Retention force and fatigue strength of mandibular single-implant overdenture attachment systems

UNIVERSITY OF THE
WITWATERSRAND,
JOHANNESBURG

Schalk Jacobus van der Linde
Student number: 304599

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Department of Oral Rehabilitation, School of Oral Health Science,
Faculty of Health Sciences, University of the Witwatersrand

Supervisors:
Prof. C.P. Owen
Prof. J.L. Shackleton

Declaration

I, SCHALK JACOBUS VAN DER LINDE hereby declare that this research report is my own work. It is being submitted for the degree of Master of Dentistry (MDent) at the University of the Witwatersrand, Johannesburg, South Africa. It has not been submitted previously for any degree or examination at this or any other university.

Signed: Schalk van der Linde …………………………

This 1st day of June 2023

Dedication

I dedicate this research report to my beautiful and loving wife, Dr. Krystle Moodley, whose sacrifice and unwavering support allowed me to complete this research report. And to my parents, my biggest supporters from day one who always believed that I could complete any task I set out to do.

Acknowledgements

Prof. C.P. Owen for his monumental contribution and guidance during the initial research protocol, as well as the writing up of this research report. Without him I truly would not have been able to complete this research report.

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Abstract

Purpose

A single mandibular implant-retained overdenture is now recognised as a viable alternative to the more conventional two implant-retained overdenture. Historically, ball abutments and high performance synthetic polymers for the matrix have been used as the attachment system, but regular prosthetic maintenance can be a significant drawback. This *in-vitro* study aimed at determining the mechanical properties of a novel prototype matrix designed with ease of replacement in mind to reduce the prosthetic maintenance burden.

Method

Custom test bases with a simple holding device were made, to enable tensile and fatigue testing for the experimental prototype (OBZ abutment and a polyetheretherketone (PEEK) matrix) and control attachment system (OT-Equator® abutment with standard nylon matrix). Each assembled sample was subjected to 10 tensile pull tests to determine initial retention values. For fatigue testing samples were immersed in saline after which they were manually pulled apart and re-seated, whilst being re-immersed in the saline after a designated number of cycles. Tensile test values were measured until a pre-determined retention force value of 20 N was reached, representing clinical failure. Volunteers (five clinicians/technicians and five non-trained individuals) were recruited to replace both attachment systems, and the replacement time taken, and perceived ease of replacement were recorded for each participant.

Results

The prototype PEEK matrix system was significantly more retentive ($p < 000.1$) than the control system after initial tensile testing. Simulated fatigue testing following saline immersion revealed no significant difference ($p > 0.05$) after 100 cycles; saline immersion reduced the values in both attachment systems. There was no significant difference ($p > 0.05$) in mean retention force value at point of failure, but there was, however, a significant difference ($p \leq 0.05$) in failure point between the two attachment systems, with the OBZ abutment with prototype PEEK matrix failing much earlier. Participants found replacement of the prototype PEEK matrix significantly easier, regardless of their level of experience.

Conclusion

For a mandibular single implant-retained overdenture the clinically acceptable retention values of the OBZ abutment with prototype PEEK matrix, together with its ease of replacement, mean that it can be considered a viable alternative to the current OT-Equator® abutment with standard retention nylon matrix.

Chapter 1 . INTRODUCTION AND LITERATURE REVIEW

1.1 Introduction

A mandibular overdenture retained by two endosteal dental implants has been proposed as the first-choice standard of care when rehabilitating the edentulous mandible (Feine *et al.*, 2002). However, Fitzpatrick (2006) argued that “no single treatment modality, material, or technique for tooth replacement can fit all patient requirements.” In reviewing the literature on all available treatment modalities for rehabilitation of the edentulous mandible (complete tissue-supported removable dentures, implant-retained and tissue-supported removable overdentures, and implant-supported and retained fixed prostheses), Fitzpatrick concluded that “there is no strong evidence supporting a single standard of care in the edentulous mandible as defined by a specific treatment modality.” (Fitzpatrick, 2006). Instead, bearing socioeconomic and patient autonomy in mind, it would be prudent to follow a Minimum Acceptable Protocol (MAP) for a particular intervention, irrespective of the treatment option selected by the patient. As such, available resources can then be adapted to present day clinical circumstances without compromising patient care (Owen, 2004; 2009).

1.2 Factors that affect global implant incidence and prevalence

Although endosteal dental implants have been shown to be a predictable and successful tooth replacement alternative (Buser *et al.*, 2017), they contribute relatively little to global prosthodontic treatment performed (Carlsson, 2016). This is in large part due to socioeconomic factors amongst the partially dentate and edentulous population who cannot afford such treatment (Owen, 2009; Carlsson, 2016). Global incidence and prevalence studies on implant placement are scarce. Elani *et al.* (2018) reported that the prevalence of dental implants in a representative United States population increased from 0.7% in 1999-2000 to 5.7% in 2015-16. The greatest absolute increase in prevalence (12.9%) was amongst individuals aged 65-74 years. Dental implant prevalence was expected to increase to 17% by 2026, with an upper value of 23% estimated should trends continue to increase.

Cost constraints are not the only reason for individuals declining implant therapy. Walton and MacEntee (2005) offered prospective edentulous patients free implants to improve the retention and stability of their mandibular dentures but found that approximately one third (36%) of the 101 respondents refused the offer of implant treatment, even at no cost; 43% of participants listed concerns over surgical risks as the main reason for refusal.

1.3 The single mandibular implant-retained overdenture: A viable alternative?

In attempts to address concerns such as cost constraints and surgical risks, various clinical trials have investigated the feasibility and outcomes of a single mandibular implant-retained overdenture as a viable alternative to a two implant-retained overdenture. Walton *et al.* (2009) reported similar patient satisfaction levels and prosthetic maintenance times following inter-group comparisons between mandibular overdentures retained by either one or two implants at the 1-year follow-up period. Mandibular overdentures retained by a single midline implant resulted in significant reductions in componentry costs, surgical time, and post-surgery denture maintenance and relines. Alsabeeha *et al.* (2011a) reported that a mandibular single-implant overdenture opposed by a conventional maxillary complete denture can be a successful treatment option for elderly individuals when using an early loading (6 weeks) protocol with different implant diameters and attachment systems. Furthermore, prosthetic maintenance was reduced when using larger attachment systems on wide body implants with greater reported success rates (83.3%) when compared with regular body implants (63.6% and 66.7% respectively) using strict prosthetic outcome criteria.

Mandibular implant overdentures offer the distinct advantage of improved retention and stability when compared with conventional dentures, especially during function. This is largely facilitated by the retentive attachment systems which generally comprise an adjustable or replaceable receptacle (the matrix), which uses either mechanical or friction fit to lock into an accompanying patrix. Matrices are incorporated into the intaglio surface of prostheses during finishing procedures or delivery, and patrices are connected to the implants themselves and provide anchorage (Anas El-Wegoud *et al.*, 2018). Attachment systems can be classified into two broad categories based on their rigidity. Rigid attachment systems allow for no movement of the involved components during function, such as by direct attachment or contact of the overdenture onto a bar. Resilient attachment systems permit a pre-determined amount and range of movement, thereby distributing any applied forces over both the implants and denture bearing mucosa. Resilient attachment systems include ball abutments, clips, Locator® abutments and magnets (Laverty *et al.*, 2017).

1.4 Desired retentive value and wear of attachment systems

Retentive values amongst different attachment systems vary greatly. Savabi *et al.* (2013) reported retention values that ranged from 35.08 to 44.12 Newton (N) for vertical dislodging forces and 32.09 to 40.46 N for postero-anterior dislodging forces for different bar/clip and stud attachment designs. The highest average retention values were obtained from a Dolder bar with 3 metal clips. There appears to be no consensus in the literature with regards to an exact, universal retentive force threshold value (Alsabeeha *et al.*, 2010). Early literature proposed that retention forces ranging from 5-7 N should be sufficient to stabilise an overdenture during function but gave no supporting evidence for this (Lehmann and Arnim, 1978 as cited by Botega *et al.*, 2004). More recently, a value of 20 N has been suggested as the minimum amount of retention required to ensure patient satisfaction with a mandibular two implant-retained overdenture (Alsabeeha *et al.*, 2010; Türk *et al.*, 2014).

Petropoulos *et al.* (1997) defined a ‘release period’ as “the time it takes for the attachment to lose its retentiveness”. They considered it a “built-in safety mechanism” by allowing the matrix to release from the patrix, and speculated that the faster an attachment releases, the less stress would be placed on the abutment(s). A prolonged release period with gradual loss of attachment without complete disengagement might expose the abutments and prostheses to undue stress as the patient may continue to function without realising that initial disengagement had occurred (Petropoulos *et al.*, 1997).

Multiple factors affect the retention and wear of attachment systems. These include implant and attachment angulation, inter-implant distance, the direction of applied dislodging forces, and attachment system matrix material, design, dimension, and mode of retention (Savabi *et al.*, 2013). Continuous wear results in a loss of retention with patients seeking treatment to either tighten or replace these attachment systems (Alsabeeha *et al.*, 2009). Multifactorial in nature, potential mechanisms of wear could be adhesive, abrasive, surface fatigue and corrosion. Plastic deformation of softer polymeric and gold-alloy attachment systems may also take place (Alsabeeha *et al.*, 2011b). As such, any proposed novel attachment system should possess adequate longevity.

1.5 Attachment system selection

Ball attachment systems appear to be the preferred choice for mandibular single implant-retained overdentures based largely on their wide universal application, simplicity, and cost effectiveness (Walton *et al.*, 2009; Kronstrom *et al.*, 2010; Alsabeeha *et al.*, 2011b). Long-term clinical data (5-year follow-up) have revealed that the most common maintenance procedures with regards to ball attachment systems are adjustment, reattachment, and replacement of the attachment systems (Bryant *et al.*, 2015). Adjustments are usually in the form of reactivation of the matrix or tightening of a patrix on the implant. Inter-group comparisons between one and two implant-retained overdentures using ball attachment systems have, however, revealed no significant difference in cumulative attachment system maintenance events when followed up over 3 and 5 years (Kronstrom *et al.,* 2014; Bryant *et al.*, 2015). Single mandibular implant-retained overdentures did, however, experience twice as many fractures, usually adjacent to the single midline implant attachment (Bryant *et al.*, 2015). The lack of statistically significant differences in maintenance between mandibular overdentures retained by either one or two implants was further corroborated in a systematic review by Alqutaibi *et al.* (2017). However, the authors acknowledged that the results should be interpreted with caution due to the low number of studies (3) which met their inclusion criteria, as well as the high risk of bias amongst all included studies.

