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QUANTIFICATION OF STRUCTURE LOSS FROM DIAMOND BURS AFTER
SIMULATED CLINICAL USE

by

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A thesis submitted to the Faculty of the
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ABSTRACT

Quantification Of Structure Loss From Diamond Burs After Simulated Clinical Use

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Introduction: In the past 10 years, the U.S. Food and Drug Administration (FDA) has advocated for the use of single-use diamond burs over multi-use (i.e., re-processable) diamond burs. There is a considerable knowledge gap regarding single-use bur quality, wear characteristics, and patient safety. Surveys of private practice dentists have indicated that many clinicians continue to re-use burs (including single-use burs), despite federal recommendations. **Objective:** The purpose of this observational in-vitro study was to quantify the amount of structure loss (metal and diamond particles) from single-use and multi-use diamond burs and to compare surface characteristics following simulated clinical use. **Methods:** Four types of medium-grit round-end chamfer burs were selected, including three single-use types and one multi-use type (n = 80). Initial masses (mg) and digital optical light microscopic images (pre) were obtained. Each bur was placed in a mounted handpiece, which cut into a simulated dentin substrate for 5 minutes using a standardized force generation apparatus under consistent speed (40,000 RPMs), force (1.0 N), and water spray (25 mL/min). Digital microscopic images (post) were obtained immediately following preparation. All burs were steam cleaned for 15

seconds, placed in an ultrasonic cleaner for 10 minutes, and dried overnight. Final mass for each bur was recorded and post-cutting/post-cleaning digital microscopic images (final) were captured. **Results:** A one-way analysis of variance (ANOVA) was used to compare mean mass change (pre- vs post-cutting). There was no significant difference in mean mass loss between groups ($p=.351$, $\alpha = 0.05$). Minimal post-cutting damage and wear patterns were observed across all groups. **Conclusions:** The quality of single-use burs is comparable to that of multi-use burs. Loss of metal/diamond particles from single-use diamond burs following tooth preparation is minimal and is considered safe in normal patient care settings.

TABLE OF CONTENTS

LIST OF TABLES	viii
LIST OF FIGURES	ix
LIST OF ABBREVIATIONS	x
CHAPTER 1: Introduction	1
Background	1
Usage Patterns Among Practitioners	2
Federal Recommendations	3
CHAPTER 2: Materials and Methods	8
Study Design	8
CHAPTER 3: Results	10
CHAPTER 4: Discussion.....	11
CHAPTER 5: Conclusions	13
REFERENCES	23

LIST OF TABLES

Table 1. Mean Mass Change Results	14
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LIST OF FIGURES

Figure 1.	Recording Mass Measurements.....	15
Figure 2.	Sample Imaging with Digital Microscope.....	16
Figure 3.	Standardized Force Generation Apparatus.....	17
Figure 4.	Meisinger (Single-Use)	18
Figure 5.	Microcopy NeoDiamond (Single-Use).....	19
Figure 6.	CrossTech (Single-Use).....	20
Figure 7.	Meisinger (Multi-Use).....	21
Figure 8.	Post-Cutting Debris Levels.....	22

LIST OF ABBREVIATIONS

CDC	Centers for Disease Control and Prevention
DHCP	Dental Health Care Personnel
FDA	Food and Drug Administration
IRB	Institutional Review Board
ISO	International Association for Standardization
WRNMMC	Walter Reed National Military Medical Center

CHAPTER 1: Introduction

BACKGROUND

Carbide and diamond dental burs are essential instruments in dentistry for cutting and preparing teeth for restorations. In the past, dental burs were routinely sterilized and re-used on multiple patients until their cutting efficiency became noticeably reduced. Over the years, as concerns over infection control and instrument processing in dentistry have increased, regulatory agencies such as the FDA and CDC have helped shape policy regarding the use of such instruments. Many manufacturers of diamond burs have shifted to the production of single use burs, as single use burs offer numerous advantages over multi-use burs from the perspective of the dental practitioner. Single use burs, in contrast with multi-use burs, are relatively inexpensive, disposable, do not require re-sterilization, and are less likely to be associated with sharps exposure incidents among employees as they do not need to be re-processed. Additionally, recent FDA guidance has made it more difficult for bur manufacturers to market their products as multiple-use items, as manufacturers must submit specific data to the FDA regarding their recommended cleaning and sterilization methods, along with laboratory evidence to validate the effectiveness of the proposed protocols.

