Cleaning of dental handpieces : a method to test its efficiency, and its evaluation with a washer-disinfector-lubricator-dryer

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Conflicts of interest : none

Abstract :

Dental handpieces (HP) are reusable semi-critical medical devices according to the Spaulding classification. When they stop working in the mouth, a phenomenon of backflow occurs, which leads to an external and internal soiling and contamination of the HP. This happens both in the body of the latter and in the narrow air/water pipes associated therewith. The HP need to be sterilized between each patient and this sterilization must be preceded by a thorough cleaning.
This work aims to establish a method for testing the effectiveness of the cleaning of the HP. Indeed, there is a methodoligical gap concerning the validation of their cleaning because the HP are not designed to be dismantled in an other way than a meticulous and precautious one . This method is declined into a protocol using artificial soilings and ninhydrin tests to confirm the absence of proteic residues.
Its evaluation with a washer-disinfector-lubricator dryer (Bioda © from the brand vr2m) heads to validate its relevance, and to demonstrate the effectiveness of the cleaning provided by the automaton. This makes the method a good candidate for the initial steps of an operational qualification and a qualification of the performances concerning the cleaning of the HP, according to the standards NF EN ISO 15883. Moreover, this work demonstrates the need for the HP to be put into an internal rotation during the cleaning phase.

Introduction :

Historically, dental rotary instruments were used along with foot-powered dental drills [1]. Nowadays, they are inserted into dental handpieces (HP) and are put into action with the help of electric motors. These HP are coupled with narrow pipes bringing air and water to cool the cutting instrument. Therefore, during a dental surgeon's procedure, the head of the HP is right into the patient's mouth, very close to the dental organ and soft tissues, and in contact with saliva or other biological fluids (blood, pus) in a real septic environment. This explains that HP are classified as semi-critical reusable medical devices according to the Spaulding classification [2, 3, 4]. Therefore, they should follow a complete sterilization cycle before their reutilization.

Moreover, when the HP stops working into the patient's mouth, a physical phenomenon of backflow occurs [5, 6, 7, 8, 9, 10, 11]. Since the head of the HP is running in a septic environment, a retro-contamination and an internal soiling (fig. 1) of the HP occurs, in addition with an external contamination and soiling. This contamination takes place at different levels : the head and body of the HP [10, 11, 12, 13, 14, 15, 16, 17], and the narrow pipes dedicated to bring air and water to the dynamic instrument [18, 19].

Fig. 1 : Microscopic view of the inner surface of the head of a HP with soiling

Indeed, the head of the HP is not isolated from its body, neither in a watertight nor in a airtight way. This appears obviously by applying compressed air at one end of the head and observing an air outlet to the other end (fig. 2).

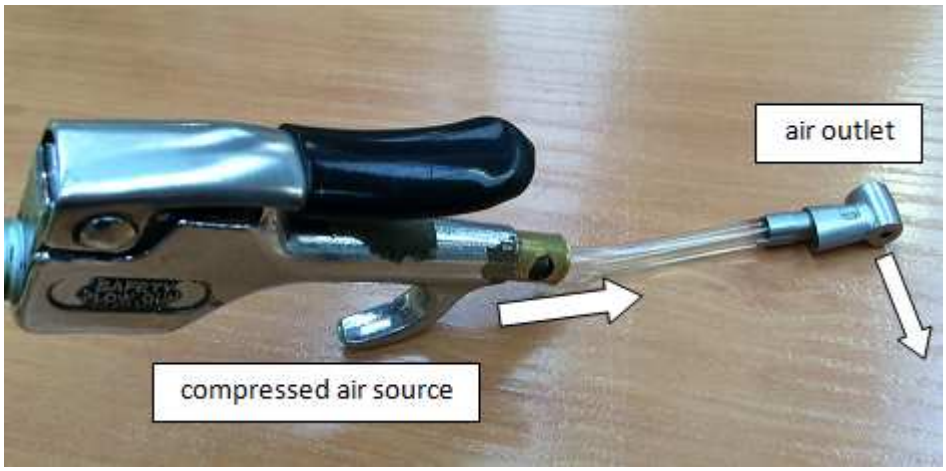

Fig. 2 : Experience of highlighting of the non-airtight junction between the head and the body of the HP

