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ORIGINAL ARTICLE

Development of a validated process for manual preparation of dental transmission instruments

Andre Büchter · Birgit Kruse-Loesler

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Abstract The goal of the study was to develop a validated manual preparation process that conforms to the requirements of validation guidelines. Twelve dental transmission devices from various manufacturers (turbines, handpieces, and contra-angle handpieces) were artificially contaminated with bovine hemoglobin for the test. Ten microliters (corresponding to 800 μg) of bovine hemoglobin solution (concentration 80 mg/ml) was pipetted into the spray water and spray air channels. The manual preparation was conducted by blowing air through the spray channels of the transmission instruments through an attachment to a treatment unit (model 1060T, KaVo, Biberach, Germany) for 5 s. The spray channels were cleaned with WL-Clean (Alpro, Georgen, Germany) as directed by the manufacturer. The spray channels were disinfected with WL-Cid (Alpro) and the spray channels were blow-dried with WL-Dry (Alpro) at the end of the exposure time as directed by the manufacturer. To determine the protein content (protein residue analysis) in the channels of the transmission instruments, 2 ml of an alkaline SDS solution (1%; pH 11) was flushed through the channels. For the quantitative protein residue analysis, the Biuret method was used as described in DIN EN 15883-1:2006. After the application of this method, all results of the protein residue analysis were within the acceptance criteria of the validation guideline. The newly developed manual preparation process is therefore confirmed as suitable from a hygienic viewpoint for preparation of transmission instruments in the dental practice.

Keywords Dental turbines · Hand and contra-angle pieces · Dental instruments · Protein analysis

A. Büchter (✉)
Hohenzollernring 10,
48145 Münster, Germany
e-mail: a.buechter@citykom.net

B. Kruse-Loesler
Department of Cranio-Maxillofacial Surgery,
University of Münster,
Waldeyerstraβe 30,
48129 Münster, Germany

Introduction

Many dental procedures require the use of turbines or handpieces and contra-angle handpieces. Not only external contamination of such transmission instruments by micro-organisms from the oral cavity of a patient but also contamination of the internal passages poses a danger of infection for the next patient. The internal passages consist of various channels such as air and water channels that are connected to the dental unit. The extent to which contra-angle handpieces may be involved in transmission of pathogenic and facultative pathogenic disease carriers, which therefore poses a danger of infection, is subject to controversy [1–4]. This is particularly applicable for the interior of contra-angle handpiece such as the drive channel. Even though this channel does not come into direct contact with the oral cavity, tests have demonstrated that it can be contaminated [5].

As demonstrated by Gräf et al., pauses in the treatment procedure when the rotating grinder stops involve aspiration into the interior of the spray/water spray/air channels, resulting in contamination with saliva and possibly blood residues from the patient's mouth [6]. The water used to operate the dental treatment unit may also cause internal contamination [7–10]. In the dental practice, there has long been discussion about whether thermal preparation of the transmission units is required between two treatments, as is standard practice for all other instruments. In general, only

the surface of the transmission instrument has been wiped with an alcoholic surface disinfectant [3, 11]. According to the Robert Koch Institute (www.RKI.de) and the BfArM recommendation (Federal Institute for Drugs and Medical Devices; www.bfarm.de), dental handpieces and contra-angle handpieces are to be classified in the semicritical B or critical B risk classes for use on patients. Regardless of the classification of the instruments, all the required preparation steps must be conducted using a validated process. Medical devices must be prepared in conformity with the regulations governing medical devices. They cover all stages of preparation such as cleaning, care, disinfection, packaging, and sterilization. The care, packaging, and sterilization of transmission units are not a problem for any dental practice. However, the situation is different for internal cleaning and disinfection because most devices on the market are approved for care only but not for cleaning and disinfection in accordance with EN 15883.

There is only one device on the market that conforms to all points. However, it is very expensive to purchase for the dental practice. The goal of this study was to develop a suitable process that is as simple as possible to ensure validated, manual cleaning and disinfection of handpieces and contra-angle handpieces.

Materials and methods

The test devices were 12 different new handpieces, contra-angle handpieces, and turbines from five well-known manufacturers (Table 1).

