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A comparative study of the cutting efficiency of diamond burs with different grit sizes on zirconia restorations

MSc Dentistry: Prosthodontics

by

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DECLARATION

I, Dr Ané van Aswegen hereby declare that this research report is of my own, unaided work. The content and outcomes reported herein reflect accurate and original results, with highest attention paid to detail and honesty within my capabilities. It is being submitted in fulfilment of the degree MSc in Dentistry, Prosthodontics at the University of Pretoria, South Africa.

	10/11/2022
Dr A van Aswegen	Date

EXECUTIVE SUMMARY

Background: The use of zirconia-based restorations in modern dentistry has increased due to its excellent mechanical properties, superior biocompatibility, and satisfactory aesthetics. This has led to a demand for more efficient machinability thereof. However, little attention has been given to the difficulty experienced by clinicians when cutting zirconia restorations. The cutting of zirconia in dentistry is necessary for the purpose of occlusal reduction, to gain root canal access, or for the removal of restorations. Zirconia used in clinical dentistry is much harder than some other dental prosthetic materials, making it more arduous to cut. It also has an increased susceptibility to fracturing. To date, there is insufficient evidence on which grit size and type of bur is best for the purpose of cutting zirconia.

Aim: The aim of the present study was to identify the most efficient diamond bur grit size for cutting zirconia. Efficiency was measured by comparing the cutting depth of each bur into zirconia, analysing zirconia specimens for any surface damage after cutting and measuring bur deterioration. The most efficient bur achieved maximum productivity (cutting depth) with minimum wasted time and expense (bur deterioration and substrate fractures).

Hypothesis: Diamond burs with finer grit sizes are more efficient in cutting zirconia than coarser burs due to increased surface area to substrate ratio and decreased damage to the substrate.

Method: Zirconia specimens of the same thickness were used as test samples, and cut with burs with different grit sizes, using an electric handpiece with the same amount of force (1.7N) and speed (40 000rpm) for a constant amount of time (1min.) and a constant water flow rate of 25mL/min to produce comparative data.

Results: The results obtained revealed the following: 1) The greatest cutting depth was achieved with the fine (F) bur. 2) The most damage to zirconia was done by the coarse (C) and super coarse (SC) burs, with no damage to the super fine (SF), fine (F), and medium (M) burs. 3) The least amount of bur deterioration was found on the super fine (SF) burs, with the most amount of deterioration on the super coarse (SC) burs.

Conclusion: Within the limitations of the present study, it can be concluded that the most efficient diamond bur was the fine (F) bur with grit sizes between 40-50 µm. The fine (F) bur group achieved the greatest cutting depth with no detectable macroscopic damage to the zirconia substrate and minimal bur deterioration. The empirical findings in the present study provide a new insight into efficient cutting of zirconia and will aid clinicians in selecting the correct armamentarium when working with zirconia intra-orally.

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LIST OF ABBREVIATIONS

ANOVA	Analysis of Variance
ASTM	American Society for Testing and Materials
C	Coarse diamond bur grit size
c	Cubic phase of zirconia
DDS	Dental Drilling Simulator
F	Fine diamond bur grit size
FDP	Fixed Dental Prostheses
ISO	International Organization for Standardization
L	Leucite glass–ceramics
LDS	Lithium disilicate glass–ceramics
M	Medium diamond bur grit size
m	Monoclinic phase of zirconia
PCA	Poly-crystalline Alumina
rpm	Revolutions per minute
SC	Super coarse diamond bur grit size
SD	Standard deviation
SEM	Scanning Electron Microscopy
SF	Super fine diamond bur grit size
t	Tetragonal phase of zirconia
TZP	Tetragonal Zirconia Polycrystal
VHN	Vickers Hardness Number
WFR	Water Flow Rate
WEDC	Whitworth Electronic Digital Calliper
Y3-TZP	Yttria Tetragonal Zirconia Polycrystal

CHAPTER 1:

DEFINING THE RESEARCH PROBLEM

An increased life expectancy amongst many populations, combined with longer retention of teeth has led to new developments in the field of fixed prosthodontics and restorative dental materials.[1] The use of zirconia in dentistry has increased due to its excellent mechanical properties, superior biocompatibility, and satisfactory aesthetics.[1,3] This has led to a demand for more effective fabrication techniques and efficient machinability thereof.[4]

Once applied within the clinical setting, alteration to the zirconia restoration may be necessary.[1,3-4] This may include interfacial reductions to adjust occlusion, creating access cavities for endodontic treatments, or removal of failing zirconia restorations.[1-3]

One of the fundamental properties of interest is the hardness of zirconia. A common hardness test for dental ceramics is the Vickers hardness test. Zirconia exhibits high Vickers hardness of around 1300 VHN and meets the requirements of the American Society for Testing and Materials (ASTM) F1873 of at least 1,200.0 VHN.[5-7] This value is much higher than other dental materials used for fixed dental prostheses (FDP) such as lithium disilicate glass–ceramics (LDS) and leucite glass–ceramics (L) with Vickers hardness values of below 735 VHN and 615 VHN respectively.[1-4,8]

The resultant clinical problem, is that the characteristic hardness of zirconia makes it time-consuming and difficult to cut, resulting in rapid deterioration of burs, increased chair-time, and more discomfort to the patient.[1, 3-4] To date, there is insufficient evidence on which grit size and type of dental bur is best for the purpose of cutting zirconia.[3]

Contrary to the common notion that more abrasive burs would be more effective in cutting zirconia, it was hypothesised that smoother burs would be more efficient due to a higher surface area to substrate ratio.

The present study aimed to identify the most efficient bur used in the cutting of zirconia. This was done by comparing the cutting depth of diamond burs with different grit sizes on zirconia, analysing surface damage on the zirconia substrate after cutting, and examining bur deterioration. The most efficient bur achieved maximum productivity (cutting depth) with minimum wasted time and expense (bur deterioration and substrate fractures).

CHAPTER 2:

LITERATURE OVERVIEW AND MOTIVATION

2.1 CERAMICS IN DENTISTRY

Ceramics have been used in dentistry since the 18th century due to its biocompatibility, chemical stability and aesthetic properties.[8] Advanced ceramic materials such as poly-crystalline alumina (PCA), leucite reinforced glass ceramics (L), lithium disilicate glass ceramics (LDS) and zirconia-based ceramics are widely used for dental prostheses to overcome the aesthetic shortcomings of metals in the aesthetic zone.[5,8-10] Of these ceramics, zirconia has been proven to have the greatest survival rate and clinical performance based on its superior mechanical properties and acceptable colour.[4,6] Today, it is used in composites, as extra-coronal attachments, post and core materials, orthodontic brackets, implant abutments, veneers and full and partial coverage FDPs.[6] Consequently, the demand for predictable zirconia restorations in dentistry has increased considerably over the past decades. [3,4]

2.2 ZIRCONIA

Zirconia can be categorised according to its crystallographic phases: cubic (c), tetragonal (t) and monoclinic (m).[6] Zirconia currently used in dentistry is a tetragonal zirconia polycrystal (TZP) that has been metastabilized with 3% Yttrium (III) Oxide (Y_2O_3).[4] The existing literature on this partially stabilized yttria zirconia polycrystalline (Y3-TZP) is extensive and focuses particularly on its excellent mechanical properties.[4-7] Y3-TZP exhibits high strength and hardness, fracture resistance, wear resistance, good frictional behaviour, low thermal conductivity, corrosion resistance in acids and alkalis, modulus of elasticity similar to steel and coefficient of thermal expansion similar to iron.[4,6]

2.3 THE INTRA-ORAL ENVIRONMENT

The oral environment is constantly subjected to the presence of many different micro-organisms, some of which adhere to teeth and dental restorations. This is a primary concern in dentistry.[2,4,7,10] If pathogenic micro-organisms are allowed to colonise and aggregate, they can induce a host response and susceptible hosts might develop infections in these areas.[2] It is therefore important to not only promote good oral hygiene practices amongst all patients, but to employ the use of restorative materials that will prevent or reduce colonization by pathogens.[2] Extensive research has shown that bacterial colonisation and adherence to dental and oral surfaces are largely influenced by the use of different types of dental materials and their surface roughness.[2,4,7,11,12] Recent evidence suggests that zirconia has the lowest bacterial adherence compared to tooth enamel, nano-composites, LDS and amalgam, making it well suited for use in dental restorations and prostheses.[12]

2.4 THE CLINICAL PROBLEM

When working with zirconia in clinical practice, the clinician is presented with certain difficulties.[1-4] Of particular concern is the characteristic hardness of zirconia, which results in prolonged cutting time when adjusting or drilling through a zirconia restoration.[1-4] Excessive heat and stress, generated while grinding, can cause the polymorphic t-phase of zirconia to become less stable and change.[4,6] Data from several studies suggest that these phase changes are influenced by the type of grinding apparatus, speed of grinding, force applied and grit size of burs.[3,13-14] Işerı et al. showed that flexural strength of zirconia can also be affected by grinding and polishing.[15] Garvie et al. demonstrated that excessive phase changes do not only decrease the strength of zirconia, but also result in the formation of cracks and surface irregularities on the zirconia substrate.[16] These studies have shown that cracks and surface defects act as stress concentration sites where zirconia is more susceptible to fracture once more stresses are applied.[15-17] This may result in reduced clinical functionality and longevity of the zirconia restoration.

The clinical problems discussed above has led to the need for identifying more effective and predictable ways to cut zirconia. The following sections will review and discuss the current evidence available on the cutting efficiency of different materials on TZP.

2.5 BURS

Dental burs are used for cutting, grinding and polishing of teeth and dental materials. The International Organization for Standardization (ISO) has classified dental burs according to 5 aspects: material type, shank, shape, grit size and head diameter.[18] With regards to the type of material, zirconia can be cut with either tungsten carbide or diamond burs.[18] The cutting area of tungsten carbide burs (ISO 500) are made of metal alloy, which improves their physical properties compared to all-steel burs.[18] Diamond burs (ISO 806) are metal burs with carbon particles (diamond) galvanized to the cutting area.[18] This increases the abrasive ability of the bur.[18,19] The size of the carbon particles are referred to as the 'grit size' of the bur.[19] Peters et al. reported that diamond burs were significantly more effective at cutting zirconia than tungsten carbide burs.[1] Specifically designed zirconia-cutting diamond burs have emerged on the market that aim to avoid excessive heat and stress generation.[1,3,13,20] Lee et al. advocates the use of these zirconia-specific diamond cutting burs.[13] Conversely, other studies reported that there were no significant difference in cutting efficiency between the dedicated zirconia burs and conventional diamond burs within the first five minutes of cutting.[1,3,20]

Evidence clearly shows that diamond burs are more effective in cutting zirconia than tungsten carbide burs.[1,21] However, evidence on the improved effectiveness of zirconia-specific diamond burs compared to conventional diamond burs remain inconclusive.[1,20]

2.6 BUR GRIT SIZES

The grit size of a bur refers to the specific size of the abrasive grain on the shaft of the bur.[19,20,22] In the case of diamond burs, the grains are made of carbon particles.[18,22] The larger the grains or grit size, the coarser the bur.[19] Conversely, the finer the grains on the bur, the smoother the bur and, by convention, the less aggressively it will cut. The scanning electron microscope (SEM) images indicated in figures 1a and 1b show the difference in particle size between a courser and finer diamond bur.

