FRACTURE STRENGTH AND FRACTURE BEHAVIOUR
PATTERNS OF CUSP-REPLACING FIBRE STRENGTHENED
COMPOSITE RESTORATIONS

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DECLARATION

I, the undersigned, hereby declare the work contained in this dissertation is my own original work and that I have not previously in its entirety or in part submitted it at any other university for the purposes of obtaining a degree.

Signature:

Date: 1 October 2015
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- My wife, Sandra for her endless encouragement, love and support.
- My Creator, God Almighty for blessing me with amazing miracles every day of my life.
ABSTRACT

Key words: Fibre strengthened composites, fibre sub-structure, cusp-replacing composite restorations, fracture patterns, fracture strength of posterior composite restorations, fracture pattern behaviour, glass-fibre reinforced composite restorations, posterior composite restorations, everStick®

Objectives: This in vitro study investigated and compared the fracture strength and behaviour patterns of a conventional posterior composite resin, a composite resin reinforced with nano-scale electrospun glass-fibres and a conventional composite resin placed on a fibre substructure, all used in cusp-replacing posterior composite resin restorations.

Methods: Seventy-five extracted, lower, left, first and second molars were prepared to accept standardized restorations replacing the mesio-lingual cusp. The specimens were randomly divided into 3 groups of 25 each: Group A (control) was restored with a conventional posterior composite resin, Group B was restored with the composite resin reinforced with nano-scale electrospun glass fibres and Group C was restored with a conventional posterior composite resin reinforced with a fibre substructure. All restored specimens were thermocycled for 500 cycles between 5°C and 55°C with a dwell time of 30 seconds, then imbedded in plastic cylinders in acrylic resin. The specimens were loaded at a 30° angle to the long axis of the tooth, using a jig mounted in a universal testing machine until fracture occurred. Fracture strength was recorded and specimens were then stained to highlight fracture patterns and subsequently studied under a microscope. Fractures were classified as restorable/non-restorable. Sub-classification included adhesive and cohesive failures.

Results: Compared to Group A both techniques of fibre inclusion significantly strengthened the cusp-replacing composite restoration (ANOVA p = 0.05) Compared to Groups A and B the group of restorations placed on a fibre sub-structure (Group C) exhibited significantly more fractures that were classed as restorable. Compared to Group A and C the group restored with the composite resin reinforced with nano-
scale electrospun glass fibres (Group B) displayed significantly more fractures that were classed as non-restorable (Fisher's Exact Test \( p = 0.05 \)).

**Conclusion:** Both fibre inclusion techniques significantly strengthened cusp-replacing posterior composite restorations. Fracture behaviour patterns differed significantly between the two fibre-strengthening techniques.
TABLE OF CONTENTS

DECLARATION ......................................................................................................................................... ii
ACKNOWLEDGEMENTS .......................................................................................................................... iii
ABSTRACT ............................................................................................................................................... iv
TABLE OF CONTENTS .............................................................................................................................. vi
LIST OF FIGURES ................................................................................................................................... viii
1. INTRODUCTION .................................................................................................................................... 1
2. LITERATURE REVIEW .......................................................................................................................... 3
  2.1 COMPOSITE RESIN RESTORATIVE MATERIALS .............................................................................. 3
  2.2 FIBRE STRENGTHENING .................................................................................................................. 3
  2.3 HISTORY AND DEVELOPMENT OF FIBRE STRENGTHENING .................................................... 4
  2.4 PROPERTIES OF FIBRE STRENGTHENING .................................................................................... 5
     2.4.1 Fibre orientation .................................................................................................................. 5
     2.4.2 Fibre types ......................................................................................................................... 6
     2.4.3 Ratio between fibres and matrix ........................................................................................... 9
     2.4.4 Quality of fibre resin impregnation ....................................................................................... 9
     2.4.5 Adhesion of fibres to the polymer matrix ............................................................................. 10
     2.4.6 Location of the fibres in the structure .................................................................................... 11
     2.4.7 Fibre substructure ............................................................................................................. 11
  2.5 TESTING OF FIBRE STRENGTHENING ......................................................................................... 12
     2.5.1 Load type ............................................................................................................................ 12
     2.5.2 Load speed .......................................................................................................................... 12
     2.5.3 Load intensity and classification of fractures .......................................................................... 12
     2.5.4 Angle of load application ..................................................................................................... 12
     2.5.5 Testing machine, jig and tip used during static load testing ................................................ 13
  2.6 ADHESION CONSIDERATIONS ....................................................................................................... 15
3. OBJECTIVES ........................................................................................................................................ 16
4. MATERIALS AND METHODS ............................................................................................................... 17
  4.1 NUMBER OF SPECIMENS .............................................................................................................. 17
  4.2 COLLECTION AND STORING OF SPECIMENS ........................................................................... 17
  4.3 SELECTION CRITERIA AND STANDARDIZATION OF SPECIMENS ............................................. 18
  4.4 IMBEDDING THE SPECIMENS ...................................................................................................... 20
  4.5 PREPARATION OF THE SPECIMENS ............................................................................................ 21
LIST OF FIGURES

Figure 1: Fibers act as a crack-deflecting mechanism .......................................................... 5
Figure 2: Fiber orientation and strengthening efficiency – Krenchel’s factor based on mathematical calculation .................................................................................................................. 6
Figure 3: Different types of strengthening fibers ........................................................................... 8
Figure 4: Uni-directional glass fibre bundles: Fibres not impregnated during manufacturing (left) vs. pre-impregnated fibres (right) ................................................................................................................... 9
Figure 5: Silane treated E-glass fibre .......................................................................................... 10
Figure 6: Conventional flat-tipped rod ....................................................................................... 13
Figure 7: Round-tipped rod ......................................................................................................... 14
Figure 8: Loading of specimen with a round-tipped rod ............................................................... 14
Figure 9: SEM demonstrating the polymethylmethacrylate (PMMA) sheath covering an everStick® strengthening fibre bundle, aiding in the formation of intermediate resins. ........................................ 15
Figure 10: Auto-polymerizing acrylic resin, measuring containers and plastic cylinder ............... 20
Figure 11: Imbedded specimens ................................................................................................. 21
Figure 12: Standardized MOL cavity preparation lingual view ....................................................... 22
Figure 13: Standardized MOL cavity preparation occlusal view .................................................... 23
Figure 14: CE Junction identified and marked ............................................................................ 24
Figure 15: Manufacturing the Twinky Star® stent ................................................................. 25
Figure 16: Checking the preparations ....................................................................................... 26
Figure 17: Twinky Star® stent (x10) ......................................................................................... 26
Figure 18: Etching enamel margins 15 seconds ........................................................................ 27
Figure 19: Dentine etching 10 seconds .................................................................................... 27
Figure 20: Bonding agent and etchant ........................................................................................ 28
Figure 21: Bonding agent applied and cured ....................................................................... 28
Figure 22: Quixfill® ................................................................................................................... 29
Figure 23: Tofflemire matrix band placed ................................................................................. 29
Figure 24: Aelite® (BISCO) nano-scale filler micro-hybrid composite ........................................ 30
Figure 25: Proximal step filled (Restored) ................................................................................ 31
Figure 26: Schematic - placement everStick® fibre bundle ....................................................... 32
Figure 27: everStick® (StickTech Ltd) fibre bundle placed ......................................................... 32
Figure 28: EsthetX® flow .......................................................................................................... 33
Figure 29: Positioning fibre bundle with the re-fix silicone aid .................................................. 33
Figure 30: Close-up: positioning fibre bundle with the refix silicone aid ............................................. 34
Figure 31: Specimens marked with grooves on plastic cylinders ............................................................... 35
Figure 32: Specimen fixed in jig with rod positioned ............................................................................... 36
Figure 33: Collected, numbered and mounted fractured parts of specimens ............................................. 36
Figure 34: After immersion in India ink .................................................................................................. 37
Figure 35: Close-up: After immersion in India ink .................................................................................... 37
Figure 36: After immersion in India ink .................................................................................................. 38
Figure 37: Digital stereo microscope ...................................................................................................... 38
Figure 38: Digital stereo microscope connected to personal computer .................................................... 39
Figure 39a & b: Fractures occlusal of the simulated bone level ............................................................... 40
Figure 40a & b: Fractured below the simulated bone level ....................................................................... 41
Figure 41: Schematic illustration of a non-repairable fracture ................................................................. 41
Figure 42: Schematic sub-classification Group C fractures (Green=fibre sub-structure) ............................. 42
Figure 43: Fracture exposing the pulp .................................................................................................... 60
Figure 43 (b): Fracture exposing the pulp (x10 magnification) ............................................................... 60
Figure 44: Cohesive fracture .................................................................................................................. 61
Figure 44 (b): Cohesive fracture x 10 magnification ............................................................................... 62
Figure 45: Adhesive fracture .................................................................................................................. 62
Figure 45 (b): Adhesive fracture x 10 magnification ............................................................................... 63
Figure 46: Fracture between fibre sub-structure and composite resin ..................................................... 64
Figure 46 (b): Fracture between fibre sub-structure and composite resin ............................................. 65
LIST OF TABLES