As the demand for less expensive single-use burs has increased, one may speculate that diamond bur manufacturers have had to adjust their processes to maintain profits, possibly leading to a degradation in quality. Various studies have examined cutting efficiency between single-use and multi-use burs, with inconsistent results. Few studies have examined the degree of material or structure loss from burs during use. The

present study sought to address three aims: First, quantitatively determine how much metal structure is lost from diamond instruments during tooth preparation; second, compare surface characteristics between single-use and multi-use diamond instruments following tooth preparation; and third, determine, among single-use burs, which specific types or designs exhibit less structure loss than others.

USAGE PATTERNS AMONG PRACTITIONERS

According to a 2014 survey, diamond burs are widely used within the modern dental office, with most dentists expressing a preference for diamond burs (75%) over carbide burs (15%) or other bur types (10%) (Sharma et al, 2014). The same survey found that 85% of the dentists polled used their burs “until they were worn out.” A 2021 survey found that about 83% of dentists reuse diamond burs (Mills & Daw, 2021).

Various studies have demonstrated that diamond burs can be reused for up to four or five tooth preparations before cutting efficiency begins to degrade (Emir et al, 2018). A number of explanations for this loss of cutting efficiency have been proposed, including clogging by debris, shedding of diamond particles, and pull-out of the metal matrix. One study which utilized scanning electron microscopy found that most of the reduction in cutting efficiency is related to blunting of the diamond particles rather than diamond pull-out, clogging, or damage to the binder layer (Regev et al, 2010).

Diamond burs have traditionally been viewed as reusable devices that can be processed and sterilized for use multiple times or until cutting efficiency degrades. However, over the past few decades, infection control guidelines within dentistry have continued to evolve. Diamond burs present unique difficulties when it comes to

disinfection, cleaning, and sterilization. The highly irregular surface of diamond instruments makes it nearly impossible to completely remove accumulated debris. Cleaning and sterilization procedures can also damage surface structure, leading to possible breakage during patient care. A 2009 study found that initial sterilization procedures for unused burs or endodontic files was 100% effective, however contamination rates ranged from 15-58% following an additional sterilization process after the first usage (Morrison & Conrod, 2009). An experiment using *Streptococcus sanguinis* demonstrated that autoclaving alone is not sufficient for decontaminating diamond burs. The authors assessed the effectiveness of manual scrubbing, soaking in an enzymatic bath, and washer-disinfection and found that washer-disinfection was the only effective pre-sterilization cleaning method. They concluded that manual scrubbing and immersion in an enzymatic bath as pre-cleaning methods were inconsistent and prone to operator error (Whitworth et al, 2004). Another study found that 5% of reused burs demonstrated residual microbial contamination after sterilization (Al-Jandan et al, 2016). Such experiments have demonstrated the theoretical possibility of iatrogenic transmission of spore-forming bacteria, blood-borne viruses, or prions from diamond burs within the dental setting.

FEDERAL RECOMMENDATIONS

In 2003, the Centers for Disease Control released guidance recommending that all dental burs and endodontic instruments be considered single-use devices (Centers for Disease Control and Prevention, 2003). Classifying such items as single use eliminates both the possibility of patient-to-patient contamination and deterioration issues related to

re-processing. The publication, titled *Recommendations for Infection Control in Dental Settings*, advised dental providers to consult manufacturer instructions for use to determine whether or not such products could be reused (Centers for Disease Control and Prevention, 2003). There is certainly a degree of ambiguity within the text, however:

“Because of the physical construction of certain devices (e.g., burs, endodontic files, and broaches) cleaning can be difficult. In addition, deterioration can occur on the cutting surfaces of some carbide/diamond burs and endodontic files during processing and after repeated processing cycles, leading to potential breakage during patient treatment. These factors, coupled with the knowledge that burs and endodontic instruments exhibit signs of wear during normal use, might make it practical to consider them as single-use devices.”