This internal contamination can spread to the engine that puts the HP in action, and the contamination of the air/water pipes can spread to the entire unit waterline [6, 8]. The latter can then constitute a secondary reservoir of micro-organisms which are aggregated in biofilms. These biofilms could potentially grow from micro-organisms that come from the mouth of patients, but also from micro-organisms that come from the general water supply network. Far from being trivial, the contamination of a unit waterline can lead to serious infections, and even death of patients [21]. Therefore, we are dealing with a real objectivity of the infection risk, which should be seriously integrated in the context of the safety of the procedures and in the management of this risk [22].
If the contaminated HP does not follow an adequate treatment, it can then become a source of cross-infection endangering the health of the following patients and the health of the healthcare team by exposing them to an increased risk of infection [5, 6, 14, 19, 20]. Contamination of HP can be of various kinds : many pathogens were found into the HP such as hepatitis B virus [13], or Pseudomonas spp and Staphylococcus aureus [19]. A mathematical modeling conducted by the Institut de Veille Sanitaire (InVS) in 2009 shows that each year in France, the neglected treatment of HP would be responsible for 200 contaminations by the virus of hepatitis B, 2 contaminations by the virus of hepatitis C, and one by the HIV [11].

To expose patients to this infectious risk while there are ways to minimize it, including a correct treatment of the HP, is ethically unacceptable [2, 5, 23]. In order to meet our professional and moral commitments, and to be in good standing with the regulations concerning the treatment of semi-critical medical devices, it is necessary, essential and mandatory to sterilize the HP between each patient [2, 3, 4, 5, 8, 9, 10, 14, 15, 17, 18, 24, 25, 26, 27]. However, only cleaned instruments can be candidates for an efficient sterilization. To ensure a complete and efficient sterilization of the HP and any other instrument, and to ensure that the steam can reach the whole surface that has to be sterilized, the instruments must previously be cleaned [3, 4, 14, 20, 21, 28, 29, 30]. Many studies also emphasize this point: it is essential that HP have benefited from an optimal cleaning to ensure the effectiveness of their sterilization [10, 12, 27, 32, 33, 34]. That is where difficulties appear. On one side, the external cleaning of the HP does not raise problems. On the other side, we know that the internal cleaning of the HP is best with using a machine compared to a manual cleaning [31]. But though, great difficulties remain to realize this cleaning effectively [22, 31, 35] mainly because of the complex internal architecture of the HP and the very reduced dimensions of the air/water pipes [22, 28, 3436].

Many manufacturers have tried to develop an automaton to perform a thorough cleaning of the HP, both external and internal. They were faced with the difficulty to develop such an automaton [31, 33, 37, 38], because residues still remain on the surfaces which should appear clean, even if the machine cleaning is more effective than the manual cleaning [31]. Moreover, it is difficult to assess the good internal cleaning of the HP, because they are mostly designed not to be dismantled. That means they are fragile and they are not designed to be dismantled on a regular basis otherwise than in a precautious and meticulous way. Literature also raises the question of a proven method to control the good internal cleaning of HP which is a problem concerning the HP that are not meant to be dismantled [15, 28, 35]. Indeed, the standards for the general requirements of washer-disinfectors performances [39] advocates a visual validation of the good cleaning of instruments. If this validation does not raise problems for full instruments, it is not the case for the hollow instruments, neither is it for the ones that should not be dismantled.

Objective :

The aim of this original study is to fill methodological gaps about the HP cleaning validation. This is reflected by the development of a validation protocol of the cleaning of the HP as complete as possible without being destructive, and its application with a washer-disinfector-lubricator-dryer dedicated to HP.

