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From the Field

Evaluation of a method for pre-treatment of reusable medical devices based on pressurized sodium bicarbonate (BICARmed®)

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Summary

The persistence of organic soils on reusable medical devices (MD) can lead to the proliferation of microorganisms within biofilms with the risk of an iatrogenic event for the patient. The BICARmed® permits the pretreatment of MDs by the use of a pressurized jet of sodium bicarbonate. The objective of this study is to evaluate the effectiveness of the BICARmed® treatment on reusable MDs.

For this, soiled instruments are included in 3 different groups:

- Group A: washer-disinfector (WD) → OneLife DETECT® → BICARmed® → WD
- Group B: BICARmed® → WD → OneLife DETECT → BICARmed® → WD
- Group C: WD → OneLife DETECT → WD
- Group D: BICARmed® → WD → OneLife DETECT → WD

The residual contamination after washing of each instrument is estimated by a score using the OneLife DETECT method. The calculated means of contamination rates are compared statistically by the reduced deviation test (Z test).

A total of 614 instruments were included in group A (series 1: n = 254; series >1: n = 360), 467 in group B (series 1: n = 162; series >1 n = 305) and 370 in group C. The average contamination rates between group A series 1 (m = 136.5), group B series 1 (m = 135.3) and group C (m = 155.4) are equivalent (p = 0.048; = 0.86; = 0.97, α = 5%). On average, instruments are more contaminated in group A series >1 (m = 98.5) compared to group B series >1 (m = 15.4) (p = 7.7, α = 5%). The mean contamination rates are significantly lower in group B between series 1 and series> 1 (p = 6.24, α = 2.5%).

In conclusion, the results show the effectiveness of the BICARmed® treatment in the pretreatment of reusable MDs. However, this method of pretreatment offers a real benefit when it is performed regularly.

Keywords

- reusable medical devices
- pretreatement
- sodium bicarbonate
- BICARmed®

Introduction

The cleaning of reusable medical devices (RMDs) is a step carried out prior to packaging and sterilization. This step follows predisinfection and is aimed at the removal of contamination from the RMDs to the level required for further reprocessing and for the intended use [1]. According to standard EN 15883-5, cleaning must assure a contamination level of < 3μg/cm² instrument [2]. The persistence of organic soils on the RMDs can lead to the survival of microorganisms in biofilm, posing a risk to the patient. A study conducted earlier by the Chambéry Reprocessing Unit for Medical Devices (RUMED) confirmed the persistence of soils following cleaning in a washer-disinfector [3]. The surgical instruments most commonly affected were from gynaecology, dentistry, ear, nose and throat, visceral surgery and orthopaedics.

It is sometimes difficult to obtain a clean medical device without manual precleaning, swabbing or even ultrasonic cleaning. With BICARmed®, RMD pretreatment can be carried out using a pressurized jet of water or sodium bicarbonate. To that effect, the instruments to be treated are placed in a sealed enclosure and then cleaned manually by a reprocessing agent using the pressurized jet (Fig. 1). One of the main advantages of bicarbonate is that it is not harmful to humans or the environment.

Hence, the aim of our study was to evaluate the effectiveness of BICARmed® for precleaning RMDs compared to conventional reprocessing in a washer-disinfector.

Fig. 1: The mechanical action is ensured by the impact of sodium bicarbonate molecules with a calibrated granulometry (400 microns) and will allow the elimination of stains without causing abrasion of the surface of stainless instruments.

Fig. 2: Detection of residual soils after cleaning (OneLIFE DETECT®)

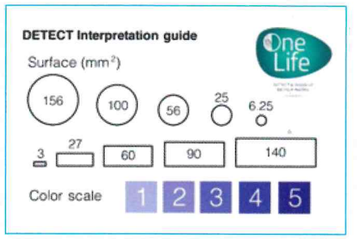

Fig. 3: OneLIFE DETECT® interpretation guide: colorimetric scale and surface area measured

Materials and method

The instruments originating from the operating rooms (ORs) were first predisinfected in a 0.5% solution of Aniosyme X3 and then transported to the RUMED. The surgical sets selected for the study were from the surgical specialties most susceptible to residual soils: dental extractions, curettage and tonsillectomy. To determine the effectiveness of BICARmed® compared with conventional reprocessing, the RMDs were divided into four arms: A, B, C and D, as described in Table 1. Automated cleaning was conducted in Belimed® WD 290 washer-disinfectors. The detergents used were Mediclean forte® 0.4% for standard cycles (instruments, coelio, etc. and Septoclean® 1% for prion cycles. The duration of the cleaning step was 10 minutes for each qualified cycle according to EN 15883.

