



Evaluation of the mechanical cleaning efficacy of dental handpieces

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SUMMARY

Background: Dental handpieces undergo a decontamination process before reutilization. Thorough cleaning is a prerequisite to effective sterilization, to guarantee safety and prevent cross-infections.

Aim: To assess the cleaning efficacy offered by devices dedicated to dental handpieces.

Methods: PIDTests[®], which are patented tubes made of transparent material and designed to replace handpieces in cleaning devices, were artificially stained by Soil Test[®] (Browne/STERIS). Three cycles were performed with PIDTests[®] connected to every handpiece adapter in the four different machines tested: X-Cid 2[®] (Micro-Mega) with a total of nine PIDTests[®]; iCare+[®] (NSK) with nine PIDTests[®]; DAC Universal[®] (W&H) with 18 PIDTests[®]; and BioDA 80[®] (VR2M) with 24 PIDTests[®]. A visual evaluation and a biuret reaction test were performed.

Findings: In three of the tested cleaning devices (X-Cid2[®], iCare+[®] and DAC Universal[®]), all of the PIDTests[®] showed Soil Test[®] residues, on the internal and external surfaces indicating cleaning was ineffective. Only the BioDA 80[®] showed no residual stains on all the PIDTests[®] and negative biuret reaction test results, making the cleaning effective.

Conclusions: Manufacturers should optimize the cleaning device parameters, based on the Sinner circle (grouping compensatory parameters which influence the effectiveness of a cleaning process, such as pressure, temperature, time, detergent concentration), to improve cleaning efficacy and enable dental surgeons to ensure the safety. Although PIDTests[®] are the only tool to provide visual indications on the cleaning efficacy of washer-disinfectors dedicated to handpieces, manufacturers should continue with the development of improved and validated tools to assess cleaning efficacy.

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Introduction

Dental handpieces (HPs) are medical devices that are largely used in dental procedures. Utilized in a patient's

mouth, they are inevitably soiled and contaminated on their external surface by biological fluids such as blood, saliva, pus, or dentinal smear layer [1–3]. Moreover, many studies report a phenomenon of backflow when HPs stop running [1–6]. Consequently, these devices are also soiled and contaminated on their inner surfaces (narrow air/water manifolds, drive shaft, gears); allowing potential cross-infections [3,7–10] and a dangerous microbial quality of the water which runs through the dental unit [4,5,10,11]. Indeed, hepatitis B viruses and

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Staphylococcus aureus have already been found on the inner surfaces of HPs [2,12].

These biofouling and contaminations mean that, HP are classified as semi-critical reusable medical devices regarding the Spaulding classification. They must undergo a sterilization process in order to prevent cross-infections and guarantee the safety of care [1,3,5,6,8,13–17]. To ensure the efficacy of sterilization, the steam must reach the internal cavities and surfaces of HPs [1,3,15,18]. A class B steam sterilizer complying with the standard EN 13060 is then required for the vacuum sterilization process [1]. An unavoidable prerequisite is that HPs must have prior thorough cleaning [7,13,17,19,20]. According to the standard ISO 15883 part 2 (performance of washer-disinfectors), this cleaning process has to be performed during an internal rotation of HPs. Although manufacturers of HPs provide instructions for cleaning these devices, there are no validation processes [18]. Apart from visual assessment which is only feasible on the external surfaces, as reported in standard ISO 15883, there is a methodological gap regarding HP cleaning evaluation [3].

Moreover, there is a lack of information [21,22] and results [1,3,17] regarding the condition of inner surfaces, and there is a need for tools to facilitate this assessment [10,23]. Often, HPs are not reprocessed in accordance with recommendations [18,24], and mathematical modelling conducted by the National Institute of Health Surveillance (INVS) showed that each year, in France, the poor reprocessing of HPs could be responsible for 200 cross-transmissions of hepatitis B, two of hepatitis C, and one of HIV [24]. The practice of disinfection of HP with 70% w/v alcohol appears inadequate to thoroughly clean and disinfect these devices [17]. Moreover, it is not recommended to soak HPs in any disinfectant solution [8,25] due to corrosion risks, and because air bubbles in inner lumens can reduce the activity of the disinfectant [26]. A daily maintenance regime that follows the manufacturer's instructions also significantly reduces damage to HPs [26,27].

