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Clinical Evaluation of a Chairside Amalgam Separator to Meet Environmental Protection Agency Dental Wastewater Regulatory Compliance

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Clinical Relevance

US dental practices that routinely place and remove amalgam restorations are now required to use an amalgam separator with ≥95% efficiency. This independent study evaluated and characterized the performance of a chairside amalgam separator, demonstrating that minimum standards for compliance can be met.

SUMMARY

Objectives: The aim of this study was to evaluate the performance of a commercially available chairside amalgam separator (CAS) in a clinical setting in which a relatively high number of amalgam restorations are placed. Performance parameters investigated included service life, amalgam collected, mercury concentrations in effluent, and solids retention efficiency.

Methods and Materials: CASs were tested per International Organization of Standardization (ISO) 11143:2008 prior to installation in a military dental treatment facility and after removal from service (n=4) in order to confirm compliance with the recently enacted United States Environmental Protection Agency (EPA) Effluent Limitations Guidelines and Standards for the Dental Category. During the units' time in service, biweekly effluent grab samples were collected from the high-

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volume evacuation system of each chair (n=6) and analyzed for total mercury concentration by inductively coupled plasma mass spectrometry (ICP-MS). The mean total accumulated solids at the end of service life (n=6) was determined for potential design optimization. The service life expectancy in a military dental treatment facility was determined in terms of calendar and workdays. Procedural data were collected to determine the daily mean number of amalgam surfaces placed during the service life of each chairside amalgam separator (n=9).

Results: The CAS evaluated met minimum EPA compliance requirements when used in a military dental treatment facility. The solids removal efficiency at the end of service life was 99.82% ± 0.14% (n=4). The mean service life (n=8) was 131.6 ± 45.1 calendar days (67.1±37.6 workdays). Effluent mercury concentrations ranged from 0.05 to 11.93 mg/L. Total solids accumulated in each CAS (n=6) at the end of service life was 195.4 ± 63.4 g. The mean number of amalgam surfaces placed per workday during the service life span of each CAS was 8.4 ± 1.4.

INTRODUCTION

Dental amalgam has been used as a restorative material for over 150 years, though use has decreased since the 1970s.[1] To this day, however, many dental professionals and patients still prefer amalgam in some cases over other restorative materials because of its durability and relatively low cost. Additionally, many serviceable amalgam restorations are in place today that will likely need replacement sometime in the future.[1] Despite the controversy surrounding amalgam restorations, the American Dental Association, US Food and Drug Administration, and World Health Organization are among many scientific organizations that have released consensus statements, literature reviews, and rulings, affirming the safety and effectiveness of dental amalgam for patient use.[2-4] While the mercury in amalgam is stable under the conditions present within the oral cavity, its release in dental wastewater poses an environmental hazard if improperly managed. The international concern over anthropogenic sources of mercury and mercury-containing compounds released into the environment culminated in the Minimata Convention on Mercury United Nations Treaty, signed by over 100 nations, including the United States, which did so in November 2013. The Minimata Convention went into effect on August 16, 2017, with the aim to protect human health and the environment by reducing mercury release.[5] In roughly the same time-frame, dental amalgam waste generated by dental offices has become the focus of environmental regulations by the Environmental Protection Agency (EPA).[6] The reduction of anthropogenic mercury released to the environment has recently become a topic of international scope and policy.

According to the EPA,[6] amalgam containing wastewater from dental offices is the main source of Hg loading to publically owned treatment works (POTWs). Concentrations of Hg in dental wastewater can range from 100 to 2000 mg/L.[7,8] The EPA's most recent estimate is that 5.1 tons of Hg and 5.3 tons of other dental amalgam metals (ie, Ag, Cu, Sn, and Zn) are collectively discharged to POTWs annually in the United States.[6] The Hg discharges from dental offices have been attributed to approximately half of total Hg loading to POTWs in the United States.[9]

Advancements in filtration technology, including amalgam chairside traps capable of capturing amalgam scrap and large particles >700 μm,[10] as well as amalgam separators capable of capturing smaller particles,[11] have significantly reduced Hg loading to POTWs. Amalgam wastes are typically composed of metal scrap ranging from <1 μm to 1 mm in diameter.[11] Most amalgam scrap is captured by in-line chair side amalgam traps, which prevent vacuum line blockage by removing the larger tooth fragments and dental material waste particles.[11] The remaining smaller amalgam particles, the majority of which are <100 μm,[11] are usually removed from the dental wastewater by an amalgam separator using filtration, sedimentation, centrifugation, or a combination of these methods, before the wastewater is released into POTWs.[6] The remaining amalgam particulate that is too fine to be removed by standard separation methods is passed on to the POTWs where it is extracted as sewage sludge, which may be discarded in landfills, incinerated, or introduced to agricultural land as fertilizer.[6] Incineration releases gaseous Hg into the atmosphere, where it is adsorbed onto the atmospheric aerosol and subsequently precipitated.[12] Whether leached from landfills or crop fields, or precipitated from the atmosphere, mercury eventually finds its way into the water table.