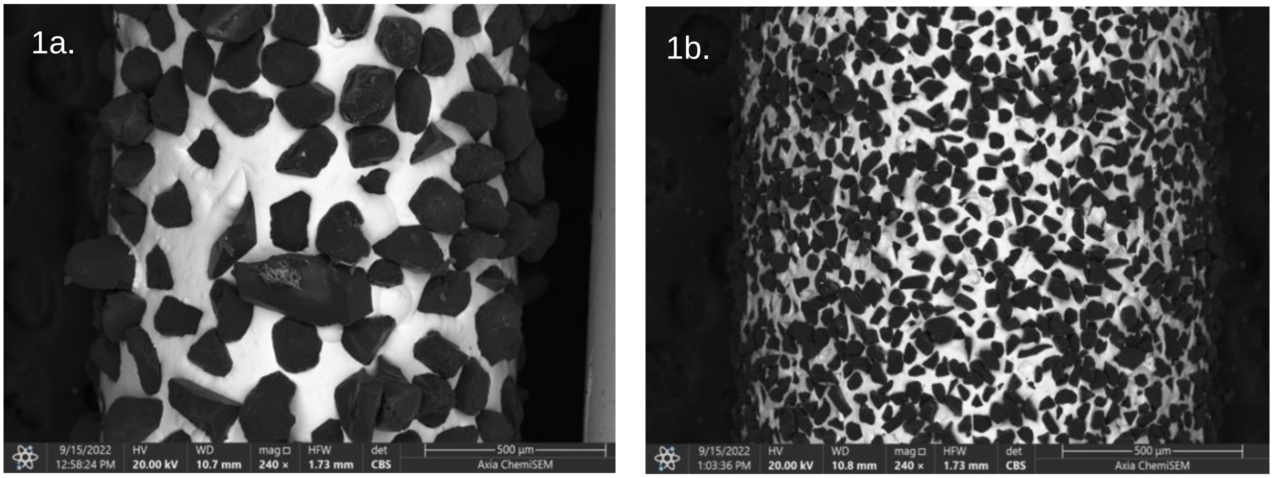

Figure 1a & b: Scanning electron micrographs of diamond burs showing carbon grit of (a) super coarse and (b) fine burs. (Southern Implants (PTY) LTD, Centurion, RSA), (SEM: Axia ChemiSEM, Thermo Fisher Scientific Inc., USA).

Song et al. investigated the quantitative influence of diamond grit size on subsurface damage induced in dental adjustment of feldspar prosthetic porcelain.[24] It included coarse, medium and fine grit sizes (10 – 125µm) and confirmed diamond grit size to be a controlling factor in determining the degree of substrate damage.[24] The study concluded that smaller grit sizes should be used to adjust dental porcelains to minimise subsurface damage.[24] Zirconia, however, is much harder than feldspar porcelain and much more difficult to cut.[5-7] For this reason, coarser burs are more commonly chosen to cut zirconia because it is expected to be more effective than smoother burs.[19-23]

Kim et al. examined the cutting efficiency of zirconia specific diamond burs compared with conventional diamond burs.[20] The study concluded that zirconia specific diamond cutting burs are not more efficient in cutting zirconia than conventional diamond burs.[20] It also concluded that finer diamond burs resulted in less damage to the zirconia and suggested that coarse diamond burs should be used to cut zirconia intra-orally.[20]

Anecdotal evidence has emerged suggesting that smoother burs provide more efficient cutting of zirconia due to a higher bur surface area to substrate ratio.[6] Vagkopoulou et al. reported that coarse burs introduced deeper surface flaws when cutting Y-TZP, which may result in reduced strength of the zirconia substrate.[6] These deep surface flaws can act as stress concentrators, making it weaker and more susceptible to fracture.[6] A study by Li et al. has shown that the use of smoother burs yield smoother ceramic restoration surfaces, resulting in less bacterial adhesion and improved internal adaptation.[25] Vagkopoulou et al. recommended using a grit size as small as 25µm for grinding TZP rather than coarse machining.[6] Surface scratches made by super coarse burs on zirconia are demonstrated in figure 2.

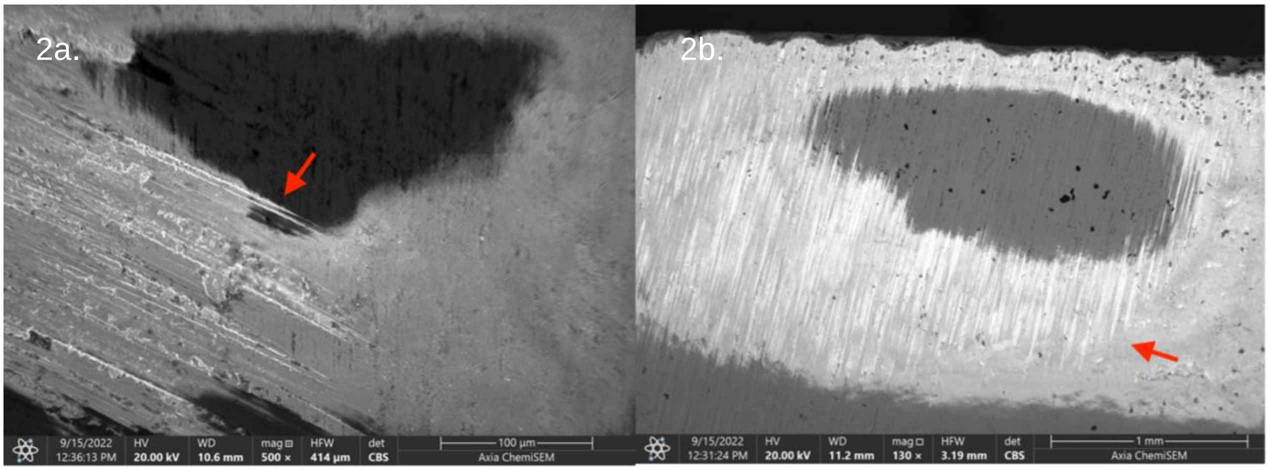

Figure 2a & b: Scanning electron micrographs showing surface scratches (indicated by arrows) made on zirconia by super coarse burs. (Southern Implants (PTY) LTD, Centurion, RSA, SEM: **Axia ChemiSEM, Thermo Fisher Scheintific Inc., USA)**

There is a large volume of published studies investigating the cutting efficiency of burs with different grit sizes on zirconia.[1,3,4,14,15,19,20,25] Some of these studies, however, are unsatisfactory because they only tested the efficiency of burs with coarser grit sizes: medium, coarse and super coarse.[1,3,4,14,15,21,22,23] Yin et al. included only ultrafine (10µm), fine (41µm) and coarse (172µm) in their study, and omitted super fine, medium and super coarse grit sizes.[19] Kim et al. included only fine (±50 – 70 µm) and coarse burs (±180µm) and omitted super fine, medium and super coarse grit sizes.[20]–Consequently, these studies are restricted to limited comparisons of different grit sizes. The research to date has failed to include sufficient evidence on cutting efficiency of zirconia with burs with all grit sizes.[1,3,4,14,15,19-23,25] Additionally, the grit sizes of diamond burs are not always disclosed by manufacturers or revealed in research.[3,23] Consequently, the lack of research that includes and compares all burs grit sizes, especially smoother burs, and omission of grit sizes make it difficult to establish a specific grit size group that will optimally cut zirconia. This indicates a need to better examine the cutting efficiency of diamond burs with a wider range of different known grit sizes on zirconia.

The present study intends to analyse the cutting efficiency of diamond burs on zirconia, using conventional straight fissure diamond burs with a wide range of known grit sizes (30-250µm). This includes: super coarse (SC), coarse (C), medium (M), fine (F) and super fine (SF) burs.

2.7 DRILLING HANDPIECES

In addition to different burs for cutting, clinicians can also use different types of drills for intra-oral cutting.[3,21,22] Contra-angle drills can be used for slower cutting (<15 000rpm) and high speed cutting (>20 000rpm) which can be done with air-turbines or electric motor handpieces.[21,22] Previous studies on drilling efficiency of zirconia mostly made use of air-turbines, rather than electric handpieces.[1,13,14,19,21-23] Although air-turbine handpieces generally function at a higher speed of rotation, Nakamura et al. has shown that electric handpieces are more efficient in cutting ceramic specimens than air-turbine handpieces, because of the increased torque provided by electric handpieces.[3] Loss of torque while cutting is seen in both types of handpieces, but a greater loss of torque has been noted with air-turbines, especially during the initial cutting process.[3,4,14,21,22]

2.8 CUTTING SPEED

Many studies that investigated the cutting efficiency of diamond burs on dental zirconia with air-turbine handpieces, used cutting speeds of 200 000rpm - 320 000rpm.[1,19-22] Electric motor handpieces operate at a much lower speed of rotation (rpm) than air-turbines.[21,22] This reduces stress and heat to zirconia and decreases the amount of trauma to the dental pulp if restorations are trimmed intra-orally.[3,22] Vagkopoulou et al. showed that manual grinding with less stress and constant water coolant is more beneficial to the structural soundness of the zirconia restoration.[6] In addition, electrical handpieces can be programmed to run at a controlled speed of rotation by adjusting its settings.[3] This is not possible for air-turbine handpieces. Jahanmir[14] concluded that cutting with a higher speed of rotation reduces surface damage on the ceramic substrate.[14] The maximum cutting speed on most electric handpieces are 40 000rpm. Therefore, an electric handpiece with electric motor was used for the present study at a speed of 40 000rpm.

2.9 CUTTING FORCE

Few studies have investigated the ideal force with which to cut zirconia clinically. Peters et al. and Nakamura et al. both recommended using a force of 0.9N, as this is the average force generated by clinicians when cutting intra-orally.[1,3] These studies, however, are not relevant clinically as they evaluated the cutting of pre-sintered zirconia, which is much softer and more brittle than zirconia that has already been furnaced.[1,3] Before zirconia is applied clinically, it has to undergo a sintering process where it is furnaced at very high temperatures.[1,3,6] This process includes a heating, sintering and cooling phase in order to optimize the properties of the zirconia and enhance the durability of the restoration.[5,6,26] A greater force is needed to cut this harder form of zirconia timeously.[3] Nakamura et al. increased the cutting force to 1.8N to attempt to achieve more effective cutting.[3] Yin et al. and Kim et al. applied a constant force of 2N on zirconia.[19,20] Evidence has shown, however, that increased force resulted in increased zirconia surface damage and increased deterioration of burs.[3] Chung et al. performed cutting efficiency tests on sintered zirconia using a cutting force of 1.7N (170mg).[27] The present study used the force recommended by Chung et al. (1.7N), because it is sufficient to cut zirconia without causing unnecessary damage to the bur and substrate and it is more clinically relevant, than that of Peters et al. and Nakamura et al.[27]

2.10 ANGLE AND CONTACT OF BUR

In clinical practice multiple points of the bur are directed to the substrate to elicit an efficient cutting rate.[6] The clinician changes the angle, speed, direction and position of the bur throughout cutting.[6] The current study assessed single point contact with zirconia on a single plane to ensure standardisation throughout all repetitions.[1] Peters et al. and Nakamura et al. utilised a customised device to ensure that the bur was held at a fixed horizontal and vertical position while conducting the study, as opposed to the clinical setting where the bur is applied to the substrate at different angles and spatial dimensions during cutting.[1,3,6] A similar device was designed and built for the purpose of the present study.

2.11 WATER FLOW RATE

Water flow rate (WFR) is delivered to the dental handpiece during tooth preparations to ensure that cutting temperatures remain low in order to protect the dental pulp and prevent heat-induced damage of the cut substrate.[1,3,19-21] It also helps to remove cut debris to improve visualisation and it helps keep the bur clean.[20,21] WFR is another variable that has been shown to affect cutting efficiency.[21] A WFR of at least 15mL/min is advocated when cutting intra-orally.[22] Peters et al. and Kim et al. chose a constant WFR of 25mL/min in their studies, as it was enough to ensure efficient cutting and debris removal without causing deflection of the handpiece.[1,20]

2.12 STUDY DESIGN

The aim of the present study was to identify which of the five different diamond bur grit sizes are the most efficient in cutting zirconia. When considering efficiency of a bur, both the substrate and the bur itself should be examined. For this reason, cutting depth into zirconia, damage to the cut zirconia and extent of bur deterioration was assessed. The most efficient bur would achieve the greatest cutting depth, the least amount of substrate surface damage and minimal bur deterioration, in the shortest time.

CHAPTER 3:

AIM, OBJECTIVES AND HYPOTHESIS

3.1 AIM

The aim of the present study was to identify the most efficient diamond bur grit size group for cutting zirconia. Efficiency was measured by comparing the cutting depth of each bur into zirconia, analysing zirconia specimens for any surface damage after cutting and measuring bur deterioration.

3.2 OBJECTIVES

1) To measure the cutting depth of diamond burs with different grit sizes using the same amount of force (1.7N) on Y3-TZP specimens with a constant cutting speed of 40 000rpm and constant water cooling of 25mL/min for a duration of 1min.[1]
2) To assess the zirconia substrate for initiation and propagation of surface fractures and damage after cutting.
3) To measure the extent of bur deterioration of each bur in the five different grit size groups.