To effectively clean HPs externally and internally is a challenge, due to the internal complex architecture, their fragility, and narrow lumens [1,3,8,11,15]. Novel methods have been proposed to assess the cleaning, but their implementation was too technical to be routinely utilized in hospitals or private practices [3]. However, many manufacturers of cleaning devices advocate that their apparatuses dedicated to HPs can ensure adequate cleaning [28–31].

One of the main challenges regarding cleaning HPs is in measuring and proving efficacy both for internal and external surfaces. Whilst ISO 15883 describes a number of methods for assessing the surface cleanliness of reusable medical devices, there is no specific procedure for evaluating the efficacy in dental HPs [18]. The control and measurement of cleaning efficacy of internal and external surfaces of HPs by different devices on the market is therefore of paramount importance to ensure the quality, safety and consequently the sustainability of dental care.

Materials and methods

The objective of our study was to assess the cleaning efficacy of some devices dedicated to the cleaning of dental HPs. To perform such an evaluation, we used a new cleaning assessment tool, which has been patented, PIDTest® (VR2m,

Saint-Cyr-en-Val, France). The name is derived from the French acronym 'PID' (*porte-instrument dynamique*) meaning 'dental handpiece'. We assessed the cleaning offered by three different cleaning devices: X-Cid 2® (Micro-Mega, Besançon, France), iCare+® (NSK, Paris, France), DAC Universal® (W&H, Eckbolsheim, France); and a washer-disinfector: BioDA 80® (VR2M, Saint-Cyr-en-Val, France).

The PIDTest® consists of a tube made of a transparent material whose closed end presents an orifice of a diameter equal to the normalized diameter (ISO 14457) of a rotary tool (1.6 mm). The other end, whose inner lumen diameter is equal to the standard diameter of an HP (ISO 3964), has two lateral vents allowing the correct filling of the device during the cleaning phase. Due to their normalized dimensions, PIDTests® can be inserted and connected into washer-disinfectors instead of HPs during the test cycle (Figure 1).

The internal and external surfaces of PIDTests®, meant to model the internal and external surfaces of a dental HP, were brushed to half-height with a fouling test (Soil Test®, Browne/STERIS, Le Haillan, France) and allowed to dry for 12 h, which corresponds to the drying time for the Soil Test®. Soil Test® was chosen due to its adaptability and adequacy with biological fouling, equivalent to the soil test described in ISO 15883 part 5 Annex N [3,32]. PIDTests® were then connected to all of the contra-angle adapters of the four devices and a clean cycle was performed, in accordance with the manufacturer's recommendations (Figure 2). Each of the four cleaning devices (X-Cid2®, iCare+®, DAC Universal®, BioDA 80®) was tested for three cycles (Figure 3).

Three cycles of the X-Cid2® (three connections) corresponded to nine PIDTests®. Three cycles of the DAC Universal® (six connections) corresponded to 18 PIDTests®. Three cycles of the iCare+® (three connections, plus one connection specific to a dental turbine not tested) corresponded to nine PIDTests®. Three cycles of the BioDA 80® (eight connections) corresponded to 24 PIDTests®. After each cleaning cycle, the PIDTests® were analysed according to standard ISO 15883, and compared to a control test corresponding to a PIDTest® which had not been subjected to any cleaning cycle.

A visual control was performed under the same conditions for every PIDTest® (same operators, same light conditions). If Soil Test® stains were visible to the naked eye, the cleaning was described as ineffective. If there were no stains, a biuret reaction using swabs (CleanTrace® Surface Test Protein Plus, 3M, Cergy, France) was performed to detect residual proteins. All the surfaces were rigorously rubbed with the swabs and were then incubated at 55°C for 15 min, as specified by the manufacturer.

If the biuret reaction test was positive (presence of residual proteins), the cleaning was described as ineffective. If the biuret reaction test was negative (absence of residual proteins), the cleaning was described as successful (Figure 4).