Inorganic Hg, transmitted hydrologically from immediate catchments to wetland and aquatic environments, is gradually converted to organic Hg compounds, such as methylmercury (MeHg).[12] In the case of MeHg, the organic Hg compound is released into water and biomagnified in algal cells or benthic periphyton, increasing concentration by a factor of 10^4 to 10^6.[13,14] As MeHg is transmitted through the food chain to higher-level organisms, it accumulates within the tissue of the consumers. Thus, MeHg concentration is magnified across trophic levels. Biomagnification increases MeHg levels by a factor of two to five from one trophic level to the next and are highest in piscivorous fish, birds, and mammals.[14-16] Environmentally significant concentrations of MeHg have been observed in dental effluent samples collected from two different clinics in which amalgam restoration removals and placements were performed. The reported MeHg levels were 8.26 μg/L for a 30-chair facility and 26.77 μg/L for a 107-chair facility,[17] considerably higher than the recommended freshwater criteria maximum concentration for MeHg in ambient waters (1.4 μg/L).[18] To minimize toxic effects to wildlife and humans alike, it is of the utmost importance to minimize anthropogenic release of Hg, including that which is introduced through dental waste into POTWs.

In 1991, the US Naval Institute for Dental and Biomedical Research (NIDBR), in collaboration with the American Dental Association, began evaluating the solids removal efficiency (SRE) of commercially available amalgam separators in order to mitigate Hg discharges from Navy dental treatment facilities (DTFs). NIDBR then founded a mercury management program that developed pretreatment systems for amalgam process wastewater. In 2001, NIDBR began a global effort to install and monitor pretreatment systems in Navy DTFs to ensure compliance with local and international discharge limits. The NIDBR Mercury Abatement Program became the Navy's lead agent for testing and evaluating pretreatment systems for Hg mitigation in wastes from DTFs. One pretreatment device, a filtration-based chairside amalgam separator (CAS), was developed by NIDBR in 2008 as a relatively low-cost alternative or addition to centrally located pretreatment systems.[19] NIDBR's original CAS featured a replaceable polypropylene filter element with a nominal pore size of 0.5 μm, which demonstrated 96.8% SRE when tested per International Organization of Standardization (ISO) 11143:2008 protocols.[19,20] Further development of the original NIDBR CAS concept was continued at the Naval Medical Research Unit San Antonio, where the Navy Mercury Abatement Program continues to test heavy metals control devices and provide guidance on CAS installation and maintenance to DTF personnel. The most recent version of the NIDBR CAS concept is commercially available as the DD2011P (Dennis J. Duel & Associates, Mundelein, IL, USA).[21] This model has been certified per ISO 11143:2008[20] test methods for 99.6% SRE and is currently in use in several Navy DTFs (Figure 1).

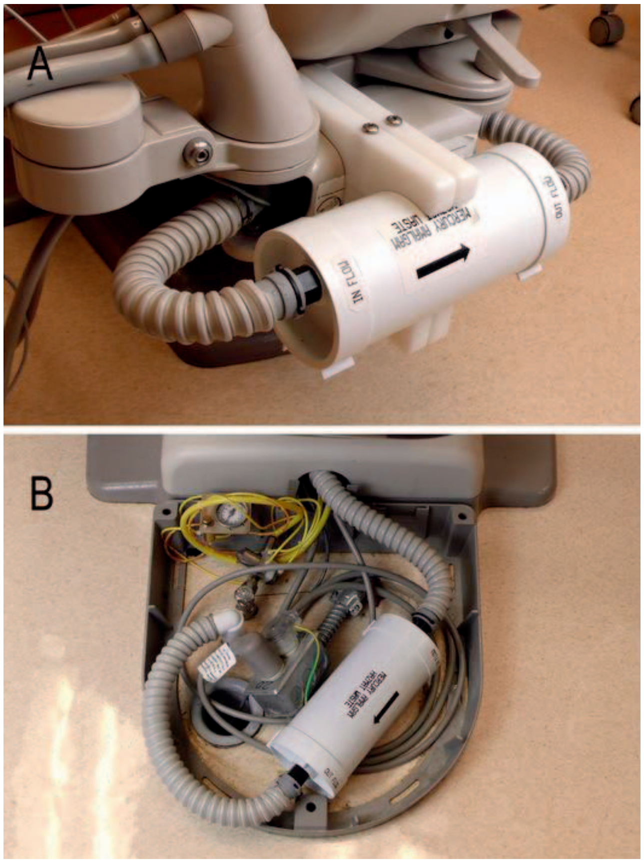

Figure 1. *A typical installation of the DD2011P chairside amalgam separator (white cylinder) on the rear support link of an A-Dec 500-Series dental chair (A). This particular installation makes use of the optional mounting brackets (white clamps with screws). An alternative installation (B) in which the separator is contained within the floor box under the chair.*

In order to reduce the discharge of Hg-containing dental amalgam to POTWs, the EPA published the final rule of the Effluent Limitations Guidelines and Standards for the Dental Category under 40 Code of Federal Regulations Part 441 with the effective date of July 14, 2017. Dental offices that discharge to POTWs must demonstrate compliance by July 14, 2020. The rule mandates the installation of dental amalgam separators that meet ISO 11143:2008[20] requirements of ≥95% SRE as a pretreatment standard for amalgam process wastewater. Existing sources (ie, dental offices operating before July 14, 2017) must submit a one-time compliance report to their respective control authority no later than

October 12, 2020. New sources (ie, dental offices operating for the first time after July 14, 2017) must submit said compliance report no later than 90 days after the wastewater is first discharged to POTWs. The rule exempts mobile units, as well as practices in which amalgam restoration placement and removal are not typically performed, including the exemption of practices limited to the specialties of oral pathology, oral and maxillofacial radiology, oral and maxillofacial surgery, orthodontics, periodontics, and prosthodontics. With the combination of these new pretreatment standards preceding POTW loading, EPA estimates a reduction in POTW discharge of dental amalgam-sourced Hg to receiving waters from 1003 to 11 lb/y, as POTWs typically remove 90.2% of the Hg from the wastewater. The final rule will cost affected dental offices on average approximately $800 per year. The EPA projects the total annual cost of the final rule to be $59-$61 million.[6]

The primary goal of this study was to characterize the real-world performance of a CAS unit in a large military dental group practice, selectively evaluated on the chairs of providers who place a large number of amalgam restorations. Our secondary aim, after completion of and based on the analysis of chairside separator performance, was to propose possible avenues for future CAS design improvement.