The OT-Equator® attachment system (Rhein83, Bologna, Italy) is a low profile stud-type attachment specifically designed and advocated when insufficient prosthetic space exists for alternative, larger attachment systems (Taha *et al.*, 2020). Its design combines the simplicity of ball abutments with the ease of replacement and various retention levels of Locator® attachment systems (Zest Dental Solutions, Carlsbad, USA) (Ammar *et al.*, 2016). Limited *in vitro* and *in vivo* clinical data exist with regards to OT-Equator® attachment systems use in mandibular overdentures, specifically with regards to comparison with ball attachment systems (Ammar *et al.*, 2016; Aunmeungtong *et al.*, 2017; Marcello-Machado *et al.*, 2018; Mínguez-Tomás *et al.*, 2018).

Only two known studies have directly compared some form of standard dimension ball attachment (ø 2.25mm) to the OT-Equator® attachment system (Gonuldas *et al.*, 2018; Marin *et al.,* 2018). Both of these studies used the conventional practice of two mandibular implants in their test models. No studies could be found comparing larger diameter ball attachments with OT-Equator® attachment systems, specifically for mandibular single implant-retained overdentures, now recognised to be an accepted treatment protocol in the rehabilitation of the edentulous mandible.

1.6 Matrix material

High performance synthetic polymers such as nylon have historically been used to fabricate matrix inserts for ball and stud-type attachment systems. This facilitates attachment system performance by overcoming problems such as implant angulation discrepancies, specifically for two implant-retained mandibular overdentures (Wichmann *et al.*, 2020).

Recently polyaryletherketone (PAEK) attachments systems and its derivatives have shown promising *in vitro* results (Choi *et al.*, 2018; Wichmann *et al.*, 2020). Polyaryletherketones are high performance, semi-crystalline thermoplastic polymers with excellent mechanical properties such as dimensional stability, resistance against wear, as well as high tensile, fatigue and flexural strengths (Fuhrmann *et al.*, 2014). Derivatives include polyetheretherketone (PEEK) and polyetherketoneketone (PEKK) with differences in the ratio of functional ketone (-CO-) to ether (-O) groups accounting for differences in rigidity and melting points (Fuhrmann *et al.*, 2014).

Of these, PEEK has extensively been studied and used in dentistry due to its favourable properties which include easy processing, high rigidity, excellent tensile and flexural strengths, dimensional stability at high temperatures, good chemical resistance to both organic and inorganic substances, and finally good resistance to radiation damage and compatibility with other substances such as glass and carbon (Toth *et al.*, 2006; Kurtz and Devine, 2007; Fuhrmann *et al.*, 2014).

1.7 Conclusions

The literature comparing existing implant overdenture attachment systems has focused on the more conventional two implant-retained overdenture, and to the author's knowledge, there is little if any research comparing such systems for use in the setting of a single mandibular implant-retained overdenture.

Furthermore, there is paucity in the literature with regards to the use of new generation materials such as PEEK for implant overdenture matrix systems. Retentive and fatigue values for these materials are lacking, making it difficult to compare technical data to other existing implant overdenture attachment systems. Only once it has been determined that newer generation implant overdenture matrix materials have similar and clinically acceptable *in vitro* retentive and fatigue values compared to current materials, can *in vivo* clinical trials take place to assess their long term prospects.

CHAPTER 2 . AIMS AND OBJECTIVES

2.1 Aims

1. To determine the retentive value of an overdenture abutment and prototype matrix and compare this with an existing system.
2. To determine the estimated longevity of the prototype matrix.
3. To assess the ease of replacement of the matrix component.

2.2 Objectives

1. Determine the retentive value of the prototype matrix to vertical tensile forces of removal.
2. Compare these values to an existing system produced under licence by the same manufacturer.
3. Compare the effects of simulated repeated insertion and removal on the retentive force of both systems.
4. Compare the release periods of the two systems.
5. Assess and compare the ease of replacement of the matrix component of the two systems.

CHAPTER 3 . MATERIALS AND METHODS

The research methodology for the current investigation has been adapted from previous studies which investigated the retention force of overdenture attachment systems after repeated insertion and removal (Botega *et al*., 2004; Kobayashi *et al*., 2014), and the retentive force of different attachment systems used for mandibular single-implant overdentures (Alsabeeha *et al*., 2010).

3.1 Sample size and inclusion criteria

Sample size estimation was based on the ability to determine significant differences, should they exist, in retention force measurements between the two selected attachment systems. As a prototype system was to be tested, it was difficult to anticipate what the difference in retention value would be. Based on the previous studies by Gonuldas *et al*. (2018) and Marin *et al*. (2018), both of which reported large mean differences in retention values between the two attachment systems (11.35 and 30.77 N respectively), it was anticipated that the difference in retention value may be less with the new, larger diameter prototype ball attachment due to increased surface area for frictional resistance and retention. In order not to reduce the sample size too much for expected large differences, it was decided to assume a difference in the order of 5N.

With an anticipated set mean difference of 5 N and a standard deviation of 3.4 for both groups (the highest standard deviation as reported in the above mentioned studies), the two-sample t-test power calculation calculated the sample size to be 9 for each attachment system using a significance level of 5% and power of 80%.

Inclusion criteria for volunteers partaking in the study were as follows: all participants were 18 years and older, and all qualified dental clinicians or technicians had at least 3 years clinical experience to ensure adequate psychomotor skills that distinguished them from non-trained individuals. Exclusion criteria included any condition which affected manual dexterity, a physical requirement to replace the matrices.

3.2 Test base and attachment system set-up

Two pairs of identical test bases were fabricated by placing an LS12 laboratory analogue (Southern Implants, Irene, South Africa) in the centre of a clear acrylic resin filled polyvinyl chloride (PVC) cylinder measuring 24 x 12.7 mm. All laboratory analogues were coated with epoxy resin prior to incorporation into the test bases. This simulated the 4.0 mm IB external hex implant (Southern Implants, Irene, South Africa) onto which an OBZ overdenture abutment (Southern Implants, Irene, South Africa) was placed, and for which the new prototype matrix of the attachment system has been designed (Fig. 3.1).

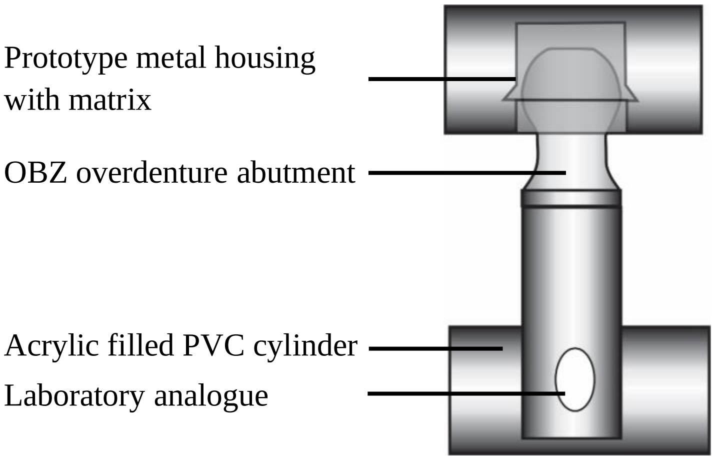

Figure 3.1 Test base and prototype matrix set-up

OBZ abutments (Southern Implants, Irene, South Africa) range in height from 2-7 mm, with 4 mm being the mean height and most commonly used. Retention of matrices is independent of abutment height, with the titanium nitride surface coated sphere standard across all abutment heights. OBZ4 overdenture abutments with accompanying prototype metal housings and PEEK matrices were retained on one pair of test bases (Fig. 3.2). The metal housings with PEEK matrices were retained in identical PVC cylinders to those used to house the analogues, and their incorporation was completed in a similar manner (epoxy resin coated, inserted into the PVC cylinder, and filling of the cylinder with clear acrylic resin). The other pair of test bases acted as the control and comprised an OT-Equator® overdenture abutment with accompanying metal housing and standard retention nylon matrices (Southern Implants, Irene, South Africa and Rhein83, Bologna, Italy) (Fig. 3.3). Metal housings and matrices of the control attachment systems were incorporated and fixated into the opposing PVC cylinders as for the prototype.

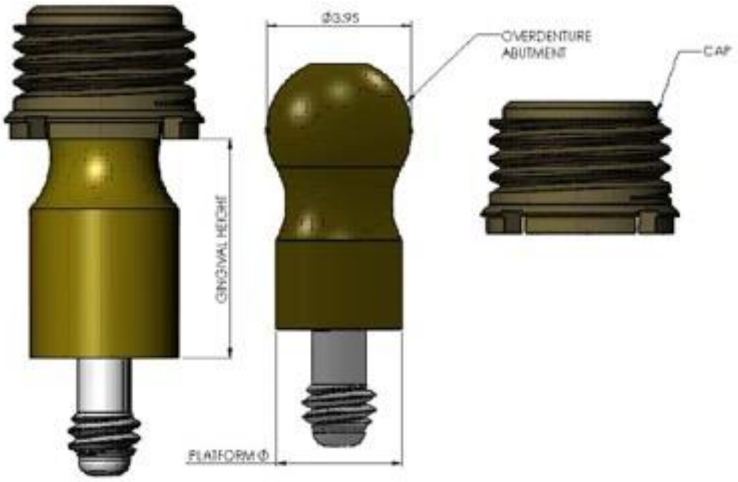

Figure 3.2 OBZ abutment with accompanying prototype metal housing and PEEK matrix (courtesy of Mr. J. Pittman, Design Engineer, and Southern Implants, Irene, South Africa)

Figure 3.3 OT-Equator® overdenture abutment with accompanying metal housing and matrix (courtesy of OT-Equator® overdenture abutments manual, Southern Implants, Irene, South Africa)

3.3 Tensile tests

Tensile tests were performed using a multi-function fatigue testing machine (ADMET eXpert 3930, Admet Inc., Norwood, USA) (Fig. 3.4).