Results

Every control test used in this study remained soiled, visible to the naked eye, and the biuret reaction tests were positive for these control tests (Figure 5). PIDTests® detected Soil Test® stains visible to the naked eye, both on their internal and external surfaces following cleaning in X-Cid2®, iCare+®, and DAC Universal® devices making the cleaning ineffective

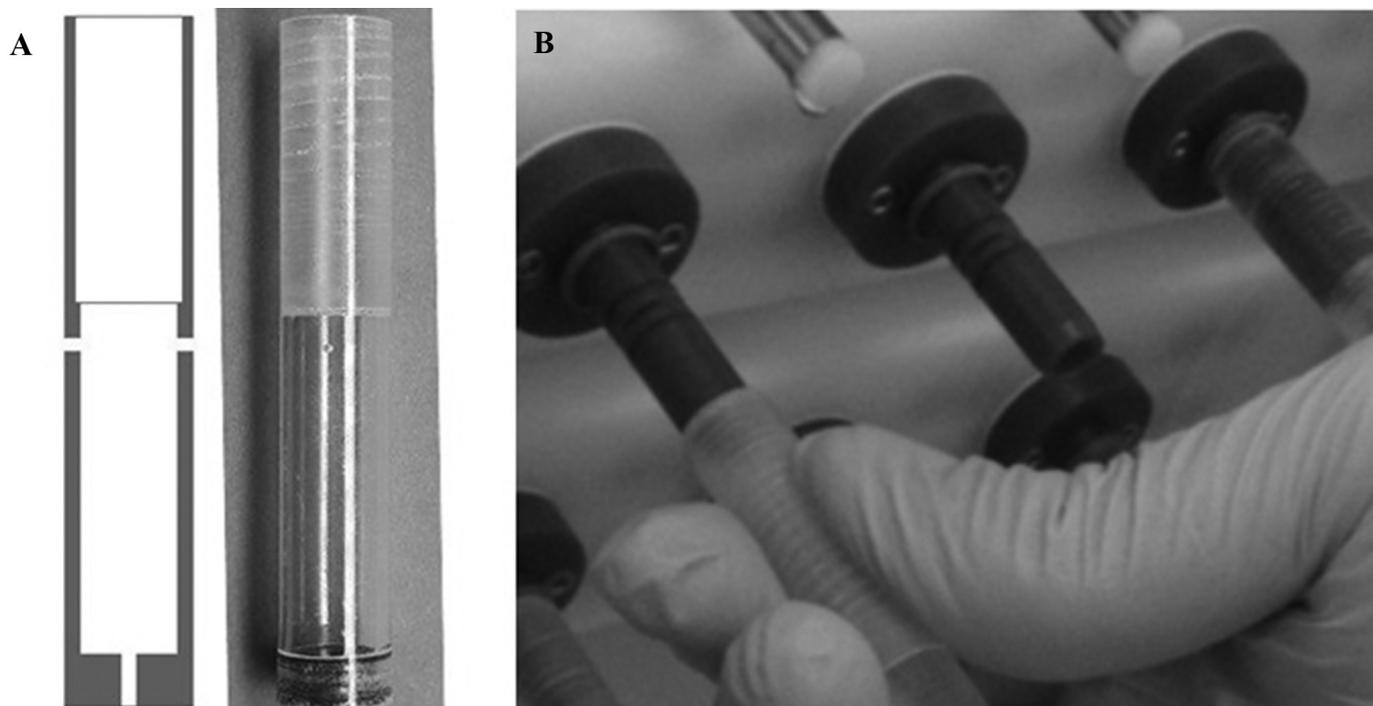


Figure 1. (A) A PIDTest© and its schematic view. (B) PIDTests© adapted to cleaning devices.

(Table 1; Figure 5). All of the PIDTests© showed an absence of Soil Test© residues visible to the naked eye, both on the internal and external surfaces following cleaning with BioDA 80©. Biuret reaction tests were negative for all of these PIDTests©, indicating that the cleaning was effective (Table 1; Figure 5).