3.3 THE NULL HYPOTHESIS TESTED WAS

There would be no significant difference between the cutting efficiency of diamond burs with different grit sizes on zirconia.

CHAPTER 4:

MATERIALS AND METHODS

4.1 STUDY DESIGN

This was an experimental, prospective analytical study.

4.2 SETTING

Cutting of zirconia specimens and data collection:

DrDentist - Dental Practice,

Dr. Elsabé Marais and Associates

1E Olienhout Avenue, Birchleigh, Kempton Park, RSA, 1632

SEM evaluations:

Southern Implants (PTY) LTD

1 Albert Rd, Irene Security Estate, Centurion, RSA, 0062

4.3 RESEARCH PROJECT PARAMETERS

An electric handpiece (S-Max M95L, NSK, Japan) was used to cut the zirconia specimens with the following specifications:
A controlled force of 1.7N; constant speed of 40 000rpm; constant water-flow rate of 25mL/min within a controlled time of 1min.[1]

These specifications have been shown in previous studies to provide the optimum conditions to achieve the best cutting efficiency of diamond burs on zirconia.[1,3,24] The recommended flow rate of 25mL/min has shown to be sufficient to prevent overheating without interfering with the cutting proccess.[1,3]

A pilot study was performed to confirm and standardise all parameters and ensure optimal results according to the specific experimental set-up. This included 5 zirconia specimens and 5 burs with different grit sizes. The zirconia specimens were cut with each respective bur. All specifications and parameters were confirmed and the study commenced.

4.4 RESEARCH OBJECT SELECTION

The following 5 diamond bur grit-size groups were evaluated: super fine (SF) 30µm, fine (F) 50µm, medium (M) 107µm - 120µm, coarse (C) 150µm - 180µm and super coarse (SC) 180µm - 250µm (Table 1, p. 12).

Thirty (30) 3Y-TZP sintered zirconia (Straumann HT+, Basel, Switzerland) specimens were prepared with a thickness of 1,5mm, width of 10mm and length of 14mm.[1] All specimens were numbered to create a *Specimen ID*. Six (6) zirconia specimens were grouped into each of the 5 grit size groups. All specimens underwent surface analysis using 3,5x magnification loupes (Zumax Medical Co., Ltd., China) and posterior illumination to exclude any existing surface flaws before cutting.

Thirty (30) commercial straight fissure diamond burs (Horico Dental Hopf, Ringleb & Co GmbH & Cie, Berlin, Germany) with similar diameters and profiles, were used according to a computer-generated randomised drilling sequence (Appendix 2, p. 48) with 6 burs for each of the 5 different grit size groups.

Grinding was repeated 6 times for each group using a new bur for each test according to the randomized drilling sequence (Appendix 2, p. 48). The quantity of 6 was chosen as it is the minimum number of replications required to perform an Analysis of Variance (ANOVA) test.

Table 1: Standard Parameters of Diamond Burs (Horico Dental Hopf, Ringleb & Co GmbH & Cie, Berlin, Germany)

Description	CODE	GRIT SIZE (μm)	Colour
Super Fine	SF	20-30	Yellow
Fine	F	40-50	Red
Medium	M	107-120	Blue/Clear
Coarse	C	150-180	Green
Super Coarse	SC	180-250	Black

4.5 MATERIALS AND METHOD

4.5.1 PREPARATION OF SPECIMENS

Thirty (30) Y3-TZP zirconia specimens were prepared from zirconia blocks (Straumann HT+, Basel, Switzerland) using a milling machine (CEREC MC X, Dentsply Sirona, Germany). These specimens were then sintered at 1450°C for 2h in a furnace (CEREC SpeedFire, Dentsply Sirona, Germany).[23] Each specimen was prepared with a thickness of 1,5mm, width of 10mm and length of 14mm, as indicated in figure 3.[1]

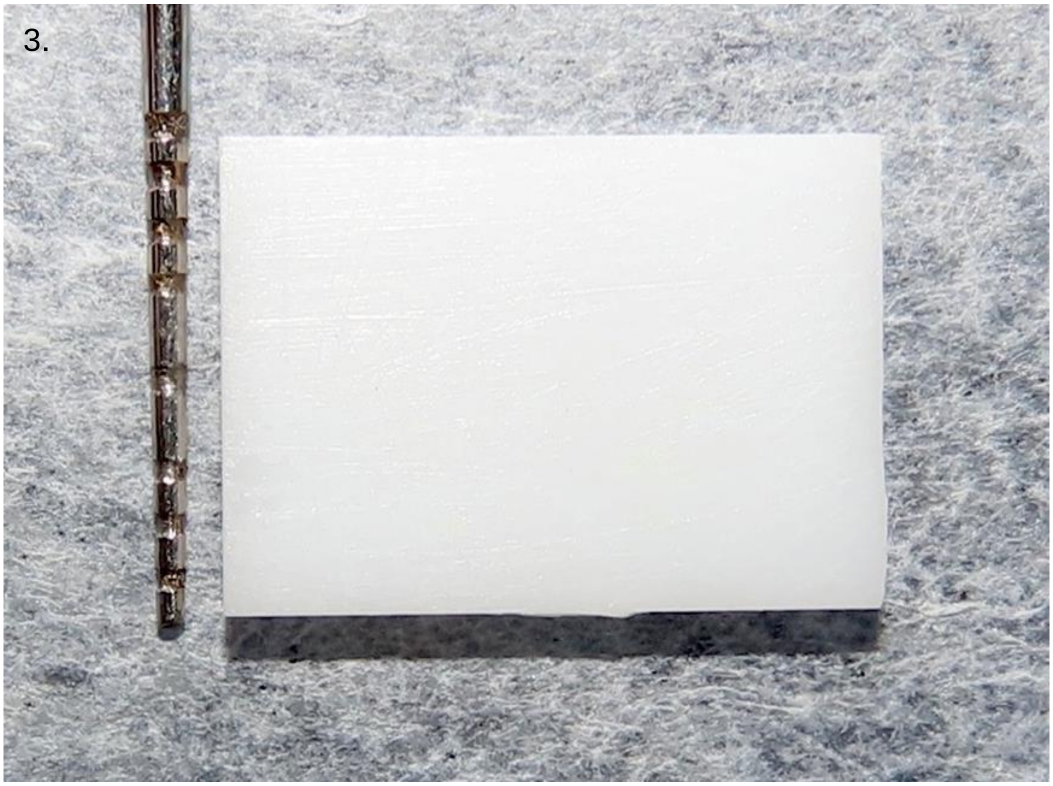

Figure 3: Zirconia specimen measuring 10mm x 14mm x 1,5mm, featuring University of Michigan “0” probe (Wright Millners, RSA).

4.5.2 PRE-EXPERIMENTAL EVALUATIONS

All zirconia specimens underwent surface evaluation using 3,5x magnification loupes (Zumax Medical Co., Ltd., China) and posterior illumination to exclude any existing macroscopic damage. Six (6) specimens were randomly selected to undergo SEM (Axia ChemiSEM, Thermo Fisher Scientific Inc., USA) to confirm initial findings, as indicated in figure 4. Apart from superficial surface irregularities, no macroscopic damage or microfractures were detected either with loupes or under SEM on any of the zirconia specimens.

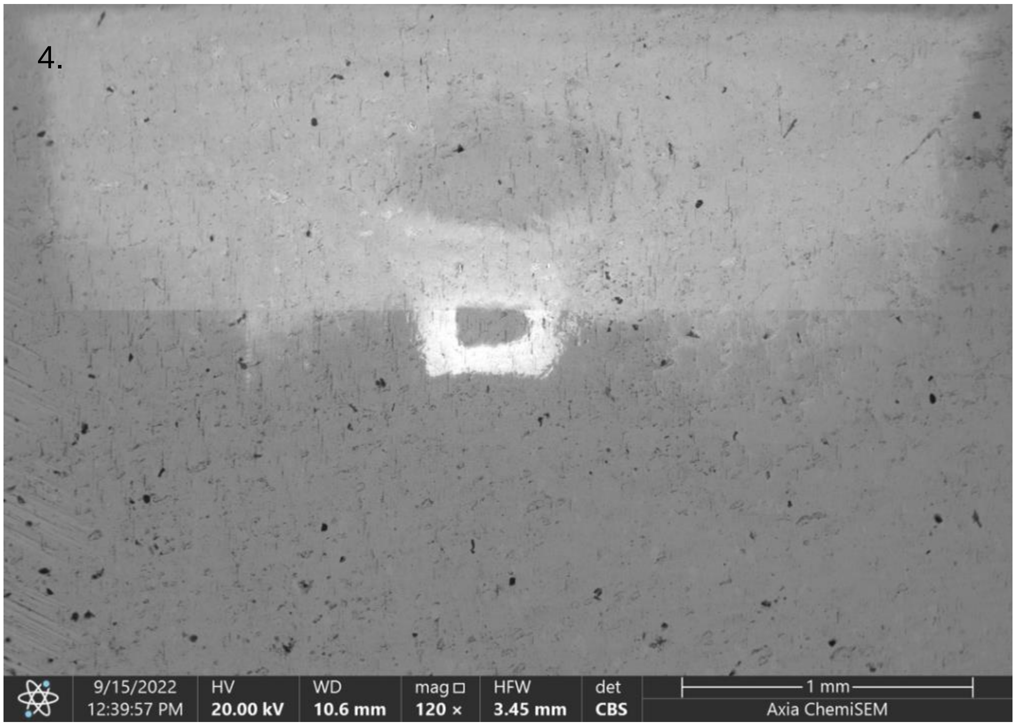

Figure 4: Scanning electron micrograph of zirconia specimen under 120 x magnification, showing no microfractures.

Each bur diameter was measured in mm using a Whitworth Electronic Digital Calliper (WEDC) (Tork Craft, South Africa). The WEDC was used for measurements as it provides accurate results up to 2 decimal places. Five (5) burs, 1 from each grit size group, indicated in figure 5, were randomly selected to undergo SEM analysis to confirm the initial WEDC findings. Figure 6 shows the SEM used for the present study. Measurements were taken for each individual bur at a random point of the parallel shaft of the bur and written under *First reading* in the relevant data collection sheet (Appendix 1.iii, p. 47).