Figure 3.4 ADMET eXpert 3930 fatigue testing machine (photo sourced from https://www.admet.com/wp-content/uploads/2015/07/eXpert-3930-Series-ElectroDynamic-Test-System-Brochure_Rev2.pdf)

The test base with its corresponding abutment was inserted into the testing machine's fixture mount and clamped into place. It was ensured that test bases were level in all directions by using a spirit level on top of the laboratory analogues prior to screwing and torquing each abutment into place (Figs. 3.5 and 3.6). Torque values applied were as per the manufacturer's recommendations.

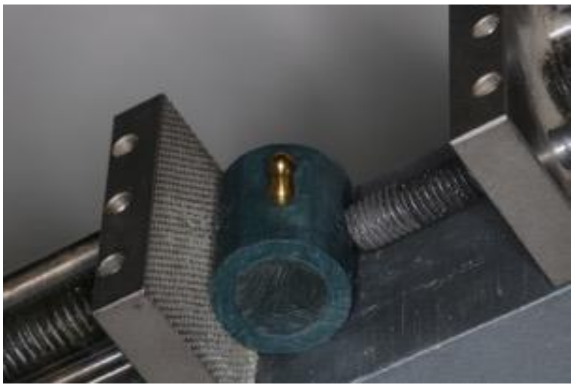

Figure 3.5 Clamped test base with OBZ abutment

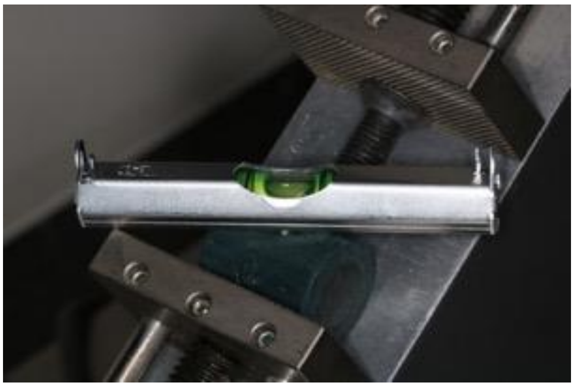

Figure 3.6 Confirmation of test base being level in all directions prior to abutment placement

Centred holes were drilled into the test bases which contained the metal housings and matrices (Fig. 3.7). This allowed them to be attached to the actuator via a simple holding device consisting of 2 steel flat bars and a nut and bolt to keep the assembly together (Fig 3.8).

Figure 3.7 Centred holes in test bases containing the metal housings and matrices of both attachment systems

Figure 3.8 Completed test assembly

A total of 180 tensile force tests (90 per attachment system, 10 per assembled sample – abutment with corresponding matrix) were conducted with a load cell of 1 kN and a pre-programmed speed of 50 mm/min. The selected speed approximates previously reported values of overdenture removal by means of a vertical dislodging force away from its retentive elements (Sarnat, 1983). Overdenture insertion and removal was performed along the implant's long axis.

At least 10-second intervals were adhered to between tensile tests to allow for adequate elastic recovery of the attachment components (Rutkunas *et al.*, 2007; Alsabeeha *et al.*, 2010). Measurements planned to be recorded were (Petropoulos *et al.*, 1997):

- Maximum (peak) load – the maximum force developed prior to separation of the attachment system from its abutment.
- Break load (autobreak load) – the recorded force that results in separation of the attachment system from its abutment.
- Displacement at the maximum (peak) load.
- Displacement at the break load.

The release period for each attachment system was to be calculated as follows (Petropoulos *et al.*, 1997):

$$\text{Release period} = \frac{\text{[break load – maximum (peak) load] x displacements}}{\text{50mm/min (constant cross-head speed)}}$$

3.4 Fatigue tests

Fatigue testing was completed manually as the tensile testing machine was unable to cyclically seat and unseat matrices from their abutments. This had the added advantage of mimicking daily insertion/removal simulation by patients, as patients never insert and remove their overdentures along a single path of insertion.

Test bases with assembled samples were initially immersed for less than 1 minute in a bath of saline (isotonic 0.9% sodium chloride solution) at room temperature (20-25° C). Upon removal, they were manually pulled apart and re-seated to simulate the clinical situation for mechanical fatigue testing. After every 10 seating/removals the samples were re-immersed in the saline to ensure that they remained coated with a layer of saline throughout fatigue testing until failure.

After 90 seating/removals, test bases with assembled samples were to be assembled in the tensile testing machine and subjected to 10 tensile pull tests and the average value calculated. This was to be repeated until that average value was found to be below 20 N, the minimum amount of retention suggested to ensure patient satisfaction (defined, therefore, as failure) (Alsabeeha *et al.*, 2010; Türk *et al.*, 2014).

However, it was found that it was impractical to complete a set of 10 tensile tests for each assembled sample after every 90 manual seating/removals, as this was expected to have to be done at 100 cycle intervals for least 1 000 cycles per sample: this was the manufacturer’s initial estimate of lifespan. Therefore, an initial test of the first assembled sample of each matrix system only was conducted prior to completing fatigue testing for the remainder of the samples, to see if it was possible to detect a trend which could be legitimately extrapolated to determine at which number of cycles the measurements would be close to failure (the threshold of <20 N).

The plotted data (Figs 3.9 and 3.10) revealed a clear pattern which was extrapolated to the remainder of the samples to serve as an approximate guide with regards to the range of the number of cycles to be performed before failure could be expected. For the prototype PEEK matrix it took 900 cycles for sample 1 to fail, and for the OT-Equator® matrix it took 2 200 cycles for sample 1 to fail. Therefore testing was carried out closer to these failure points for all subsequent samples.

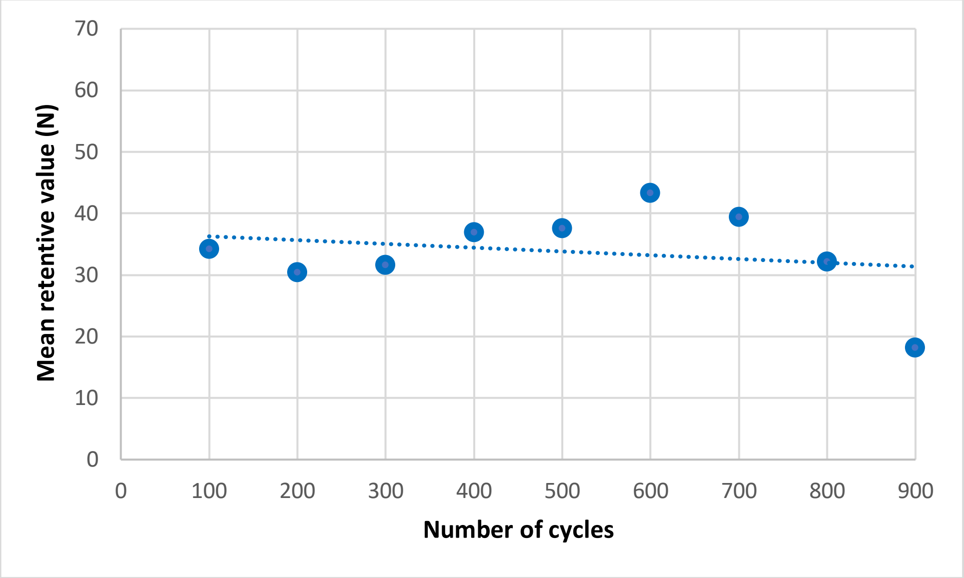

Figure 3.9 Mean retentive value and trend line to failure (at 18.2 N) at 100 cycle intervals for sample 1 of the OBZ abutment with prototype PEEK matrix

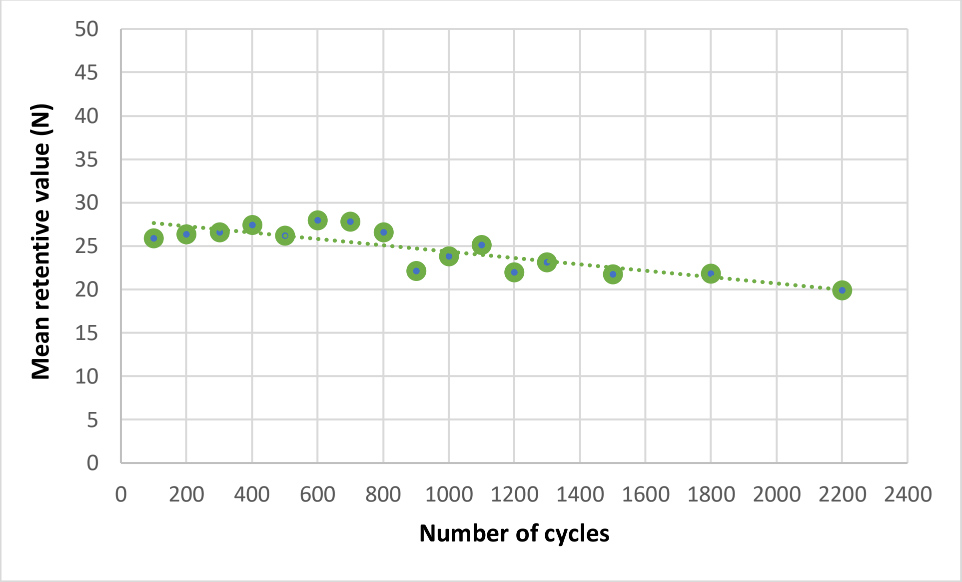

Figure 3.10 Mean retentive value and trend line to failure for sample 1 of the OT-Equator® abutment with standard retention nylon matrix. The rate of change was small for the first 1,300 cycles at 100 cycle intervals, so tests thereafter were at 1500, 1800 and 2200 cycles at which failure occurred (at 19.9 N)

3.5 Ease of matrix replacement

Ten volunteers were recruited into two groups of five, one of qualified dental clinicians or technicians, and the other of non-trained individuals, the latter simulating caregivers who would have to replace worn matrices without the need for a clinical visit. Participants were asked to perform three replacements of each matrix on three separate occasions, a total of 9 replacements per matrix system.