Discussion

Dental HPs are reusable medical devices which undergo a sterilization process; their prior cleaning is a crucial step [20,23,33]. PIDTests© are easy to handle tools, designed to simply assess the cleaning efficacy of an HP cleaning device. Nevertheless, there is no publicly available manufacturer report which describes the validation for these surrogate devices at this time. Conclusions about this study should therefore be used with caution. Indeed, PIDTests© do not contain internal channels and rotary parts, and their surfaces are smooth and straight, and consequently do not reproduce the complexity of an HP's inner architecture. Thus, a pass result on the surrogate device does not mean that the dental HP has been adequately cleaned, and equally a fail on the surrogate device does not mean that the dental HP has been insufficiently cleaned. However, PIDTests© are designed to model the surfaces of HPs, and to give some indications about the cleaning efficacy. Since there is no other tool on the market for this purpose [3,18], these indications could be helpful, even if they are not complete, to conclude about the real efficacy of a cleaning device.

The non-complex architecture of a PIDTest© compared to a real HP could be a first step to a cleaning validation, and could be a way to improve cleaning devices which demonstrate a poor cleaning efficacy. Indeed, a machine that is not able to clean a prepared PIDTest© with a simple architecture is

unlikely to present better results with an HP. These surrogate devices could be improved in the future by developing further tools mimicking the inside of an HP, potentially using 3D printing techniques and validated materials with equivalent physical properties to HPs (drying characteristics, surface adherence, etc.).

In our study, among the four devices we tested, only one (BioDA80©) achieved adequate cleaning of PIDTests© on inner and outer surfaces. There may be several reasons for this. On the one hand, these results could be explained by the non-compliance with the Sinner circle. Indeed, the effectiveness of a cleaning process depends on the Sinner circle's four factors: mechanical action, chemical action, time for action and temperature [34]. If one of these cannot be optimized, its lack needs to be outweighed by an increase in the other factors, and that is the reason it is presented as a circle. Some of the devices we tested only deliver a cold process, that is not counterbalanced with an increase of the pressure (which represents the mechanical action) to clean the devices, or with an increase in the processing time. Indeed, manufacturers highlight the speed of the cleaning cycle while cleaning is not a matter of speed, but of efficacy. Concerning the X-Cid2©, for example, although it uses a detergent-disinfectant complying with standards EN 1040, 1275, 14563 and 13727 during its cycle, this parameter was not sufficient to clean PIDTests© and should be coupled with a hot process and/or an increase of the pressure of the cleaning solution. These parameters (pressure, temperature, time, and detergent concentration) should be optimized by manufacturers to offer a better cleaning efficacy. On the other hand, we chose to allow the Soil Test© to dry for 12 h while standard ISO 15883 part 5 only demands a 2-h drying time. This certainly represents a more difficult challenge to the cleaning process than original-type tests by the manufacturer. Although the soil is meant to be representative of native soiling