Materials and methods :

Tests have been thought for the operator to be able to visualize the inside of the HP. However, the majority of the HP used in a dental practice are not designed to be dismantled. Since the task is accurate and meticulous, the tests cannot be considered as a routine, and they participate in the originality of our work. The tests took place within two cycles according to the following protocol, after having performed control experiments:

1. Dismantle the PH (fig.3)

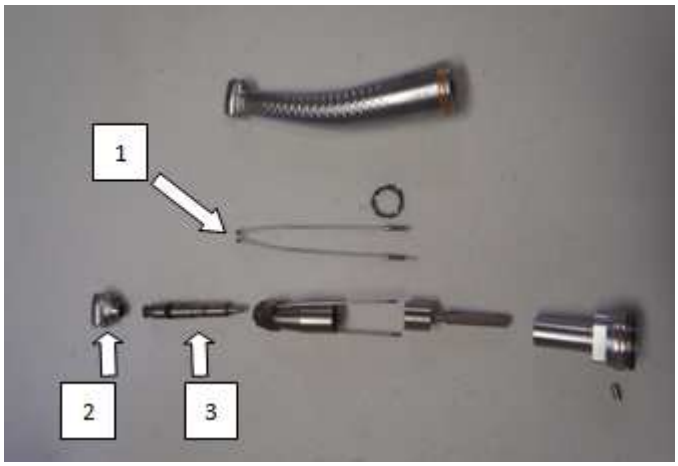

Fig. 3 : Dismantle of the HP

2. Stain the outside (body of the HP) and inside (air/water pipes, gears) using Soil Test®. Also stain the load racks (block support for the HP, sides of the tank). Soil Test® was chosen because of the good adaptability of the form in which it is presented to the protocol that is described, and its adequacy with biological fouling [40].

   The head of the HP is stained using a Soil Test® syringe (fig 4). The air/water pipes are stained using a Soil Test® syringe whose mouthpiece is suitable for their diameter. The pressure on the plunger of the syringe will be made until the Soil Test® comes out by the other side of the pipe (fig. 5).

Fig. 4 : soiling of the inside of the head of the HP

Fig. 5 : soiling of the inside of the air/water pipes

3. Reassemble the HP

4. Connect the HP in the automaton (fig. 6), run a cycle with inactivation of the disinfection phase (as specified in the standard NF EN ISO 15883-1 for washing tests [39])

