliminate cross-contamination and the potential transfer of microorganisms from the dental practice to the laboratory.

The results of this study indicated that there is a tendency towards higher dimensional deviations in the outer areas of the impression, as seen in Case 1. This effect may be attributed to the somewhat flexible experimental single-use XPC impression trays. In order to relieve tension remaining from the production process, which can lead to distortion,

The impressions were made using a one-step procedure with QTX trays as mentioned previously, rinsed with water, and disinfected with FD 322—Fast Disinfection Spray. The resulting impression, IMP22, was then autoclaved. The calculated data overlay of the IMP22 computer tomographs, as shown in Figure 10, displayed a maximum difference of only 50 µm in the dimensions of the preparation area before and after steam sterilization.

The metal-ceramic crowns were made from IMP21 and IMP22 as stated above.

The fitting accuracy of both metal-ceramic crowns determined subjectively by the dentist was identical. The crowns could be exchanged on both gypsum models without any detectable differences in fit (Figure 11).

Both crowns appeared to have the same quality of fit intraorally (Figure 12).

Discussion

Autoclaving nonaqueous elastomeric impressions provides the dentist and dental technician with an effective means to eliminate cross-contamination and the potential transfer of microorganisms from the dental practice to the laboratory.

Success or failure of autoclaving silicone-based impressions appears to depend strongly on the impression tray and adhesive used. The results of this study indicated that there is a tendency towards higher dimensional deviations in the outer areas of the impression, as seen in Case 1. This effect may be attributed to the somewhat flexible experimental single-use XPC impression trays. In order to relieve tension remaining from the production process, which can lead to distortion,
users could consider autoclaving a group of the trays before use to relieve any stresses. Ideally, a tray material and tray design should be as rigid as possible, as noted in previous published reports. 

Case 2 using dual-arch metal QTX impression trays is remarkable because any resulting dimensional changes of the tray appeared to be negligible, as shown in Figure 10, and the silicone impression material without structural support still exhibits excellent dimensional stability.

In the clinical cases described, the framework dimensions of the final restorations made from autoclaved impressions did not noticeably differ from the restorations made from conventionally disinfected impressions. The dentists and patients involved in the two clinical cases described both chose the final restorations fabricated from the autoclaved impressions. In the remaining two cases not described here, the final restorations derived from the nonautoclaved impressions were selected for final cementation.

It is clinically feasible to autoclave AFFINIS® silicone impression materials when used in rigid polycarbonate or dual-arch metal impression trays. However, additional research is needed to determine if other impression materials can be sterilized without adversely altering the resulting gypsum casts and final restorations. Of particular interest are cases of dental implants and fixed partial dentures involving more than three units.

**Summary**

Impressions made with AFFINIS® silicone impression materials in a rigid impression tray or in a dual-arch metal tray can be autoclaved. The overall dimensional stability of the impressions and the quality of the resulting restorations did not appear to be compromised. Autoclaving of AFFINIS® addition silicone impressions is possible, and the pouch color indicator change is a visual affirmation that sterilization has been achieved.

The color indicator on the pouches (Figure 2) used clearly displayed to the dental practice personnel and the dental laboratory personnel that sterilization had been performed, that cross-contamination was unlikely, and that the impressions present no health hazard during transport and further processing.

**Clinical Significance**

Autoclaving AFFINIS® silicone impressions is an alternative to the use of conventional intermediate-level disinfectants and achieves sterilization. It also eliminates the potential for microbial cross-contamination during the transport and processing of dental impressions.

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