Guidance published by the Food and Drug Administration around the same time established a firmer position in regard to the re-use of dental burs. The document, titled *Labeling Recommendations for Single-Use Devices Reprocessed by Third Parties and Hospitals; Final Guidance for Industry and FDA*, emphasized that if a manufacturer does not provide explicit and validated cleaning, disinfection, and sterilization instructions for reprocessing a specific product, the item should be considered a single-use device (Food and Drug Administration, 2003). The process for qualifying as a multi-use device involves submission of a 510(k) clearance to the FDA. The CDC has since updated its guidance regarding *Recommendations for Infection Control in Dental Settings*:

“The Food and Drug Administration (FDA) considers all diamond-coated burs and scaler tips single-use unless their manufacturers have submitted a 510(k)

for reprocessing...Dental healthcare personnel (DHCP) should always refer to the manufacturer's instructions to determine if a device is single-use. If a device does not have validated reprocessing (i.e., cleaning and disinfection or sterilization) instructions, it is considered single-use (i.e., disposable)." (Centers for Disease Control and Prevention, 2016)

In order to obtain 510(k) clearance, manufacturers must submit data that shows their recommended cleaning protocol is effective, and this type of testing must be done in strict accordance with national or international standard methods devised by organizations like the International Association for Standardization (ISO). However, at this time there is no accepted standard method available to evaluate the effectiveness of cleaning methods on the removal of hard tissue from cutting surfaces of diamond burs. In essence, no diamond bur manufacturer can successfully submit the appropriate documentation to obtain 510(k) clearance.

Nevertheless, despite guidance from the CDC and FDA, many dental providers continue to re-use diamond burs. Furthermore, many bur manufacturers still continue to market their burs as multi-use items. The CDC cannot officially enforce these guidelines, and the FDA regulations are mainly targeted towards manufacturers rather than consumers. Such guidelines are only enforceable within certain institutional settings, such as in the military health care system, Veterans Administration, or in organizations subjected to accreditation by the Joint Commission. Still, these federal recommendations emphasize that it is the responsibility of all dental healthcare providers to understand and follow the manufacturer's instructions for use.

A 2021 survey of dental health care providers assessed respondents' awareness of CDC and FDA recommendations regarding the use of diamond burs (Mills & Daw, 2021). Most respondents (71%) were aware of the FDA and CDC guidance, but 29% of respondents were unaware of the above recommendations. 96% of respondents agreed it was "important" (30%) or very important (66%) to follow the manufacturer's instructions for use when reprocessing dental instruments, and yet only 16% of respondents indicated that they always discarded diamond burs after single use.

The main reason cited for re-using burs was cost (Mills & Daw, 2021). When comparing cost effectiveness of single-use versus multi-use burs, variables to consider include initial cost, bur longevity, and overhead related to time and effort spent cleaning, sterilizing, and re-processing. Studies examining cost effectiveness between single-use and multi-use burs have shown that single-use burs are generally more cost-effective when all of these factors are taken into account. As the trend towards cheaper single-use, disposable diamonds burs continues, one might surmise that bur manufacturers need to adjust their manufacturing processes to maintain profits, which may lead to a degradation in quality. Various studies have examined cutting efficiency between single-use and multi-use diamond burs, and the majority of research demonstrates that there is little difference in cutting rates and cutting efficiency between single-use and multi-use diamond burs (Pilcher et al 2000, Siegel et al, 1996).

No studies to date have examined the environmental impact of this shift towards the use of disposable single-use burs. Two factors must be considered: First, classifying all diamond burs as single-use items means that many more burs are being discarded on a daily basis. Secondly, as previously mentioned, the predominant wear mechanism for loss

of cutting efficiency is diamond particle wear, rather than clogging. These diamond particles are released into the oral and ambient environment during tooth preparation, but it is unknown to what degree this surface loss is significant, or whether there is any difference in surface loss between single-use and multi-use diamond burs. There may be biological implications to patients and healthcare providers in terms of inhaling or ingesting diamond and metal particles. Currently no studies have assessed the degree and extent of surface structure loss from single-use versus multi-use diamond burs. The present study sought to examine the relationship between bur type (single-use versus multi-use) and surface structure loss, through changes in mass following clinical use as well as through the use of digital microscopy.

CHAPTER 2: Materials and Methods

STUDY DESIGN

This research protocol was reviewed by the Walter Reed National Military Medical Center (WRNMMC) Institutional Review Board (IRB), protocol # WRNMMC-EDO-2022-0947 and found to be a non-human subjects study. Four different brands of medium grit tapered round end diamond burs were selected for inclusion in this study. Three of the experimental groups consisted of single-use burs (Meisinger 1714.8, Microcopy NeoDiamond 878K-014, and CrossTech 878K-014) while the fourth group consisted of a multi-use bur (Meisinger 878-014). Twenty burs of each brand were obtained for a total of 80 burs. The shank of each bur was marked with a small notch using a 330 carbide bur to assist in orientation for digital microscopy photos. Initial mass measurements were made for each bur using an Ohaus Adventurer Analytical Balance (Figure 1) and initial photos of each bur were obtained with a Hirox KH-7700 digital microscope at 35x magnification (Figure 2).