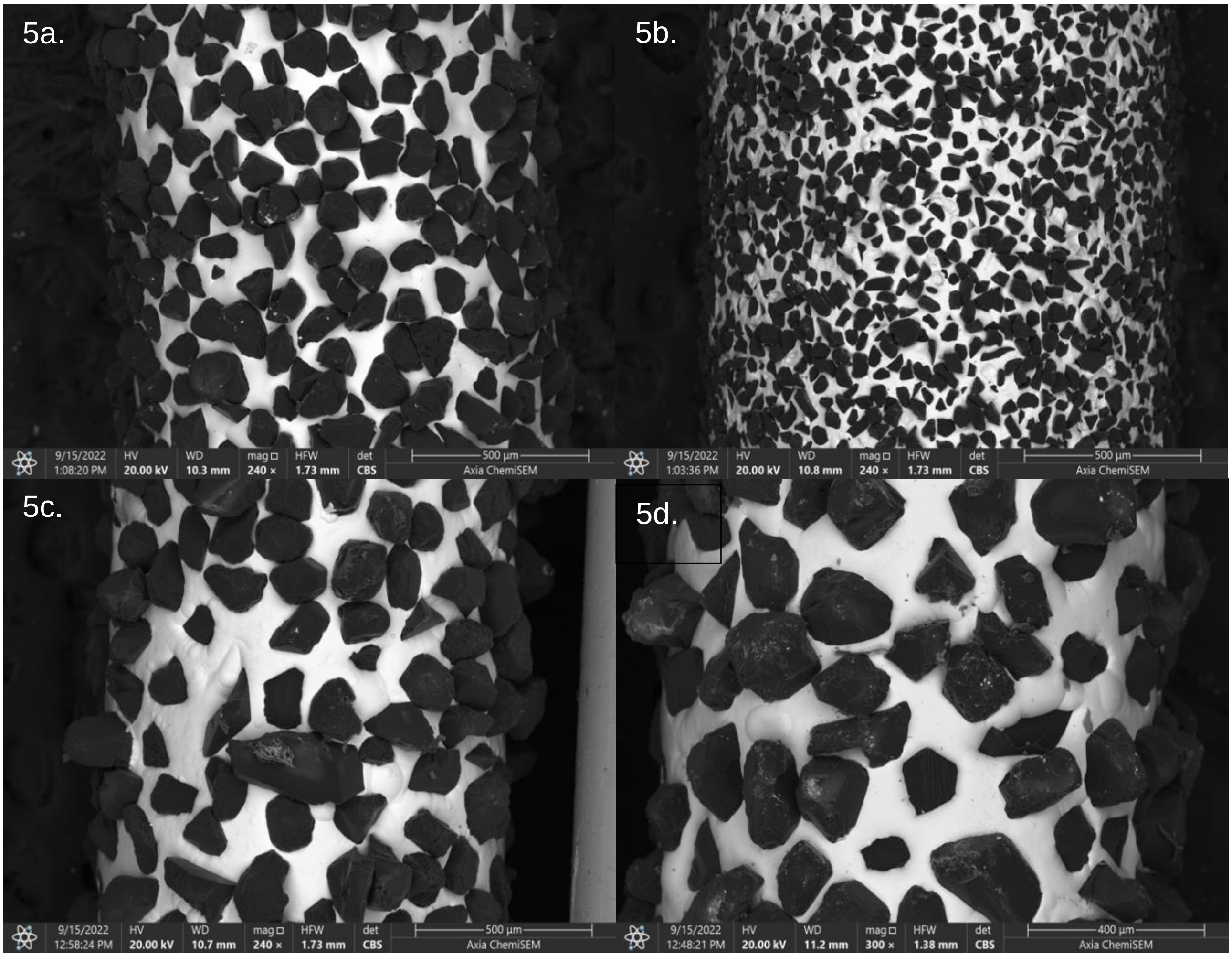

Figure 5a, b, c & d: Scanning electron micrographs of diamond burs with medium (M), fine (F), coarse (C) and super coarse (SC) grit sizes respectively.

6.

Figure 6: Scanning electron microscope used to record images of zirconia specimens and diamond burs (Axia ChemiSEM, Thermo Fisher Scientific Inc., USA).

The high-speed electric handpiece (Ti-Max Z95L, NSK, Japan) was digitally programmed to run at 40 000rpm. The desired WFR of 25mL/min was established by running water through the electric handpiece for 1 min into a measuring cup. Flow rate was adjusted until a measurement of 25ml was obtained after 1min.

Metal weights were measured using a digital scale (Salter, Manchester, England) until a reading of 170g was confirmed. This was incorporated in the experimental apparatus discussed below.

Figure 7: Salter Digital Scale used to measure 170g weight.

4.5.3 EXPERIMENTAL APPARATUS

A similar experimental set-up was used as described by Peters et al. and Nakamura et al.[1,3] The Mechanical Engineering Department of the University of Pretoria constructed a comparable custom rig for the purpose of the present study to ensure constant, reproducible results while drilling. This device will henceforth be referred to as the Dental Drilling Simulator (DDS). The DDS is a 38mm x 22mm x 18mm metal device that consists of a low friction track and cart incorporated in a vertical pulley system, shown in figure 8a and b.

A 1,5mm x 10mm x 14mm slot for the zirconia specimens was mounted on top of the cart. The slot can be tightened or loosened with a screw, ensuring that the specimens are securely fixed to the cart during cutting. This prevents deviation of the specimen, and consequently the bur, while cutting.

The measured weight of 170g was attached to the cart with string and suspended from the DDS in a vertical pulley system. Friction between the string and the underlying surface was decreased by incorporating a wheel in the pulley system that allows for smooth movement of the string and weight. Releasing the weight generated a vertical force which, along with the influence of gravity (gravitational constant 9.81m/s^2) resulted in the desired horizontal force of 1.7N.[24] Once the weight was released, the trolley with the fixed zirconia specimen moved down the tracks towards the drill at a right-angle using bearings for reduced frictional interference. It continued down the tracks until it contacted the bur, simulating dental drilling at a constant horizontal force of 1.7N.

A stopper screw was incorporated in the DDS to allow the cart to be immobilized on the tracks, preventing it from being pulled forward by the weight. Once the stopper screw was released the cart with zirconia specimen was pulled forward by the weight attached to it.

A vertical frame was soldered over the tracks with a custom-made screw clamp fixed to it. The screw clamp fit the intended electric handpiece (Ti-Max Z95L, NSK, Japan) precisely. The screw clamp with electric handpiece could be moved vertically until the desired cutting height was achieved. Once tightened, it ensured that the handpiece was secured at a fixed vertical and horizontal position, with the bur perpendicular to the flat surface throughout the study.

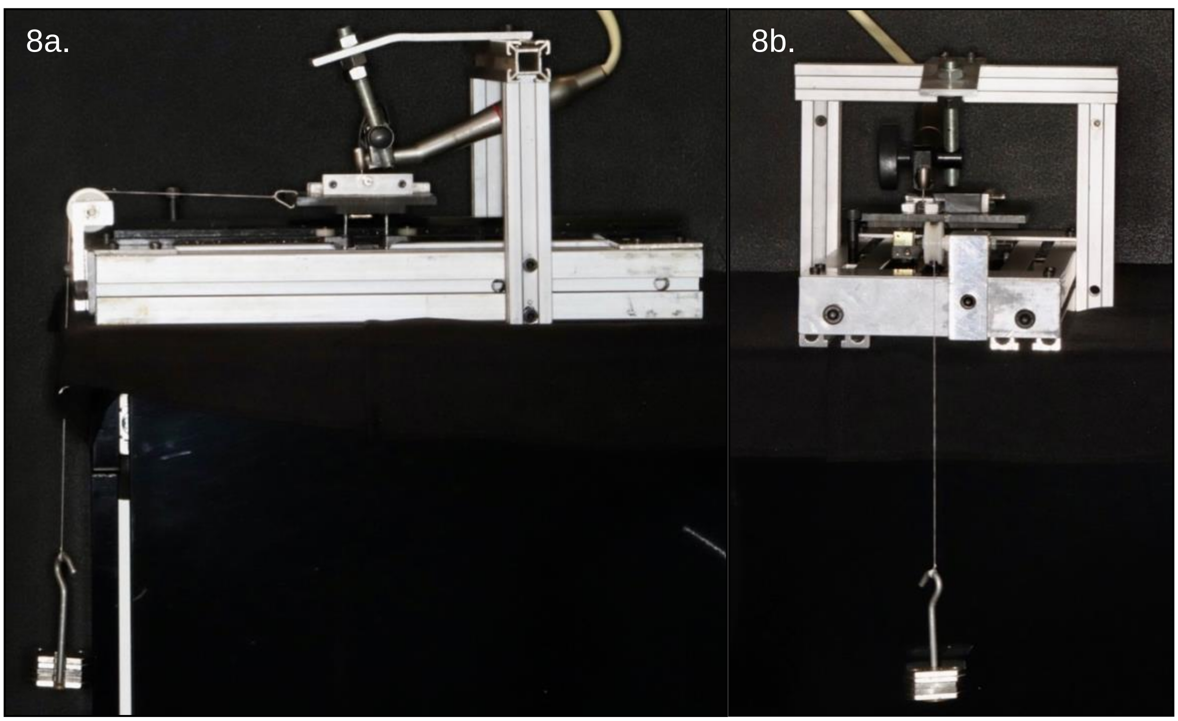

Figure 2a & b: Lateral and anterior view of fully assembled DDS showing vertical weight of 170 g with electric handpiece.

4.5.4 EXPERIMENTAL SET-UP

The DDS was placed on a smooth, horizontal surface. A level measuring instrument (Ross Manufacturing Co Inc., USA) was used to ensure the surface was completely horizontal. The high-speed electric handpiece (Ti-Max Z95L, NSK, Japan) was fixed in the screw clamps and the screw was tightened. The first diamond bur, according to the randomised drilling sequence (Appendix 2, p. 48), was placed in the handpiece. The first zirconia specimen was placed into the custom-made slot and secured with a screwdriver. The cart with the zirconia specimen was positioned directly beneath the electric handpiece, with the specimen placed 1mm from the bur point. The stopper screw was tightened and the position of the cart fixed. The weight (170g) was added, resulting in a static horizontal pull of 1.7N on the cart. The stopwatch was set at 1 min and the cutting phase commenced, as shown in figure 9a. and b.

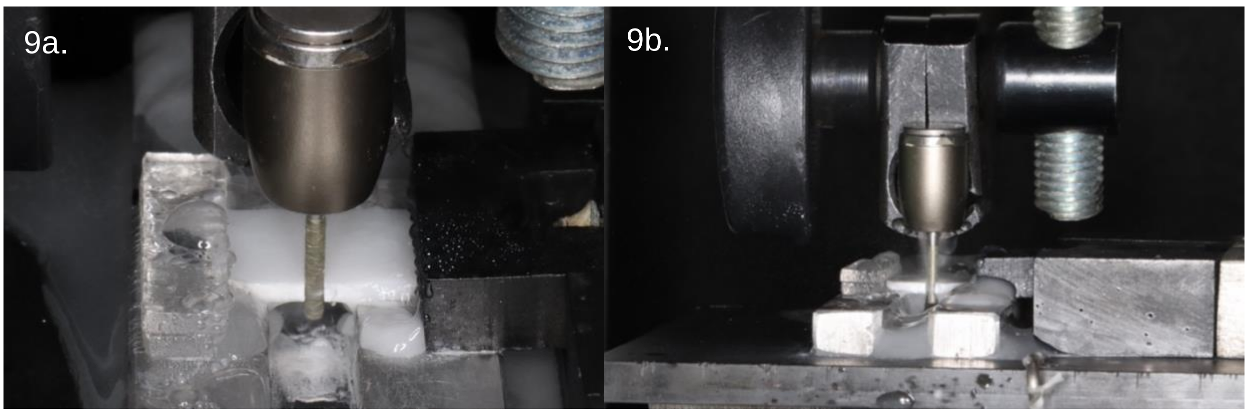

Figure 9a & b: Bur and drill positioned in DDS, cutting zirconia specimen.

4.5.5 EXPERIMENTAL PROCEDURE

1. The electric handpiece was started and allowed to reach 40 000rpm.
2. Once full speed was achieved (indicated digitally) the stopper screw was released, and the cart allowed to move along the designated path.
3. The stopwatch was started the instant the bur made contact with the zirconia specimen.
4. Cutting commenced and continued undisturbed for 1min.
5. Excess water was removed with suction, without touching or disturbing any part of the cutting process.
6. Cutting ceased immediately once 1min was reached.

7. The cart with specimen was moved to the back of the trolley and the stopper screw tightened to prevent the cart from moving.
8. The specimen was removed, wiped with an alcohol swab to remove any debris, and placed in a plastic sachet marked with its specific *Specimen ID*.
9. The bur was removed, dried, and placed with the zirconia specimen in the marked sachet to ensure that each bur can be traced back to its specific specimen.
10. The sachet with specimen and relevant bur was put aside for later evaluations, shown in figure10.
11. The DDS was assessed, dried, and cleaned in preparation for the next cutting session.
12. This process was repeated precisely for every bur and zirconia specimen in every grit size group in 6 sessions of 5 repetitions according to the randomized drilling sequence (Appendix 2, p. 48) until all thirty (30) zirconia specimens were cut.

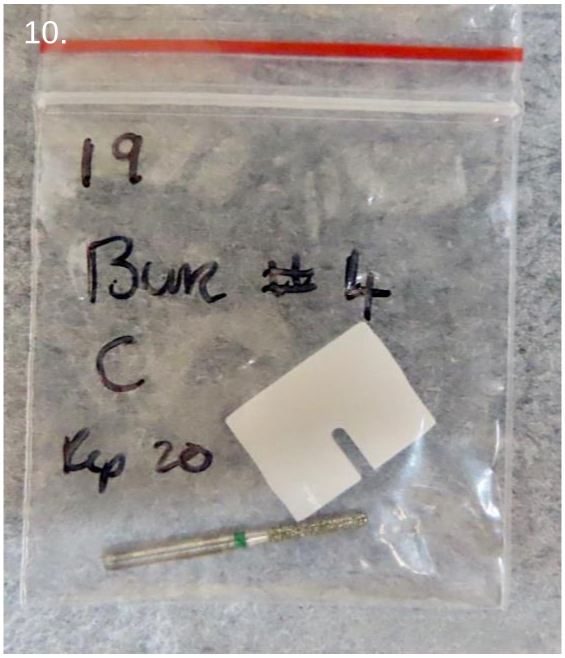

Figure 10: Collection of zirconia sample and respective diamond bur into marked sachet.