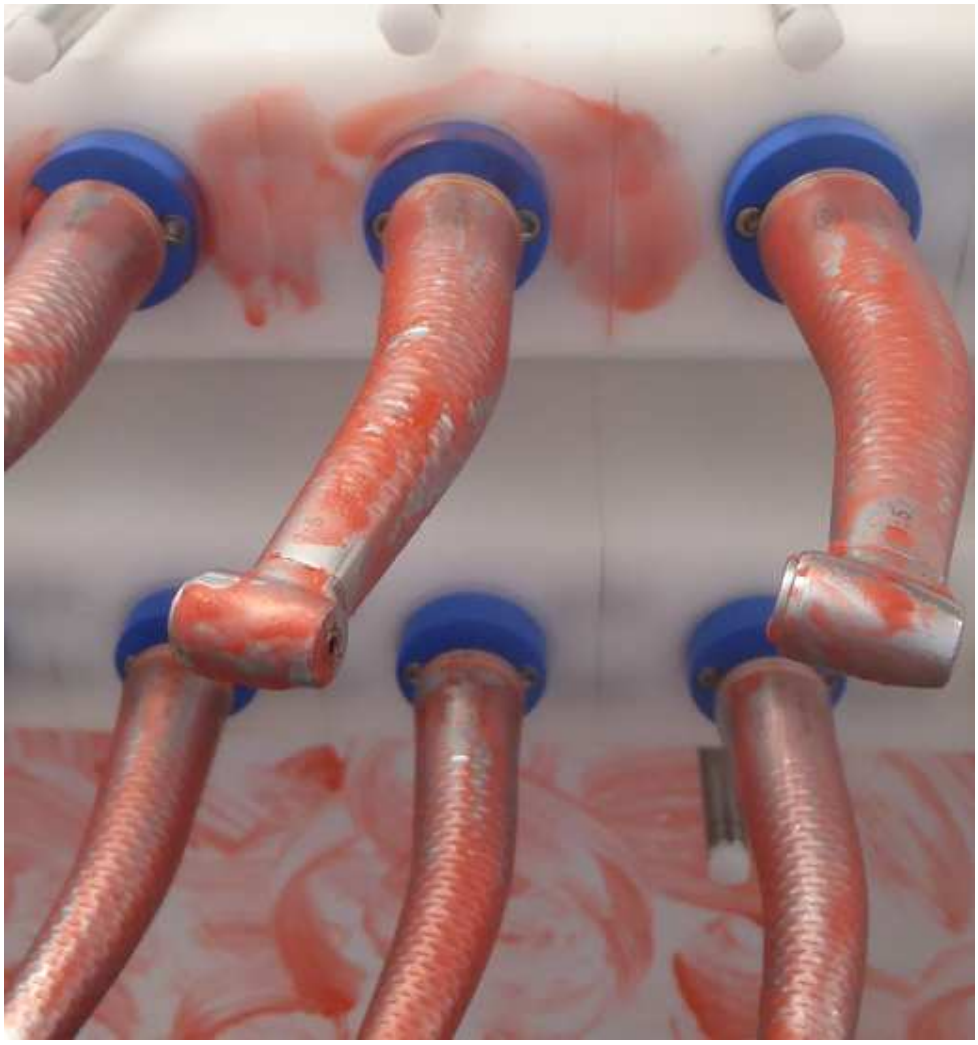

Fig. 6 : connection of the soiled HP in the automaton. Soiled load racks and tank sides

5. Visually observe the presence / absence of soiling residues on the outside of the HP. Perform a test with Ninhydrin (CleanTrace®) in case of absence.

6. Dismantle the HP

7. Visually observe the presence / absence of residues of soiling. Push a 0.7mm diameter nylon thread through the air/water pipes over a clean plate. The thread is adjusted to the diameter of the pipe and will displace any eventual residual soiling that will be observable upon its release. Observe the presence of soiling on the end and/or on the body of the thread under the microscope. Observe the presence of deposits on the plate. Perform a test with Ninhydrin (CleanTrace®) on the thread in case of absence.

8. Reassemble the HP / **or** start again at point 2. for a new cycle

Control experiment :
Control tests were performed on an artificially soiled HP according to the steps described in this protocol, but without the cleaning step. Then the same steps were followed on a HP which was naturally soiled during a normal use in dental surgery practice and treated routinely in a dedicated automaton.

First cycle :
The first tests cycle was carried out on 6 universal-fitting HP (valid for WH®, BienAir®, MicroMega®, Mont Blanc®...). The washer-disinfector-lubricator-dryer used was the Bioda® from the brand vr2m. The cleaning cycle has been set to 15 minutes, using Deconex® as detergent at 8mL per liter of water. During the start-up of the cycle, 2 HP were turning on themselves, showing an absence of rotation of the internal bearings. This was confirmed by the examination of the engines of the support brackets that were defective.

Second cycle :
The second cycle was carried out on the same 6 universal-fitting HP, previously cleaned before being soiled again using Soil Test®. The washer-disinfector-lubricator-dryer used was the Bioda® from the brand vr2m. The cleaning cycle has been set to 4 minutes, using the VR-DYME® as detergent, which are the product and the assays proposed by the manufacturer during the current cycles of the Bioda®. The engines were changed and during the cycle, all the HP have shown in internal rotation.

Results :

Control tests :
The control tests confirm the presence of Soil Test® in the air/water pipes and validate the relevance of pushing the nylon thread through these, because the thread highlights the internal staining of these pipes (fig.7). The control test on the PID stained during a normal use and treated in routine shows residues inside the head of the HP (fig.1) and inside the air/water pipes (fig. 8). Ninhydrin tests have been performed by swabbing the thread in both situations, and the results were positive (turning to purple) (fig. 9).