A standardized force generation appliance was devised using a movable wheeled cart connected via a pulley to a 100g weight (Figure 3). A cylindrical puck of simulated dentin substrate (NEMA G-10) was affixed to the movable element. Each bur was placed in a fixed handpiece mount that allowed for standardized force application as the 100 g cylinder dragged the movable cart containing the simulated dentin substrate against the bur. Previous studies have indicated that clinicians exert between 100-150 g of force during a crown prep procedure (Peters et al, 2019, Nakamura et al, 2015, Choi et al, 2010). An electric handpiece set to 40,000 RPMs and 25 mL/min water spray was secured to a mounting jig that was fabricated from modeling putty to ensure a

standardized reference position relative to the simulated dentin substrate. Each bur was run for 30 seconds at a time with 10 second rest intervals for a total contact cutting time of 5 minutes. Photos of each bur immediately following preparation but prior to cleaning were captured using the digital microscope after using the notches to align each bur in the same orientation as before. Each bur was then steam cleaned for 15 seconds and placed in an ultrasonic bath for 10 minutes. After cleaning, the final mass measurements and final microscope photos were obtained. A one-way analysis of variance (ANOVA) was used to compare changes in mean mass loss (pre vs post). Additionally, the microscope images were reviewed to subjectively compare damage patterns and surface characteristics across groups.

CHAPTER 3: Results

Mean mass loss ranged from 0.0007 to 0.0012 g (Table 1), representing a total change of less than 0.5%. No significant difference in mean mass loss across groups was observed ($p=.351$, $\alpha = 0.05$). Observable structural damage was minimal and similar post-cutting damage levels were noted across all groups (Figures 4-7). The predominant damage pattern observed was diamond pull-out. Slight differences in post-cutting debris levels were observed (Figure 8), but there was no appreciable difference across groups following steam/ultrasonic cleaning.

CHAPTER 4: Discussion

The findings of the present study indicate that there is no appreciable difference between single-use and multi-use diamond burs in terms of their structure loss. Single-use diamond burs hold up just as well as multi-use diamond burs following simulated clinical use. Furthermore, less expensive single-use diamond burs hold up just as well as more expensive single-use burs. A review of the digital microscope photos indicates that similar damage levels and patterns were observed across all groups. The primary mechanism of damage observed was diamond particle pull-out.

Taken together, these findings suggest that bur manufacturers have been able to successfully produce high quality materials at a lower price point. Dental providers can still achieve high quality dentistry using single-use diamond burs at a fraction of the cost of more expensive multi-use burs. The least expensive burs tested (CrossTech, single-use) were \$1.22 per bur and the most expensive burs tested (Meisinger multi-use) were \$8.97 per bur. A comparison of the microscope images revealed that the diamond particles on the Meisinger multi-use diamond burs appeared smaller and more uniform in size than those on the CrossTech single-use burs. However, the two different types of burs behaved similarly in terms of structure loss and damage patterns observed.

Diamond burs are essential to the practice of dentistry. Supply costs and business overhead are important variables for dental providers to consider when making decisions regarding their practice. Survey data indicates that many dental health care providers reuse diamond burs (Sharma et al, 2014, Mills & Daw, 2021) despite federal guidelines that recommend all diamond dental burs to be single-use. Single-use diamond burs are far less

expensive than multi-use diamond burs, so it is important to understand whether there is a significant cost-benefit advantage to using more expensive multi-use burs.

There are a few limitations to the present study. The composition and physical properties of the simulated dentin substrate can only approximate those of dentin and enamel, as the actual nature of the dentin/enamel complex is irregular and vastly more complex. Likewise, the standardized force apparatus designed for this study may not reliably replicate the variations in movement, force, and direction applied during an actual clinical procedure. Additionally, higher magnification could have been used to assess the damage levels and wear patterns following cutting. A 2010 study by Regev et al showed that the predominant damage pattern for diamond burs is blunting rather than pull-out or clogging, and it is plausible that higher magnification would allow for better assessment of the level of diamond particle blunting across groups. At 35x magnification, major surface changes could be seen but it was relatively difficult to compare discrete diamond particles.

Future studies could examine the effects of longer cutting intervals on structure loss and wear patterns. Future research could also focus on relative debris levels and structure loss, as the post-cutting/pre-cleaning microscope photos demonstrated slight differences in debris levels across bur types. Variations in diamond particle composition and distribution may affect the degree of clogging, which could impact both structure loss and cutting efficiency. Finally, future studies could assess the overall financial or environmental impact of the shift to single-use diamond instruments, as greater numbers of single-use burs need to be discarded per procedure.