Table 1: Anatomical variants and mitigating action taken ............................................................. 18
Table 2: Results - Raw data ................................................................................................................... 44
Table 3: Collated test results containing individual specimen numbers and fracture strength results ......................................................................................................................... 45
Table 4: Collated fracture strength results (Newton) ....................................................................... 48
Table 5: Collated results - Fracture behaviour .................................................................................. 50
Table 6: Group C – Fracture types ...................................................................................................... 54

LIST OF GRAPHS

Graph 1: Results – Raw data ........................................................................................................... 47
Graph 2: Fmin, Fmax, Faverage and standard deviation (SD) ............................................................ 48
Graph 3: Group A – Fmax .................................................................................................................. 49
Graph 4: Group B - Fmax ................................................................................................................... 49
Graph 5: Group C - Fmax ................................................................................................................... 50
Graph 6: Restorable vs. Non-restorable fractures .......................................................................... 53
Graph 7: Frequency of cohesive and adhesive fractures in Groups A, B and C .............................. 53
Graph 8: Fracture strength values comparison: Group A (Quixfill®) .................................................. 56
Graph 9: Fracture strength values comparison: Group B (Aelite®) .................................................... 57
Graph 10: Fracture strength values comparison: Group C (Quixfill® placed on everStick®) ....... 58
1. INTRODUCTION

One of the major motivations for dental materials research has been the requirement for durable, aesthetic and bondable materials in order to restore form, appearance and function of teeth.¹ Dental material scientists are challenged by the demanding conditions that exist in the oral cavity – conditions such as moisture, acidity and mechanical and thermal stress.¹ During the past few decades the use of adhesive bonding techniques to bond restorations to tooth structure have become available and new product development and improvement is still continuing.¹

Many studies have been done on improving mechanical properties of composite materials, however, the majority of studies focussed on techniques and combinations of restorative materials to increase the strength of the tooth-restoration complex.²-⁵

When the cusp of a tooth, especially a load bearing cusp, is part of the restoration, it is of vital importance to maximize the mechanical strength of the composite restoration. For this reason many studies on mechanical properties, loading conditions and load bearing have been done.³,⁶-⁹

The available treatment modalities for direct cusp-replacing aesthetic restorations remain limited. Conventional methods to restore teeth with cusp-replacing restorations include direct or indirect metal inlays/overlays, ceramic inlays/overlays and in some cases full-coverage gold/ceramic crowns.¹⁰ Although these methods have a proven track record, they often require removal of additional tooth structure, are expensive, time-consuming and necessitate the services of a dental technician.¹⁰

Employing CAD-CAM technology for chair-side manufacturing of these restorations (i.e. CEREC onlays/crowns) is certainly a possibility, although costly.¹⁰ An option to scan the preparation chair-side and then have it milled in a dental laboratory is also available. This technique reduces the financial outlay of acquiring the equipment and technology.¹ Even with all these available options, the search for high-strength restorative materials that can be processed directly in the patient’s mouth is still continuing.¹¹
Another direction that research has taken is the improvement and reinforcement of dental composite resins through the use of nano-technology, “nanofillers”, ceramic and porous fillers, optimizing filler levels and adding micro-scale glass fibers as fillers to composites such as Aelite®, a SiO$_2$ glass nanofibre reinforced composite.\textsuperscript{9,10,12} Nano-technology, and incorporating nano-fillers, has been investigated as one of the possible improvements.\textsuperscript{1} Despite all these treatment options, challenges remain and significant further improvements in the mechanical properties of dental composite resins are still needed in order to extend the use of these materials to large stress-bearing applications.\textsuperscript{10,14}

Placement of a fibre substructure under a composite resin and the placement of reinforcing fibres in a composite resin have been investigated, both with promising results.\textsuperscript{15-17} Recent research studies found that such a fibre substructure under composite restorations can improve the load-bearing capacity and may offer an alternative in overcoming some potential problems of composite restorations in high stress-bearing areas.\textsuperscript{10,14}
2. LITERATURE REVIEW

2.1 COMPOSITE RESIN RESTORATIVE MATERIALS

Despite on-going improvement in the mechanical properties of composite restorations, limitations in the use of these ‘aesthetic’ restorative materials (especially in posterior teeth), has not yet been eliminated. Sarrett found that fracture of the composite material in the posterior region are a common reason for composite failure, particularly within the first five years. The use of composite resins in larger posterior restorations involving cusp replacement is further severely limited by the low flexural strength of the composite material. SEM analysis of crack propagation in dental restorations confirmed observations that composite resin restorations, although exhibiting low wear rates, are prone to bulk fracture with crack propagation rates higher than those of porcelain. Finite element analysis determined that during mastication, the inner side of the restoration can be under severe tension, leading to fracture initiation.

2.2 FIBRE STRENGTHENING

Research suggests that by adding a fibre reinforced composite substructure under a composite resin, the load bearing capacity of the material combination is increased. A material is inherently stronger in fibre form. Being a ‘fibre’ means that the length of such a material is much greater than its cross-sectional dimension. A fibre’s small diameter also reduces the probability of critical defects. In order to achieve the full strengthening potential of fibres, a ratio of length to diameter greater than 100 is required. This is known as the aspect ratio.

Researchers have found that by changing the shape of the filling particles in a composite from crystalline to fibrous, significant strengthening of the composite is obtained. This is influenced by the following factors: Orientation of strengthening fibres, fibre type, ratio between fibres and matrix, quality of
impregnation of fibres with resin, adhesion of fibres to the matrix and location of the fibres in the structure

2.3 HISTORY AND DEVELOPMENT OF FIBRE STRENGTHENING

The development and acceptance of fibre strengthening in dentistry have been very slow in comparison with the development and widespread acceptance of fibre strengthening in other industries.\textsuperscript{10}

Since the introduction of strengthening fibres in denture bases in the 1960’s, dental applications were challenged with difficulty in manipulation and poor aesthetics.\textsuperscript{1,24} Therefore, for many years, fibre strengthening in dentistry remained more of a scientific rather than a clinical option.\textsuperscript{1} During the late 1980’s, prepps (specially formulated resin matrix systems that were reinforced with man-made fibres such as carbon, glass and aramid) and hand-held light-curing units (to polymerize composite resin restorations) were developed.\textsuperscript{26,27} As knowledge increased and products became more cost-effective, more and more clinical applications for fibre inclusion were introduced. These clinical applications included:

- Removable dentures\textsuperscript{28}
- Fixed partial dentures\textsuperscript{27,29,30}
- Orthodontic treatment\textsuperscript{31}
- Periodontal splinting\textsuperscript{32}
- Posts\textsuperscript{33}
- Implant supra-structures\textsuperscript{34}
- Space maintainers\textsuperscript{35}
- Direct replacement of lost teeth\textsuperscript{36}
- Extensive composite restorations\textsuperscript{14,15}

Clinical data on these applications are relatively short-term but very promising\textsuperscript{37}
2.4 PROPERTIES OF FIBRE STRENGTHENING

2.4.1 Fibre orientation

Fibre orientation influences the mechanical as well as the physical properties of fibre strengthening.\(^5\) This phenomenon was first described by Krenchel in 1964 and is known as the “reinforcement efficiency” or Krenchel’s factor. In theory, unidirectional fibres perpendicular to the expected fracture line will have maximum strengthening effect. The higher the Krenchel factor, the higher the strengthening effect. It is therefore critically important to place the fibres perpendicular to the expected force in order to maximise strengthening of the structure (Fig. 1&2).\(^{38}\)

Figure 1: Fibers act as a crack-deflecting mechanism
2.4.2 Fibre types

**Glass fibres:** A three dimensional network of silicon, oxygen and other atoms are the most common fibres used for strengthening composites both in dental and industrial applications. The two commonly used glass-fibres are **E-glass** (SiO$_2$ 55% by weight (wt), Al$_2$O$_3$ 14.5% wt, CaO 17% wt, MgO 4.5% wt, B$_2$O$_3$ 8.5% wt and Na$_2$O 0.5% wt) and **S-Glass** (SiO$_2$ 64% wt, Al$_2$O$_3$ 26% wt, MgO 10% wt, B$_2$O$_3$ 8.5% wt and Na$_2$O 0.5% wt). E-glass has good tensile and compressive strength but relatively poor impact resistance. S-glass fibres have higher tensile strength, but the structural difference and higher processing costs makes it more expensive than E-glass fibres (Fig. 3a).
Glass fibres stretch uniformly under stress to their breaking point, and on removal of the load short of the breaking point, will return to its original length. Coupled with the high mechanical strength of glass fibres, it enables glass fibres to store and release large amounts of energy.\textsuperscript{39}