4.6 MEASUREMENTS

The following measurements were performed after completion of the experiment.

1) Cutting depth was determined by measuring the depth that was cut into the zirconia specimens with each respective bur within the 1min time limit. Figure 11a. and b. show the cut zirconia specimen. All cutting depths were measured up to 2 decimal places in millimetres using a WEDC (Tork Craft, South Africa) and noted on the relevant data collection sheet (Appendix 1i, p. 45).
2) Incidence of initiation and propagation of surface damage and cracks on the zirconia specimens were assessed under 3,5x magnification loupes (Zumax Medical Co., Ltd., China). The specimens were illuminated from behind while undergoing assessment to enhance visibility of cracks. SEM evaluations were not performed after cutting, because backlighting was necessary to enable visualisation of any cracks through the dense zirconia specimens. The SEM that was used did not allow for evaluation of the specimens with backlighting, therefore loupes with backlighting were the chosen magnification method. Any surface damage was reported as either present (Y) or absent (N) for each zirconia specimen. This was noted on the relevant data collection sheet (Appendix 1ii, p. 46).
3) The extent of bur deterioration of each bur in each different grit size group was measured in percentage (%). Bur diameter measurements were taken before and after cutting using the WEDC (Tork Craft, South Africa).[1,3] Pre-experimental measurements were taken at any point of the parallel shaft of the cutting part of the burs. After cutting, measurements were taken at the area of most wear, where the bur made contact with the zirconia specimens. These measurements were then noted under *Second reading* in the relevant data collection sheet (Appendix 1.iii, p. 47). The difference in initial diameter and final diameter was calculated and used to get a mean percentage (%) of deterioration.

All measurements were taken by the primary researcher and by the research supervisor. An average measurement of the two observers were then taken and written down in the relevant data collection sheets.

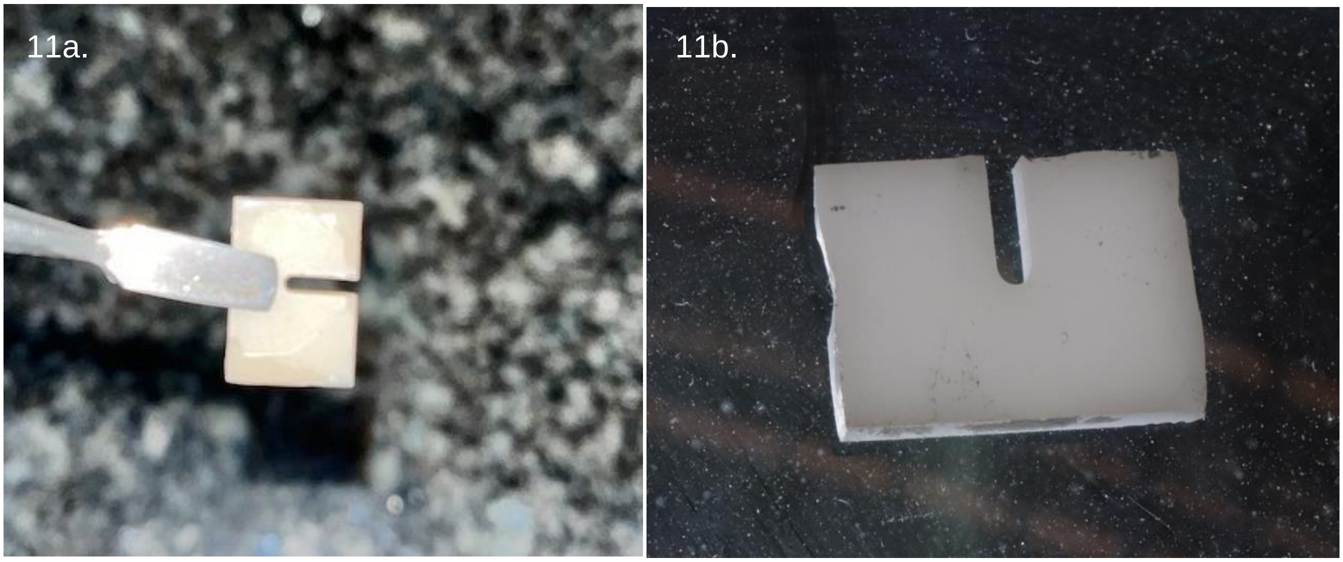

Figure 11a & b: Zirconia specimens after being cut.

4.7 DATA ANALYSIS

Assessments were made as follows:

4.7.1 CUTTING EFFICIENCY

For each of the 5 grit size groups (SF, F, M, C and SC) the mean and median drilling depth (mm) achieved in each of the 6 relevant zirconia specimens, were calculated. The 5 mean values were compared by ANOVA and the 5 median values were compared by the non-parametric Kruskal-Wallis test. Each test was followed-up with pair wise comparisons of the mean or median values if significance was indicated.

4.7.2 PRESENCE OF SURFACE DAMAGE

This was assessed by analysing the presence or absence of surface damage that occurred on each of the 6 zirconia specimens after drilling, for each grit size group. Therefore, all thirty (30) zirconia specimens were evaluated for the presence of surface damage. The frequencies were compared by the Fisher Exact test.

4.7.3 BUR DETERIORATION

This was measured as the percentage (%) of bur deterioration before and after cutting. The mean percentage (%) was calculated for each of the 5 grit size groups and were compared by ANOVA.

All the statistical procedures were performed using SAS (SAS Institute Inc, Cary, NC, USA). Statistical tests were two-sided and p-values ≤ 0.05 were considered significant.

4.8 SAMPLE SIZE

A power-driven sample size calculation cannot be done since estimations of mean and standard deviation values, which are required for the formula, are not available.

Mean and median values of the drilling depths (mm) of the burs were compared by ANOVA and by the non-parametric Kruskal-Wallis test respectively. For both these test procedures a minimum sample size of more than 5 replicates per category (bur grit size groups) is needed. For the present study a sample size of 6 replicates for each of the 5 groups of burs, was proposed, i.e., a total of 5 x 6 = 30 zirconia specimens, and 5 x 6 = 30 burs: 6 x (SF) burs; 6 x (F) burs; 6 x (M) burs; 6 x (C) burs and 6 x (SC) burs.

Each of the zirconia specimens were cut with a new diamond bur for each grit size group.

4.9 BIAS

Bias in a research study refers to a systematic error that occurs in the study design or in the way the study is conducted that leads to an incorrect conclusion. In the context of the current study, it could occur in the way in which the zirconia specimens were prepared, in the way the drilling was performed, in the way that the drilling depths were measured, or in the way in which conclusions were drawn. This was avoided as follows:

1) Following standard operating procedures for the preparation of the specimens, for drilling and for measuring the depth of drilling. This included:
   - Set-up of a controlled environment using the DDS (Figure 8, p. 18).

- Controlled, pre-programmed parameters were maintained throughout the entire study:
  - Constant speed of 40 000rpm pre-programmed into the electric motor.
  - Constant water-cooling at 25mL/min throughout the experiment.
  - Controlled cutting force of 1.7N.
  - Constant time limit of 1min for each repetition using a standard stopwatch.
- Standardization of zirconia specimens:
  3Y-TZP zirconia specimens, 14mm x 10mm x 1,5mm.
- Standard bur grit sizes were used.
- Conventional straight fissure diamond burs with similar diameters were used from the same company (Horico, Germany).

2) Burs were used according to a computer-generated randomized drilling sequence. (Appendix 2, p. 48)

3) To ensure that measurements were accurate, all assessments were done by the primary researcher and repeated by the research supervisor and an average measurement was then taken between the two observer's readings. This was done for all assessments performed before and after cutting:
   - Measuring drilling depths after cutting.
   - Identifying any surface damage before and after cutting.
   - Measuring bur diameters before and after cutting.

4) The research experiment was performed in a single day to avoid environmental changes that might have influenced the outcome.

5) Statistical analysis of data was performed by an independent statistician, avoiding analytical, interpretational and conclusion bias.

4.10 VALIDITY AND RELIABILITY

Validity is the extent to which an assessment is accurate in measuring what it intends to measure. Reliability is the extent to which an assessment will yield the same result when applied under the same circumstances either with the same or different observers, or at different times.

Validity and reliability were ensured by:

- Using the Data Collection Sheets (Appendix 1 & 2, pp. 45-48) which were compiled for the specific purpose of collecting accurate data relevant to the objectives of the study and which were used by the same researcher under the same circumstances for recording of the study data.
- Using calibrated precision measuring equipment strictly in accordance with the relevant instructions for use.
- Using the DDS device that was built for the specific purpose of providing controlled and repeatable drilling simulations for the present study.

CHAPTER 5:

RESULTS

The statistical analysis was descriptive and inferential and all the procedures were performed on SAS (SAS Institute Inc, Cary, NC, USA), Release 9.4.

The following acronym is used in the text: SD: Standard deviation

5.1 CUTTING DEPTH OF DIAMOND BURS INTO ZIRCONIA SPECIMENS

Table 2.1 represents the mean, median, minimum, and maximum cutting depths (mm) that was cut into the thirty (30) zirconia specimens of each bur grit size group within the time limit of 1min:

Table 2.1: Cutting depth (mm) of diamond burs into zirconia specimens

Bur grit size group		**Cutting depth (mm)**		
Bur	**n**	**Mean (SD)**	**Median**	**Minimum / Maximum**
Super fine (SF)	6	1.39 (0.52)	1.17	0.93 / 2.05
Fine (F)	6	5.79 (1.44)	5.87	3.64 / 7.38
Medium (M)	6	4.86 (0.41)	4.75	4.48 / 5.47
Coarse (C)	6	4.54 (1.22)	4.46	2.70 / 6.49
Super coarse (SC)	6	4.80 (0.75)	5.00	3.54 / 5.44

ANOVA for comparison of the **mean values** showed:

- That the minimum mean cutting depth was achieved with the SF bur (1.39mm), and the maximum mean depth was achieved with the F bur (5.79mm).
- That the mean cutting depth with the SF bur (1.39mm) is significantly smaller than the mean depth achieved with each of all the other burs ($p<0.001$).
- That the mean cutting depth with the F bur (5.79mm) and with the C bur (4.54mm) differ significantly ($p=0.032$).
- The mean cutting depths of the M, C and SC burs did not differ significantly.

A non-parametric analysis of variance (Kruskal-Wallis) for comparison of the **median values** showed:

- That the minimum median cutting depth was achieved with the SF bur (1.17mm), and the maximum median depth was achieved with the F bur (5.87mm).
- That the median cutting depth with the SF bur (1.17mm) is significantly smaller than the median depth achieved with each of all the other burs (p=0.004).

5.2 PRESENCE OF SURFACE DAMAGE

Table 2.2 shows the number and percentage (%) of zirconia specimens that presented with surface damage after drilling:

Table 2.2: Presence or absence of surface damage on zirconia specimens

Bur grit size group	**Presence of surface damage**	
	Yes	**No**
Super fine (SF)	-	6 (100%)
Fine (F)	-	6 (100%)
Medium (M)	-	6 (100%)
Coarse (C)	2 (33.3%)	4 (66.7%)
Super course (SC)	2 (33.3%)	4 (66.7%)

Surface damage was found on only 4 of the zirconia specimens:

- Two (2) specimens cut with the C burs, 33% of specimens.
- Two (2) specimens cut with SC burs, 33% of specimens.
- Specimens cut with SF, F, and M had 0% surface damage.

5.3 BUR DETERIORATION

Table 2.3 shows the mean and the median values of two consecutive bur diameter measurements (mm), together with the bur deterioration calculated as the percentage loss in overall bur diameter. The two p-values in the last column show the significance of the deterioration, as measured by the mean and the median respectively, and testing the null hypothesis that the deterioration is 0.