METHODS AND MATERIALS

ISO 11143:2008 Solids Removal Efficiency Testing of CASs: Preinstallation

Prior to installation at the DTF (Budge Dental Clinic, Fort Sam Houston DENTAC, JBSA Fort Sam Houston, TX), quality assurance testing per ISO 11143:2008[20] was performed on one DD2011P CAS (Dennis J. Duel and Associates) to verify that the model could attain the minimum requirement of 95% SRE. Further, obtained SRE results were compared with documented certified testing laboratory results to evaluate internal quality assurance. CAS units from the same lot as the tested unit were then installed in the DTF for evaluation.

Service Life Evaluation of CASs in a Military DTF

CAS units were evaluated in a military DTF to determine service life expectancy under heavy use. Four general dentistry providers at the DTF were identified through review of production numbers in the previous 6 months as those who placed the highest number of amalgam restorations. Each provider operated on one or two chairs exclusively. In total, six chairs were selected for this study. CAS units were tare weighed, then installed on the six A-dec 500 dental chairs (A-dec. Newberg, OR, USA). The CAS units were left in place until the end of their service lives, while suction data, effluent samples, and amalgam use data were collected and assessed (see Figure 2). At the end of each unit's service life, it was replaced, and data collection for that unit was halted. The end of a CAS unit's service life was defined by its meeting one of three criteria: the high-volume evacuation (HVE) system no longer met the required vacuum of 6-8 inHg (as specified in the Unified Facilities Criteria (UFC) 4-510-01),[22] the DTF staff reported poor HVE suction, or one year passed since installation.

Clinical Procedural Data Collection

De-identified procedural data from individual providers for the one-year test period were collected at the end of the study. Procedures which utilized amalgam (recorded in the clinical database as 2017 Current Dental Terminology codes D2140, D2150, D2160, and D2161)[23] were tabulated. The collected data were used to calculate the average number of amalgam surfaces placed per workday per chair in the study, beginning with the date the CAS was installed and continuing through to the end of its service life. For providers 1 and 2, the rate was divided by two since those providers each performed the work on two dedicated chairs. Providers 3 and 4, however, each operated on a single chair; therefore, all procedures were attributable to their single respective chair. Providers performed all amalgam restorations with Valiant Ph.D. (Ivoclar Vivadent, Amherst, NY, USA), which contains 40% to 45% Hg per capsule.[24]

Effluent Sample Collection from HVE System/CASs

Effluent samples were collected from clinically installed CAS units (n=9) every 2 weeks for up to a 12-month period in order to characterize Hg concentrations in the effluent. Prior to effluent sample collection, sample containers, tubing, and connection fittings were cleaned per EPA standard test method guidelines.[25] Two sequential 1 L volumes of Ultrapure, Type 1 water (MilliporeSigma, St Louis, MO, USA) were aspirated through the HVE system of each of the six dental chairs and collected from the outlet of each CAS unit into borosilicate glass sample containers. From each 1 L flush, three 50-mL aliquots were prepared and preserved with Fisher