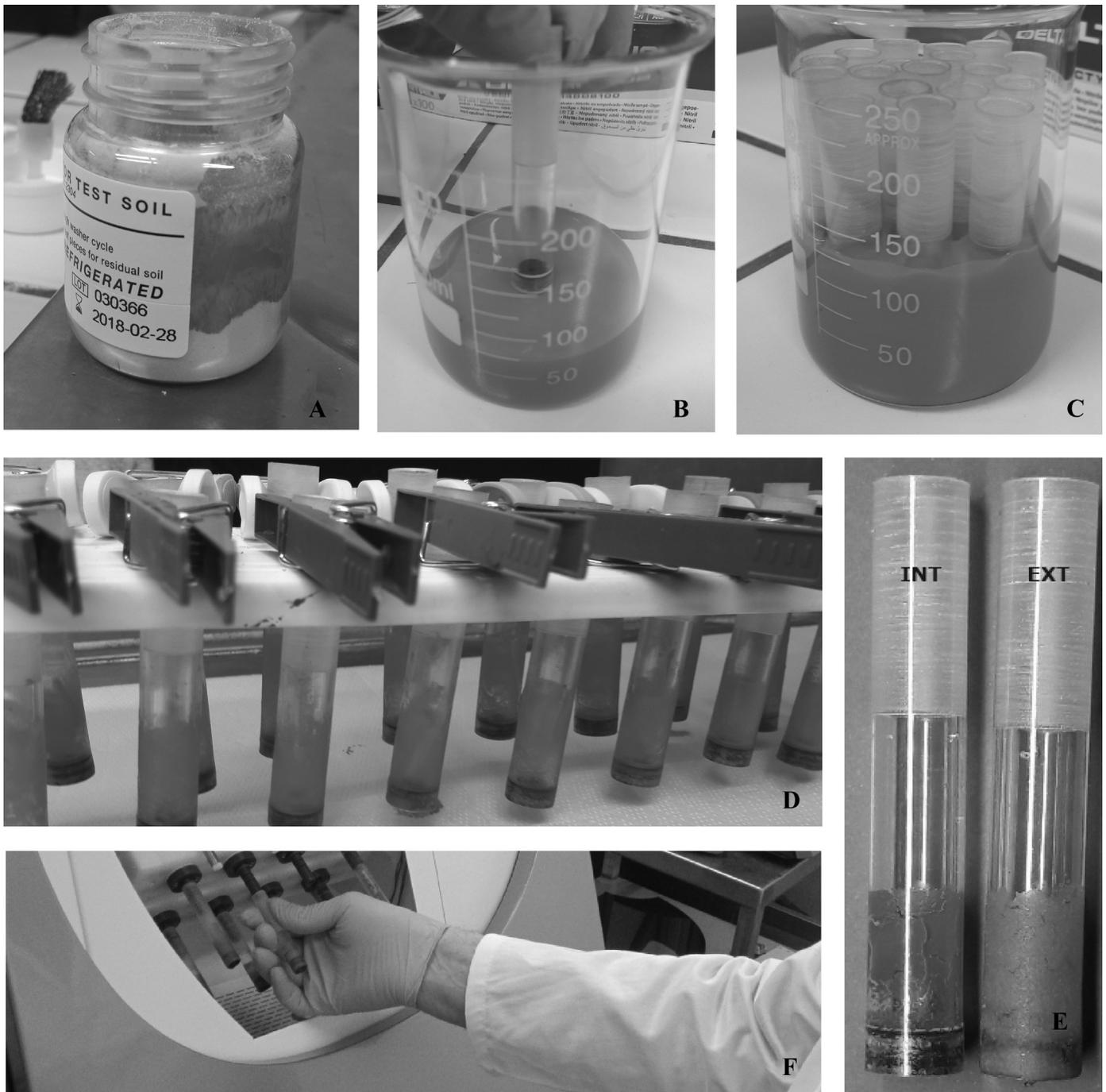


Figure 2. (A–C) Preparation of PIDTests[®] with Soil Test[®]. (D) Prepared PIDTests[®] allowed to dry. (E) PIDTests[®] are soiled on their inner (left) and outer (right) surfaces and (F) connected to the cleaning device.

which in practice is not meant to be totally dry, we know that in general practice, unfortunately, it is likely that a great amount of HPs do not benefit from adequate reprocessing [18,24], and an average of only 10% of HPs undergo a cleaning process aimed at cleaning their internal surfaces [18]. Thus, we can easily imagine that some HPs are left to air dry during a whole night without having been previously cleaned inside, allowing stains to dry for 12 h. Moreover, this situation could also represent an exceptional forgetfulness from the practitioner or his/her dental assistant, and it seems important to be able to show that

the consequently dry stains are not permanent and that there is a way to remove them. It should be noted that even if the manufacturer of the Soil Test[®] advocates a 30-min to 2-h drying time, usual practices in sterilization departments of European hospitals are of at least 12 h drying time [35–37].

Other machines designed to clean HPs exist on the market. Some of them, just like the DAC Universal[®], do not put HPs in rotation during the cycle, and thus are neither in accordance with recommendations [13] nor with the standard ISO 15883 relative to general performance requirements for washer-



Figure 3. Washer-disinfectors that were tested: (A) BioDA 80©; and cleaning devices which have been tested: (B) DAC Universal©, (C) iCare+©, and (D) X-Cid2©.