The manufacturer of the prototype PEEK matrix system also produced a specifically designed insertion/removal tool used for that system (Fig. 3.11). For the OT-Equator® matrices, the custom cap insertion and extraction tool for that system was used (Fig. 3.12). All attempts were timed, followed by calculation of the average time per individual across the 9 attempts. Individuals were also asked to indicate which matrix they felt was easier to replace based on their experience. Their answers were collected by using a 10 cm Visual Analogue Scale ranging from very easy (0) to very difficult (10).

Figure 3.11 Prototype insertion/removal tool

Figure 3.12 OT-Equator® cap insertion and extractor tool (courtesy of OT-Equator® overdenture abutments manual, Southern Implants, Irene, South Africa)

3.6 Data analysis

Continuous variables (tensile and fatigue values) were summarised by the mean and standard deviation. Shapiro-Wilks tests were used to assess the data for normality.

Parametric testing included paired samples t-tests for intragroup comparison, and independent samples t-tests for intergroup comparison after ensuring equal variance in both the prototype and control OT-Equator® groups using Levene’s test. Non-parametric tests were Mann Whitney U-tests where data were not normally distributed. Significance was set at 5%.

For ease of replacement paired samples t-tests for intragroup comparison, and independent samples t-tests for intergroup comparison were once again used to assess whether there was any difference between level of training and average time taken for matrix replacement. Finally, a two-way analysis of variance (ANOVA) test was used to assess whether there was any interaction between level of experience and matrix replacement.

CHAPTER 4 . RESULTS

4.1 Tensile tests

4.1.1 OBZ abutment with prototype PEEK matrix

The results are shown in Table 4.1 and Figure 4.1. One sample (sample 6) was considered to be a statistical outlier, but was still included after using a Shapiro-Wilks test which revealed that the data were normally distributed even with its inclusion.

Table 4.1 Mean and standard deviation for each OBZ abutment with prototype PEEK matrix sample

Sample	Mean (N)	Standard deviation
1	65.18	8.26
2	64.17	6.16
3	74.39	6.18
4	78.29	6.65
5	78.67	6.85
6	110.01	19.55
7	55.48	6.70
8	65.26	4.22
9	63.32	8.98
Mean	**72.75**	**8.17**

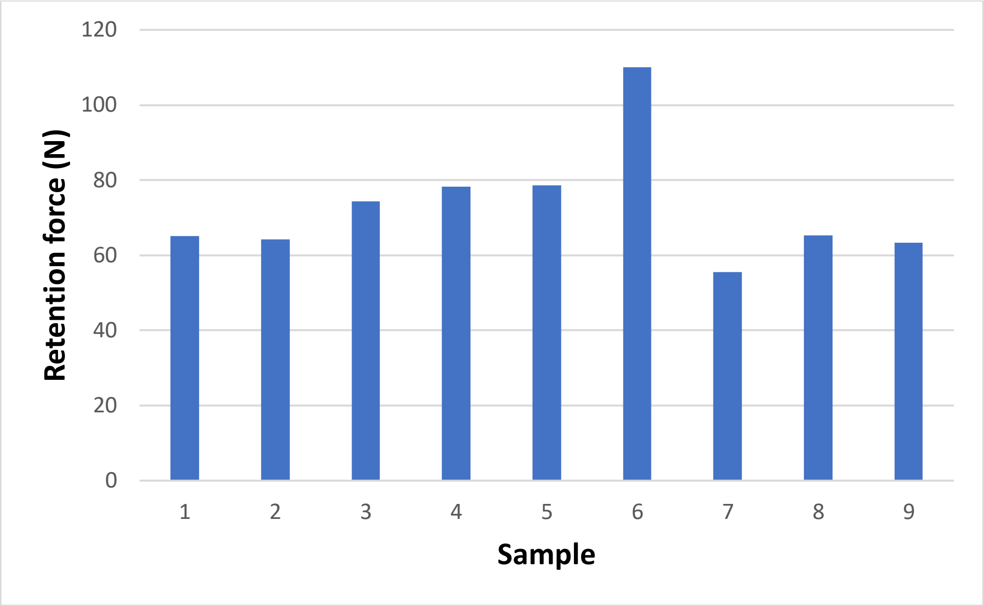

Figure 4.1 Bar graph depicting OBZ abutment with prototype PEEK matrix samples mean retention force values (N) across 10 vertical pull tests

4.1.2 OT-Equator® abutment with standard retention nylon matrix

The results are shown in Table 4.2 and Figure 4.2.

Table 4.2 Mean and standard deviation for each OT-Equator® abutment with standard retention nylon matrix sample

Sample	Mean (N)	Standard deviation
1	33.80	4.07
2	40.92	4.65
3	35.94	4.39
4	34.71	4.20
5	35.39	3.01
6	42.80	5.32
7	31.38	2.31
8	33.84	2.57
9	33.94	2.53
Mean	**35.86**	**3.67**

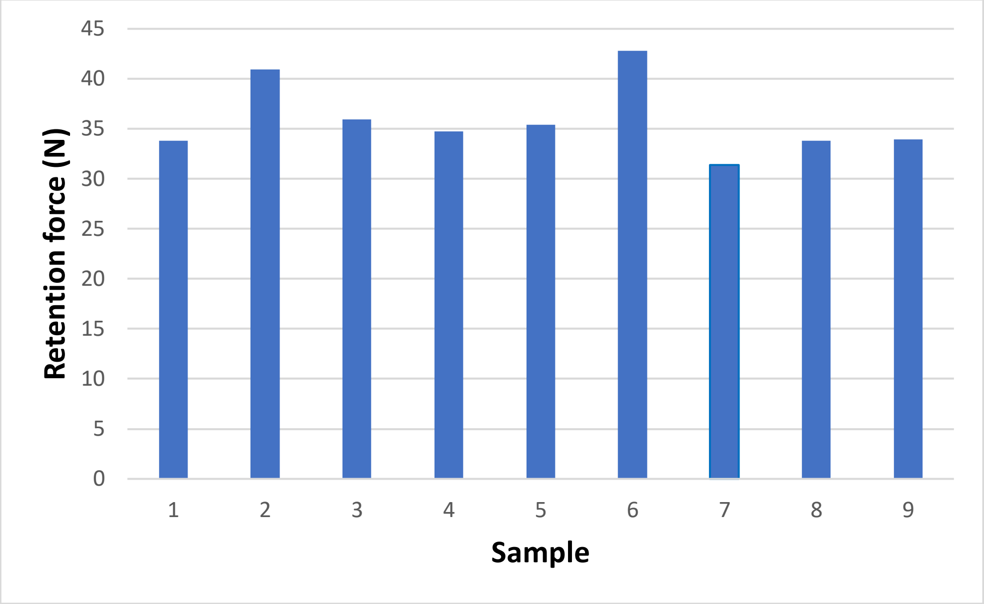

Figure 4.2 Bar graph depicting OT-Equator® abutment with standard retention nylon matrix samples mean retention force values (N) across 10 vertical pull tests

Independent samples t-test analysis comparing initial retention values of the OBZ abutment with prototype PEEK matrix samples to the OT-Equator® abutment with standard retention nylon matrix samples, revealed a statistically significant difference ($p < 0.0001$) [95% CI (30.561, 43.219)].

4.2 Fatigue results after 100 cycles

4.2.1 OBZ abutment with prototype PEEK matrix

The results are shown in Table 4.3 and Figure 4.3.

Table 4.3 Mean and standard deviation for each OBZ abutment with prototype PEEK matrix sample after 100 cycles

Sample	Mean (N)	Standard deviation
1	34.25	4.53
2	24.55	1.97
3	25.99	2.52
4	27.02	2.25
5	31.28	3.77
6	43.09	2.09
7	36.50	3.45
8	42.65	5.64
9	39.29	2.05
Mean	**33.85**	**3.14**

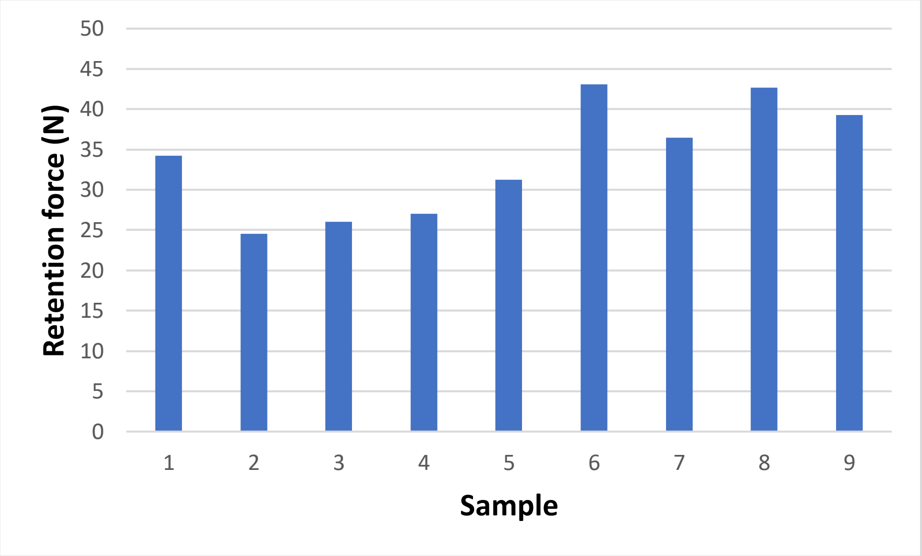

Figure 4.3 Bar graph depicting OBZ abutment with prototype PEEK matrix samples mean retention force values (N) across 10 vertical pull tests after 100 cycles

The differences between dry and wet (immersed) tensile tests for the OBZ abutment with prototype PEEK matrix samples are shown in Figure 4.4. The mean difference was 38.9 N. The difference in mean retention value was statistically significant ($p < 0.001$) [95% CI (26.607, 51.204)].