Table 2.3: Bur deterioration values of each bur grit size group

Bur grit size	n	Bur diameter (mm) and deterioration (%)		
		Mean (SD)	**Median**	**p-values***
Super fine (SF)				
First reading (mm)	6	1.33 (0.00)	1.33	
Second reading (mm)	6	1.30 (0.01)	1.31	
Deterioration (%)	**6**	**2.01 (0.91)**	**1.88**	**0.003 / 0.031**
Fine (F)				
First reading (mm)	6	1.43 (0.01)	1.43	
Second reading (mm)	6	1.37 (0.01)	1.37	
Deterioration (%)	**6**	**3.97 (0.83)**	**3.85**	**<0.001 / 0.031**
Medium (M)				
First reading (mm)	6	1.35 (0.00)	1.35	
Second reading (mm)	6	1.31 (0.01)	1.32	
Deterioration (%)	**6**	**2.84 (0.87)**	**2.59**	**0.001 / 0.031**
Coarse (C)				
First reading (mm)	6	1.35 (0.01)	1.35	
Second reading (mm)	6	1.25 (0.03)	1.25	
Deterioration (%)	**6**	**7.06 (1.99)**	**7.41**	**<0.001 / 0.031**
Super coarse (SC)				
First reading (mm)	6	1.34 (0.01)	1.35	
Second reading (mm)	6	1.22 (0.03)	1.22	
Deterioration (%)	**6**	**9.05 (2.44)**	**9.33**	**<0.001 / 0.031**

*p-values: t test/sign test

- For each bur both the mean and the median values differed significantly from 0 (all p-values are <0.05). Thus, a significant deterioration was found with each bur as measured by the mean and the median values.
- The least deterioration was found with the SF bur (mean=2.01% and median=1.88%).
- The most deterioration was found with the SC bur (mean=9.05% and median=9.33%).

ANOVA was performed for comparison of the **mean deterioration values (%)** of the five burs, followed by pairwise comparisons of the percentages. The results are best explained when the mean values are arranged from the smallest to the largest, as indicated by table 2.4.

Table 2.4: Mean bur deterioration values (%)

Bur	SF	M	F	C	SC
Mean	2.01	2.84	3.97	7.06	9.05
Category	I	II		III	

Three categories of burs could be identified:

- Category I: Bur SF with the least mean deterioration percentage (2.01%), differed significantly from the mean deterioration of all the other burs (p≤0.039), except bur M (p=0.363).
- Category II: The mean deterioration percentages for burs M and F (2.84% and 3.97%) do not differ significantly from each other (p=0.220) but differ significantly from burs C and SC (p<0.002).
- Category III: The mean deterioration percentage for burs C and SC (7.06% and 9.05%) differ significantly from each other (p=0.036), and furthermore both differ from all the other burs (p<0.002).

A non-parametric analysis of variance (Kruskal-Wallis) was performed for comparison of the **median deterioration values (%)** of the five burs, followed by pairwise comparisons of the percentages. The results are best explained when the median values are arranged from the smallest to the largest, as indicated in table 2.5.

Table 2.5: Median bur deterioration values (%)

Bur	SF	M	F	C	SC
Median	1.88	2.59	3.85	7.41	9.33
Category	I	II		III	

The same three categories of burs as above could be identified:

- Category I: The median deterioration percentage of bur SF with (1.88%) differed significantly from the deterioration of all the other burs (p=0.010), except bur M (p=0.418).
- Category II: The median deterioration percentages for burs M and F (2.59% and 3.85%) do not differ significantly from each other (p=0.052) but differed significantly from burs C and SC (p<0.010).
- Category III: The median deterioration percentages for burs C and SC (7.41% and 9.33%) do not differ significantly from each other (p=0.148), but both differed significantly from all the other burs (p<0.010).

Figure 12 below summarizes the difference in mean bur deterioration between the five bur grit size groups.

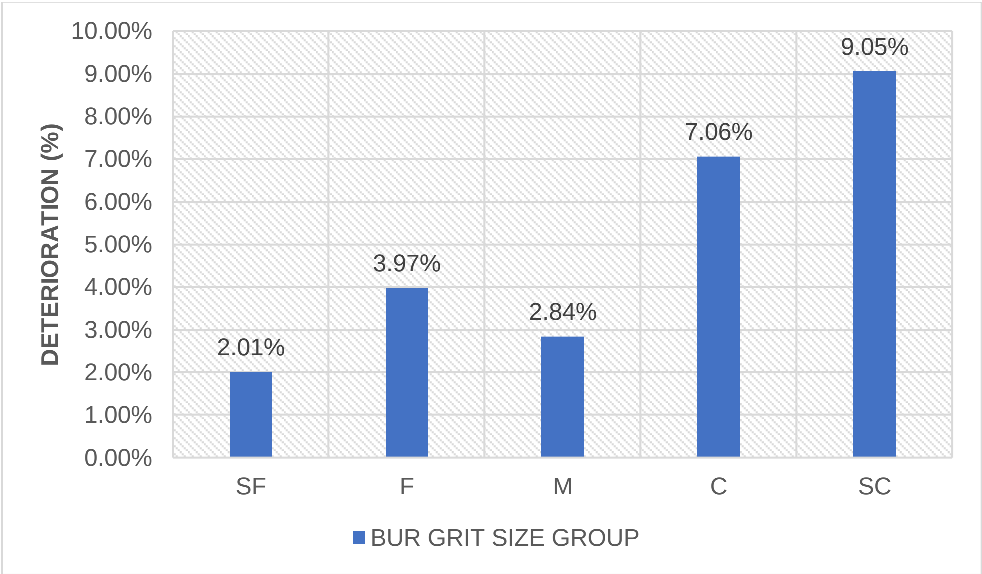

Figure 12: A bar graph representing the mean bur deterioration of each bur group after 1 min of cutting zirconia.

5.4 VALIDITY

Given the small sample sizes and the data achieved in the study, retrospective power calculations were performed to evaluate the validity of the significant differences of pairwise comparisons of mean values by t-tests in the ANOVA for drilling depth and for bur deterioration. The following results were found:

The power for comparison of the mean cutting depth for burs F and C (5.79% and 4.54% respectively) was 30%. The power for all the other comparisons were above 90%.

The power for comparison of the mean deterioration percentages for burs SF and M (2.01% and 2.84% respectively) were 29% and for comparison of burs C and SC (7.06% and 9.05% respectively) were 27%. The power for all the other comparisons were above 83%.

With only three exceptions, the power calculations were all sufficient and above 83%. Power is normally expected to be ≥80% in clinical research, which supports the reliability of this study.

CHAPTER 6:

DISCUSSION

The present study aimed to identify the most efficient diamond bur grit size for cutting zirconia. Many studies have investigated the cutting efficiency of diamond burs on dental zirconia.[1,3,4,19-22,27] However, to the authors' knowledge, this appears to be the first study to clearly define and include all relevant diamond bur grit sizes, namely SF, F, M, C and SC, to determine the most efficient grit size for cutting zirconia using an electric handpiece. When cutting zirconia, both the bur and the substrate undergo deterioration.[1,3,19-22,] Consequently, the extent of deterioration of each bur, damage to the cut zirconia and the cutting depth into zirconia were assessed. The most efficient bur would achieve the greatest cutting depth, minimal substrate surface damage, and the least bur surface deterioration, in the shortest time.

According to the results obtained from this study, the null hypothesis that there would be no significant difference between the cutting efficiency of diamond burs with different grit sizes on zirconia was rejected as there was a significant increase in cutting efficiency with the F bur grit size group.

6.1 CUTTING DEPTH

The first objective of the study was to identify the bur that would achieve the greatest cutting depth into zirconia after 1min of cutting. Interestingly, the maximum mean cutting depth (5.79mm) and maximum median cutting depth (5.87mm) was achieved by the F bur group with grit sizes between 40μm - 50 μm. This is contrary to previous studies that have found that coarser burs are more capable of achieving greater cutting depths in zirconia than finer burs.[1,3,19-23,29] However, most of these studies only investigated the use of burs with M to SC grit sizes (107μm - 250μm) and omitted the possible effect of finer burs (<100μm).[1,3,22,23,28,29]

Two studies included finer burs, but omitted other bur grit sizes.[19,20] Yin et al. used ultra-fine (10μm), fine (41μm) and coarse (172μm) burs in their study, but omitted super fine (20μm – 30μm), medium (107μm – 120μm) and super coarse burs (180μm - 250μm).[19]

Compared to the present study that used a cutting force of 1,7N, cutting time of 1min and an electric handpiece that cut at a speed of 40 000rpm, they had an increased applied force of 2N within a prolonged cutting time and an air-turbine handpiece that was used at increased speeds of 260 000-320 000rpm.[19] Kim et al. investigated the cutting efficiency of conventional diamond burs compared to zirconia removal diamond burs, but included only fine (40µm - 50µm) and coarse (150µm - 180µm) burs in their study.[20] A greater cutting force of 2N, longer cutting time of 5min and higher cutting speed of 200 000rpm was also used, compared to the present study.[20] The increase in force, time and speed in these studies resulted in more rapid bur deterioration compared to the present study.[19,20] Both studies advocated the use of coarser burs over that of finer burs for cutting zirconia.[19,20] This contradicts the results of the present study that suggested that F burs are more effective in cutting zirconia. A likely reason for this contradiction is that the change in drilling parameters that lead to increased bur deterioration resulted in less effective cutting and ultimately a different outcome than that of the present study.

Another possible explanation for the F bur being more successful in the present study, is that there is an increased surface area to substrate ratio with the F bur, due to an increased quantity of particles present on the F bur, resulting in more effective cutting. Cutting time was limited to 1min, preventing excessive wear on these smaller carbon particles, and ensuring maximum efficiency of the bur.

The present study also contradicts the findings of that of Alexander.[21] In her study, 7 burs (x2 SC, x2 C, x1 M, x1 F and x1 unknown grit size) from different manufacturers were used to cut zirconia with a high-speed air-turbine handpiece at a constant force of 0.9N, constant WFR of 16mL/min for a duration of 5mins.[20] Alexander concluded that SC, C and M grit sizes are more efficient in cutting 3Y-TZP zirconia than F burs, and that cutting efficiency was maximized for all burs when limited to 100 seconds of cutting.[21] Likewise, Alenezi used similar cutting parameters than that of Alexander and came to the same conclusions that coarser burs are more efficient in cutting zirconia, and that cutting rate was significantly reduced after 100 seconds.[22] The discrepancy in outcome to the present study, is most likely due to the difference in cutting parameters. Cutting efficiency is greatly dependent on diamond particle size, cutting time and cutting force and the relationship between these variables have proven to be very complex.[3,21,22] The present study used a greater cutting force (1.7N), a decreased cutting speed (40 000rpm) and reduced cutting time (1min) compared to that of Alexander and Alenezi.[21,22] Longer cutting time (> 5min) leads to more wear of abrasive particles, that may result in different cutting outcomes for different grit sizes than a shorter cutting time.[21,22]

Nakamura et al. proposed an ideal set of parameters for cutting zirconia and Peters et al. refined these parameters.[1,3] Nakamura et al. suggested that a force of 1.8N be applied when cutting zirconia with diamond burs.[3] Peters et al., Alexander and Alenezi applied a force of 0.9N on their zirconia samples, which is insufficient to cut sintered zirconia with clinically.[1,21,22]. Hunziker et al. applied a load of 2N and 6N on their zirconia samples and concluded that, although a force of 6N decreased the cutting time, a load of 2N should rather be used to avoid excessive heat generation and consequent damage to the dental pulp.[29] Yin and Kim also used a cutting force of 2N, but this might still be excessive and cause premature damage to the bur and heat damage to the pulp.[19,20] Chung et al. performed cutting efficiency tests on sintered zirconia using a cutting force of 1.7N.[27] The present study used the force recommended by Chung et al. (1.7N), because it is sufficient to cut zirconia without causing unnecessary damage to the bur, substrate and dental pulp.[27]

Interestingly, there was no significant difference between the mean cutting depths of the M (4.86mm), C (4.54mm) and SC (4.80mm) burs. A possible explanation for the similarity in cutting depth of these burs might be the short cutting time that was used in the present study (1min). Alexander suggested that M, C and SC diamond burs might have comparable cutting depths over a short period of time, but that C and SC burs might show improved efficiency over longer cutting periods (5+min) than M burs due to larger abrasive particles and a higher grit load on the substrate.[19,21] This outcome might also suggest that there is a threshold below which the surface area of the abrasive particles of the bur ceases to make a significant difference in cutting efficiency. To investigate whether these speculations are plausible, future evaluations of cutting efficiency, that include shorter (1min) and longer (>5min) cutting times, could be carried out with M, C and SC burs on zirconia.