Bovine hemoglobin was used as the test contaminant in accordance with DIN ISO/TS 15883-5:2006 Appendix J. Contamination with blood, which is used for checking the cleaning performance in the validation guideline, is not suitable for transmission instruments. Coagulation of the blood in the narrow spray water and spray air channels causes blockages that cannot be removed. Ten microliters (corresponding to 800 μg) of the prepared bovine hemoglobin solution (concentration 80 mg/ml) was pipetted into the spray water and spray air channel. The test instruments were then left for 10 min at room temperature. This corresponds to approximately the time between application of the instrument on the patient and the start of preparation in the practice. Then the cleaning performance was checked.

To determine the protein content (protein residue analysis) in the channels of the transmission instruments, 2 ml of an alkaline SDS solution (1%; pH 11) was flushed through the channels. The solution was then flushed through the channels of that instrument twice (elution).

The quantitative protein residue analysis was conducted based on the Biuret method described in DIN EN 15883-1:2006. The protein residue was determined in accordance with the guidelines of the DGSV (German association for care of sterile materials; www.dgsv-ev.de) and the AKI (instrument preparation work group; www.a-k-i.org) for validation and routine monitoring of machine cleaning and disinfection processes for thermostable products and the basic requirements for device selection in micrograms per instrument. The loss calculated in the ”determination of the loss rate due to the method” was added to the measured protein residue amount. To calculate the loss rate due to the method, all transmission instruments were contaminated as described in the test contamination and then the protein residue analysis was conducted as described above.

The study was conducted in three runs. All results were reduced to an average value and the loss due to the method was calculated from the average. A total of three runs were conducted.

Study procedure

1. Contamination of the transmission instruments with bovine hemoglobin in the laboratory

Table 1 Overview of transmission instruments

No.	Instrument type and manufacturer	Product identification	Serial number
1	Sirona turbine	T2 mini	300179
2	Sirona contra-angle handpiece red	C200 1:5	4124
3	Sirona contra-angle handpiece green	C6L 6:1	15949
4	NSK turbine	Ti-Max X 600KL	A7100137
5	NSK contra-angle handpiece green	Ti-Max Ti15L	B7200003
6	NSK contra-angle handpiece red	Ti-Max Ti95L	B4905449
7	KaVo turbine	Super-Torque 640B	C381814
8	KaVo contra-angle handpiece blue	Gentlepower 20 LP	06-2013316
9	Morita turbine (with KaVo adapter)	Twinpower 4H PAR-4HX-O KV	U20002
10	W&H turbine	Synea TA-98 L	5701
11	W&H contra-angle handpiece red	Synea TA-99 L	1334
12	W&H contra-angle handpiece green	Synea WA-66 LT	8464

2. Determination of the loss rate of protein on every transmission instrument in the laboratory
3. Contamination of the transmission instruments with bovine hemoglobin in the laboratory
4. Procedure for manual preparation (see below)
5. Elution of every transmission instrument with alkaline SDS solution
6. Protein residue analysis using the Biuret method
7. Cleaning the transmission instruments after the protein residue analysis in the Sirona DAC, Bensheim, Germany

Manual preparation procedure

1. Rinse spray channels of transmission instruments with water for 5 s through an attachment to a treatment unit (model 1060T, KaVo, Biberach, Germany).
2. Blow out spray channels of transmission instruments with air for 5 s through an attachment to a treatment unit (model 1060T, KaVo).
3. Clean the spray channels (WL-Clean, Alpro, Georgen, Germany) as directed by the manufacturer.
4. Disinfect the spray channel (WL-Cid der Firma Alpro, Georgen, Germany) as directed by the manufacturer
5. Blow-dry spray channels (WL-Dry der Firma Alpro) after exposure time as directed by the manufacturer.

Acceptance criteria

Quantitative evaluation

The quantitative evaluation of the cleaning performance followed the requirements of the validation guideline (Table 2).

Maintenance of the reference value (<100 µg protein per test instrument) means that the cleaning performance is sufficient to ensure that the success of the following preparation stage is not endangered.