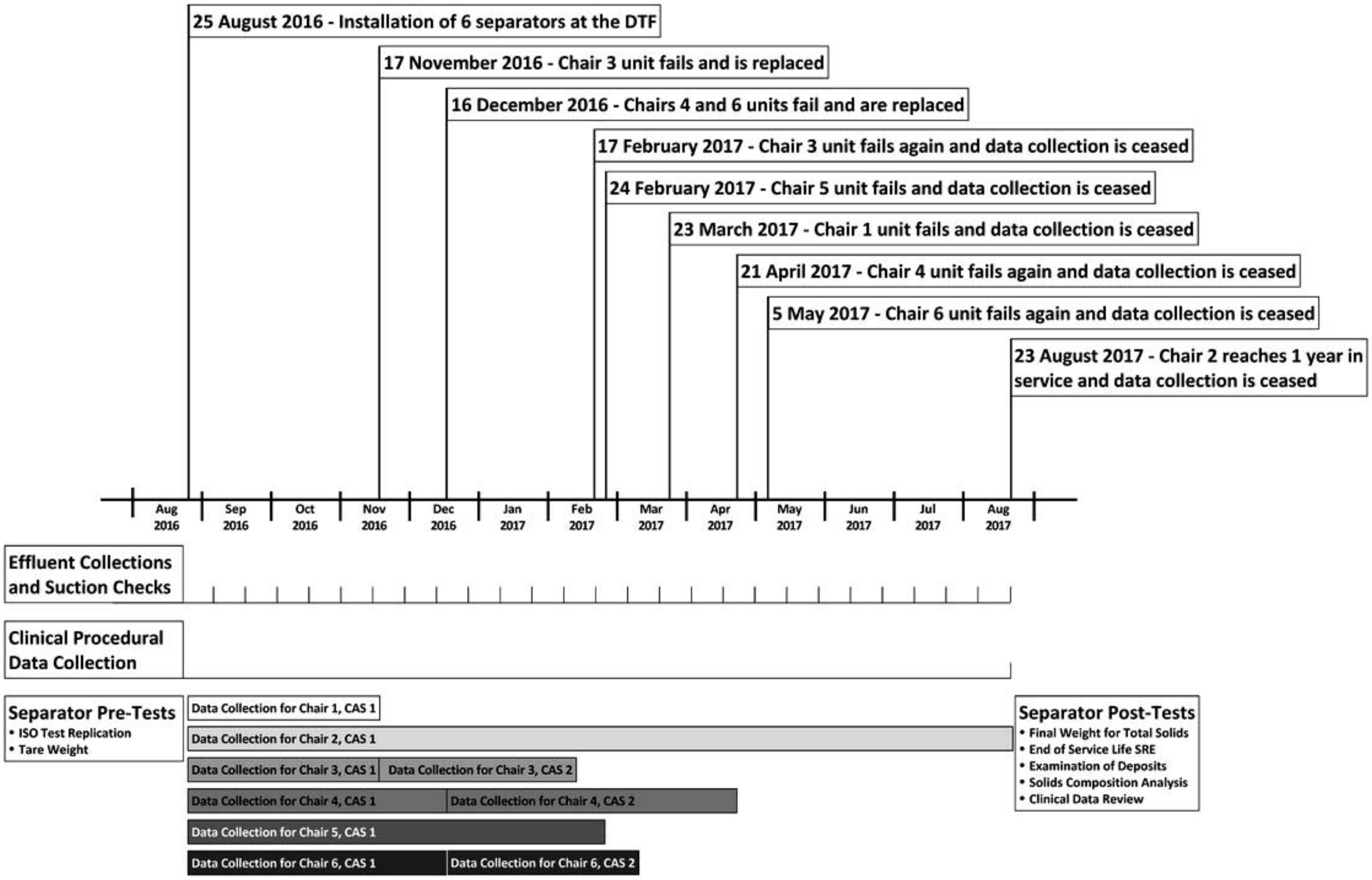

Figure 2. *Timeline of the study, beginning August 2016 and running 1 year. Installation of six DD2011P CAS units, including three units replaced during the study (total n=9), and the ends of all CAS service lives are indicated with the flags at the top of the figure. Effluent samples were collected and HVE system suction was checked at biweekly intervals from separators remaining on study, per the comb beneath the timeline. Clinical data were collected at the end of the study, after all separator data collection was terminated. Bars at the bottom of the figure indicate pre-study test elements, the data collection periods for each CAS, and post-study test elements.*

Chemical TraceMetal grade HNO_3 (Thermo Fisher Scientific, Waltham, MA, USA) per the EPA standard test methods indicated for aqueous total Hg and aqueous total metals.[26] Effluent sample collections were terminated when end of service life criteria were met as described earlier. To ensure compliance with UFC 4-510-01, vacuum levels through the HVE aspirator were measured with a Flowcheck vacuum meter (RAMVAC, Spearfish, SD, USA) immediately after each effluent sample collection.

Effluent Sample Preparation, Hg Analysis by Inductively Coupled Plasma Mass Spectrometry, and Statistical Analysis

CAS effluent samples were prepared for trace metals analysis by microwave-assisted acid digestion per EPA Method 3015A.[26] Aliquots were diluted in a digestion matrix comprised of 45 mL of Ultrapure, Type 1 water (MilliporeSigma), 4 mL of concentrated Fisher Chemical TraceMetalGrade HNO_3, and 1 mL of concentrated Fisher Chemical TraceMetalGrade HCl (Thermo Fisher Scientific). The diluted aliquots were then transferred to 75 mL perfluoroalkoxy vessels and digested in a MARS 6 microwave digestion oven (CEM Corporation, Matthews, NC, USA). Each digestion batch of analytic samples included quality control samples in accordance with EPA Methods 3015A and 6020B in order to evaluate laboratory performance and analyte recovery bias and precision.[26,27] Digests were analyzed for Hg concentrations on a Thermo Scientific iCAP Q inductively coupled plasma mass spectrometry (ICP-MS) instrument (Thermo Fisher Scientific) per EPA Method 6020B.[27] The Hg concentration means with standard deviations were calculated from the concentrations of the three aliquots collected from each HVE system effluent collection. Data distribution of the Hg concentration means was assessed for normality using the Shapiro-Wilk test. Statistical difference in the pooled mean Hg concentrations between the first and second HVE effluent samples was assessed using a Student *t*-test with the type I error rate (significance level) set at 0.05 ($\alpha=0.05$).

ISO 11143:2008 SRE Testing of CASs: Postinstallation

At the end of service life, four randomly selected CAS units recovered from the clinic were tested using ISO 11143:2008 §9.3.2.2 to §9.3.2.8[20] standards to ensure that the SRE remained above the minimum requirement of 95%.

Mass of Total Solids Accumulated by CASs After End of Service Life

The CAS units were evaluated for mass of total solids captured during each unit's service life using a modified version of Method 2540 B by Rice and others[28] The tare weight of each CAS unit was measured prior to installation in the DTF by drying at 103-105°C for 1 hour, cooling in a desiccator at 23°C, and then weighing the CAS. This desiccation and weighing cycle was repeated until a consistent weight (<4% difference) was observed. After each separator reached the end of its service life, the desiccation and weighing process was performed again to determine the final weight of each CAS. Total solids accumulated for each CAS were calculated by subtracting the tare weight from the final weight.

We determined the mass of amalgam that could theoretically occupy the fillable space of the CAS unit, defined as the space between the filter element and the housing, as follows: An unused CAS unit was opened by removing the end cap near the inlet with a drywall saw; it was then filled with 1 mm diameter glass beads. The beads were then poured out to measure the volume of the CAS unit and weighed to calculate the density. Finally, the volume of beads was multiplied by the density of amalgam test powder prepared from cured Tytin spherical dental amalgam (Kerr Corporation, Orange, CA, USA), which has a density of 1.694 g/cm^3 for the specific particulate composition described by ISO 11143:2008[20], in order to estimate the theoretical maximum amalgam mass that could occupy the CAS unit.