**Ultra-high molecular weight polyethylene fibres:** These are some of the strongest reinforcement fibres and are used in various dental applications.\textsuperscript{39} It consists of aligned polymer chains which are chemically inert, white in colour, have a low density and show high elongation and good impact resistance (Fig. 3b).\textsuperscript{37,40} Despite these favourable properties, these fibres have low compressive strength in laminate form, a high creep rate and are difficult to bond to the matrix.\textsuperscript{39,41,42} Tanner \textit{et al} reported an increased retention of oral micro-organisms on the surfaces of these fibres, but it may have been caused by the woven structure used in his research.\textsuperscript{43}

**Carbon/Graphite fibres:** Made from polyacrylonitrile and sometimes cellulose through controlled oxidation, carbonisation and graphitisation of carbon-rich organic precursors are already in fibre form.\textsuperscript{42} It has the highest stiffness amongst commercially available fibres, high strength (both in compression and tension) and high resistance to corrosion, creep and fatigue.\textsuperscript{42} Its impact strength is lower than that of glass.\textsuperscript{44} The black colour, difficulty in manufacturing, sizing and poor handling properties limit clinical applications (Fig. 3c).\textsuperscript{45} Carbon/graphite fibres are mostly used as fibre posts in dentistry.\textsuperscript{33}

**Aramid/Kevlar fibres:** Made from an aromatic polyamide produced by spinning solid fibre from a liquid chemical blend.\textsuperscript{42} It has high tensile strength, good impact resistance and low density but poor compression strength. It shows good resistance to degradation caused by abrasive, chemical and thermal forces.\textsuperscript{42} Kevlar/Aramid fibres are bright yellow in colour and this limits aesthetic dental applications (Fig. 3d).\textsuperscript{44}
Figure 3: Different types of strengthening fibers

a) Glass fibres
b) Polyethylene fibres
c) Carbon/graphite
d) Aramide/kevlar fibres
2.4.3 Ratio between fibres and matrix

The mechanical properties of fibre strengthening are determined by the relative proportions of matrix and reinforcement phases, normally expressed as weight or volume fractions. This is known as the rule of mixtures. Maximum flexural strength of 1250 MPa was reported for glass fibres at 65 per cent volume percentage.

2.4.4 Quality of fibre resin impregnation

Impregnation is the embedding of fibres within resin, a critical step for optimum strengthening (Fig. 4). To be effective, the resin must come into full contact with the surface of every fibre. This is difficult to achieve with resins of high viscosity. Carefully controlled impregnation during the manufacturing process produces constant and better quality impregnation.

Figure 4: Uni-directional glass fibre bundles: Fibres not impregnated during manufacturing (left) vs. pre-impregnated fibres (right)
2.4.5 Adhesion of fibres to the polymer matrix

Proper adhesion between strengthening fibres and polymer matrix makes it possible to transfer stress from the matrix to the strengthening fibres. Poor adhesion, which can be due to mechanical and/or chemical reasons, will result in low mechanical properties and water sorption. The use of coupling agents such as silane, that is chemically reactive with both the polymer matrix and the strengthening fibre, can modify the surfaces of the matrix and/or the fibre and has been successfully used in many applications.

Silane coupling.

Methacrylic resin-based dental composites normally use a bifunctional silane coupling agent (gamma-methacryloxypropyl-trimethoxysilane). The silane coupling agent contains an intermediary carbon-connecting segment to provide the interfacial phase that holds together the organic polymer matrix and the reinforcing inorganic phase (Fig. 5). Debnath et al. determined that the flexural strengths of composites with silanated fillers were greater than that of composites without silanated fillers. Silanization of glass fibres has been shown to increase mechanical properties whilst it had the opposite effect on poly-ethylene fibres.

Figure 5: Silane treated E-glass fibres

![Resin “tags” or connections formed between silane-treated E-glass fibres](image)
Plasma treatment

With plasma treatment, the surfaces of polymers can be improved in terms of hydrophilicity by forming oxygen-containing functional groups, such as C=O and –OH groups.\textsuperscript{52,53} Plasma is a gas (partially or totally ionized) with a roughly equal number of positively and negatively charged particles.\textsuperscript{54}

In dentistry, only a few plasma applications have been used to improve the adhesive properties of polymers.\textsuperscript{55,56} The main reason for this is the important requirement that the composition of the plasma gas must match the chemical structure of the polymer in order to improve the latter’s adhesive properties.\textsuperscript{57}

2.4.6. Location of the fibres in the structure

Placement of fibres in a sub-structure is important for the performance of the strengthened composite.\textsuperscript{58} Tension side reinforcement was found to be the most effective in increasing flexural strength in static loading tests.\textsuperscript{59} Dyer \textit{et al.} reported an increase in the elastic modules with the placement of uni-directional glass fibres in the compression side and they also reported a 150 per cent increase in the modulus of elasticity (compared to control composites that were not strengthened by means of fibres) when both the compression and tension side of the specimen were strengthened with uni-directional glass fibres.\textsuperscript{59}

2.4.7 Fibre substructure

It has been proven in various research projects that fibre reinforcement of composite resin strengthens the composite resin material.\textsuperscript{16,21-23,60-62} First described by Belli \textit{et al.} and Fennis \textit{et al.}, recent research studies found that using fibre-reinforced composite as substructure under composite restorations can improve the load-bearing capacity and may offer one alternative in overcoming some potential problems of composite restorations in high stress-bearing areas.\textsuperscript{9,13-16}
2.5 TESTING OF FIBRE STRENGTHENING

2.5.1 Load type

The objectives of the study influence the applied load type. Most experimental studies have been performed by applying static loads. Static tests permit the investigation of mechanical properties of a material to different types of loads. However, dynamic tests are needed in order to analyse restorative systems over time.

2.5.2 Load speed

Load speed should simulate oral functions and crosshead speed is usually set according to the specifications of the loading machine that will be used to test the specimens. Too high a speed will cause non-homogenous stress, whereas too low a speed will not be representative of oral function. Using this as basis, specimens are usually loaded at a speed ranging from 0.5 to 2 mm/min.

2.5.3 Load intensity and classification of fractures

According to the literature, during most static tests, the specimens are loaded from 0 Newton until fracture occurred ($F_{\text{max}}$). Furthermore, fractures can be classified as restorable/non-restorable and also as cohesive/adhesive.

2.5.4 Angle of load application

Posterior teeth have to withstand occlusal and masticatory forces whilst anterior teeth are responsible for tearing and functional guidance. Experimental load angulations remains a controversial topic in the literature and various angulations have been suggested. In the case of in vitro assessments of posterior teeth, forces applied at a range of angles between 30° and 45° to the longitudinal axis of the teeth, have been recommended. Antagonist cusps do not reach the central fissure of the occlusal surface during function, therefore teeth should be loaded on the slope of the cusp, simulating forces created during mastication.
2.5.5 Testing machine, jig and tip used during static load testing

Static mechanical tests are performed with a universal testing machine, linked to a computer with dedicated software to record fracture values ($F_{\text{max}}$) and load-deformation curves. Specimens should be fixed in the metal holder (jig) of the testing machine in such a way that the teeth themselves distribute the applied force along the cuspal slopes. Traditionally stainless steel rods with flat tips are often used to test fracture strengths of specimens using a universal testing machine (Fig. 6). However, the contact surface of these rods are wider than the mean width of opposing teeth. Stainless steel rods with rounded tips should therefore be used to load the specimens and the width of the tips should be carefully considered in order to ensure that it reproduces the mean cuspal width of antagonist teeth. It is recommended in the literature that the tip is rounded to a cross section of 2 mm measured across the diameter of the tip (Fig. 7&8).

Figure 6: Conventional flat-tipped rod
Figure 7: Round-tipped rod

Figure 8: Loading of specimen with a round-tipped rod
2.6 ADHESION CONSIDERATIONS

Adhesion is defined as the mechanism that bonds two materials in intimate contact across an interface through interfacial force. Adhesion mechanisms include chemical adhesion, van der Waals physical interactions, hydrogen bonding, mechanical interlocking, electrostatic interactions and mutual molecular diffusion. The adhesion of the everStick® fibre substructure to composite resins are brought about by the formation of intermediate resins. Intermediate resins are defined as a combination of hydroxyethylmethacrylate (HEMA), methylmethacrylate (MMA) and dimethacrylates like TEGDMA (triethyleneglycol dimethacrylate) (Fig. 9). Adhesion takes place by means of inter-diffusion bonding.

Figure 9: SEM demonstrating the polymethylmethacrylate (PMMA) sheath covering an everStick® strengthening fibre bundle, aiding in the formation of intermediate resins.
3. OBJECTIVES

For the purpose of this dissertation the author completed two research projects which were performed to evaluate the effect of the inclusion of a uni-directional glass-fibre substructure under a conventional composite resin and alternatively adding micro-scale glass fibres to a conventional composite.