The SF bur achieved the smallest cutting depth. The mean (1.39mm) and median (1.17mm) results were significantly lower than any of the other bur groups. These results are hypothesised to be related to the small carbon particles that represents the abrasive grit of the SF bur (20µm – 30µm). Although the surface area to substrate ratio may be larger, the particles are likely too small to elicit any significant effect on the hard zirconia substrate. Yin et al. stated that finer burs are more prone to metal matrix damage due to the smaller space available between abrasive particles for debris removal.[19] They proposed that the cutting debris cause abrasion on the carbon particles of the bur, resulting in grit loss, which decreases cutting efficiency.[19]

WFR was another variable that affected the cutting efficiency. As stated in the literature review, a minimum flow rate of 15mL/min is required when cutting intra-orally to prevent pulp damage by heat generation and to ensure sufficient debris removal.[3,22,28] Grinding with less stress under water coolant spray also promotes the t-m phase transformation of zirconia that is necessary for stability.[6] Lin et al. used an insufficient WFR of 5mL/min, whereas Yin et al., Alexander and Alenezi used the minimum required WFR of 15-16mL/min.[19,21-23] These studies all mentioned an increased rate of grit loss, which might be partially related to the insufficient WFR. Nakamura et al. used a WFR of 20mL/min, while Peters et al., Kim et al. and Chung et al. used a WFR of 25mL/min.[1,20,27] This flow rate was chosen for the present study, as it has been shown to be optimal to reduce heat generation and pulp damage, while also preventing bur deflection during cutting.[1, 20, 27] Keeling et al. and Hunziker et al. used a WFR of 40mL/min and 90mL/min respectively, which was necessary to accommodate for the heavy cutting load that was used (2N-6N), but might have been excessive.[28,29] A WFR that is too heavy can deflect the bur while cutting, resulting in changed cutting angles and consequently loss of standardization of the experiment.[1,3,22]

Most of the literature available on the cutting efficiency of burs on zirconia, used air-turbine handpieces for cutting.[1,13,14,19,21-23] Although air-turbines function at much higher speeds (240 000rpm and above), the overall performance of an electric handpiece has been shown to be superior, due to its ability to sustain high torque at a constant speed.[3,20,28] For this reason, an electric handpiece (S-Max M95L, NSK, Japan) was used for the present study.

6.2 PRESENCE OF SURFACE DAMAGE

The second objective was to identify the presence of surface damage on the zirconia specimens after cutting. Edge retention at restoration margins and the achievement of close dimensional adaptation to teeth are important factors in the success rate of a zirconia restoration as it prevents bacterial colonisation and restoration leakage, and ensures structural durability and overall restorative longevity of the zirconia.[2,19] No surface damage was detected on any of the specimens cut with the SF, F or M burs. However, damage was detected on two of the specimens cut in the C bur group (33,3%) and two specimens cut in the SC bur group (33,3%). This agrees with current evidence that coarser burs have an increased tendency to generate subsurface cracks, with concomitant strength degradation and decreased longevity of the restoration.[19]

These observations could be attributed to the roughness of the C and SC burs and the hardness of the abrasive carbon particles, creating micro-impacts onto the zirconia substrate during the cutting process, resulting in the formation of subsurface damage.[19,28] Increased grit size is accompanied by a reduction in number of carbon particles and a resultant increase in grit load.[19,22] Higher grit load causes increased grit penetration into the substrate, which results in a higher removal rate and increased generation of substrate damage.[19]

The presence of surface damage was assessed with loupes (Zumax Medical Co. Ltd., China) using x3,5 magnification and backlighting. Because of the density of zirconia, and limited damage due to a short cutting time, it was nearly impossible to visualise any cracks on the specimens. Illumination from behind with slight magnification proved to be the most effective way to identify surface flaws and cracks. The SEM that was used (Axia ChemiSEM, Thermo Fisher Scientific Inc., USA) did not allow for posterior illumination as specimens were fixed to metal rests and scanned from the top. This, as well as the increased magnification which resulted in loss of reference, made it more difficult to identify surface cracks. For this reason, dental loupes were the preferred method of post-experimental evaluation in this section.

6.3 BUR DETERIORATION

The final research objective was to measure the extent of bur deterioration of each bur in the five different grit size groups after cutting. This assessment relates to the cost-effectiveness of individual burs. The overall efficiency of the bur decreases with increased rate of deterioration, as bur replacement becomes more frequent, resulting in increased cost to the dentist.

The present study found that the rate of bur deterioration was, with the exception of the F and M bur groups, directly related to the coarseness of the bur. Thus, the coarser the bur, the more deterioration was observed. The observed correlation between bur coarseness and deterioration is likely due to the fact that coarser burs have larger, yet fewer abrasive particles than finer burs.[1,3] The decreased abrasive surface area results in an increased rate of deterioration as the abrasive particles are lost quicker, resulting in a greater measurement of overall material loss.[1,3,28] Furthermore, Yin et al. explains that finer diamond particles are generally stronger than larger particles due to the lower flaw population in finer burs.[19] The original flaws in the larger particles are eliminated by crushing the coarse diamond particles when finer grit is made.[19]

Similarly, Nakamura et al. suggested that finer grains might be more resistant to cutting damage than coarser grains due to the tightly packed diamond grains in finer grit.[3] The function of the damaged diamond grains would be compensated by the packed adjacent grits.[3]

This contradicts the findings of Peters et al. that stated that there were no obvious correlation between the size of the diamond particles and the amount of grit damage after cutting for 5mins.[1]

The smoother F bur underwent more deterioration (3.97 %) than the coarser M bur (2.84%). The reason for this contradictory result is not clear but is possibly related to the cutting efficiency of the F bur. This bur was able to cut deeper into the zirconia specimen than the M bur after 1min. Deeper cutting resulted in more damage to the bur, explaining why the F bur underwent more deterioration than the M bur.

Peters et al. investigated the cutting efficiency of both marketed zirconia cutting diamond burs and conventional diamond burs.[1] In their study, the zirconia cutting burs were more durable than conventional diamond burs when cutting zirconia.[1] This may be because of increased bonding strength between the bur and the diamond particles, as well as an anti-clogging coating that minimises heat production.[1] They did not, however, observe a noticeable difference between the overall cutting efficiency of these burs compared with conventional diamond burs.[1] Likewise, Kim et al. reported that zirconia specific diamond burs did not provide an increased cutting efficiency than conventional diamond burs.[20]

Keeling et al. evaluated the cutting efficiency of single-use (disposable) diamond burs compared to multiple-use burs.[28] They observed that single-use burs were superior in cutting and strongly advised the use thereof due to its improved cutting efficiency, cost-effectiveness and the decreased risk of cross-contamination.[28] Observations of the present study was limited to multiple-use conventional diamond burs.

Bur deterioration can also be affected by the type of zirconia that is cut.[20] Higher translucency zirconia would be expected to cut quicker and result in less bur deterioration than medium or low translucency zirconia, since the high translucency zirconia particles are less densely packed.[5-7] High translucency zirconia is more commonly used in clinical practice, due to its improved ease of cutting and improved aesthetics.[6] For this reason, the present study used a high translucency zirconia (Straumann HT+, Basel, Switzerland).

The study was successful as it was able to identify the most efficient bur grit size group for cutting zirconia, namely the F bur group. This confirms the hypothesis that finer burs are more efficient in cutting zirconia than coarser burs due to an increased abrasive surface area to substrate ratio and decreased damage to the cut zirconia.

The clinical relevance of this study is significant. It not only confirms the ideal parameters for cutting zirconia clinically, but also aids the clinician in selecting the correct armamentarium when cutting zirconia intra-orally to yield the most efficient, cost-effective, and durable results.

6.4 RECOMMENDATIONS AND LIMITATIONS

The present study was done with a small sample size: 6 samples per group. Although this was sufficient and power calculations were mostly above 83%, it is recommended that future studies are done with larger sample sizes.

In the clinical setting, materials are cut using multiple contacts of the bur. The present study was limited to single point contact to the zirconia sample with constant force. Although this was necessary to ensure standardisation, it does not completely reflect clinical practice and is a limitation of the study. A natural progression of this work is to analyse cutting efficiency in a way that reflects clinical cutting more accurately.

Additionally, the present study was limited to only one brand of zirconia (Straumann HT+, Basel, Switzerland) and one commercial brand of diamond burs (Horico Dental Hopf, Ringleb & Co GmbH & Cie, Berlin, Germany). Further research using different brands of zirconia and diamond burs, should be undertaken to obtain more extensive scientific information. More research can also be done on the cutting efficiency of single-use versus multiple-use diamond burs on zirconia.

Another recommendation is that SEM images of the qualitative aspects of bur deterioration and zirconia specimen damage after cutting should be taken in future studies on cutting efficiency of diamond burs on zirconia, to allow for better understanding and visualisation of the microscopic damage of the cut and cutting surfaces.

CHAPTER 7:

CONCLUSIONS

The purpose of the current study was to identify the most efficient diamond bur for cutting zirconia. The results obtained in the present study revealed the following:

- The greatest cutting depth was achieved with the F bur.
- The most damage to zirconia was done by the C and SC burs. With no damage to the SF, F, and M burs.
- The least amount of bur deterioration was found on the SF burs, with the most amount of deterioration on the SC burs.

Within the limitations of the present study, it can be concluded that the most efficient diamond bur was the F bur group with grit sizes between 40-50μm. The F bur achieved the greatest cutting depth with no detectable macroscopic damage to the zirconia substrate and minimal bur deterioration.

The empirical findings in the present study provide new insights into efficient cutting of zirconia in the clinical setting. The use of fine (F) diamond burs, rather than coarse (C) burs are therefore, advocated when cutting zirconia to ensure more efficient cutting, less damage to the zirconia substrate and decreased frequency of deterioration of the bur.

ETHICAL CONSIDERATIONS

This was an *in vitro* study and does not affect any human or animal subjects or their identities. There are no conflicts of interest. The research proposal was submitted for review to the research committee of the School of Dentistry (RESCOM) as well as the Faculty of Health Science Research Ethics Committee of the University of Pretoria and was approved by both.

DECLARATION OF INTEREST

There is no bias or financial gain towards the companies donating and supplying equipment used for the present study.