Composition of Solids Accumulated by CASs at End of Service Life

Six CAS units collected from the DTF at the conclusions of their service lives were randomly selected for solids composition analysis. Following removal, the CAS inlet and outlet ports were capped and the CAS units were transported to the Naval Medical Research Unit for solids recovery and analysis. The ISO Method 11143:2008 testing apparatus was assembled with the CAS installed in reverse orientation to generate backflush. Each CAS was flushed from outlet to inlet with 1 L deionized H_2O and the effluent containing captured sediment was collected. Effluent collected from the six CAS units was combined in a single 6-L container. The polyvinyl chloride housing of each CAS was opened by removing the end caps with a drywall saw, as close to the inlet ends as possible. Sediment that remained inside the CAS housing and on the filter surface after backflush was removed by scraping and irrigating and then pooled with the effluent and sediment collected by backflush. Sediment and effluent were homogenized by orbital shaking, and then the solids were allowed to sediment at the bottom of the container. The supernatant was then transferred to another container and discarded. Sediment was dried overnight using a Thermo Scientific Heratherm laboratory benchtop incubator. Metals composition was determined by homogenizing the sediment to a uniform mixture, then three 250-mg aliquots were taken and digested per EPA Method 3051A: microwave assisted acid digestion of sediments, sludges, soils, and oils. Digested samples were then diluted by serial dilution to concentrations of 1/100, 1/10,000, 1/100,000, and 1/1,000,000. ICP–MS was used as described previously to determine concentration of Hg, Ag, Cu, and Sn.

RESULTS

Determination of CAS Service Life and Average Amalgam Surfaces Placed Per Day During Service

The mean number of amalgam surfaces placed per workday during the service life of each CAS was 8.4 ± 1.4 (n=9). The mean service life (n=8) for the CAS units was 131.6 ± 45.1 calendar days, or 67.1 ± 37.6 workdays (Table 1). One CAS remained in use for 363 calendar days without loss of performance to the HVE system. However, it was removed from the study after 1 year of use. This particular unit, Chair 2 – CAS 1, proved to be a statistical outlier by Grubbs' test and was excluded from mean service life calculations.

Hg Concentrations in Effluent Grab Samples

No significant difference in mean CAS effluent Hg concentration was observed between the first and second HVE system flush ($p=0.3345$); calculated

Table 1: *Service Life in Workdays, Total Amalgam Surfaces Placed, and Amalgam Surfaces Placed Per Day During the Service Life of Each Amalgam Separator*[a]

Provider No.	Chair (CAS) No.	Service Life (Workdays)	Total Amalgam Surfaces Placed	Amalgam Surfaces Placed/Day
Provider 1	Chair 1 (1)	93	528	5.7
	Chair 2 (1)	157	1200	7.6
Provider 2	Chair 3 (1)	42	400	9.5
	Chair 3 (2)	38	336	8.8
	Chair 4 (1)	57	544	9.5
	Chair 4 (2)	64	474	7.4
Provider 3	Chair 5 (1)	42	311	7.4
Provider 4	Chair 6 (1)	51	510	10.0
	Chair 6 (2)	60	549	9.2
		67.1±37.6	539±263	8.4±1.4

Abbreviation: CAS, chairside amalgam separator.

[a] Selected clinical data were collected for the dates during which each CAS unit was in service. The number of workdays (days on which procedures were recorded) and number of amalgam surfaces placed (procedures logged as codes D2140, D2150, D2160, and D2161) were determined for each chair. The average number of amalgam surfaces placed per day was calculated as Total amalgam surfaces placed/Service life (Workdays). The means±standard deviation are indicated (n=9) for service life (workdays), total amalgam surfaces placed, and amalgam surfaces placed per day.

means did not follow a normal distribution ($p<0.05$). Therefore, mean CAS effluent Hg concentrations were calculated from Hg concentration data measured in both HVE flushes. Mean CAS effluent Hg concentrations ranged from 0.95 ± 0.89 mg/L to 4.15 ± 2.51 mg/L. The minimum and maximum Hg concentrations measured in CAS effluent grab samples were 0.05 mg/L and 11.93 mg/L. respectively, and mean concentration was 1.99 ± 2.09 mg/L (Table 2).

ISO 11143:2008 Solids Removal Efficiency Testing of CASs

At the end of service life, the mean SRE of the CAS units by ISO 11143:2008[20] was 99.82 ± 0.14% (n=4), with a range of 99.65% to 99.95% (Table 3). The accredited testing lab that performed ISO certification tests on the DD2011P reported 99.906% for the empty test condition and 99.626% for the full test condition.[29]

Table 2: *Mean (SD), Maximum, and Minimum ^{202}Hg Concentrations Measured in Aliquots of DD2011-P CAS Effluent Grab Samples*

Chair (CAS) No.	Mean (SD), mg/L	Maximum, mg/L	Minimum, mg/L
Chair 1 (1)	2.41 (1.82)	6.56	0.19
Chair 2 (1)	0.93 (0.95)	4.70	0.09
Chair 3 (1)	2.20 (1.12)	4.15	0.43
Chair 3 (2)	1.68 (1.45)	4.63	0.19
Chair 4 (1)	4.07 (3.60)	11.93	1.17
Chair 4 (2)	4.15 (2.51)	10.85	0.15
Chair 5 (1)	0.95 (0.89)	3.62	0.05
Chair 6 (1)	2.75 (2.27)	7.62	0.43
Chair 6 (2)	1.36 (1.20)	4.67	0.10
	1.99 (2.09)	11.93	0.05

Abbreviations: CAS, chairside amalgam separator; SD, standard deviation.