Table 2 Acceptance criteria for quantitative protein residue remaining on medical devices

Value	Requirement
Limit value	All test instruments must be visually clean; the protein residue must not be >200 µg protein per test instrument
Warning value	>100 µg to <200 µg protein per test instrument
Reference value	<100 µg protein per test instrument

Statistical evaluation

The protein concentrations were compared by variance analysis. *P* values below 0.05 were considered significant for the statistical calculations.

Results

Calculation of the loss rate due to the method

To calculate the loss rate due to the method, the transmission instruments were treated as described above. The protein amount after contamination was, on average, 775.4 µg/instrument (±1.75). Because in the contamination process a protein amount of 800 µg per instrument was applied, this means that there was an absolute loss of 24.6 µg protein and a percentage loss rate of 3.2% (Fig. 1).

Residual protein amounts

The residual protein amounts of the individual transmission instruments after preparation with the manual sample process were increased by the loss rate due to the method of 3.17% and then rounded up or down to the nearest whole number. The average contamination was 21.8 µg (±3.19) and could therefore be reduced in all tests below the critical limit of 100 µg. The residual protein amount was significantly (P= 0.001) lower than after the contamination. The residual contamination per instrument, therefore, is clearly <100 µg and conforms to the relevant requirements [12, 13].

Discussion

A dental practice contains numerous items of equipment and devices that could act as carriers of pathogenic and

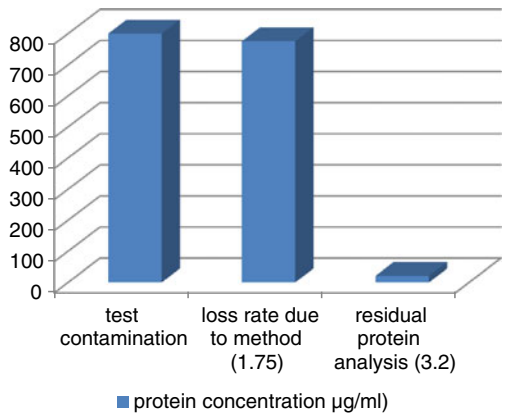

Fig. 1 Protein concentration, geometrical average, and standard error of the water channels

facultatively pathogenic germs. Significant items include handpieces and contra-angle handpieces and turbines because they come into contact with the saliva and the oral mucosa of the patient in all conservative, prosthetic, and surgical treatment procedures, and their complex structure provides a wide range of niches for microorganisms. The literature reports that virtually no protein contamination could be detected in analytical examinations of the external surfaces of the transmission instruments immediately after cleaning and disinfection of handpieces and contra-angle handpieces because these areas are very easy to clean and disinfect [14]. This is the main reason why we have not addressed this area in this study. In contrast, the internal parts of the transmission instruments without preparation in Schmidt-Schwap et al. had protein contamination well over 100 μg. It is important to eliminate these impurities before sterilization; otherwise, the sterilization may be inadequate [15]. During cleaning of the interior, it must be noted that an alcohol solution cannot be used initially because it may simply fix the proteins [16]. Other authors specify precleaning before sterilization as a particularly important step [17] or a rinsing stage to reduce microorganisms. This is taken into consideration in machine preparation by the DAC system or G 7881 Washer-Disinfector made by Miele & Cie KG (Gütersloh, Germany) [14, 18]. Sufficient efficiency of these devices with reduction of contamination significantly below 100 μg/instrument has been confirmed in the literature [14, 18]. However, in continuous operation in the dental practice, it cannot be ensured that employees have always attached the transmission instruments securely and correctly to the adapters because visual inspection is not possible during operation. These closed systems also prevent visual monitoring of whether the cleaning agent has really penetrated the instruments completely. If an internal channel is blocked, it is often not noticed. Another significant disadvantage is the expense for an individual practice. Therefore, this validated manual preparation has confirmed that a process is available that achieves comparable cleaning results to those of the washing and disinfecting machines on the market [14, 18, 19]. Recognition of the above manual preparation (for critical B products) by the various countries and approval by manufacturers of transmission instruments for a manual preparation process would be desirable.

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Conflict of interest The authors declare that they have no conflict of interest.

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