CHAPTER 5: Conclusions

Within the limitations of the present study, it can be concluded that single-use diamond burs behave similarly to multi-use diamond burs in terms of structure loss and damage patterns. Furthermore, less expensive single-use diamond burs behave similarly to more expensive single-use diamond burs in terms of structure loss and damage patterns. There seemed to be a link between overall cost and size/uniformity of diamond particles (Meisinger multi-use diamond particles were smaller and more uniform), which could suggest more stringent quality control. Overall, however, there appears to be no appreciable degradation in quality associated with the trend towards the use of single-use diamond burs. There may be differences in debris buildup/diamond clogging across bur types, which may impact cutting efficiency. Additional studies are needed to assess potential changes after longer cutting intervals, and/or how debris clogging the abrasive surface (the spaces between the diamond particles) impacts structure loss.

Table 1. Mean Mass Change Results. Mean differences in pre-and post-cutting mass following 5 minutes of cutting on a simulated dentin substrate.

Bur Type	N	Initial Mass (g)	Final Mass (g)	Mean Mass Loss (g)	Std Deviation
Meisinger (Multi-Use)	20	0.2546	0.2539	0.0007	0.00073
Meisinger (Single-Use)	20	0.2552	0.2544	0.0009	0.00067
Microcopy NeoDiamond (Single-Use)	20	0.2287	0.2274	0.0012	0.00095
CrossTech (Single-Use)	20	0.2473	0.2462	0.0012	0.00081

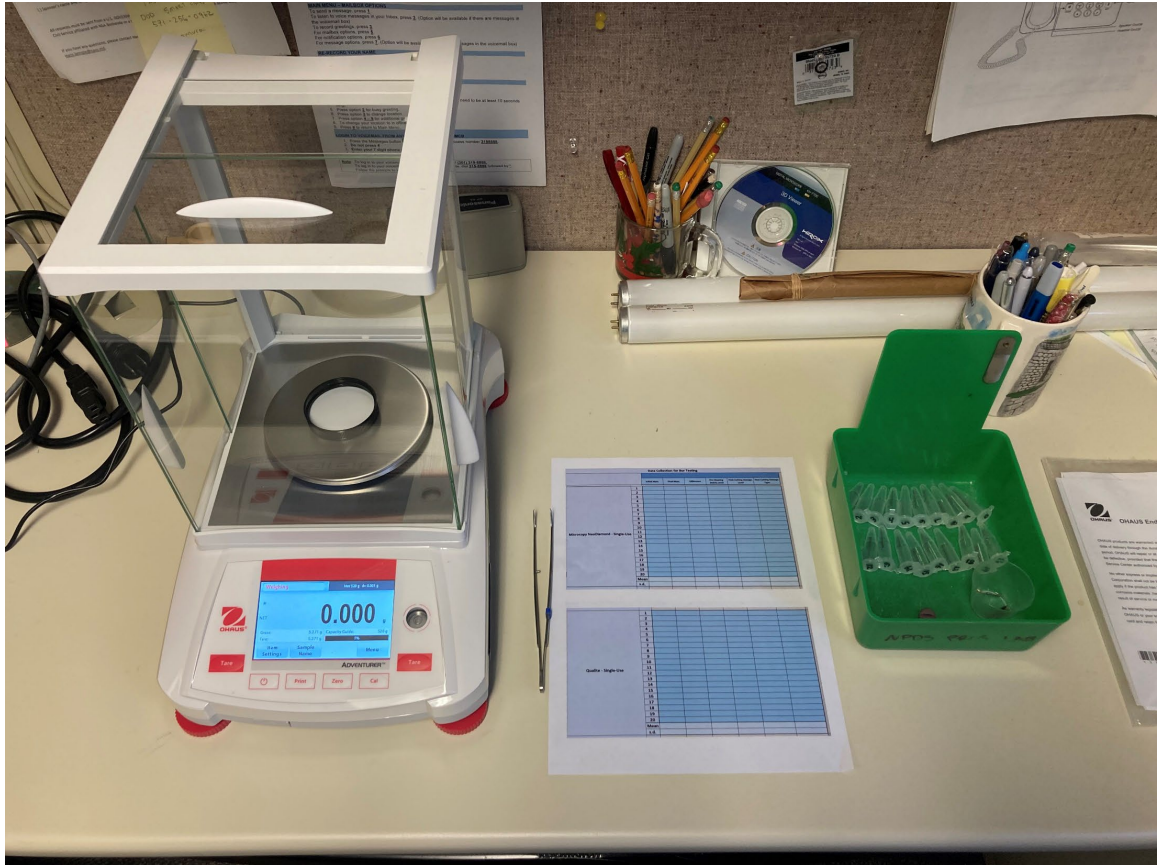


Figure 1. Recording of Mass Measurements. All measurements recorded to three decimal points using Ohaus Adventurer Analytical Balance.