Mass of Total Solids Accumulated by CASs at End of Service Life

The mean total solids accumulated in each CAS at its respective end of service life was 195.4 ± 63.4 g (n=6) (Table 4). Figure 3 shows that solids accumulation in each unit was mainly due to filtration, as can be seen by the presence of particulate material coating the filter media. Sedimentation within the filter housing only accounted for a small portion of the total accumulated solids, as was evidenced by only a small amount of particulate residing within the space between the filter media and the interior housing wall of the CAS.

The fillable volume of the CAS was determined to be 500.4 cm^3, and the corresponding mass of material occupying the fillable volume of the separator was determined to be 634 g of 1 mm glass beads and 2953 g of amalgam powder (of the specific particulate composition described by ISO 11143:2008[20]).

Composition of Solids Accumulated by CASs at End of Service Life

Composition of the material accumulated in the CASs (an average of 254.933 g) during their service lives was determined to be 57% non-amalgam materials (145.422 g), while the remaining 43%

Table 3: *DD2011P SRE at End of Service Life* [a]

Provider No.	Chair No.	Final SRE (%)
Provider 1	Chair 2	99.95
Provider 2	Chair 3	99.76
	Chair 4	99.92
Provider 3	Chair 5	99.65
		99.82±0.14

Abbreviations: CAS, chairside amalgam separator; SRE, solids retention efficiency.

[a] Four DD2011P CAS units were recovered at the ends of their service lives. The CAS units were dried and weighed for total solids analysis and then re-wetted and subjected to a modified efficiency test based on the ISO 11143:2008 method: A defined mixture of dental amalgam particulate was suspended in filtered water and passed through the spent CAS units. The mass of dental amalgam exiting the separators was weighed to calculate the efficiency. The mean efficiency of four CAS units±standard deviation is indicated (n=4).

was amalgam (109.511 g). Mercury (20.9%) was the major metal of the recovered solids, with silver (11.7%), tin (6.1%), and copper (4.3%) making up the remaining amalgam constituents (data not shown).

DISCUSSION

The main objective of this study was to perform quality assurance testing per ISO 11143:2008[20] on the CAS to confirm EPA compliance in a clinical setting in which a relatively high volume of amalgam restorations are placed on a routine basis. The results of ISO 11143:2008[20] testing in our lab show that the CAS exceeds the minimum SRE requirements of the EPA dental effluent guidelines. Four randomly selected units that had reached the ends of their service lives in clinical use showed a mean SRE of 99.82 ± 0.14%. The end of service life SRE results we obtained were consistent with the SRE values reported in the independent ISO 11143:2008[20] test report provided by the manufacturer (ie, 99.906% on the empty test and 99.626% on the full test). These results suggest that while failure ultimately occurs due to HVE obstruction by trapped particulate matter, SRE remains, through the entire service life, more than adequate to satisfy the EPA rule. This outcome demonstrates that cleaning solutions, human tissues and fluids, and microorganisms, which are present in the clinical application of the amalgam separator but not the ISO test method, have no detrimental effect on long-term separator performance.

Table 4: *DD2011P Total Solids Captured During Service Life* [a]

Provider No.	Chair (CAS) No.	CAS Tare Weight, g	CAS Final Weight, g	Total Solids, g
Provider 1	Chair 1 (1)	409.55	563.65	154.10
	Chair 2 (1)	409.33	661.55	252.22
Provider 2	Chair 3 (1)	402.74	604.04	201.30
	Chair 4 (1)	419.41	664.41	245.00
Provider 3	Chair 5 (1)	407.42	638.57	231.15
Provider 4	Chair 6 (1)	420.44	509.02	88.58
				195.40±63.40

Abbreviation: CAS, chairside amalgam separator.

[a] Tare weights of the first six CAS units prior to installation were recorded after the drying procedure (104±1°C for 2 hours, then stabilized in a desiccator for 24 hrs). At the ends of their service lives, separators were weighed again, following the same drying/stabilization procedure to determine final weight. Total solids are the difference between the tare weight and the final weight. The weights of accumulated solids for six individual CAS units are shown. The mean weight of accumulated solids±standard deviation is indicated (n=6).

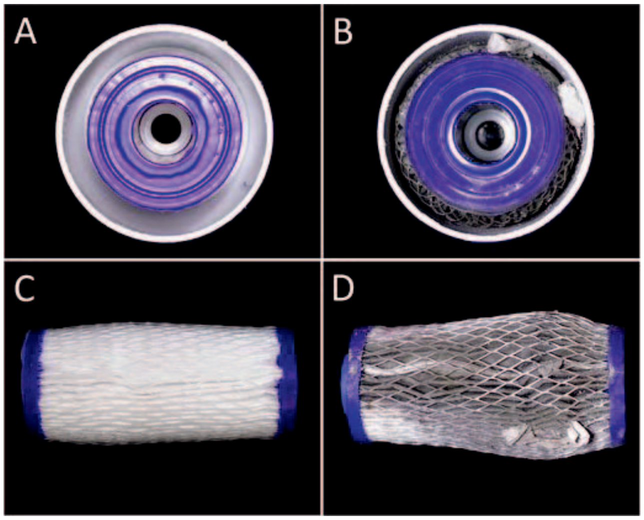

Figure 3. *Cross-sectional view of a DD2011P CAS before installation (A). Cross-sectional view of the CAS at the end of service life (B). Note the minimal amount of accumulated sediment (white arrow) within the interior space between the filter element and the plastic filter housing. Panel (C) shows the interior filter medium removed from a new DD2011P CAS unit. Panel (D) shows the same filter.*