The two research projects were done on the fracture strength and the fracture behaviour patterns of cusp-replacing composite resin restorations within three groups of restorations:

**Group A**: Conventional composite

**Group B**: Conventional composite with added micro-scale glass fibres

**Group C**: Conventional composite on a fibre substructure

The hypothesis tested were, that as far as the two properties tested were concerned, a uni-directional glass-fibre substructure does improve the fracture strength of cusp-replacing composite resin restorations and that a uni-directional glass-fibre substructure does improve the fracture behaviour patterns of cusp-replacing composite resin restorations.

If proven to be true, it could be justified to place a uni-lateral glass-fibre substructure in cusps replaced with composite resin restorations.
4. MATERIALS AND METHODS

4.1 NUMBER OF SPECIMENS

The number of specimens used by different researchers seems to be a controversial issue in the literature and vary from one research project to the other. According to a literature review undertaken by Naumann et al., the number of specimens used in research projects varied from 5 to 44 teeth with a median of 10. Between 8 and 12 specimens per group is seen as a compromise between feasibility and the minimum required for statistical requirements.

For the purpose of this research project, 25 specimens per group were selected. The decision on the number of specimens was taken in order to derive ‘normal values’ for the different fibre techniques, as recommended by the statistical consultant, in order to perform a one-way analysis of variance (ANOVA), Fisher’s least significant differences (LSD) in pair-wise comparison and Fisher’s exact test at a level of 0.05 significance. ‘Normal values’ means that the sample size will be sufficient in numbers to derive a ‘normal distribution curve’ or bell curve. As the study was overpowered with regard to strength testing, results were interpreted with caution by the statistical consultant.

4.2 COLLECTION AND STORING OF SPECIMENS

After extraction, all teeth were cleaned under running water. A cursory examination of the specimens was done in order to validate the suitability for inclusion in this study. At this stage only gross caries and tooth morphology (such as tooth size, position in the dental arch, occlusal area and configuration of fissures (see paragraph 4.3, Table 1) was taken into account when suitability for inclusion was decided. Originally 108 extracted teeth were collected. Teeth deemed suitable were then stored in 0.5% chloramine-trihydrate as per ISO recommendation ISO/TS 11405 and put in a fridge at seven degrees centigrade (8ºC). The solution was replaced weekly. No specimen was stored for longer than 90 days before being used in the study.
4.3 SELECTION CRITERIA AND STANDARDIZATION OF SPECIMENS

One of the major challenges in research projects is standardizing. Some factors that may influence results like cross-head speed of the testing machine and collating results are easy to control. However, factors that might influence dentine bonding such as sclerotic dentine and dead dentinal tracts could not be controlled. The sample size, as recommended by the statistical consultant, was selected in order to compensate for these influences.

The effect of the anatomical variations was mitigated as much as possible by applying criteria described in Table 1:

Table 1: Anatomical variants and mitigating action taken

<table>
<thead>
<tr>
<th>Variant</th>
<th>Mitigating action taken</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anatomically variations</td>
<td>All teeth were selected on anatomical form and size as basis. This included tooth size, occlusal area, attrition and configuration of fissures</td>
</tr>
<tr>
<td>Age</td>
<td>All specimens were collected from patients between 40 and 60 years of age</td>
</tr>
<tr>
<td>Position of the tooth in the arch</td>
<td>The study was limited to lower left 1\textsuperscript{st} or 2\textsuperscript{nd} molars</td>
</tr>
<tr>
<td>Attrition</td>
<td>Any specimen with attrition was excluded from the study</td>
</tr>
<tr>
<td>Caries</td>
<td>All teeth with caries deemed to influence the size of the preparation were discarded</td>
</tr>
<tr>
<td>Variant</td>
<td>Mitigating action taken</td>
</tr>
<tr>
<td>---------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Size of the preparation (footprint)</td>
<td>Parameters were described in paragraph 2.6. A stent was made in order to assure a standard cavity preparation as described in paragraph 2.6(k)¹⁶,⁶⁶</td>
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<tr>
<td>Depth of the preparation</td>
<td>Parameters were described in paragraph 2.6. A stent was made in order to assure the depth of the preparation as described in paragraph 2.6(k)¹⁶</td>
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<td>Position of the CEJ</td>
<td>This was seen as critical. Measurements were taken with the CEJ as basis. Where no clear CEJ could be established, teeth were discarded</td>
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<tr>
<td>Position of the bone crest</td>
<td>Great care was taken in positioning the bone crest. Classification of breaking patterns heavily relied on the bone crest</td>
</tr>
<tr>
<td>Material used to simulate the periodontal ligament</td>
<td>Root anatomy ruled out conventional methods to construct an artificial periodontal ligament. The use of a plastic cylinder to embed the specimens compensated for this - as highlighted by fracture testing graphs.</td>
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<tr>
<td>Material used to simulate bone</td>
<td>Auto-polymerizing acrylic resin was used to simulate mandibular bone for the purpose of this study (Fig. 9)</td>
</tr>
<tr>
<td>Angle of force applied</td>
<td>A special jig was used so that an angled load force of 30⁰ to the long axis of the tooth could be applied.⁶⁶,⁸⁰</td>
</tr>
<tr>
<td>Tip used for testing specimens</td>
<td>A rounded machined tip with a circumference of 2 mm was specially made for the purpose of this study.⁸⁰</td>
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4.4 IMBEDDING THE SPECIMENS

Plastic cylinders with a diameter of 18 mm and length of 20 mm were obtained. These cylinders fitted perfectly into the custom-made angled jig that was used during the testing of the specimens.

Auto-polymerizing acrylic resin was mixed according to the manufacturer’s instructions. (EXCEL Rapid repair Material, Wright Millners, Jhb, SA). Care was taken to ensure that a standardized mix was achieved by carefully measuring the power-liquid ratio (Fig. 10).

Figure 10: Auto-polmerizing acrylic resin, measuring containers and plastic cylinder.

After mixing the auto-polymerizing acrylic resin, it was placed in the plastic cylinder. The specimens (teeth) were then placed in the auto-polymerizing acrylic resin so that the CEJ was exactly 1 mm above the top of the cylinder (acrylic level). All excess acrylic resin was carefully removed and the acrylic resin was allowed to polymerize (Fig.11). Specimens that were not conforming (CEJ to high or too low above the simulated bone crest) were removed from the project.
4.5 PREPARATION OF THE SPECIMENS

A standardized MOL cavity, in which the mesio-lingual cusp was removed and that conforms to the following specifications was prepared on all specimens: (Fig. 12 & 13)
Figure 12: Standardized MOL cavity preparation lingual view
Each cavity preparation was standardized as follows:

a) The CE junction was located by visual examination and marked (Fig. 14).
b) A standardized MOL cavity was prepared using a number 142 size 018 dome-shaped diamond fissure bur in an aeroter hand piece operating with continuous water spray. The bur was replaced after every three cavities were cut.

c) Dimensions of the cavity preparation are illustrated in Fig. 12 & 13. The following vertical dimensions were adhered to: the depth of the preparation, as measured between the deepest fissure and the floor of the cavities, was 3 mm, the depth of the occlusal step was 1 mm and the distance between the CEJ and the proximal step was 1 mm. The horizontal dimensions that were adhered to: the mesio-distal length was 8 mm (2a), the width of the proximal step was 1 mm (2b), the maximum bucco-lingual width was 6 mm (2c) and the width of the isthmus was 5 mm (2d).

d) The mesio-lingual cusp was removed 1 mm occlusal of the CEJ.

e) All internal line angles were rounded.

f) A proximal step was prepared.

g) The depth of the proximal step was 1 mm. (Fig. 12)

h) The proximal step did not exceed the original 1 mm line occlusal of the CE junction (Fig. 12 & 14)

i) The width of the proximal box was determined by the occlusal anatomy of the
specific tooth – the mesio-occlusal fissure was incorporated into the preparation, as well as the mesio-lingual cusp (Fig. 13).

j) The preparations were performed by a single operator and examined for the correct dimensions by a second operator. The second operator was a qualified dentist with at least 5 years clinical experience. If the preparation did not conform to the specified dimensions, the preparation was corrected (if possible); if not, the specimen was removed from the experiment and replaced by another tooth.

k) To ensure conformity, a physical “footprint” or stent was made and applied to every preparation. A compomer material with a contrasting colour was used to manufacture an inlay according to the diameters of the original prepared cavity (Twinky Star®, VOCO, Cuxhaven, Germany). The inlay was fixed to a micro-application tip. Thus a stent was obtained and was used to check the conformity of the cavities prepared on the specimens. If no reasonable fit could be obtained on the specimen, the specimen was removed from the study and replaced by another specimen (Fig. 15-17). All 75 specimens were checked with the same stent.