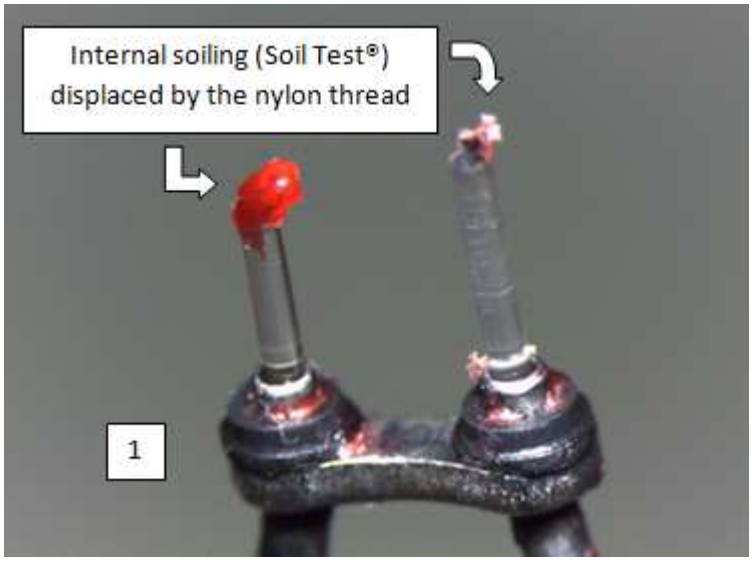

Fig. 7 : highlighted interest of pushing a nylon thread through the air/water pipes

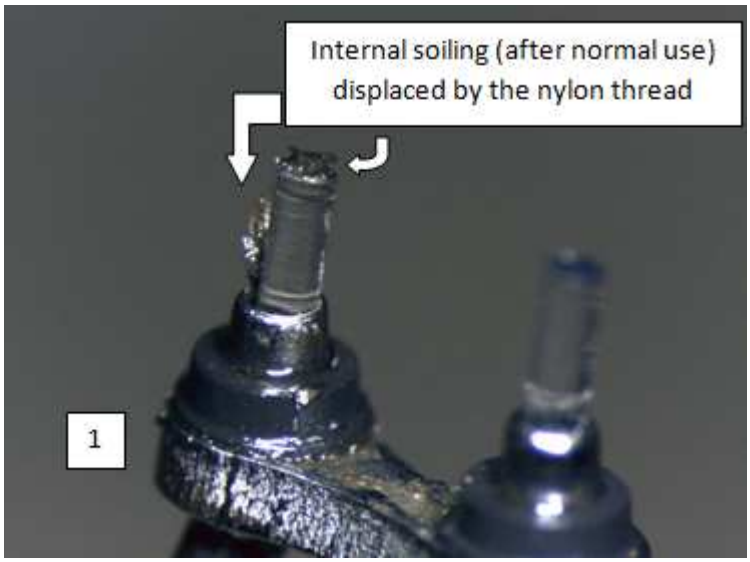

Fig. 8 : highlighting soiling from the inside of the air/water pipes after normal use

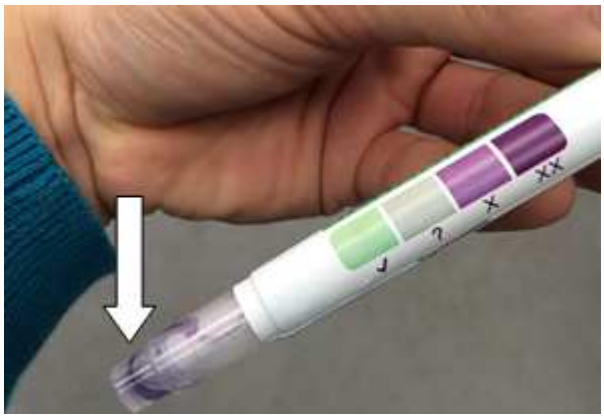

Fig. 9 : positive ninhydrin test

First cycle :

At the end of the washing cycle (15 minutes), the HP have been disconnected from the Bioda® and handled with gloves. Visual examination showed a lack of residual soiling on the body of the PID as well as on the load racks (fig. 10).