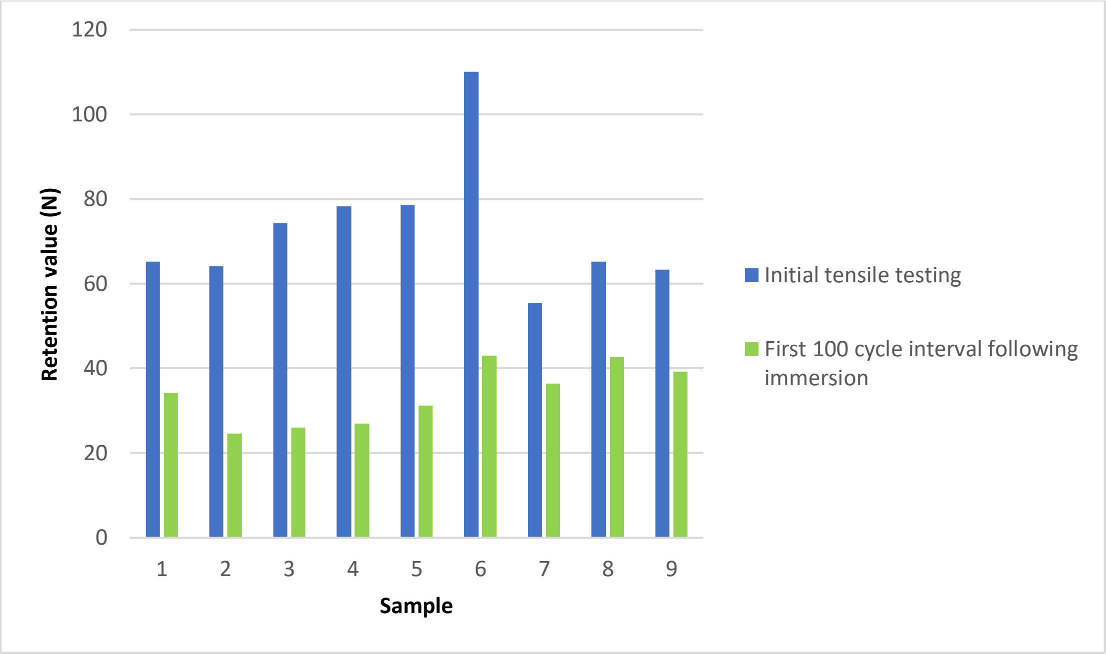

Figure 4.4 Bar graph depicting difference in OBZ abutment with prototype PEEK matrix samples mean retention force values (N) after initial tensile testing and first 100 cycle interval following immersion

4.2.2 OT-Equator® abutment with standard retention nylon matrices

The results are shown in Table 4.4 and Figure 4.5.

Table 4.4 Mean and standard deviation for each OT-Equator® abutment with standard retention nylon matrix sample after 100 cycles

Sample	Mean (N)	Standard deviation
1	25.89	4.42
2	28.84	3.03
3	35.51	0.89
4	25.29	1.45
5	29.94	1.34
6	26.92	1.96
7	30.12	2.05
8	34.37	3.59
9	49.41	4.16
Mean	**31.81**	**2.54**

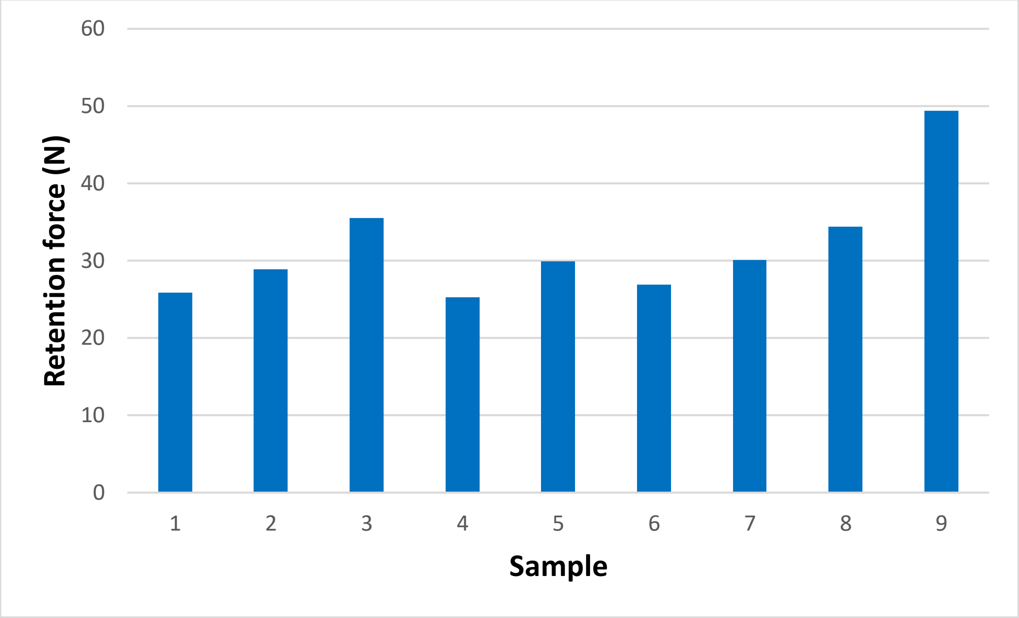

Figure 4.5 Bar graph depicting OT-Equator® abutment with standard retention nylon matrix samples mean retention force values (N) across 10 vertical pull tests after 100 cycles

The differences between dry and wet (immersed) tensile tests for the OT-Equator® abutment with standard retention nylon matrix samples are shown in Figure 4.6. The mean difference was 4.1 N. There was an anomaly in that sample 9 showed a markedly higher wet (immersed) value than dry. If this is excluded, the mean difference was 6.5 N. When all samples were included, the difference in mean retention value was not significant ($p = 0.222$) [95% CI (-3.003, 11.098)]. With sample 9 excluded, the difference in mean retention value remained not significant ($p = 0.17$) [95% CI (1.547, 11.428)].

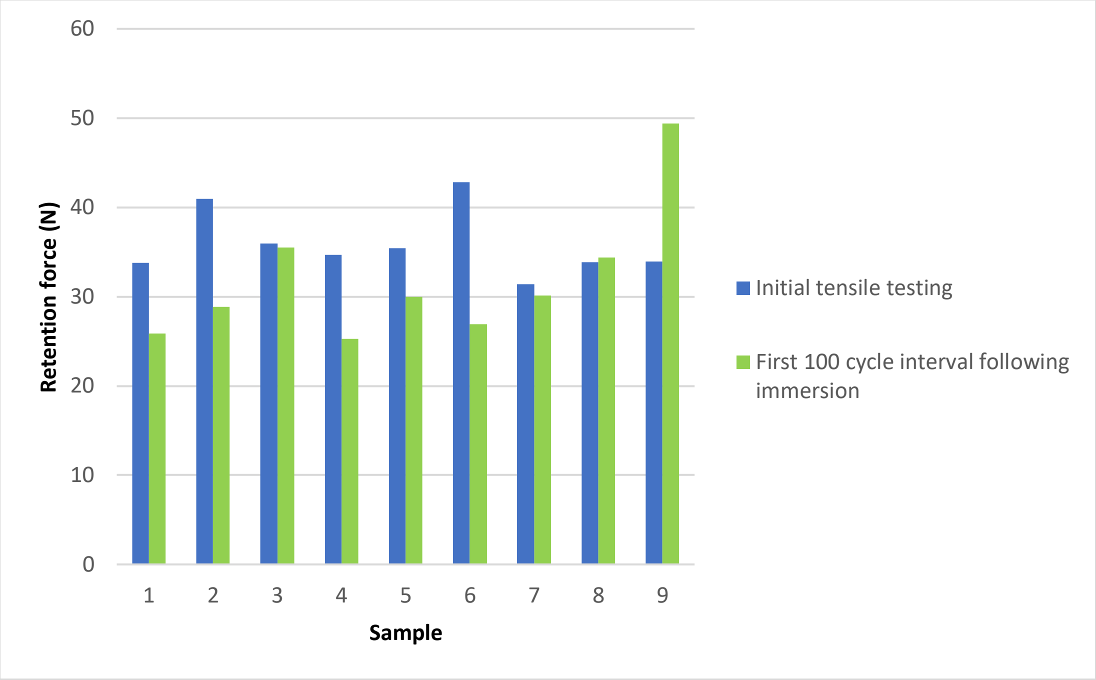

Figure 4.6 Bar graph depicting difference in OT-Equator® abutment with standard retention nylon matrix samples mean retention force values (N) after initial tensile testing and first 100 cycle interval following immersion

4.2.3 Comparison of OBZ abutment with prototype PEEK matrix and OT-Equator® abutment with standard retention nylon matrix

Intergroup comparison of mean retention force values after 100 cycles revealed no significant difference ($p > 0.05$) [95% CI (-0.814, 4.894)] when comparing the two groups, irrespective of whether OT-Equator® sample 9 was included or excluded. With inclusion the calculated p-value was 0.561, and when excluding OT-Equator® sample 9 the calculated p-value was 0.151. Both values support the decision to include the outlier, as the t-tests were robust to the assumption of normality.

4.3 Fatigue tests – Failure

All 9 samples as outlined in the methodology were subjected to manual fatigue testing until failure, deemed to occur when the mean of the 10 vertical pull tests were less than 20 N at the point of failure, the minimum amount of retention required for an implant overdenture (Alsabeeha *et al*., 2010; Türk *et al*., 2014). However, for the prototype PEEK matrix, for samples 6 and 8 this level was not reached after 5 500 cycles at which point the values were 31.3 and 23.6 N respectively. Therefore they have been excluded from Table 4.5.