Figure 15: Manufacturing the Twinky Star® stent
Figure 16: Checking the preparations

Figure 17: Twinky Star® stent (x10)
l) All enamel margins were given a bevel in order to remove any unsupported enamel prisms and to maximise the exposed enamel margins.

4.6  RESTORING THE SPECIMENS

a) The specimens of all groups were etched with 37 per cent phosphoric acid; all enamel margins were etched for 15 seconds, and then all the exposed dentine (including the enamel) were etched for an additional 10 seconds (Fig. 18 & 19).

Figure 18: Etching enamel margins 15 seconds

Figure 19: Dentine etching 10 seconds
b) The acid was rinsed off with water. Care was taken to ensure that all etchant was removed.

c) The specimens were then lightly air-dried ensuring that all dentine surfaces remained slightly moist.

d) A bonding agent was applied and light-cured, according to the manufacturer's instructions (XP Bond®, Dentsply, Konstanz, Germany) (Fig. 20 & 21). XP Bond was selected as a bonding agent for this study because of its high bond strength to enamel and dentin, easy and comfortable application and a high degree of technique robustness. XP Bond is highly visible when uncured because of the yellowish tint which disappears when cured and it contains inter alia triethyleneglycol dimethacrylate (TEGDMA) resin.

Figure 20: Bonding agent and etchant

![Figure 20: Bonding agent and etchant](image)

Figure 21: Bonding agent applied and cured

![Figure 21: Bonding agent applied and cured](image)
e) The specimens were now randomly divided into three groups of 25 specimens each. (Group A, Group B and Group C).

**Specimens in Group A** were restored with a conventionally-filled hybrid composite resin restoration (Quixfill®, Dentsply, Caulk, USA) (Fig. 22). For the purpose of this study it was decided to use Quixfill® as it is a micro-hybrid posterior composite containing triethylene glycol dimethacrylate (TEGDMA), di- and tri-methacrylate resins and silica glass fillers. A Tofflemire matrix band was placed. (Fig. 23).81-83 Subsequently, the inter-proximal step was filled with the composite resin and light-cured for 20 seconds.

**Figure 22: Quixfill®**

![Figure 22: Quixfill®](image1)

**Figure 23: Tofflemire matrix band placed**

![Figure 23: Tofflemire matrix band placed](image2)
Subsequently, for each specimen, the rest of the restoration was completed using an oblique layering technique with incremental layers not exceeding 2 mm. Each layer was cured for twenty seconds with a hand-held LED curing light (LEDEX™ WL-070, Dentmate Technologies Co. Ltd, New Taipei City, Taiwan). Each completed restoration was subsequently ‘post-cured’: 20 seconds from occlusal, 20 seconds from buccal and 20 seconds from mesial.

Each restoration was finished and polished according to the following protocol: all the enamel margins were finished with a Dura-White Stone (Shofu Dental GmbH, Ratingen, Germany) using a friction-grip hand piece operating with continuous water spray. Polishing was done with Sof-Lex™ polishing discs (3M ESPE, Dental Products, St. Paul, Minnesota, USA), from coarse to ultra-fine. Final polishing was performed with Enhance® Polishing Cups (Dentsply, Konstanz, Germany) and Enamel Plus Shiny 1 micron diamond paste (GDF GmbH, Rosbach, Germany). Exactly the same finishing and polishing protocol was followed with Groups B and C.

**Specimens in Group B** were restored using Aelite® All-Purpose Body composite resin. (Aelite®, Bisco, Schaumburg, Illinois, USA). Micro-scale glass fibres and silica glass are incorporated as fillers into this composite (Fig. 24). A Tofflemire matrix band was placed and the inter-proximal step filled with the Aelite® All-Purpose Body composite and light-cured for 20 seconds.

*Figure 24: Aelite® (BISCO) nano-scale filler micro-hybrid composite*
The restorations were placed using an oblique layering technique with incremental layers not exceeding 2 mm. Each layer was cured for twenty seconds by a hand held LED curing light. Additionally the restorations were ‘post-cured’ for an additional 20 seconds per surface as described for Group A above. Finishing and polishing was performed as described for Group A above.

**Specimens in Group C**: A Tofflemire matrix band was placed and the interproximal step was filled with Quixfill® composite resin and light-cured for 20 seconds (Fig. 25).

![Figure 25: Proximal step filled (Restored)](image)

In order to maximize the Krenchel factor, a uni-directional glass fibre bundle was placed supporting the removed cusp (Fig. 26 & 27). It was decided to use everStick® as the fibre substructure in this study because of the following reasons: it is a uni-directional glass bundle containing E-glass fibres; it is pre-wetted and it is covered with a PMMA sheath that makes it easy to handle and lastly the PMMA (polymethylmethacrylate) sheath integrates easily with the TEGDMA (triethyleneglycol dimethacrylate), di- and tri-methacrylate resins in Quixfill®.
Figure 26: Schematic - placement everStick® fibre bundle

Legend:
Brown = inter-proximal step filled with conventionally filled composite (Quix’fill)
Green = glass fibre bundle
Black = 45 degree angulation

Figure 27: everStick® (StickTech Ltd) fibre bundle placed
The glass-fibre bundle was secured in position with a flowable composite as per recommendation of the manufacturers of everStick® (Stick Tech Ltd, Turku, Finland). EsthetX® flow (Dentsply) was used because of its handling properties (a smooth flow without flowing over the cavity margins), it is classified as a micro-hybrid and it contains TEGDMA (triethyleneglycol dimethacrylate) resin (Fig. 28).

Figure 28: EsthetX® flow

Close contact between the fibre bundle and the floor of the cavity was ensured by means of a silicone refix forming aid (Stick Tech Ltd, Turku, Finland). The refix positioning aid is made from transparent silicone and ensures that the fibre bundle is positioned in close contact with the floor of the cavity. While keeping the fibre bundle in position, the fibre bundle and flowable luting composite is cured using a hand held LED curing light (Fig. 29 & 30).

Figure 29: Positioning fibre bundle with the refix silicone aid
First the glass-fibre bundle was light-cured and then the refix fibre placing aid was carefully positioned and whilst kept in position, the fibre bundle and flowable composite was cured for 20 seconds. The ‘refix’ was then removed and the fibre bundle and flowable composite was cured for an additional 20 seconds. The restorations were then completed with Quixfill® using an oblique layering technique with incremental layers not exceeding 2 mm.

After the restorations were placed it was ‘post-cured’ cured, finished and polished using the protocol described for Group A in paragraph 4.6-f) above

The specimens (Groups A-C) were marked by means of placing grooves in the plastic cylinder (Fig. 31)

The curing light output was checked after completion of every 10 specimens.

(Curing light meter model 662, DentAmerica Inc, San Jose Ave, City of Industry, California, USA)

During the whole procedure, the teeth were stored in saline (0.9% w/v isotonic NaCl) until loading.\textsuperscript{84,85}
Figure 31: Specimens market with grooves on plastic cylinders

4.7 THERMOCYCLING

Following the placement of the restorations all specimens were stored in saline and subjected to thermocycling (500 cycles between 5° and 55° centigrade with a dwell time of 30 seconds). The specimens of the groups were mixed in order to ensure uniformity.

4.8 TESTING

Following thermocycling the specimens were stored in saline for a maximum of 24 hours before testing. The specimens were fixed in a metal holder and positioned in a Zwick 1446 universal testing machine using the TestXpert V 11.02 programme (Zwick, Ulm, Germany) with the long axis of the roots at an angle of 30 degrees to the direction of the load, using a specially made jig (Zwick, Ulm, Germany). A stainless steel cylindrical rod (tip diameter 2 mm) (Fig. 6) was used to load the specimens until fracture occurred. The site of loading was the central fissure of the occlusal surface of the restoration in the direction of the mesio-lingual cusp (Fig. 32 & 41). The force was applied at a crosshead speed of 0.5 mm/min.
The load at fracture ($F_{\text{max}}$) in Newton was recorded by means of a personal computer linked to the testing machine.

Testing of specimens was done in a research laboratory by an independent operator. Individual specimen numbers were allocated as the tests were performed randomly between the different groups. The part of the specimen that fractured off was collected, mounted on a transparent sheet and numbered for investigating at a later stage (Fig. 33).
After testing, the fractured specimens were stored, immersed in India ink for 24 hours to highlight the fracture lines (Fig. 34-37).  