Fig. 10 : Clean external surfaces of the HP and load racks

After having dismantled the HP, the areas likely to be soiled in a usual dental surgeon's practice appeared to be clean on the 4 HP for which the motor worked properly. The nylon thread in the pipes showed no deposit on the thread itself, or on the plate over which it was conducted (fig. 11).

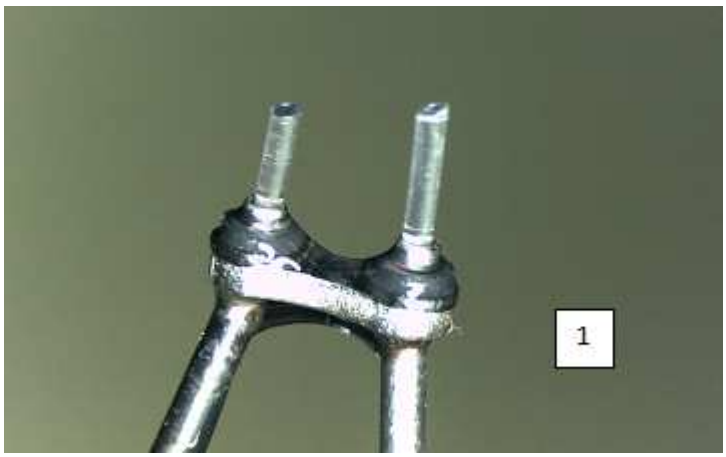

Fig. 11 : highlighted cleanliness of the air/water pipes of the HP

Ninhydrin tests were performed on these soilless surfaces, and were negative.
Concerning the 2 HP which had not been put into an internal rotation, a residual soiling was apparent on the half of the surface of one gear, the other half appeared clean. This is shown on fig. 12 through the blue marker and demonstrates the importance of the internal rotation of the HP during the cleaning cycle.

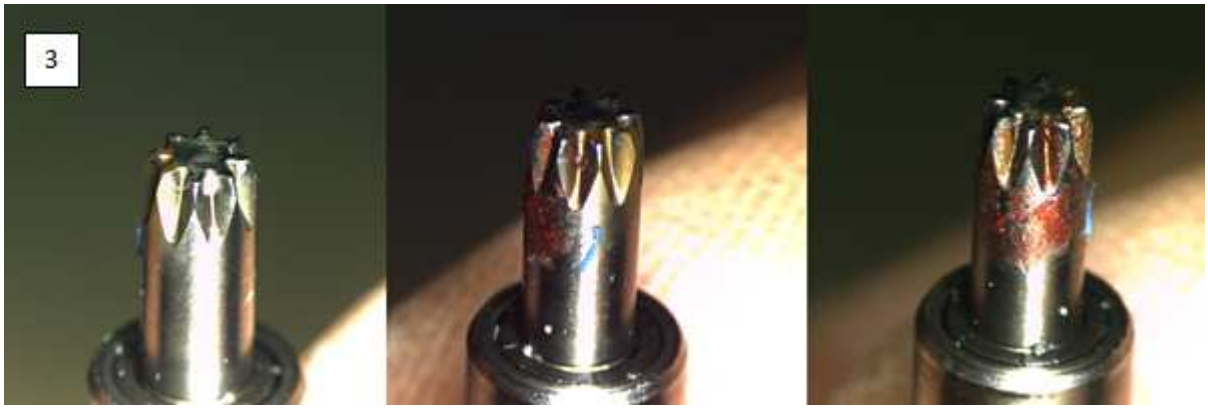

Fig. 12 : highlighted soiling on the half of the same gear, due to the non-internal rotation of the HP

Second cycle :
At the end of the washing cycle (4 minutes), the HP have been disconnected from the Bioda® and handled with gloves. Visual examination showed a lack of residual soiling on the body of the PID as well as on the load racks.
After having dismantled the HP, the areas likely to be soiled in a usual dental surgeon's practice appeared to be clean (fig. 13). Ninhydrin tests were performed on these soilless surfaces and were negative (fig. 14).