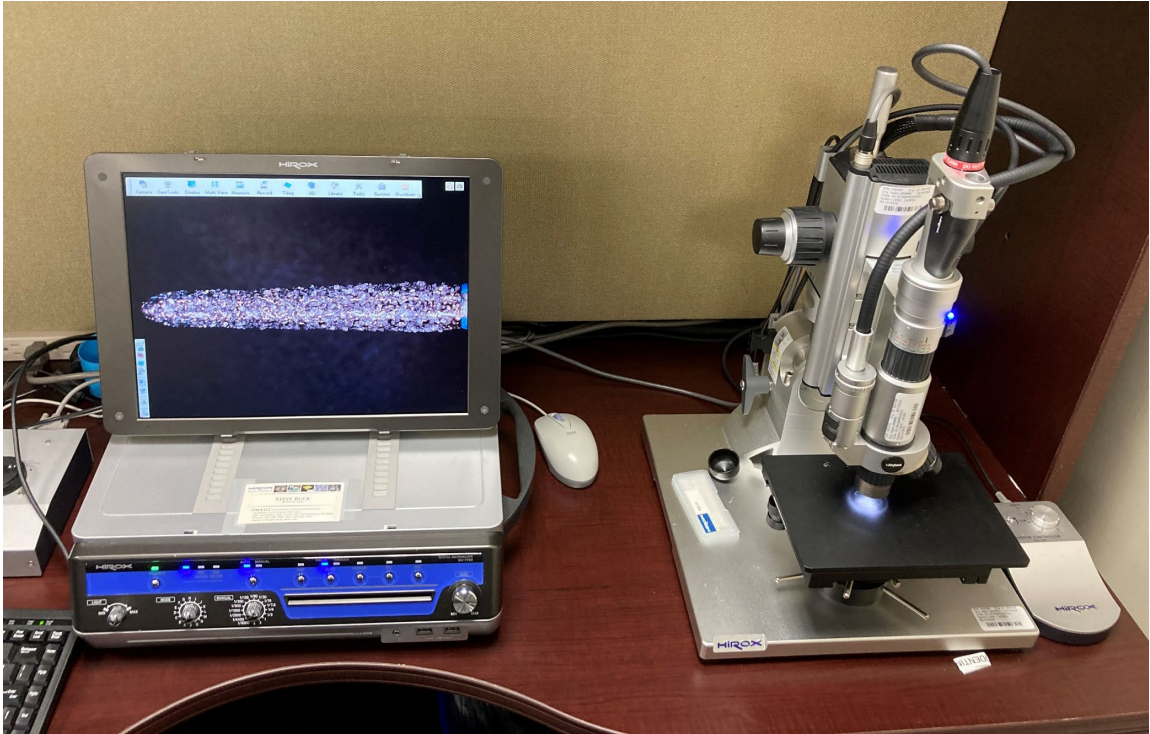


Figure 2. Sample Imaging with Digital Microscope. Photos taken prior to cutting, after cutting but before cleaning, and after cutting/cleaning.



Figure 3. Standardized Force Generation Apparatus. The simulated dentin substrate (NEMA G-10) is affixed to a movable element on wheels, which is attached to a 100 g cylinder. The handpiece with bur inserted is affixed to a stationary element such that the bur exerts consistent force against the dentin substrate.