Figure 34: After immersion in India ink

Figure 35: Close-up: After immersion in India ink
The failure mode was evaluated by two observers, both visually and microscopically, using a digital stereo microscope (Celestron 5 MP Hand held Digital Microscope Pro, Torrance, California, USA) at 10x magnification (Fig. 38 & 39). The part of the specimen that fractured was also studied in order to confirm the failure mode.
4.9 CLASSIFICATION OF FRACTURES

Literature describes fractures as either restorable (repairable/favourable) or unrestorable (non-repairable/un-favourable) and also as cohesive/adhesive.\(^{79,87-89}\). All fractures were therefore classified as follows:

**Fractures in Group A**: Restorable fractures were defined as **repairable failures** which include cohesive/adhesive failures that occurred occlusal of the simulated level of bone (Fig. 39a & b).
Fractures in Group B: Non-restorable fractures were defined as non-repairable failures including (root) fractures and visible fracture lines apically to the level of the simulated bone level (Fig. 40a & b; Fig. 41).
Figure 40 a & b: Fractured below of the simulated bone level

Figure 41: Schematic illustration of a non-repairable fracture
4.10 SUB-CLASSIFICATION OF FRACTURES

For the purpose of this study it was decided to further refine the classification with the following sub-classification (Fig. 42):

- **Type 1 fracture**: Fracture of the conventionally filled composite resin (cohesive composite failure).
- **Type 2 fracture**: Fracture between tooth and composite resin (adhesive fracture). (This type of fracture is only applicable in Groups A and B where no fibre bundle substructure is present).
- **Type 3 fracture**: Fracture between the fibre bundle and the composite resin (cohesive-adhesive failure).
- **Type 4 fracture**: Fracture of the fibre bundle (cohesive failure).
- **Type 5 fracture**: Fracture between the fibre bundle and tooth (adhesive failure).
- **Type 6 fracture**: Fracture of the tooth (cohesive failure).
- **Type 7 fracture**: Any combination between types 1 to 6.

Figure 42: Schematic sub-classification Group C fractures (Green=fibre sub-structure)
During all evaluations disagreements were resolved by discussion. If no agreement could be reached, the specimen was discharged from the experiment.
5. RESULTS

5.1 FRACTURE STRENGTH RESULTS

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Table 3: Collated test results containing individual specimen numbers and fracture strength results

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Table 3: Collated test results containing individual specimen numbers and fracture strength results

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</table>

**Average** 313.008 393.1944 461.644

**Maximum** 418.94 636.15 662.58

**Minimum** 125.78 205.90 336.55

**Standard Deviation** ± 64.3 ± 92.3 ± 62

---

**Graph 1:** Results – Raw data

[Graph showing stress versus time]

**Graph 1:** Vertical axis ‘Stress’ measured in Newton (N) and horizontal axis ‘Time’ measured in Seconds (s)
Table 4: Collated fracture strength results (Newton)

<table>
<thead>
<tr>
<th></th>
<th>Group A Control (n=25)</th>
<th>Group B (n=25)</th>
<th>Group C (n=25)</th>
</tr>
</thead>
<tbody>
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<td>$F_{\text{min}}$</td>
<td>125.78</td>
<td>205.90</td>
<td>336.55</td>
</tr>
<tr>
<td>$F_{\text{max}}$</td>
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<td>636.15</td>
<td>662.58</td>
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<tr>
<td>$F_{\text{average}}$</td>
<td>313.008</td>
<td>393.1944</td>
<td>461.644</td>
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<tr>
<td>SD</td>
<td>± 64.3</td>
<td>± 92.3</td>
<td>± 62</td>
</tr>
</tbody>
</table>

**Graph 2** illustrates the comparison between $F_{\text{min}}, F_{\text{max}}$ in the three groups as summarised in Table 3.

**Graph 2: $F_{\text{min}}, F_{\text{max}}, F_{\text{average}}$ and standard deviation (SD)**

**Graph 3** illustrates the fracture test results ($F_{\text{max}}$) for Group A - Quixfill® (Control)
Graph 3: Group A – Fmax

Graph 4 illustrates the fracture test results (Fmax) for Group B - Aelite®

Graph 4: Group B - Fmax
Graph 5 illustrates the fracture test results \( (F_{\text{max}}) \) for Group C - Quixfill® and everStick®

Graph 5: Group C - Fmax

![Graph 5: Group C - Fmax](image)

### 5.2 FRACTURE BEHAVIOUR PATTERNS RESULTS

Table 5 illustrates the collated fracture behaviour results for Groups A-C

**Table 5: Collated results - Fracture behaviour**

<table>
<thead>
<tr>
<th>Group A: Control (n=25)</th>
<th>Group B (n=25)</th>
<th>Group C (n=25)</th>
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<td>Group A: Control (n=25)</td>
<td>Group B (n=25)</td>
<td>Group C (n=25)</td>
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</table>
**Graph 6** illustrates the comparison between restorable and non-restorable fractures between the 3 groups.

**Graph 6: Restorable vs. Non-restorable fractures**

![Graph 6](image)

**Graph 7** illustrates the frequency between cohesive and adhesive failures compared between the 3 groups.

**Graph 7: Cohesive vs. Adhesive failures**

![Graph 7](image)
Table 6: Group C – Fracture types

<table>
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<tr>
<td>Type 3</td>
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</table>
5.3. STATISTICAL ANALYSIS

For the three groups, the breaking strengths were summarized by using means, standard deviations and 95 per cent confidence intervals, while for break type data, the proportions (percentages) and 95 per cent confidence intervals were analysed. For the primary objective (fracture strength), the groups were compared in a one-way analysis of variance (ANOVA) and specific differences were tested using Fisher’s least significant differences (LSD) in pair-wise comparisons. For the secondary objective (fracture behaviour patterns), the groups were analysed in a contingency table using Fisher’s exact test. All testing were evaluated at the 0.05 level of significance.
6. DISCUSSION

6.1 FRACTURE STRENGTH

Fracture strength values of the composite resin used as a control (Group A - Quixfill®), varied from 125.78 N (F\textsubscript{min}) to 418.94 N (F\textsubscript{max}) with a mean of 313.008 N (F\textsubscript{average}) and standard deviation (SD) of 64.3 N. These results are illustrated in Graph 8.

Graph 8: Fracture strength values comparison: Group A (Quixfill®)

Comparing the fracture strength values of this study with the values obtained by other researchers in the same field indicate very similar values.\textsuperscript{14} It can therefore be concluded that fracture strength values of the composite resin used as control falls within acceptable parameters as demonstrated by other researchers in the same field.

Fracture strength values of the composite resin reinforced with nano-scale glass fibre reinforcement (Group B – Aelite®) varied from 205.9 N (F\textsubscript{min}) to 636.15 N (F\textsubscript{max}) with a mean of 393.194 N (F\textsubscript{average}) and a standard variation (SD) of 92.3 N. These results are illustrated in Graph 9.
Tain et al. found an average increase of 23 per cent in fracture strength values when electrospun nano-scale glass fibres were incorporated in a composite resin. The values of the current study produced an average increase of 25.5%, in flexural strength which is slightly higher, but not statistically significantly so, than the values published by Tain et al. It is, however, less than could be expected if the Krenchel Factor is applied (a 36% increase to be theoretically expected).

Fracture strength values of a composite resin placed on a uni-directional glass-fibre substructure (Group C - Quixfill® placed on everStick®) varied from 336.55 N (F_{min}) to 662.58 N (F_{max}) with a mean of 461.644 N (F_{average}) and standard deviation (SD) of 62 N. These results are illustrated in Graph 10.
This is an increase of 48 per cent in fracture strength values compared to the control group and 18 per cent compared to Group B (composite resin reinforced with nano-scale fibres). Again, the increase in fracture strength values are less than could be expected if the Krenchel Factor is applied (100%) but it might be explained by the fact that it is impossible to predict exactly where the fracture will occur and therefore exactly where to place the fibre substructure. It is also important to remember that Krenchel values are part of a mathematical calculation and that it might be a much more complicated calculation when biological specimens are evaluated.