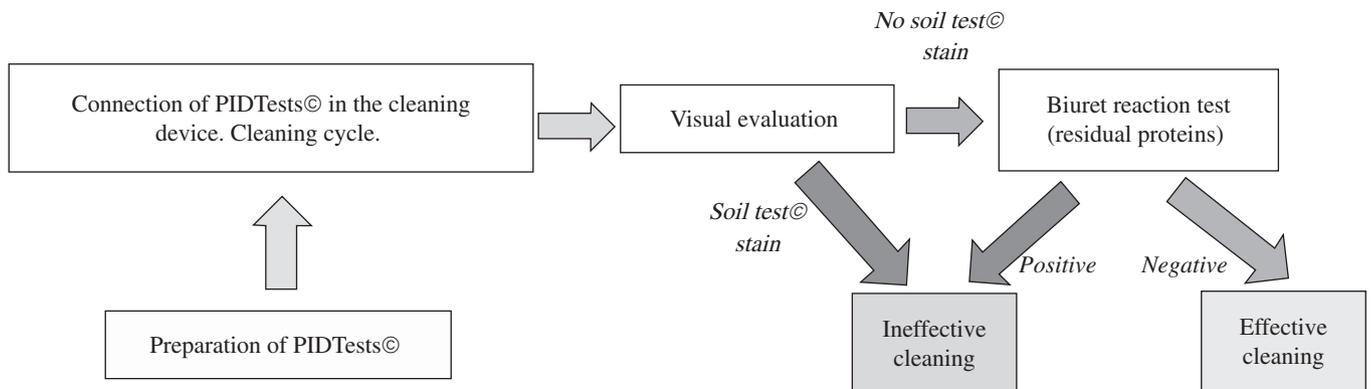


Figure 4. Cleaning assessment procedure.