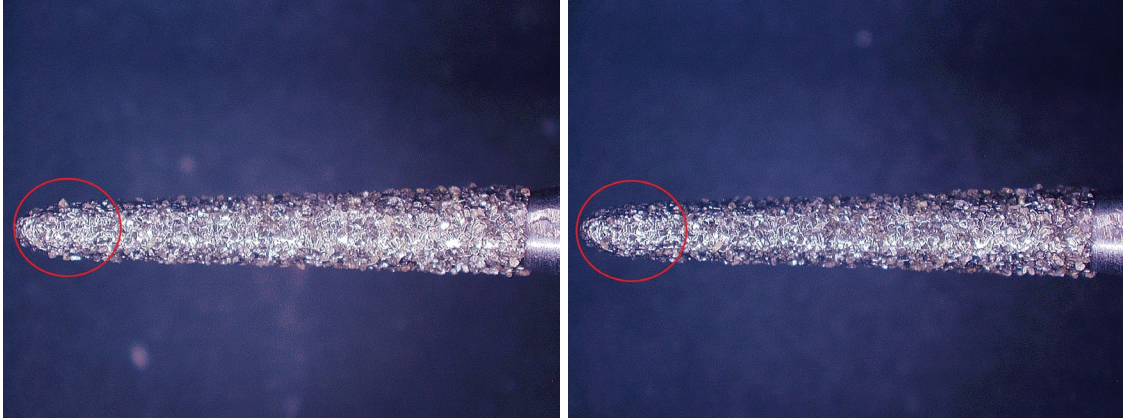


Figure 4. Meisinger (Single-Use). Comparison of pre-cutting (left) and post-cutting (right) digital microscope images (35X magnification).

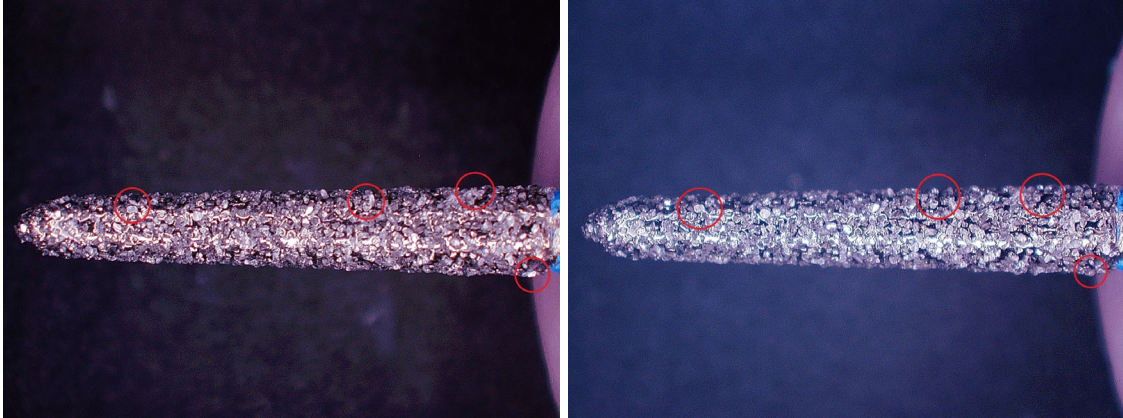


Figure 5. Microcopy NeoDiamond (Single-Use). Comparison of pre-cutting (left) and post-cutting (right) digital microscope images (35X magnification).

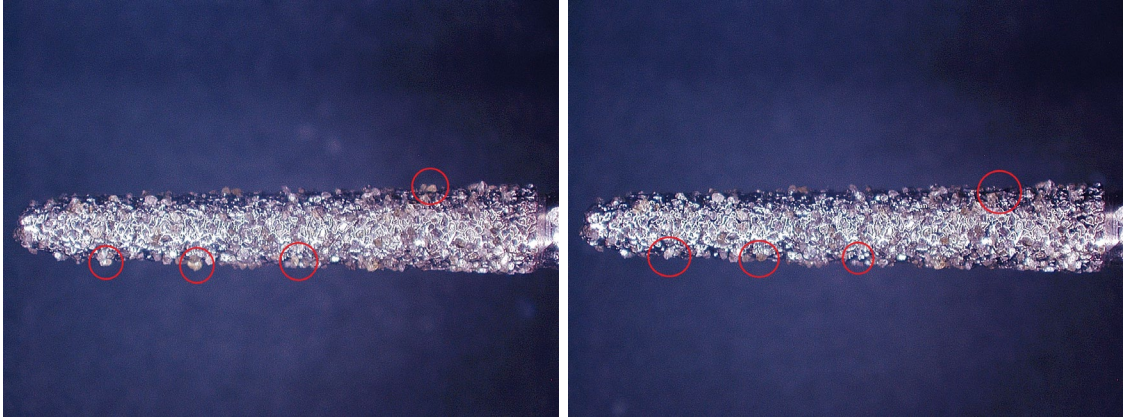


Figure 6. CrossTech (Single-Use). Comparison of pre-cutting (left) and post-cutting (right) digital microscope images (35X magnification).