Both the inclusion techniques, fibres placed as a substructure or fibres included in the composite material itself, had significantly increased the fracture strength values of the composite resin restorative material. This is in line with results obtained by other researchers. Fennis et al. concluded in their study that uni-directional fibres in cusp-overlaying composite resin restorations not only lead to higher reinforcement values but also produced less consistent results than reinforcement substructures placed on woven (bi-directional) fibre netting. This differs from results published by Belli et al. and results obtained by this research. Research comparing the strengths of full-cover crowns made out of composite and reinforced by either a fibrous substructure or short multi-lateral fibres indicated that crowns
reinforced with the latter fibres showed a higher load-bearing capacity. These crowns were manufactured in a laboratory and were heat and pressure-cured.\textsuperscript{16}

\subsection*{6.2 FRACTURE BEHAVIOUR PATTERNS}

Fracture patterns are broadly classified in the literature as either restorable, (fractures above the simulated bone crescent) and non-restorable (fractures below the simulated bone crescent).\textsuperscript{79,87,89}

The composite resin used as a control in this study (Group A - Quixfill\textsuperscript{®}) fractured in 44 per cent (11 out of 25 specimens) of tests in a restorable manner; the composite resin reinforced with nano-scale glass fibre reinforcement (Group B – Aelite\textsuperscript{®}) fractured in 12 per cent (3 out of 25 specimens) in a restorable manner and the composite resin placed on a uni-directional glass-fibre substructure (Group C - Quixfill\textsuperscript{®} placed on everStick\textsuperscript{®}) fractured in 84 per cent (21 out of 25 specimens) in a restorable manner (Graph 6). This was statistically significant (Fishers Exact Test, p,0.05)

Fennis \textit{et al.} determined that composite resin restorations placed on bi-directional fibre netting fractured in a restorable way in 62 per cent of specimens. In comparison, when composite resin restorations were placed on a uni-directional fibre sub-structure, 77 per cent of the specimens fractured were graded as restorable.\textsuperscript{99} Studies by Akman \textit{et al.} and Lammi \textit{et al.} and others also indicated that if a multi-directional substructure were used, 66-80 per cent of fractures were restorable.\textsuperscript{15,70,100,101}

Not only did the composite resin reinforced with nano-scale glass fibre (Group B – Aelite\textsuperscript{®}) fracture in a non-restorable manner in 88 per cent of specimens tested; it was also noted that 28 per cent (7 out of 25) of these specimens fractured in such a manner that pulp tissue was exposed (Fig 40a & 43).
This was the only group in this study in which pulp-exposing fractures occurred. This catastrophic type of fracture also occurred when conventionally-filled composite resin was placed on a substructure of short multi-directional fibre composite. The main reason for incorporating short multi-lateral fibres instead of long uni-directional fibres
lies in the easier handling properties of new products such as everX\textsuperscript{®} Posterior (GC Corporation, Tokyo, Japan) in the clinical situation.

According to the literature, some researchers also use a broad classification system based on the type of fracture, being either cohesive (Fig. 39 a and 44) or adhesive (Fig. 45a & b).\textsuperscript{79,87, 89}

Figure 44: Cohesive fracture
Figure 44 (b): Cohesive fracture (x 10 magnifications)

Figure 45: Adhesive fracture
A more detailed investigation of fracture patterns in this study (Graph 2) show that in Group A, the fractures were more or less evenly distributed between cohesive and adhesive fractures. 52 per cent, or 13 out of 25, were cohesive fractures (Graph 7). This differs from the finding of Taha et al. who found mainly adhesive fractures.\textsuperscript{69} Data from this current study, however, support the findings of other researchers.\textsuperscript{63,80,103}

Graph 7: Frequency of cohesive and adhesive fractures in Groups A, B and C
In **Group B** most of the fractures were cohesive (68%, 17 out of 25 specimens) (Graph 7). This seems to support the results as measured during the fracture tests, that the inclusion of nano-scale fibres in a composite resin significantly strengthened the composite.

In **Group C** 16 per cent (4 out of 25) of fractures were adhesive, while 68 per cent (17 out of 25 specimens) were cohesive. 16 per cent (4 out of 25) of fractures were a combination of cohesive and adhesive fractures (Graph 7). This is similar to the finding of Tezvargil *et al.*

In all of the 68 per cent of cohesive failures the fracture occurred between the fibre substructure and the composite resin, as illustrated in Figure 46a & 46b. This supports the theory that the fibre-substructure acts as a crack-reflecting mechanism, enabling the composite resin restoration to endure significantly higher force before fracture. This argument becomes even stronger when 16 per cent combination fractures (cohesive and adhesive) are added to the 68 per cent adhesive fractures, meaning that 84 per cent of the fractures are either cohesive or a combination thereof (Table 6).

*Figure 46: Fracture between fibre sub-structure and composite resin*
It is speculated that the short multi-lateral fibre substructure was the reason for the fractures that occurred in Group B in such a manner that the pulp was exposed. This speculation is supported by a recent publication by Fráter et al.102

7. LIMITATIONS

Results of all research findings have to be interpreted with care, even more so when biological material is investigated.90,91 It is just not possible to control all variables, therefore specimens have been carefully selected using anatomical criteria, age of the patient and position in the mandible. However, factors that might influence dentine bonding, such as sclerotic dentine and dead dentinal tracts, could not be controlled. On the other hand, sample size, tooth preparation, placement technique, specimen preparation; testing and analysis of results could easily be standardized.
7.1 STORAGE OF TEETH DURING RESEARCH

Storing the specimens in saline instead of artificial saliva might be questioned by some researchers (after preparation, placing of the restoration and thermocycling). However, the researcher is of the opinion that there would not have been any difference in fracture strength or fracture patterns. The use of saline for storage of teeth has been chosen by many researchers. It seems that, according to the literature, many researchers prefer to store the prepared specimens in distilled water prior to testing. Raum et al. recommended storage in artificial saliva; Kitasako et al. concluded that there is no difference between storage in distilled water and saline, while Jaffer et al. concluded that dry storage or storage in ethanol is not recommended because of desiccation.

7.2 TESTING

It would have been ideal to perform the loading tests during thermocycling, but it was found to be logistically and practically impossible. Again, the effect on the fracture strength and fracture patterns is questionable.

7.3 RADIOGRAPHS

Radiographs from each specimen should have been taken after the restoration is placed and before testing. This would have determined the exact position of the pulp in relation to the restoration. The position of the pulp may play a role in pulp-exposing fractures. However, when this study was designed there was no evidence in the literature of this phenomenon (it was first described by Fräter in 2014).
8. CONCLUSION/ETHICAL ACCEPTABILITY / FUTURE RECOMMENDATIONS

8.1 CONCLUSION

Within its limitations, this research project clearly shows a significant difference in the fracture strength of the three different types of restorations studied, with the conventionally-filled composite placed on a uni-directional fibre substructure being the strongest.

Analysing fracture patterns in this study indicates a statistically significant difference between the three groups of restorations studied. The conventionally-filled composite placed on a uni-directional fibre substructure showed the most favourable (restorable) fracture pattern; with the composite restoration incorporating nano-scale glass fillers the least favourable fracture pattern. It can therefore be concluded that placing a fibre substructure under a conventionally filled composite restoration will ‘improve’ the fracture pattern, whilst incorporating short multi-lateral fibres either as a substructure or in the composite might lead to less-favourable fracture patterns.

Based on the results of this research, the following hypothesis was proven: as far as the two properties tested were concerned, that a unidirectional glass fibre substructure did significantly improve the fracture strength of cusp-replacing composite resin restorations and that a unidirectional glass-fibre substructure did significantly improve the fracture behaviour of cusp-replacing composite resin restorations.

8.2 ETHICAL STATEMENT

This research project involves in vitro testing of three different groups of specimens. These ‘specimens’ were extracted, human lower, left, first and second molars, selected on anatomical criteria, then prepared, and restored with a Mesio-Occlusal-Lingual (MOL) cusp-replacing restoration. Three different restorative techniques were followed and evaluated in terms of fracture strength and fracture patterns.
Consent for the use of the extracted teeth for research purposes was obtained during registration of patients at the Oral and Dental Hospital, a copy attached (14.1). Teeth used in this study have been extracted for periodontal disease reasons only. No information on the fracture strength or fracture behaviour patterns was divulged to any donor.

8.3 FUTURE RECOMMENDATIONS

- The use of a short multi-lateral fibre sub-structure should be investigated further before its routine use in the dental practice can be recommended.
- Radiographs from each specimen should be taken after the restoration is placed and before testing. This will determine the exact position of the pulp in relation to the restoration.
REFERENCES


ADDENDA

1. COPY OF INFORMED CONSENT

PRO FORMA

PATIENT INFORMATION LEAFLET AND INFORMED CONSENT

Each patient must receive, read and understand this document before the start of the treatment and study.

Study Title:

Study Number:

You are invited to volunteer for a research study. This information leaflet is to help you to decide if you would like to participate. Before you agree to take part in this study you should fully understand what is involved.

INTRODUCTION

You have been diagnosed as suffering from Periodontal (gum) Disease. Periodontal Disease is fairly common in the population between 40 and 60 years old and it causes bleeding gums and bad breath, leading eventually to teeth becoming mobile (loose), making it difficult to chew. In your specific case the molars (back teeth) has become so loose that you cannot chew on them anymore without experiencing pain and discomfort. Hence your visit to the Clinic to obtain help, resulting in your request to have the offending tooth/teeth removed.

We would like you to consider taking part in a research study by donating your extracted tooth/teeth to research.
If you have any questions which are not fully explained in this leaflet, do not hesitate to ask the investigator. You should not agree to take part unless you are completely happy about all the procedures involved.

**WHAT IS THE PURPOSE OF THE STUDY?**

The aim of the research is to evaluate different methods of restoring (filling) teeth.

**WHAT IS THE DURATION OF THE STUDY?**

Your personal involvement will be having the offending tooth/teeth extracted. Your mouth will also receive a thorough dental examination that may include dental X-rays and you will receive a written dental report and recommended treatment plan. You will be under no obligation to go ahead with the treatment plan, should you decide not to. In the event that you, at a later stage do not want to go ahead with this treatment, your decision will not be held against you.