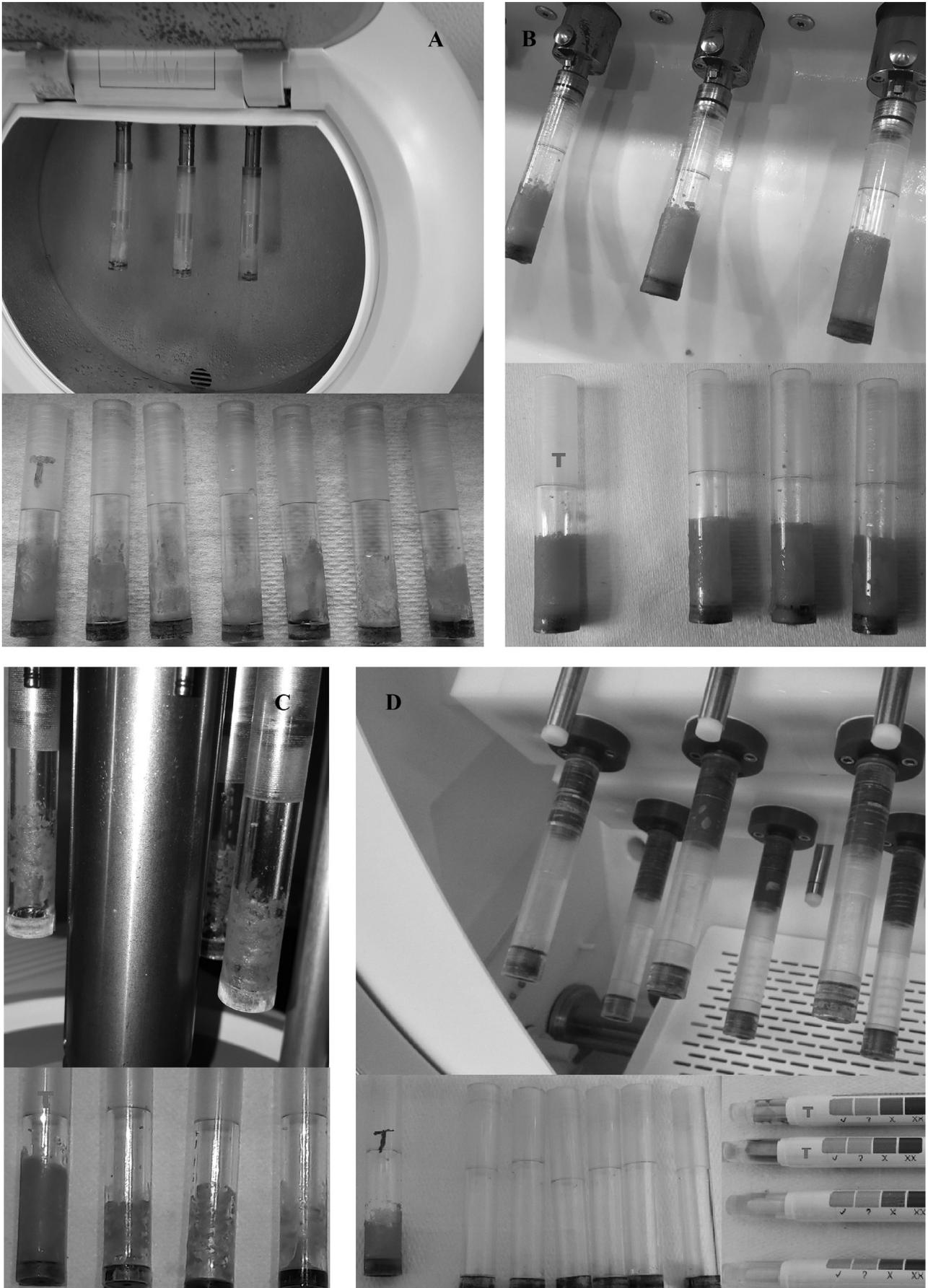


Figure 5. PIDTests[®] after the cleaning cycle (T = control test), following manufacturer’s recommendations for (A) X-Cid2[®], (B) iCare+[®], (C) DAC Universal[®], and (D) BioDA80[®] with additional biuret reaction tests.

Table I
Results from the cleaning devices.

Automaton	Total number of PIDTests®	Visual evaluation		Biuret reaction test (if applicable)	Cleaning
		External surface	Internal surface		
X-Cid2®	9	Soiling (9 tests)	Soiling (9 tests)	Not applicable	Ineffective
iCare+®	9	Soiling (9 tests)	Soiling (9 tests)	Not applicable	Ineffective
DAC Universal®	18	Soiling (18 tests)	Soiling (18 tests)	Not applicable	Ineffective
BioDA 80®	24	No soiling (24 tests)	No soiling (24 tests)	Negative (24 tests)	Effective

disinfectors. Indeed, it has been shown that a lack of internal rotation produces an incomplete clean because fluids cannot reach all the surfaces of HPs [3]. Consequently, these devices have not been tested. The DAC Universal® has been tested because of its wide utilization by dental surgeons.

Since PIDTests® are the only tools to provide visual indications about the cleaning efficacy of washer-disinfectors to date, on both external and internal surfaces, these surrogate devices represent an interesting option for the initial qualifications (operational and performance qualifications) of a washer-disinfector required in the standard ISO 15883, but also for routine tests. However, it is important to keep in mind that as long as there is no documented validation for these tools, PIDTests® can only deliver indications and no opposable results. Therefore, two strategies should be considered in the future: (1) to validate the PIDTest®, or to develop a more precise tool in the line of the idea of a cost-effective solution to fill the methodological gap that prevents an easy and accurate assessment of the cleaning offered by cleaning devices dedicated to HPs [3,10,22], and (2) to work on the dental surgeons' behavior regarding hygiene procedures deploying various methods [38] in order to use more accurate tests compared to real general practice, for which a 2 h drying time of the soil test would be sufficient, as described in the standard ISO 15883.

Conclusions

Dental HPs are reusable semi-critical medical devices that need to undergo a decontamination process before their reutilization. A thorough clean is an unavoidable prerequisite for an effective sterilization, guaranteeing the safety of care and the prevention of cross-infections. Until now, no simple method had been proposed to evaluate the cleaning process which is offered by washer-disinfectors dedicated to HPs without having to destroy HPs in order to see their internal surfaces. PIDTest® seems to be an interesting and easy-to-handle tool to provide further information about this cleaning, although it needs further validation. It provided indications about the cleaning efficacy of three different cleaning devices and one washer-disinfector, in deliberately difficult conditions. Among the X-Cid2®, iCare+®, DAC Universal® and BioDA 80®, only the BioDA 80® met the requirements for the cleaning process in this study. The general cleaning difficulties offered by devices which are available on the market raise public health issues with a negative impact on the quality, the safety and the sustainability of dental care. Manufacturers should optimize some of their device parameters, according to the Sinner circle (pressure, temperature, time, detergent concentration), to reach a real cleaning efficacy, with development of improved and validated tools to

assess the cleaning efficacy of cleaning devices dedicated to HPs.

Conflict of interest statement

None to declare.

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