Fig. 13 : clean HP head inner surface

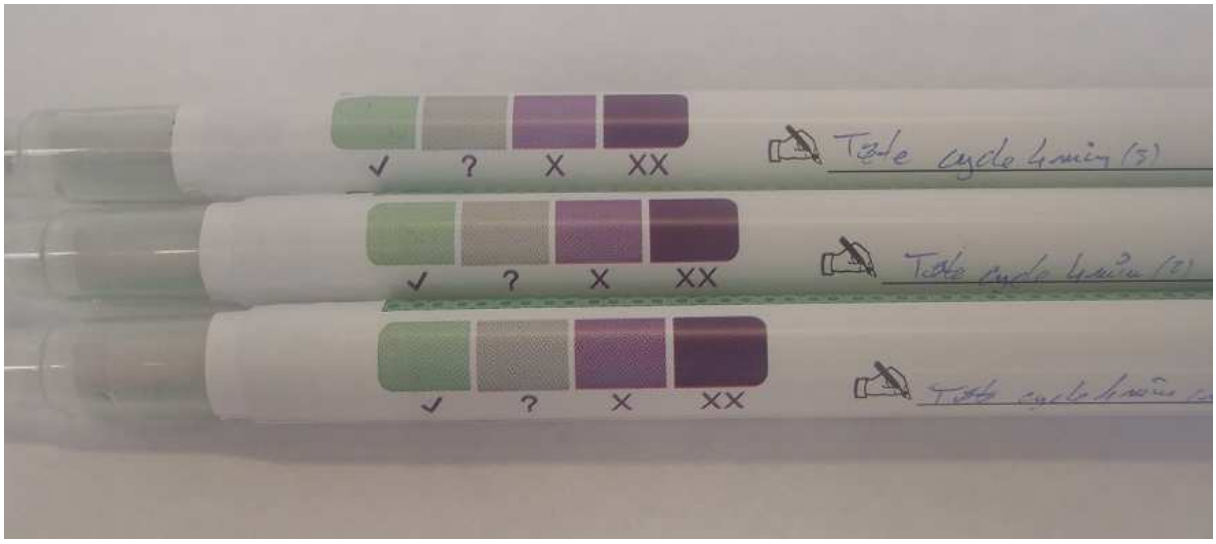

Fig. 14 : negative results of Ninhydrin tests performed inside the heads of the HP

The nylon thread in the pipes showed no deposit on the thread itself, or on the plate over which it was conducted. Ninhydrin tests were performed on the nylon threads, and the results were negative (fig. 15).