The means and standard deviations for the remaining samples of both attachment systems are shown in Tables 4.5 and 4.6, along with the number of cycles at which failure occurred.

Table 4.5 Point of failure with mean and standard deviation for each OBZ abutment with prototype PEEK matrix at failure point

Sample	Point of failure	Mean (N)	Standard deviation
1	900	18.23	1.98
2	1 200	18.89	0.66
3	1 100	17.53	1.39
4	1 700	17.36	1.04
5	1 700	19.41	1.41
7	1 300	17.96	1.14
9	1 300	16.16	1.00
Mean	**1 314**	**17.93**	**1.23**

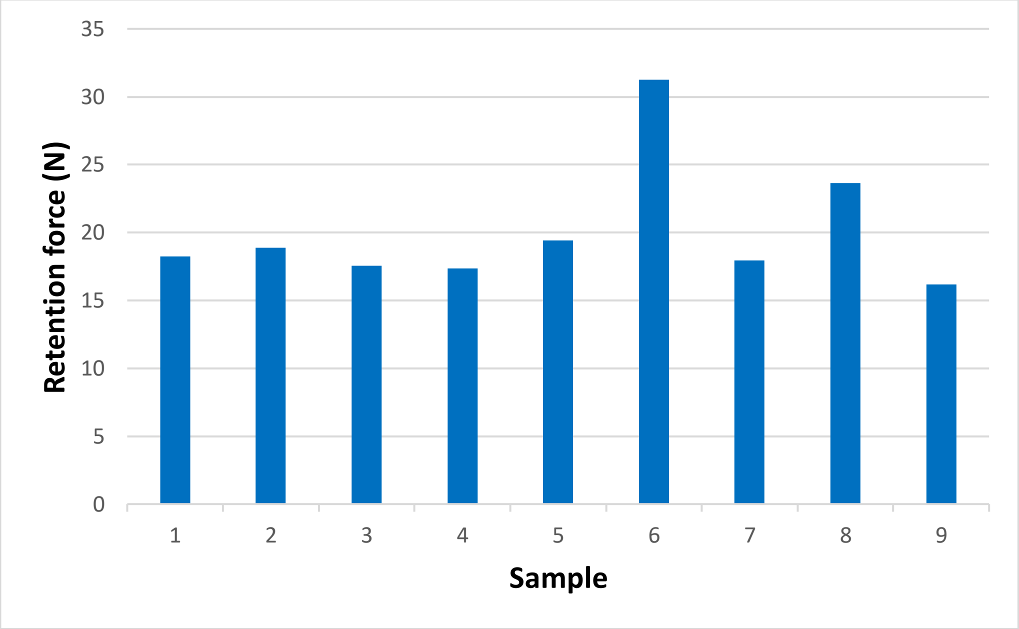

Figure 4.7 Bar graph depicting OBZ abutment with prototype PEEK matrix samples mean retention force values (N) across 10 vertical pull tests at point of failure (samples 6 and 8 did not fail)

Table 4.6 Point of failure with mean and standard deviation for each OT-Equator® abutment with standard retention nylon matrix at failure point

Sample	Point of failure	Mean (N)	Standard deviation
1	2 200	19.92	1.48
2	2 500	18.99	0.83
3	2 500	19.86	0.70
4	2 400	18.31	0.51
5	2 900	19.73	1.62
6	1 600	19.80	0.88
7	1 000	19.49	0.71
8	3 500	19.67	0.40
9	1 000	19.01	0.73
Mean	**2 178**	**19.42**	**0.87**

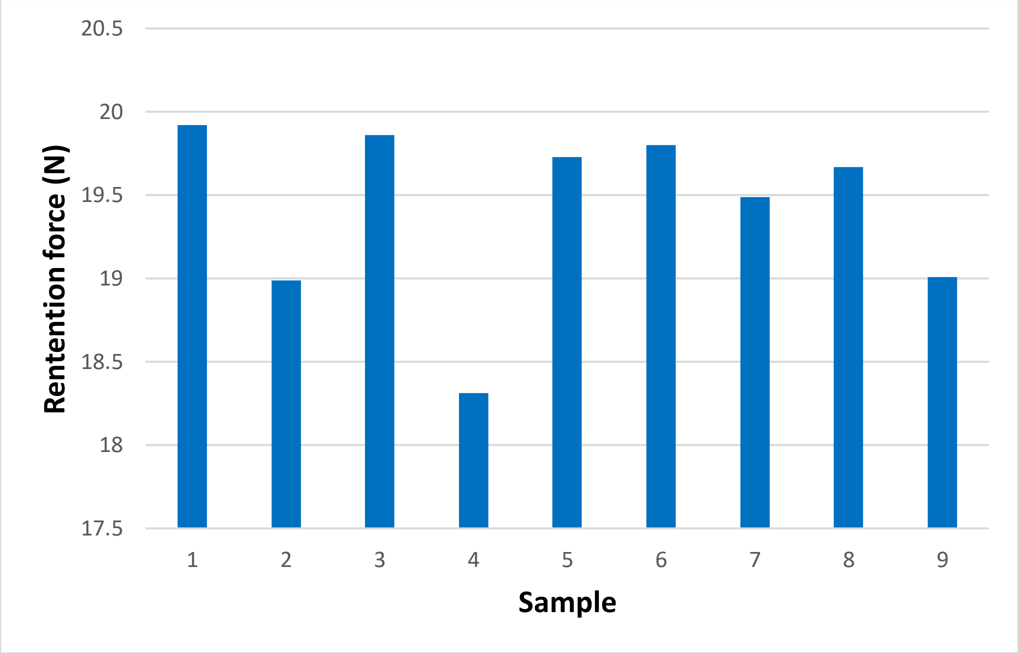

Figure 4.8 Bar graph depicting OT-Equator® abutment with standard retention nylon matrix sample mean retention force values (N) across 10 vertical pull tests at point of failure (all 9 samples failed)

Analysis of retention force values with an independent samples t-test revealed no significant difference (p = 0.696) [95% CI (-0.517, 1.777)] in mean retention force value of both attachment systems at failure, even with the inclusion of statistical outliers.

With regards to point of failure, there was a significant difference (p = 0.022) [95% CI (862.876, 865.124)] in failure point between the two attachment systems if the OBZ abutment with prototype PEEK matrix sample outliers 6 and 8 were excluded. Inclusion of both samples skewed results with analysis then revealing no significant difference (p = 0.923) [95% CI (87.853, 90.150)] in failure point between the two attachment systems.

4.4 Release period

Four, clearly distinguishable measurements are required from the load profile curve (graphical representation of load versus displacement) to calculate the release period as described by Petropoulos *et al*. (1997). These are maximum (peak) load (A), break load (C), displacement at maximum (peak) load (B) and displacement at break load (D) (Figure 4.9).

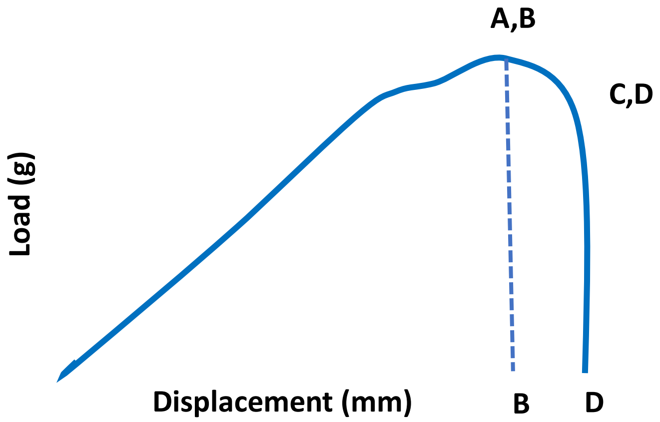

Figure 4.9 Re-drawn graphical representation of generated load profile curves of implant overdenture attachment systems as reported by Petropoulos *et al*. (1997)

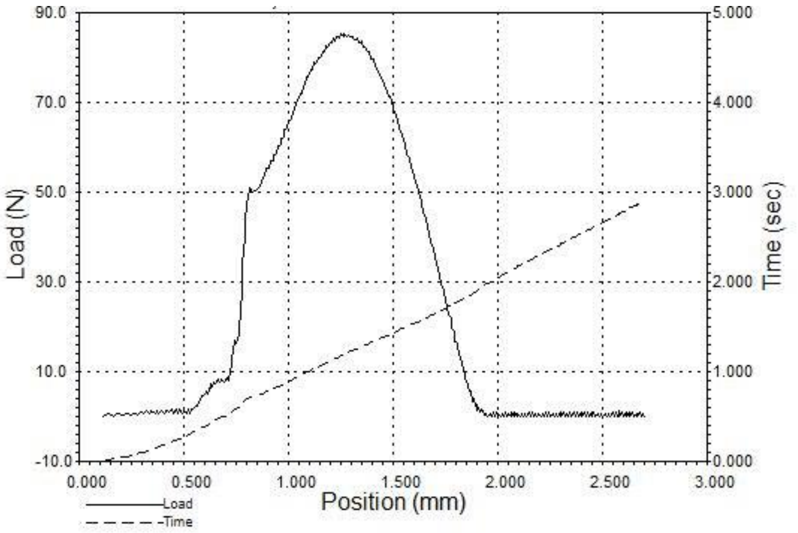

Figure 4.10 Example of load profile curve generated for OBZ abutment with prototype PEEK matrix

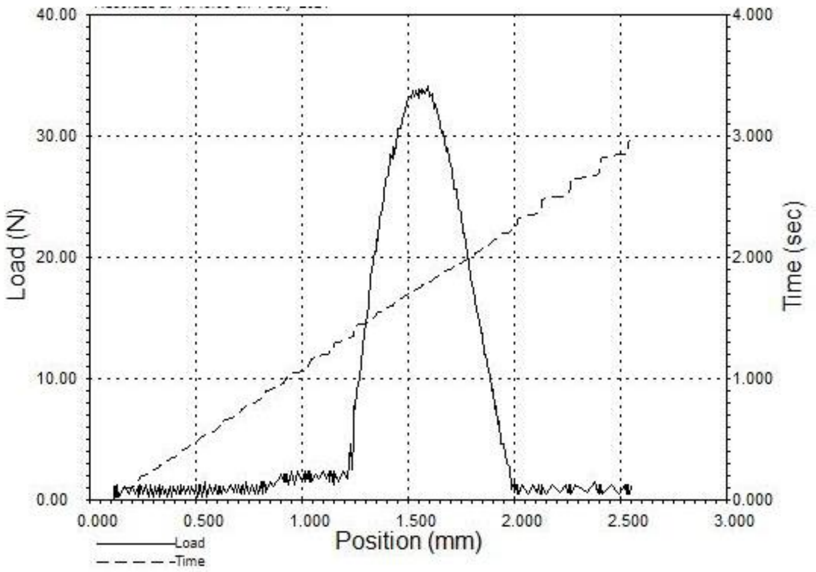

Figure 4.11 Example of load profile curve generated for OT-Equator® abutment with standard retention nylon matrix

For both matrix systems the maximum (peak) load and displacement at the maximum (peak) load could be measured. Values for the break load and the displacement at the break load could, however, not be clearly identified. Therefore the release period could not be calculated.