CAS effluent grab sampling and subsequent Hg concentration quantification by ICP-MS were used to monitor separator performance throughout the service life of the CAS, as ISO 11143:2008[20] SRE testing was restricted to preclinical deployment and end of service life time points. For context, in terms of Hg concentrations in CAS effluent, few historical data are available, with the exception of a study conducted by Stone and others[19] in which 4.25 ± 6.35 mg Hg/chair/d was observed in effluent composite samples (defined as samples taken over a designated time interval, as opposed to a grab sample) of a CAS with a 0.5-μm filter cartridge. In direct comparison to Stone and others,[19] Hg concentrations observed in the effluent of the CAS evaluated in this study, which also has a nominal pore size of 0.5 μm, appear to be comparable, as the mean Hg concentration observed in the current study was 1.99 ± 2.09 mg/L. However, Stone and others[19] performed composite sampling, whereas this study utilized biweekly grab sampling. The grab sampling method only reflects the Hg concentrations in the CAS effluent at the point in time during which the samples were collected, whereas composite sampling may better reflect total mass discharge of Hg over time. However, the grab sampling technique used in this study may provide a worst-case estimate of Hg discharge at a given time, as the two consecutive 1 L flushes of the HVE system used for the effluent grab sampling procedure are comparable to routine tap water flushes, which typically occur at the beginning of the workday and between patient seatings. Under normal operating conditions, influent reaches the CAS at a rate on the order of mL/h, rather than in large boluses on the order of mL/s. While the grab sample method used in this study does not account for all effluent, by our estimates, the 2 L collected on a sample day represent the majority of that day's effluent, with perhaps 1 L of other fluids contributing to an estimated daily volumetric total of 3 L of effluent per chair on sample collection day, totaling an approximate 3 mg Hg/chair/d compared with the 4.25 mg Hg/chair/d reported by Stone and others. It is debatable whether effluent arriving in large boluses is more or less effective than the gradual delivery of small fluid volumes at extracting mobile-phase amalgam into the effluent, and thus represents an additional source of variability. Further, the daily mean number of amalgam surfaces placed per chair recorded by Stone and others[19] (19.11±12.31) was greater than in the current study (8.4±1.4). Therefore, CAS influent Hg concentrations observed in the study by Stone and others[19] were likely higher, which may explain why the effluent concentrations were greater than those observed in this study. Since sampling in both studies was collected from the CAS effluent, which goes on to be diluted into the entire facility's effluent, it should be noted that the Hg concentrations reported by both Stone and others[19] and this study do not reflect the final concentration ultimately discharged to POTWs.

A limitation of our approach is that we did not choose the dental practice or providers randomly. Our goal was to evaluate the performance of a specific chairside separator design commonly used in Navy and other military DTFs. We selected a military DTF and selectively installed CAS units to be evaluated on the chairs of providers whose practices were primarily limited to operative dentistry, with the additional criteria that they be high users of amalgam. We chose this evaluation design to best reproduce a worst-case scenario of frequent amalgam use in practice to better evaluate how well the CAS would perform under these conditions with respect to EPA compliance. Other providers within the same group practice, other nonmilitary large group practices, and smaller private practice offices may have significantly different usage rates of amalgam. With respect to service life, our evaluation results are limited to the conditions under which the separators were evaluated. However, the range of service lives for the CAS units in our study indicate that there are a number of uncontrolled factors beyond amalgam use rates that contribute to separator filter obstruction and ultimate failure. Therefore, our findings that the CAS units failed due to HVE obstruction and loss of suction rather than failure to maintain EPA-compliant SRE is likely to be a generalizable finding in any practice setting, despite variability in service life.

According to the EPA Dental Effluent Guidelines, dental offices that remove or place dental amalgam only under "unanticipated circumstances" are exempt from any requirements described in the final rule for the exception of the one-time compliance report.[6] However, dental providers who do not place amalgam but know they will periodically see patients that require amalgam removals must install an amalgam separator. These providers may consider installing CAS units as a lower-cost alternative to a centralized amalgam separator in order to meet compliance requirements. Such providers may also consider restricting amalgam removals to a dedicated dental chair or chairs with an installed CAS, rather than placing a CAS on every chair in their office. No correlation was observed between service life and the rate of amalgam use, indicating that other dental particulate and total accumulated solids are the major contributors to failure. Therefore, a CAS installed on a dental chair in which no amalgam placement or removal is performed would similarly become obstructed and require replacement. Additionally, for dental practices that place and/or remove amalgam restorations regularly and have centralized amalgam separators installed in their facilities, CAS units installed upstream of the centralized system may serve as an additional control measure that may increase the efficiency and service life of the centralized amalgam separator. One key advantage of the CAS concept over the centralized amalgam separator is its location at the point of initial discharge, which mitigates amalgam accumulation in downstream plumbing, especially in low points and longer horizontal sections. The UFC 4-510-01,[22] which governs federal medical and dental facilities, for this very reason, instructs that amalgam separators "shall be incorporated as close to the source point as feasible."