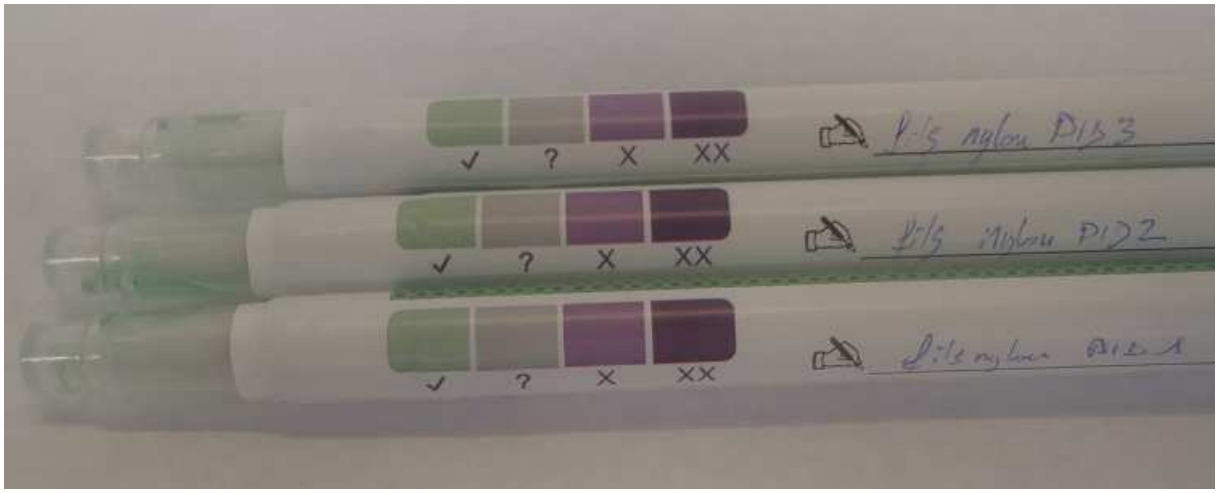

Fig. 15 : negative results of Ninhydrin tests performed on nylon threads that went through the air/water pipes

Discussion :

This protocol is novel and original because it is the first protocol ever proposed to control the internal cleaning of the HP without having to destroy them. Such a method of evaluation can easily be used in the initial steps of an operational qualification or a qualification of the performance of a washer-disinfector-lubricator-dryer. Indeed, the standards for the general requirements of washer-disinfectors performances [39] demands a primary validation of the cleaning of the HP using an artificial soiling before their use in an actual practice. Until now, this validation was not feasible, or at least not applicable to the internal surfaces of the HP.

In only two cycles, the tests show the effectiveness of the cleaning that offers the Bioda®. Indeed, the HP and the load racks appear clean after the two cycles (15 minutes, and even after a shorter cycle of 4 minutes). Disassembly also shows a cleaning efficiency in the visible areas beneath the body of the HP and *a priori* into the air/water pipes too. Finally, the results of these tests are confirmed by the absence of reaction with Ninhydrin.

The tests also show that it is absolutely essential that the HP are put in internal rotation (as it is when they are used by the dental surgeon as he is working in the patient's mouth) during the cleaning process. Indeed, a lack of internal rotation, as it was the case for 2 HP in the first cycle produces an incomplete cleaning because fluids cannot reach all the surfaces.

This validation method is consistent with the initial applications of standard NF EN ISO 15883 concerning the cleaning of the instruments. However, some limits should be mentioned : since the final validation of the cleaning is based on a visual assessment, it is impossible to scientifically ensure the good cleaning inside the parts of bearing without being destructive, because they are not removable and are not accessible to swabs or nylon threads. The protocol appears to be meticulous to achieve and the manipulations are very delicate, because they were made on HP which are not designed to be disassembled and removed items are very easily breakable. It may very well find its place into the initial qualifications of an automaton dedicated to the treatment of the HP, but it seems hardly applicable to periodic requalification of these automata in a routinely dental practice.

Other tests may be performed in the future in order to strengthen the relevance of this method and optimize the automaton washing time.

Conclusion :

HP are reusable semi-critical medical devices. Their use in dental procedures generates soilings and contamination, through the backflow phenomenon inter alia, on their outer surface but also on their inner surface and in the narrow air and water pipes. This initial contamination can become the source of cross-contaminations. Also, the good treatment of the HP is a moral and regulatory obligation, and has to follow a sterilization process between each patient, preceded by an effective cleaning.
The validation method of the cleaning of the HP presented in this article clearly fits with an approach of improving the safety of practices and the management of the risk of infection in dental care procedures, both for patients and for the healthcare team. It fills the methodological gaps concerning the cleaning of the HP. Although its implementation is

meticulous and accurate, it allows at lower cost to assess the HP cleaning that offer dedicated washer-disinfectors. Regarding the tests performed in this study, the Bioda® from the brand vr2m shows a demonstrated external and internal cleaning efficiency of the HP.

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