The OneLIFE DETECT® detection method is suitable for semi-quantitative colorimetric determination of the presence of residual proteins. Visual inspection showing the presence of blue stains on an instrument highlights the persistence of proteins after cleaning (test sensitivity: 2 μg/cm²) (Fig. 2). For each arm the residual contamination scores per instrument after treatment were estimated using a score obtained with the colorimetric scale of the OneLIFE DETECT® method (Fig. 3). The intensity of staining is proportional to the protein concentration. This intensity was rated on a colorimetric scale and then multiplied by the surface area of the stain to obtain a score. Each surgical set included in the study was identified and followed up.

The term "restore to original (blank) state" is used when the instruments are precleaned with BICARmed® after marking the soils blue, thus permitting targeted cleaning of each soiled instrument. The same set, after complete reprocessing and

Table 1: Details of instrument treatment in the different arms

Arm	A	B	C	D
Aim	Effect of WD: ▪ 1st inclusion (series 1): on soiled and encrusted instruments ▪ Inclusion n+1 (series n+1): on instruments after use and restoration to original state	Effect of BICARmed® : ▪ 1st inclusion (series 1): On soiled and encrusted instruments ▪ Inclusion n+1 (series n+1): on instruments after use and restoration to original state	Effect of LD on soiled and encrusted instruments	Effect of BICARmed® on soiled and encrusted instruments without restoration to original state
Reprocessing steps	WD → OneLIFE DETECT® → BICARmed® → WD	BICARmed® → WD → OneLIFE DETECT® → BICARmed® → WD	WD → OneLIFE DETECT® → WD	BICARmed® → WD → OneLIFE DETECT® → WD

reuse in the OR, can be included once again in the study. The sets belonging to arms A and B were restored to their original state following pretreatment with BICARmed® and could therefore be randomly included again in one of the two arms. The sets in arms C and D were used exclusively in these arms. For the purpose of statistical analysis the instruments in arms A and B were subdivided into two groups: instruments included for the firsttime in the study (series 1) and those included several times (series n+1) and which therefore were restored to their original state after pretreatment with BICARmed®. This subdivision within the arms makes it possible to identify the cumulative effect of sodium bicarbonate treatment. The treatment of RMDs with BICARmed® and estimation of the contamination score for each instrument were performed by the same agent. The mean contamination scores calculated were statistically compared using the reduced deviation test (Z test).

Results

A total of 739 instruments representing 23 surgical sets were included in the study: in total 416 instruments in arms A and B, 243 in arm C and 80 in arm D. These 739 instruments were visually inspected 1691 times (Table 2).

The mean contamination scores per instrument are presented in Table 3. The mean contamination scores between arm A series 1 (m = 136.5), arm B series 1 (m = 135.3) and arm C (m = 155.4) did not differ significantly (p = 0.048; = 0.86; = 0.97, = 5%).

For the n+1 series, the instruments were on average more contaminated in arm A (m = 98.5) compared to arm B (m = 15.4) (p = 7.7, = 5%). The mean contamination scores were significantly reduced in arm B between series n+1 and series 1 (p = 6.24, = 2.5%). By contrast, it is not possible to conclude that the mean contamination scores were lower in series n+1

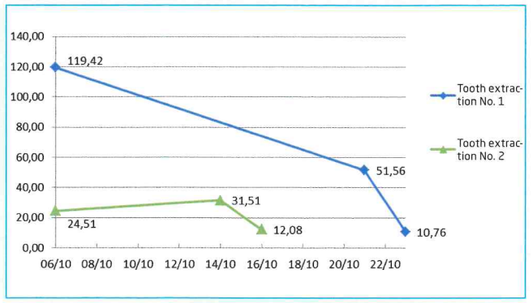

Figure 3: Follow-up of two surgical sets: progression of the contamination score over time temps

compared with series 1 in arm A (p = 2.18, = 2.5%), = 2,5%). The contamination scores were, on average, significantly lower in arms A and B series n+1 versus arm C (p = 3.31; = 10.02, = 2.5%).