Examination of the dissected CAS units at the ends of their service lives (Figure 3) revealed that sedimentation accounted for only a small portion of total accumulated solids, as roughly $<1\%$ of the interior space between the filter element and the plastic filter housing was occupied. We determined that if the fillable volume were filled entirely with lighter materials (ie, tooth or composite particles), our observed total accumulated solids would occupy approximately 31% of the fillable space, while if the fillable volume were filled entirely with amalgam, our observed total accumulated solids would occupy only about 7% of the fillable space. In reality, the actual composition of the accumulated solids would be somewhere between these two extremes, with the ratio of tooth and composite to amalgam particulate varying with the frequency of amalgam placements and with placement technique. We determined from a pooled random sample of six spent separators that only 43% of the accumulated solids were amalgam. While we did not specifically determine the origin of the other 57%, we can safely surmise it is comprised of tooth structure, dental composite, abrasive particles, and other particulate dental and oral materials. This is not meant to be a robust determination, applicable to all dentists in all facilities, but it does illustrate the point that a filtration-based separator captures more than just amalgam. The ratio of amalgam to other captured material will vary with amalgam placement/removal technique, as well as the size and frequency of these procedures.

The fact that separators reached the end of their service lives with relatively little accumulated material inside them suggests that the housing could be redesigned to be considerably smaller while still accommodating the accumulated solids. The CAS is designated a Type 3 amalgam separator, meaning that it removes dental amalgam particles via filtration alone. The end of service life images also show that the recovered filter cartridges are almost entirely coated with accumulated dental material solids, confirming the intended functional specification. However, the integration of other amalgam separation methods, such as sedimentation, into the CAS design could potentially prolong service life without compromising SRE and HVE suction.

We conducted grab sampling of CAS effluent via a two-step method, whereby two 1 L boluses were sequentially aspirated through the HVE/CAS system and collected separately. This was done to determine the degree to which dissolved mercury contributed to the effluent levels, based on the premise that particulate amalgam trapped within the separator would, over time, leach some amount of Hg into the wet milieu of the separator's interior. A limitation of this method was that the activity of the CAS (or lack thereof) prior to our sample collection was unknown to us, but it was hypothesized that we would see a small difference between the first and second effluent collections, with any observed difference being due to metals that had dissolved into the milieu in the time since the most recent usage. While on occasion this was true for individual data points, including notable outliers that we included in the analysis, overall the difference in effluent Hg concentration between the first and second flushes was insignificant. These results are consistent with the EPA's assertion that only 0.4% of Hg in dental effluent is in the dissolved state.[6]

Based on feedback from providers that used the dental chairs on which the CAS units were installed, it was determined that there is also a need for a more ergonomic chairside design or an alternative installation location. In an attempt to improve ergonomics for the providers, CAS units were successfully installed within the floor box of chairs 5 and 6 (Figure 1). However, if the diameter of the CAS were decreased by 10% to 15%, the unit would be perfectly suited for floor box installation in A-dec 500 dental chairs. In its current form, it precludes full closure of the floor box cover and requires ample creativity to route the tubing appropriately through a tight and crowded space. Further, a smaller CAS design could decrease per-unit purchase price by lowering material costs and, where amalgam waste is managed on a volumetric basis, reduce disposal costs as well.

One fundamental consideration behind the final EPA rule was the current state of best-available amalgam separator technology balanced with economic achievability. Two constraints inform this standard: 1) which technologies are mature enough to implement on a broad, national scale, and 2) which of these technologies can be used in the vast majority of dental practices without imposing undue financial burden. The current state of amalgam separator technology exceeds EPA Dental Effluent Guidelines compliance requirements, as the median

SRE of commercially available, ISO-certified amalgam separators in the United States is 99.3%.[6] Therefore, the CAS we evaluated may be considered a competitive product in terms of SRE, cost, and installation versatility.

It should be noted that certain state and local municipalities have promulgated additional compliance requirements, including, but not limited to, defined Hg discharge limits and compliance monitoring (eg, inspections) by local POTWs.[8,30] Dental providers should consult their respective control authorities to determine their specific compliance requirements, as the final rule of the EPA Dental Effluent Guidelines represents only the federal-level compliance benchmark.[6]

Finally, according to the EPA,[6] dissolved Hg accounts for $\leq$0.4% of dental amalgam process wastewater. The current EPA guideline limits Hg-containing amalgam separation to particulate and does not account for dissolved Hg. While the CAS design tested is ISO11143:2008-certified for 99.6% SRE, downstream polishing processes (eg, ion-exchange resin) could be added to account for dissolved Hg should future compliance requirements necessitate additional control measures.

CONCLUSIONS

1) The CAS evaluated meets the ISO standard for particulate amalgam removal, and its use on dental chairs that place/remove amalgam will meet the EPA dental wastewater effluent guideline.
2) The clinical evaluation of the CAS shows variability in service life due to a variety of clinical factors beyond the amount of amalgam used in practice.

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Regulatory Statement

This study was conducted in accordance with all the provisions of the local human subjects oversight committee guidelines and policies of the Naval Medical Research Institute in San Antonio, Texas.

Disclosure

The views expressed in this article are those of the authors and do not necessarily reflect the official policy or position of the Department of the Navy, Department of Defense, or the US Government. Dr D Olivera is an employee of the US government, and LCDR N Hamlin is a military service member. This work was prepared as part of their official duties.

Although samples and operative procedure data were obtained from a military dental treatment facility, neither patient personal health information nor personal identifying information was revealed to the authors of this study. Therefore, this study was exempt from Institutional Review Board review. This document is not intended to be a comprehensive summary or review of the EPA Effluent Limitations Guidelines and Standards for the Dental Category, 40 Code of Federal Regulations Part 441. Approved for public release; distribution is unlimited.

Conflict of Interest

The authors of this manuscript certify that they have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in this article.

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