**WHAT WILL HAPPEN TO MY TOOTH/TEETH AFTER IT IS REMOVED?**

After your tooth/teeth have been removed under local anaesthetic, you will receive post-op instructions as per standard protocol. Your tooth/teeth is/are then cleaned and will receive a restoration (filling). The filling will be tested for strength on a special machine and fracture patterns of the restoration (how the filling breaks) will be studied, with the aim to place better dental fillings in future.

**HAS THE STUDY RECEIVED ETHICAL APPROVAL?**

The study has been structured in accordance with the Declaration of Helsinki (last update: October 2000), which deals with the recommendation guiding doctors in biomedical research involving human subjects. A copy of which may be obtained from the investigator should you wish to review it. This study has been approved by the Research Committee, Dental School, University of Pretoria.
WHAT ARE MY RIGHTS AS PARTICIPANT IN THIS STUDY?

Your participation in this study is entirely voluntary and you can refuse to participate or stop at any time without stating any reason. Your withdrawal will not affect your access to other dental care from this Clinic. The investigator retains the right to withdraw you from the study if it is considered to be in your best interest.

IS ALTERNATIVE TREATMENT AVAILABLE?

Unfortunately, at this stage the offending tooth/teeth in your mouth can not be saved as your gum disease has progressed too far. The only viable option is to have it removed. However, your remaining teeth will be thoroughly examined by a dental professional and you will receive a dental treatment plan. Again, it is entirely your choice should you decide not to go ahead with the proposed treatment. It will not be held against you should you seek any further dental treatment from this Clinic.

MAY ANY OF THE STUDY PROCEDURES RESULT IN DISCOMFORT OR INCONVENIENCE?

The only discomfort you will experience will be during the surgical period of extraction. You will be given a local anaesthetic and you will receive post-op instructions as per standard protocols. This will help to minimise your discomfort. The injection may result in a bruise at the puncture site, or less commonly fainting, swelling of the extraction site, infection and bleeding from the site. Your protection is that the procedures are performed under surgical conditions by experienced personnel. If there is any risk of infection, you will be informed and you will receive appropriate medication.

WHAT ARE THE RISKS INVOLVED?

All dental extractions carry some risks, however small. Your treatment will be done by experienced persons that are properly trained to perform extractions. Risks might include possible fracture of your tooth during extraction, bleeding, swelling and pain. If you carefully follow your post-op instructions you will experience minimal discomfort. However, we urge you to return to the Clinic should you experience any adverse effect.
ARE THERE ANY WARNINGS CONCERNING MY PARTICIPATION IN THIS STUDY?

Periodontal disease might be the result of an underlying medical condition like Type 2 Diabetes. It has also been associated to Heart Disease. We therefore strongly recommend that you contact your medical doctor as soon as possible.

CONFIDENTIALITY

All information obtained during the course of your extraction and/or the research study is strictly confidential. Data that may be reported in scientific journals will not include any information which identifies you.

Any information uncovered regarding your state of health will be held in strict confidence. You will be informed of any finding of importance to your health but this information will not be disclosed to any third party without your written permission. The only exception to this rule will be cases in which a law exists compelling us to report individuals infected with communicable diseases. In this case, you will be informed of our intent to disclose such information to the authorised state agency.

INFORMED CONSENT

I hereby confirm that I have been informed by the investigator, Dr ………about the nature, conduct, benefits and risks of my condition and treatment. I have also received, read and understood the above written information (Patient Information Leaflet and Informed consent) regarding the study.

I am aware that no personal details regarding my sex, age, date of birth, initials and diagnosis will be included in a research report.

I may, at any stage, without prejudice, withdraw my consent and participation. I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate.

I have been fully informed of the surgical procedure and subsequent research and possible complications thereof. I hereby give my consent and request treatment and the administering of a local anaesthetic as decided by the doctor for myself/wife/child
Patient's name ........................................ (Please print)

Patient's signature ...................................................

Date .................................................................

I, Dr ........................................... herewith confirm that the above patient has been fully
informed about the nature, conduct and risks of the treatment and research.

Signature.........................................................

Witness’s name ..................................................... (Please print)

Witness’s signature ................................................

Date........................................................................

Consent Procedure should be witnessed whenever possible.
INFORMED CONSENT FOR PARENTS/GUARDIANS

(on behalf of minors under 18 years old)

Dr …………………………………………………has provided me with a copy of the Patient Information Leaflet and Consent Form and has fully explained to me the nature, risks, benefits and purpose. He/she has given me the opportunity to ask any questions. It has been explained to me that I will be able to withdraw my child at any time, without any disadvantage to future care. I have understood everything that has been explained to me and I consent for my child to receive this treatment.

I have been fully informed of the surgical procedure and subsequent research and possible complications thereof. I hereby give my consent and request treatment and the administering of a local anaesthetic as decided by the doctor for myself/wife/child

Parent/Guardian(s) Name ………………………………………………… (Please print)

Parent/Guardian(s) Signature ………………………………………………

Date ………………………………

Patient’s Name ………………………………………………………………………… (Please print)

Patient’s Signature ………………………………………………………………

Date ………………………………

(Minors competent to understand must participate as fully as possible in the entire procedure.)

Investigator’s Name ……………………………………………………………… (Please print)
Investigator’s Signature …………………………………………………

Date ……………………………

Witness’s Name ………………………………………………………… (Please print)

Witness’s Signature ……………………………………………………

Date ……………………………
VERBAL PATIENT INFORMED CONSENT

(applicable when patients cannot read or write)

I, the undersigned, Dr ……………………………., have read and have explained fully to the patient, named …………………………….. and/or his/her relative, the patient information leaflet, which has indicated the nature and purpose in which I have asked the patient to participate. The explanation I have given has mentioned both the possible risks and benefits and the alternative treatments available for his/her illness. The patient indicated that he/she understands that he/she will be free to withdraw at any time for any reason and without jeopardising his/her future dental treatment at this Clinic.

I have been fully informed of the surgical procedure and subsequent research and possible complications thereof. I hereby give my consent and request treatment and the administering of a local anaesthetic as decided by the doctor for myself/wife/child

Patient’s Name ………………………………………………………………………. (Please print)

Investigator’s Name ……………………………………………………………… (Please print)

Investigator’s Signature …………………………………………………………… Date ………………………………

Witness’s Name ……………………………………………………………………… (Please print)

Witness’s Signature …………………………………………………………………

Date ………………………………..

You have not waived any of the legal rights which you otherwise would have had by signing this form.
2. LIST OF EQUIPMENT AND MATERIALS MANUFACTURERS

1. Chloramine trihydrate: MEDICHEM, Tokai, Cape Town, South Africa
2. EXEL Rapid Repair Material: wright Millners, Johannesburg, South Africa
3. Number 142 size 018 diamond fissure bur: HORICO Dental Hopf, Ringleg & Co, GmbH, Germany
4. Twinky Star®: VOCO, Cuxhaven, Germany
5. Phosphoric Acid: DENTSPLY, Konstanz, Germany
6. XP Bond: DENTSPLY, Konstanz, Germany
7. Quixfill: DENTSPLY, Konstanz, Germany
8. LEDEX™ WL-070 Curing Light: Dentmate Technologies Co Ltd New Taipey City, Taiwan
9. Dura White® Stone: Shofu Dental, GmbH, Germany
10. Soflex™ polishing discs: 3M ESPE, Dental Products, St. Paul, Minnesota, USA,
11. Enhance™: DENTSPLY, Konstanz, Germany
12. Enamal Plus® Shiny 1 micron: GDF Gmbh, Rosbach, Germany
13. Aelite® All Purpose Body: BISCO, Scaumburg, Illinois, USA
14. Toffelmire Matrix band: Garrison Dental, 150 DeWitt Lane, Spring Lake, MI 49456, USA
15. everStick®: Stick Tech Ltd, Turku, Finland
16. EsthetX® Flow: DENTSPLY, Konstanz, Germany
17. Refix® forming aid: Stick Tech Ltd, Turku, Finland
18. Curing light meter model 662: DentAmerica Inc, San Jose Ave, City of Industry, California, USA
19. Saline: Dis-Chem Pharmacies, South Africa
20. TestXpert V 11.02: Zwick, Ulm, Germany
India Ink: Wells Printing Materials
Company Ltd, Guandong, China

21. Digital Stereo Microscope: Celestron 5 MP Hand held Digital Microscope Pro,
Torrance, California, USA

3. CONFLICT OF INTEREST STATEMENT

Conflict of Interest

I, Herculaas Jacobus Visser declare that I am a Director of Stick Bond Dental CC, a Dental
Company that imports one of the key products used in this research.

Signature:

Date: 1 October 2015