4.5 Ease of replacement

The average times taken by each group of volunteers for each matrix system is summarised in Tables 4.7 and 4.8 and Figures 4.12 and 4.13 respectively.

Table 4.7 Average times taken for trained individuals to replace both the prototype PEEK and control OT-Equator® matrices

	Average time taken to replace matrix (sec.)	
Participant	**Prototype PEEK matrix**	**Control OT-Equator® matrix**
1	25.22	50.33
2	11.78	28.22
3	15.22	25.11
4	17.11	31.22
5	19.89	48.33
Mean	**17.84**	**36.64**

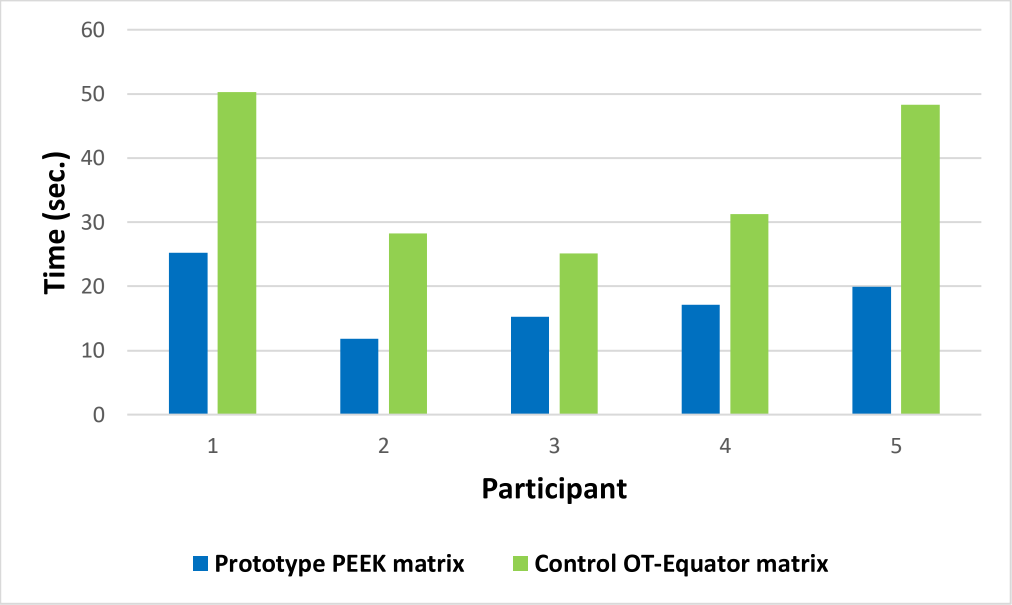

Figure 4.12 Bar graph depicting average time taken by trained individuals to replace both attachment system matrices

Table 4.8 Average times taken for non-trained individuals to replace both the prototype PEEK and control OT-Equator® matrices

	Average time taken to replace matrix (sec.)	
Participant/volunteer	**Prototype PEEK matrix**	**Control OT-Equator® matrix**
1	21.11	29.44
2	15.11	46.44
3	17.33	30.78
4	26	49.33
5	40	100.78
Mean	**23.91**	**51.35**

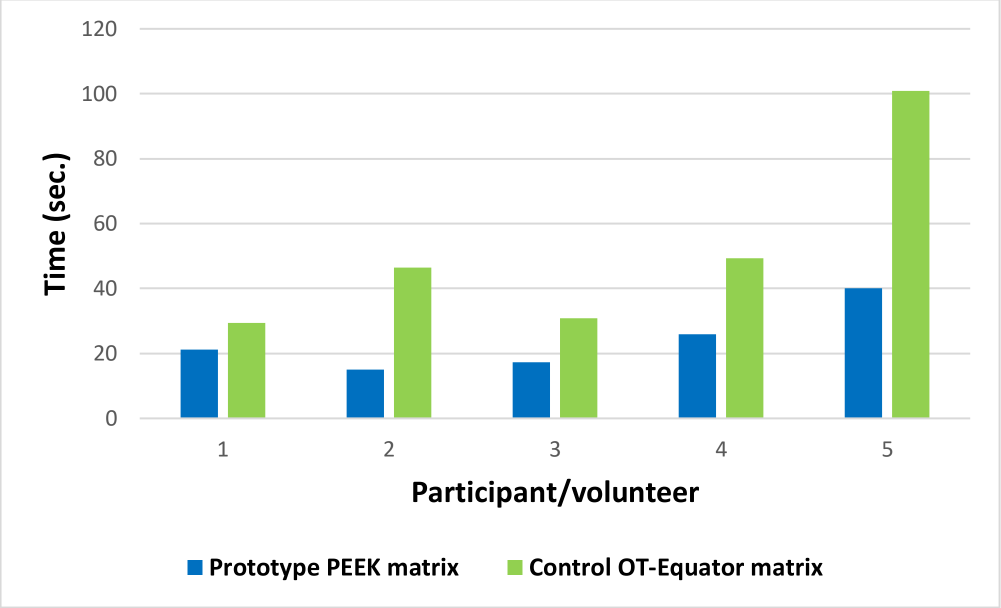

Figure 4.13 Bar graph depicting average time taken by non-trained individuals to replace both attachment system matrices

Table 4.9 Average VAS scores of trained and non-trained individuals on ease of replacement of both the prototype PEEK and control OT-Equator® matrices

Level of training	**Average VAS score (out of 10)**	
	Prototype PEEK matrix	**Control OT-Equator® matrix**
Trained	0.84	6.02
Non-trained	2.02	6.78

An analysis to compare whether the mean replacement time between the prototype PEEK matrix and control OT-Equator® matrix were equal irrespective of level of training, revealed a statistically significant difference (p = 0.006) in the mean replacement time taken to replace both matrix systems.

With regards to level of training, statistical analysis revealed that there was no significant difference (p = 0.260) in the mean replacement time between trained and non-trained individuals to replace both matrix systems.

A two-way analysis of variance (ANOVA) test to examine the effect of the matrix system and level of training on mean replacement time revealed that there is no interaction effect between the matrix systems and level of experience. The only significant effect was due to the matrix system (F(1, 16) = 0.338, p = 0.569). The calculated effect size for trained individuals was -0.7, while for non-trained individuals it was -1, in both instances the negative value indicating that the effect (new matrix design) decreased the mean time taken to replace the two different attachment systems.

Comparison of VAS scores for both trained and non-trained individuals between attachment systems revealed a significant difference (p = 0.016) [95% CI (-8.757, -1.603)] for trained and non-trained (p = 0.002) [95% CI (-6.626, -2.894) individuals in the difficulty experienced to replace the two different matrices.

Finally, comparison of VAS scores of trained and non-trained individuals per matrix system revealed no significant difference for the prototype PEEK matrix (p = 0.333) [95% CI (-4.161, 1.801)] and control OT-Equator® matrix (p = 0.576) [95% CI (-4.234, 2.714)] respectively.

CHAPTER 5 . DISCUSSION

5.1 Rationale for the study

Mandibular single implant-retained overdentures have been shown to be a viable alternative to the more conventional two implant-retained overdenture (Walton *et al*., 2009; Alsabeeha *et al*., 2011a). Ball attachment systems remain the preferred choice when planning and executing a mandibular single implant-retained overdenture (Walton *et al*., 2009; Kronstrom *et al*., 2010; Alsabeeha *et al*., 2011b), but the same challenges with regards to wear and loss of retention of the attachment system continues to persist irrespective of the amount of implants used.

Historically, high performance synthetic polymers have been used for matrix inserts, but plastic deformation of these components, which then require replacement, contributes a large portion to the prosthetic maintenance that has to be performed (Bryant *et al*., 2015). Another drawback of existing attachment systems is that they need to be replaced by a trained dental professional, which in turn necessitates at least one clinical visit to the clinician’s surgery.

Multiple studies have investigated the difference in retention between various attachment systems. Limited studies have, however, compared the use of the OT-Equator® attachment system in mandibular overdentures, with other ball attachment systems (Ammar *et al*., 2016; Aunmeungtong *et al*., 2017; Marcello-Machado *et al*., 2018; Mínguez-Tomás *et al*., 2018).

Only two known studies have directly compared some form of standard dimension ball attachment (ø 2.25mm) to the OT-Equator® attachment system (Gonuldas *et al*., 2018; Marin *et al*., 2018). Both of these studies used the conventional practice of two mandibular implants in their test models. No studies could be found comparing larger diameter ball attachments with OT-Equator® attachment systems, specifically for mandibular single implant-retained overdentures.