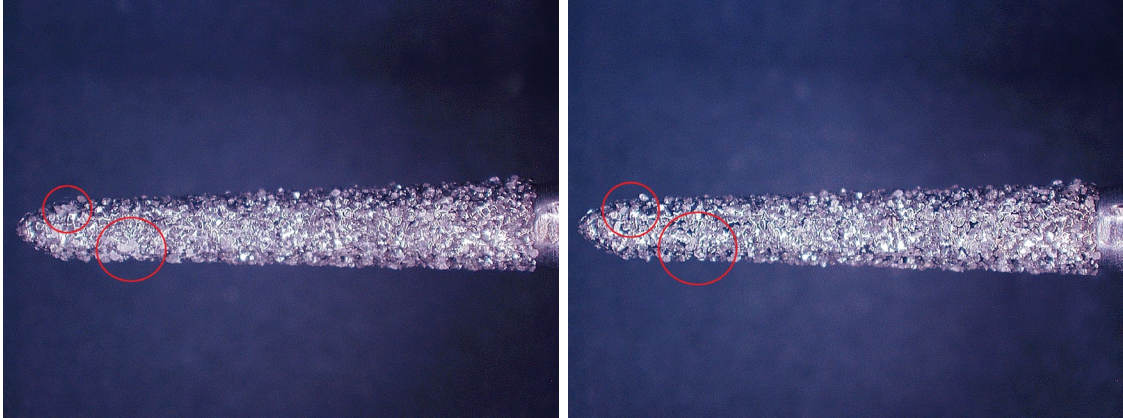


Figure 7. Meisinger (Multi-Use). Comparison of pre-cutting (left) and post-cutting (right) digital microscope images (35X magnification).

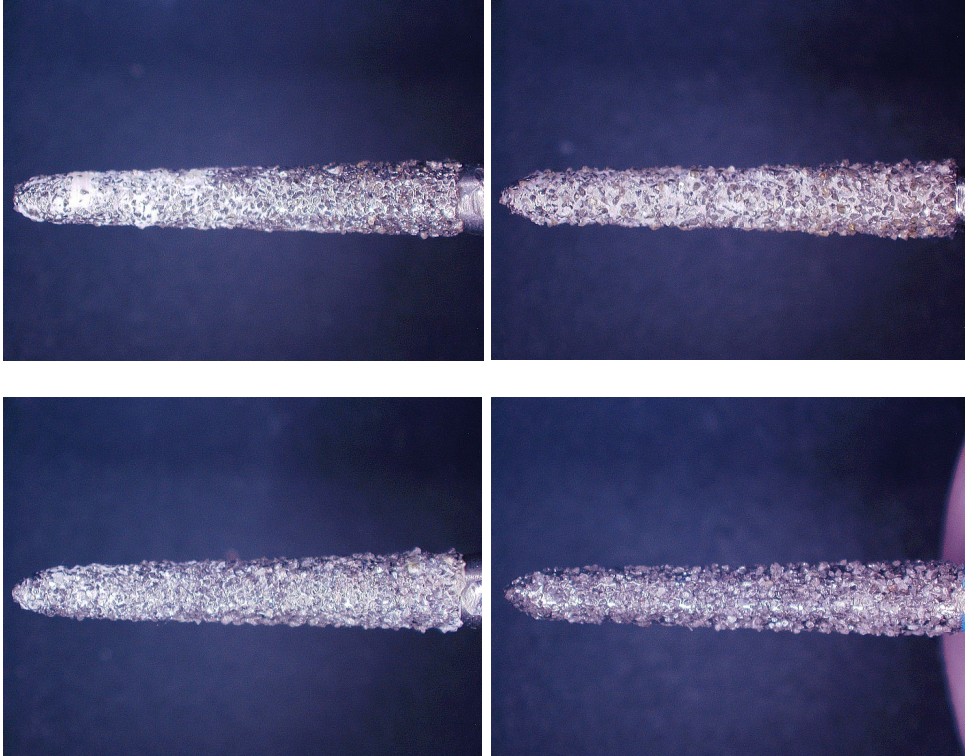


Figure 8. Post-Cutting Debris Levels. Images prior to steam cleaning/ultrasonic. Clockwise, from upper left: Meisinger (single-use), CrossTech (single-use), Microcopy NeoDiamond (single-use), Meisinger (multi-use) (35X magnification).

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