Figure 4 shows the progression of the contamination score per instrument belonging to two surgical sets after having been used several times. For the tooth extraction set No. 1, after its first inclusion on 06/10 in arm D, the set was used five times in the OR and conventionally reprocessed in the RUMED five times before being re-included in the study on 21/10. Between these two inclusions, a decrease in the contamination score from 119.42 to 51.56 was observed. The set was used again in the OR and then included a third time on 23/10, again lowering the contamination score to 10.76. In the case of the tooth extraction set No. 2, between the two inclusions in arm D on 6/10 and 14/10, the surgical set was used in the OR and then reprocessed conventionally in the

Table 2: Effects on instruments as per reprocessing arms

Arm	A		B		C	D
	Series 1	Series n+1	Series 1	Series n+1		
Instruments	416				243	80
Visual Inspection	254	360	162	305	370	240

Table 3: Mean contamination score per instrument for each reprocessing arm

Arm	A		B		C	D
	Series 1	Series n+1	Series 1	Series n+1		
Mean contamination score per instrument	136.5	98.4	135.3	15.4	155.4	NA

Table 4: Comparison of mean contamination scores per instrument based on the reduced deviation table

Arm	A series 1	A series n+1	B series 1	B series n+1
A series n+1	$p = 2.18\ \alpha = 2.5\%$	NA	NA	NA
B series 1	$p = 0.046\ \alpha = 5\%$	NA	NA	NA
B series n+1	NA	$p = 7.7\ \alpha = 2.5\%$	$p = 6.24\ \alpha = 2.5\%$	NA
C	$p = 0.97\ \alpha = 5\%$	$p = 3.31\ \alpha = 2.5\%$	$p = 0.86\ \alpha = 5\%$	$p = 10.02\ \alpha = 2.5\%$

RUMED two times. The contamination score increased between these two dates. After using in the OR and a third inclusion, the contamination score decreased.

Discussion

A previous study carried out at Padua Hospital inspected the instruments before and after treatment with BICARmed® using electron microscopy. This demonstrated the effectiveness of this technique in cleaning the instruments. A team at Vittotorio Veneto Hospital compared the BICARmed® technology to conventional cleaning in a washer-disinfector for 57 instruments. The study concluded that only 42% of the instruments were truly clean after cleaning in a washer-disinfector compared to 98% with the BICARmed®. The mean residual protein level on five instruments was 26.5 μg after cleaning versus 1.48 μg after BICARmed® treatment [4].

The residual protein detection method used in our study is a semi-quantitative and sensitive method. It does not allow the interpretation of a rate in μg/cm2 of residual proteins according to the requirements of the EN 15883 standard, but by following up its variations it is possible to analyse or compare the effectiveness of a cleaning process. Consequently, it is not possible to define an acceptable target or limit value, but the presence of blue coloration after cleaning indicates a drawback or inadequacy of the cleaning process. The results of this study demonstrate the effectiveness of the BICARmed® technology for pretreatment of RMDs. However, this pretreatment method is only of real benefit when it is routinely carried out. The effectiveness of this process could not be demonstrated when it was first used on a complement of soiled and encrusted instruments. The results of series 1 of arms A and B compared to arm C, show that the contamination scores were not significantly different between these three groups. By contrast, the BICARmed® method was immediately effective against recent soils, since the contamination scores of series n+1 of arm B (15.4) are significantly lower than those of arm A (98.4) (Table 4). Besides, it can be observed that the BICARmed® does not systematically achieve a zero contamination level. When using this technology "blindly", i.e. without prior marking of the soils, it was not possible to obtain an exhaustive result, although it was far superior to the use of the washer-disinfector alone.

The results of arm D were not sufficiently numerous to reach a definitive conclusion. However, it appears that with routine and repeated use of this method it is possible to lower the contamination score. This concept seems to be confirmed by the follow-up of the two tooth extraction sets. When the BICARmed® is used in each reprocessing process in the RUMED, recent soils that had not become encrusted because of repeated and insufficient reprocessing were more easily removed.

Conclusion

The BICARmed® technology is suitable for pretreatment of RMDs based on the use of pressurized sodium bicarbonate. This method proved to be effective in underpinning cleaning in a washer-disinfector by reducing the level of contamination on surgical instruments harbouring soils after use. Repeated and systematic use in each reprocessing cycle in the RUMED appears to be the chief determinant of the benefit of BICARmed®, because occasional use of this procedure did not show any significant improvement in the cleanliness of soiled and encrusted RMDs following cleaning. This novel pretreatment procedure perfectly meets the quality requirements for reprocessing reusable medical devices. The next steps will be to determine the organizational measures needed to incorporate this method into our daily practices.

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