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APPENDICES

APPENDIX 1:

DATA COLLECTION SHEETS

i) DRILLING DEPTH

Bur	Replicates					
	1	**2**	**3**	**4**	**5**	**6**
Super Fine (SF)						
Specimen ID	*1*	*2*	*3*	*4*	*5*	*6*
Drilling depth (mm)	2,05	1,30	2,01	0,99	1,03	0,93
Fine (F)						
Specimen ID	*7*	*8*	*9*	*10*	*11*	*12*
Drilling depth (mm)	3,64	4,90	6,50	5,23	7,08	7,38
Medium (M)						
Specimen ID	*13*	*14*	*15*	*16*	*17*	*18*
Drilling depth (mm)	4,92	5,22	4,51	4,57	4,48	5,47
Course (C)						
Specimen ID	*19*	*20*	*21*	*22*	*23*	*24*
Drilling depth (mm)	4,58	6,49	4,28	4,84	4,33	2,70
Super Course (SC)						
Specimen ID	*25*	*26*	*27*	*28*	*29*	*30*
Drilling depth (mm)	5,33	4,41	5,43	4,66	5,44	3,54

ii) PRESENCE OF SURFACE DAMAGE

Bur	**Replicates**					
	1	**2**	**3**	**4**	**5**	**6**
Super Fine						
Specimen ID	*1*	*2*	*3*	*4*	*5*	*6*
Surface damage: Y/N	N	N	N	N	N	N
Fine						
Specimen ID	*7*	*8*	*9*	*10*	*11*	*12*
Surface damage: Y/N	N	N	N	N	N	N
Medium						
Specimen ID	*13*	*14*	*15*	*16*	*17*	*18*
Surface damage: Y/N	N	N	N	N	N	N
Course						
Specimen ID	*19*	*20*	*21*	*22*	*23*	*24*
Surface damage: Y/N	N	Y	N	Y	N	N
Super Course						
Specimen ID	*25*	*26*	*27*	*28*	*29*	*30*
Surface damage: Y/N	Y	N	N	N	Y	N

iii) BUR DETERIORATION

Bur	Replicates					
	1	**2**	**3**	**4**	**5**	**6**
Super Fine						
Specimen ID	*1*	*2*	*3*	*4*	*5*	*6*
First reading (mm)	1,33	1,33	1,33	1,33	1,33	1,33
Second reading (mm)	1,29	1,31	1,30	1,29	1,31	1,32
Deterioration (%)	3,0	1,5	2,26	3,0	1,5	0,75
Fine						
Specimen ID	*7*	*8*	*9*	*10*	*11*	*12*
First reading (mm)	1,43	1,43	1,43	1,43	1,40	1,43
Second reading (mm)	1,38	1,36	1,38	1,37	1,36	1,36
Deterioration (%)	3,5	4,9	3,5	4,2	2,86	4,9
Medium						
Specimen ID	*13*	*14*	*15*	*16*	*17*	*18*
First reading (mm)	1,35	1,35	1,35	1,35	1,35	1,35
Second reading (mm)	1,32	1,29	1,31	1,32	1,31	1,32
Deterioration (%)	2,22	4,44	2,96	2,22	2,96	2,22
Course						
Specimen ID	*19*	*20*	*21*	*22*	*23*	*24*
First reading (mm)	1,35	1,35	1,33	1,35	1,35	1,35
Second reading (mm)	1,24	1,22	1,22	1,26	1,28	1,29
Deterioration (%)	8,15	9,63	8,27	6,67	5,19	4,44
Super Course						
Specimen ID	*25*	*26*	*27*	*28*	*29*	*30*
First reading (mm)	1,33	1,35	1,33	1,35	1,35	1,35
Second reading (mm)	1,21	1,22	1,23	1,28	1,20	1,19
Deterioration (%)	9,02	9,63	7,52	5,19	11,11	11,85

APPENDIX 2:

RANDOMIZED DRILLING SEQUENCE

Session	Drilling sequence: Specimen number and bur				
Session 1	24 C	7 F	14 M	4 SF	26 SC
Session 2	28 SC	17 M	23 C	12 F	3 SF
Session 3	11 F	1 SF	20 C	25 SC	18 M
Session 4	29 SC	10 F	5 SF	16 M	19 C
Session 5	13 M	27 SC	2 SF	21 C	9 F
Session 6	6 SF	15 M	8 F	30 SC	22 C

APPENDIX 3:

ETHICS APPROVAL CERTIFICATE

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Health Sciences

Institution: The Research Ethics Committee, Faculty Health Sciences, University of Pretoria complies with ICH-GCP guidelines and has US Federal wide Assurance.

- FWA 00002567, Approved dd 18 March 2022 and Expires 18 March 2027.
- IORG #: IORG0001762 OMB No. 0990-0278 Approved for use through August 31, 2023.

Faculty of Health Sciences **Research Ethics Committee**

10 August 2022

Approval Certificate
New Application

Dear Dr A van Aswegen

Ethics Reference No.: 423/2022
Title: A comparative study of the cutting efficiency of diamond burs with different grit sizes on zirconia restorations

The **New Application** as supported by documents received between 2022-07-25 and 2022-08-10 for your research, was approved by the Faculty of Health Sciences Research Ethics Committee on 2022-08-10 as resolved by its quorate meeting.

Please note the following about your ethics approval:

- Ethics Approval is valid for 1 year and needs to be renewed annually by 2023-08-10.
- Please remember to use your protocol number (423/2022) on any documents or correspondence with the Research Ethics Committee regarding your research.
- Please note that the Research Ethics Committee may ask further questions, seek additional information, require further modification, monitor the conduct of your research, or suspend or withdraw ethics approval.

Ethics approval is subject to the following:

- The ethics approval is conditional on the research being conducted as stipulated by the details of all documents submitted to the Committee. In the event that a further need arises to change who the investigators are, the methods or any other aspect, such changes must be submitted as an Amendment for approval by the Committee.

We wish you the best with your research.

Yours sincerely

On behalf of the FHS REC, Dr R Sommers
MBChB, MMed (Int), MPharmMed, PhD
Deputy Chairperson *of the Faculty of Health Sciences Research Ethics Committee, University of Pretoria*

The Faculty of Health Sciences Research Ethics Committee complies with the SA National Act 61 of 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 and 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes, Second Edition 2015 (Department of Health)

Research Ethics Committee
Room 4-60, Level 4, Tswelopele Building
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www.up.ac.za

Fakulteit Gesondheidswetenskappe
Lefapha la Disaense tša Maphelo

APPENDIX 4:

RESCOM PROTOCOL APPROVAL LETTER

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Chairperson:
Prof RAG Khammissa
Secretary:
Ms Renata van Aswegen

RESCOM

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Faculty of Health Sciences

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19 July 2022

Prof SL Shangase
CEO/Chair of School
University of Pretoria Oral Health Centre

Dear Prof Shangase,

PROTOCOL APPROVAL: 2022/07

Name: Dr A van Aswegen

Title: A comparative study of the cutting efficiency of diamond burs with different grit sizes on zirconia restorations.

The protocol attached hereto was evaluated by two reviewers at the School of Dentistry. After the reviewing process was completed, the Research Committee recommended the approval of the title and the protocol.

Yours sincerely

PROF RAG KHAMMISSA
CHAIRPERSON: RESCOM

Protocol supported / not supported

PROF SL SHANGASE
CEO/CHAIR OF SCHOOL

APPENDIX 5:

STATISTICIAN LETTER OF CLEARANCE

Date: 21 May 2022

LETTER OF CLEARANCE FROM THE BIOSTATISTICIAN

This letter is to confirm that the student(s), with the Name(s)

Ané van Aswegen

studying at the University of Pretoria, discussed the Project with the title

"A comparative study of the cutting efficiency of diamond burs with different grit sizes on zirconia restorations"

with me.

I hereby confirm that I am aware of the project and undertake to assist with the Statistical analysis of the data generated from the project.

The analytical tool that will be used will be

SAS (SAS Institute Inc, Cary, NC, USA), Release 9.4

to achieve the objective(s) of the study.

Name: Prof HS Schoeman Date: 21 May 2022

Signature ________________ Tel: 082 896b 3606

Department or Unit: Biostatistician for ClinStat CC

ClinStat CC
CK 96/35541/23
082 896 3606

Official Stamp of Biostatistician

APPENDIX 6:

DECLARATION OF HELSINKI

A2

All Researchers

Please note that all researchers must from today, sign the attached declaration, when handing in a protocol at the Faculty of Health Sciences Research Ethics Committee - University of Pretoria.

WORLD ASSOCIATION DECLARATION OF HELSINKI
Ethical Principles
For
Medical Research Involving Human Subjects

Adopted by the 18th WMA General Assembly

Helsinki, Finland, June 1964

And amended by the

29th WMA General Assembly, Tokyo, Japan, October 1975

35th WMA General Assembly, Venice, Italy, October 1983

41st WMA General Assembly, Hong Kong, September 1989

48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996

and the

52nd WMA General Assembly, Edinburgh, Scotland, October 2000

A. INTRODUCTION

1. The World Medical Association has developed the Declaration of Helsinki as a statement of ethical principle to provide guidance to physicians and other participants in medical research involving human subjects. Medical research involving human subjects includes research on identifiable human material or identifiable data.
2. It is the duty of the physician to promote and safeguard the health of the people. The physician’s knowledge and conscience are dedicated to the fulfilment of this duty.

3. The Declaration of the Geneva of the World Medical Association binds the physician with the words, "The health of my patient will be my first consideration," and the International Code Medical Ethics declares that, "A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient."
4. Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects.
5. In medical research on human subjects, considerations related to the wellbeing of the human subject should take precedence over the interests of science and society.
6. The primary purpose of the medical research involving human subjects is to improve prophylactic, diagnostic and therapeutic procedures and the understanding of the aetiology and pathogenesis of disease. Even the best proven prophylactic, diagnostic and therapeutic methods must continuously be challenged through research for their effectiveness, efficiency, accessibility and quality.
7. In the current medical practice and in medical research, most prophylactic, diagnostic and therapeutic procedures involve risks and burdens.
8. Medical research is subject to ethics standards that promote respect for all human beings and protect their health and rights. Some research population is vulnerable and need special protection. The particular needs of the economically and medically advantaged must be recognized. Special attention is also required for those who cannot give us or refuse consent for themselves, for those who may be subject to giving consent under duress, for those who will not benefit personally from the research and for those for whom the research is combined with care.
9. Research investigators should be aware of the ethical, legal and regulatory requirements for research on human subjects in their own countries as well as applicable international requirements. No national ethical, legal and regulatory requirements should be allowed to reduce or eliminate any of the protections for human subjects set forth in this Declaration.

B. BASIC PRINCIPLES FOR ALL MEDICAL RESEARCH

10. It is the duty of the physician in medical research to protect the life, health, privacy and dignity of the human subject.
11. Medical research involving human subject must conform to the general accepted scientific principles, be based on the thorough knowledge of the scientific literature, other relevant

sources of information, and on adequate laboratory and, where appropriate, animal experimentation.

12. Appropriate caution must be exercised in the conduct of research which may affect the environment, and the welfare of animal used for research must be respected.
13. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol. This protocol should be submitted for consideration, comment, guidance and where appropriate, approval to a specially appointed ethical review committee, which must be independent of the investigator, the sponsor or any other kind of undue influence. This independent committee should be in conformity with the laws and regulations of the country in which the research experiment is performed. The committee has the right to monitor ongoing trials. The researcher has the obligation to provide monitoring information to the committee, especially any serious adverse events. The researcher should also submit to the committee, for review, information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest and incentives for subjects.
14. The research protocol should always contain a statement of the ethical considerations involved and should indicate that there is compliance with the principles enunciated in this Declaration.
15. Medical human research involving subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given consent.
16. Every medical research project involving human subject should be preceded by careful assessment of predictable risk and burdens in comparison with foreseeable benefits of the subject or to others. This does not preclude the participation of healthy volunteers in medical research. The design of all studies should be publicly available.
17. Physicians should abstain from engaging in research project involving human subjects unless they are confident that the risk involved have been adequately assessed and can be satisfactorily managed. Physicians should cease any investigations if the risks are found to outweigh the potential benefits or if there is conclusive proof of positive and beneficial results.
18. Medical research involving human subjects should only be conducted if the importance of the objective outweighs the inherent risks and burdens of the subject. This is especially important when the human subjects are healthy volunteers.

C. ICH GUIDELINE FOR GOOD CLINICAL PRACTICE

1. Clinical trials should be conducted in accordance with the ethical principles that have their origin in Declaration of Helsinki, and that are consistent with GCP and the applicable regulatory requirement(s).
2. Before a trial is initiated, foreseeable risk and inconvenience should be outweighed against the anticipated benefit for the individual trial subject and society. A trial should be initiated and continued if the anticipated benefits justify the risk.
3. The rights, safety and well-being of the trial subjects are the most important considerations and should prevail over interest of science and society.
4. The available non-clinical and clinical information on an investigational product should be adequate to support the proposed clinical trials.
5. Clinical trials should be scientifically sound, and described in a clear, detailed protocol
6. A trial should be conducted in compliance with the protocol that has received prior institutional review board (IRB)/independent ethics committee (IEC) approval/favourable opinion.
7. The medical care given to, and medical decisions made on behalf of, subjects should always be the responsibility of the qualified physician or, when appropriate, of a qualified dentist.
8. Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s).
9. Freely given informed consent should be obtained from every subject prior to clinical trial participant.
10. All clinical trial information should be recorded, handled and stored in a way that allows its accurate reporting, interpretation and verification.
11. The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).
12. Investigational product should be manufactured, handled, and stored in accordance with applicable good manufacturing practice (GMP). They should be used in accordance with the approved protocol.
13. Systems with procedures that assure the quality of every aspect of the trial should be implemented.