The present study compared the OT-Equator® attachment system with a novel PEEK matrix attachment system which was designed with ease of use and replacement in mind.

5.2 Initial retention values

The mean initial retention value for all 9 OBZ abutments with prototype PEEK matrices was 72.75 ± 8.17 N (Table 4.1). The range was from 55.48 N to 110.01 N (Figure 4.1). The low value for the standard deviation indicated a close distribution of the data which were normally distributed. One sample, sample 6, was found to be a statistical outlier but when included for analysis, showed that the data were normally distributed even with its inclusion. Previous studies by Gonuldas *et al.* (2018) and Marin *et al.* (2018) reported mean initial baseline retention values of 47.9 ± 2.62 N and 21.04 ± 3.29 N for their ball abutment groups respectively. In both these studies the results obtained were based on a two implant-retained test model. The OBZ abutment with prototype PEEK matrix thus showed a marked increase in initial retention value when compared with previous studies, especially when bearing in mind that only a single implant-retained test model was used.

The mean initial retentive value for all 9 OT-Equator® abutments with standard retention nylon matrices was 35.86 ± 3.67 N (Table 4.2). The range was from 31.38 N to 42.80 N (Figure 4.2). Once again, the low value for the standard deviation indicated a close distribution of the data which were normally distributed. Gonuldas *et al.* (2018) and Marin *et al.* (2018) reported mean initial baseline retention values of 36.55 ± 3.4 N and 51.81 ± 2.64 N for their OT-Equator® attachment systems respectively, but both studies were based on a two implant-retained test model. The results of the current study were thus in line with those of Gonuldas *et al.* (2018), but surprising, in that it was expected that the retention values measured for a two implant-retained test model should be markedly more than for a single implant-retained test model. The results reported by Marin *et al.* (2018) thus appear to be a more realistic representation of OT-Equator® attachment system values for a two implant-retained test model, especially for comparative purposes between single (current study) and two implant-retained test models. However, Marin *et al.* (2018) obtained their mean sample retentive values from only five tensile test measurements per sample, in comparison to the ten in this study.

When comparing the prototype PEEK matrix system to the OT-Equator® attachment system, initial tensile testing revealed that the prototype PEEK matrices were twice as retentive as the standard retention nylon matrices of the OT-Equator® attachment system (72.75 ± 8.17 N versus 35.86 ± 3.67 N). The difference in mean retentive value between the two attachment systems after initial tensile testing was statistically significant ($p < 0.0001$) [95% CI (30.561, 43.219)].

5.3 Fatigue testing – results after first 100 cycles following saline immersion

Pilot testing of the first assembled sample of each attachment system during the first part of fatigue test analysis revealed a clear influence exerted by saline immersion. There was an immediate drop in retentive values following immersion, with measured values staying reasonably constant at this lower retentive value range when measuring at further 100 cycle intervals until failure (Figures 3.9 and 3.10).

Following immersion, all 9 samples of the OBZ abutments with prototype PEEK matrices presented with mean retentive values of less than 45 N as measured at the first 100 cycle interval (Table 4.3 and Figure 4.3). The immediate drop in mean retentive value for all 9 samples was from 72.75 ± 8.17 N (Table 4.1) to 33.85 ± 3.14 N (Table 4.3), a difference of 38.9 N. A clear influence was thus exerted by saline immersion on retention values, statistical analysis revealing the difference to be statistically significant ($p < 0.001$) [95% CI (26.607, 51.204)] (Figure 4.4).

Seven samples of the OT-Equator® abutments with standard retention nylon matrices presented with lower mean retentive values of less than 36 N following immersion, with two samples (samples 8 and 9) actually increasing in mean retention value from 33.84 N to 34.37 N and from 33.94 N to 49.41 N respectively (Figure 4.5). This could be attributed to the saline potentially increasing the rigidity of the 2 nylon matrices in question by altering their chemical composition/surface which increased frictional resistance to the applied vertical dislodging/removal force. Overall the immediate drop in mean retentive value for all 9 samples was from 35.86 ± 3.67 N (Table 4.2) to 31.86 ± 2.95 N (Table 4.4), a difference of 4.1 N. With the exclusion of sample 9 (considered a clear anomaly) the mean difference was 6.5 N. Irrespective of whether sample 9 was included or not, the difference in mean retention force values remained not significant ($p > 0.05$) (Figure 4.6).

For both attachment systems differences have been reported in many studies and were often attributed to the effect of saline. Logically this would be expected to decrease the amount of frictional resistance to be overcome prior to separation. The opposite effect on two of the nylon samples is difficult to explain other than attributing it to the manufacture of the nylon itself.

5.4 Comparison of OBZ abutment with prototype PEEK matrix and OT-Equator® abutment with standard retention nylon matrix after first 100 cycles following saline immersion

There was no significant difference ($p > 0.05$) [95% CI (-0.814, 4.894)] in mean retention values between the OBZ abutment with prototype PEEK matrix and the OT-Equator® abutment with standard retention nylon matrix after the first 100 cycles following saline immersion, irrespective of whether statistical outliers were included or omitted. The effect of saline immersion was thus universal to both attachment systems.

5.5 Fatigue testing – point of failure

The lowest number of cycles recorded prior to failure of an OBZ abutment with prototype PEEK matrix was 900 cycles for sample 1, while two samples, samples 6 and 8 did not reach failure (set at 20 N) after completion of 5,500 cycles. This equates to approximately 5 years of clinical use if the average daily insertion and removal is taken as 3 times. The mean point of failure for all samples was 1,314 cycles following the omission of samples 6 and 8, which equates to approximately 1 year and 2 months' of usage. The mean retentive value at the point of failure for all samples excluding the outliers was 17.93 ± 1.23 N (Table 4.5 and Figure 4.7).

The lowest number of cycles recorded prior to failure of an OT-Equator® abutment with standard retention nylon matrix was 1,000 cycles for samples 7 and 9. All samples reached failure point prior to reaching 5,500 cycles, with sample 8 recording the highest number of cycles (3,500) prior to failure. The mean point of failure for all samples was calculated to be 2,178 cycles, which equates to approximately 2 years of use. The mean retentive value at the point of failure for all samples was 19.42 ± 0.87 N (Table 4.6 and Figure 4.8).

5.6 Comparison of OBZ abutment with prototype PEEK matrix and OT-Equator® abutment with standard retention nylon matrix at point of failure

At point of failure there was no significant difference ($p = 0.696$) [95% CI (-0.517, 1.777)] in mean retention force value of both attachment systems, even with the inclusion of statistical outliers.

There was a significant difference ($p = 0.022$) [95% CI (862.876, 865.124)] in failure point between the two attachment systems if the OBZ abutment with prototype PEEK matrix sample outliers 6 and 8 were excluded. Inclusion of both samples skewed results with the analysis then revealing no significant difference (p = 0.923) [95% CI (87.853, 90.150)] in failure point between the two attachment systems. With statistical outliers removed, the OBZ abutment with prototype PEEK matrix had a significantly shorter lifespan than the current commercially used OT-Equator® abutment with standard retention nylon matrix.

5.7 Release period

Generated load profile curves for both OBZ abutments with prototype PEEK matrices and Equator® abutments with standard retention nylon matrices did not match previously reported load profile curves reported by Petropoulos *et al*. (1997).

It is possible that the results could not be repeated if the equipment used was not sensitive enough to pick up the distinction between maximum (peak) load (height of retention) and break load (point at which matrix physically separated from abutment). Generated load profile curves depicted both of these loads as the same point.

5.8 Ease of replacement

The average times taken for 5 trained individuals to replace both the prototype PEEK and control OT-Equator® matrices were 17.84 and 36.64 seconds respectively (Table 4.7 and Figure 4.12), which was statistically significant. The average times taken by the 5 non-trained individuals to replace both the prototype PEEK and control OT-Equator® matrices were 23.91 and 51.35 seconds respectively (Table 4.8 and Figure 4.13), which was also statistically significant. However, there was no significant difference between trained and non-trained individuals.

Both trained and non-trained individuals took significantly less time to replace the prototype PEEK matrix. This was attributed to the simple threaded design of the prototype PEEK matrix and its metal housing. Participants were easily able to unscrew and screw the prototype PEEK matrix out and in of its metal housing using the designated prototype insertion/removal tool. The OT-Equator® matrices proved more difficult to remove with the designated cap insertion and extractor tool, the nylon matrices often crumbling during the removal attempt.

All participants were equally proficient in replacing the different matrices, but ultimately found the replacement of the prototype PEEK matrix easier as confirmed by the Visual Analogue Scale scores where both trained and non-trained individuals rated replacement of the prototype PEEK matrix significantly easier. Therefore, the only significant effect on the difference in mean replacement time between the two attachment systems was exclusively due to the different matrix system designs, confirmed with negative effect size values which indicate that the effect (new matrix design) was the only factor responsible for the decrease in mean time taken to replace the different matrix systems.

5.9 Clinical significance

A value of 20 N has previously been suggested as the minimum amount of retention required to ensure patient satisfaction with a mandibular two implant-retained overdenture (Alsabeeha *et al.*, 2010; Türk *et al.*, 2014). Additionally, Walton *et al.* (2009) and Alsabeeha *et al.* (2011a) have proven that the single mandibular implant-retained overdenture is a viable alternative to a two implant-retained overdenture.

Historically, high performance synthetic polymers such as nylon have been used in the fabrication of matrix inserts for ball and stud-type attachments, the two most commonly used patrix designs for overdentures. Plastic deformation is, however, a significant drawback of these types of matrices, contributing greatly to the overall prosthetic maintenance to be performed (Bryant *et al.*, 2015). The regular replacement of these nylon matrices not only carries a financial cost, but requires a clinical visit to a trained dental professional to perform the replacement.

The prototype PEEK matrix tested in this study provides an alternative solution to the more commonly used nylon matrices. Possessing twice as much initial retention as standard retention nylon matrices of the OT-Equator® attachment system, the prototype PEEK matrices maintained this advantage throughout fatigue testing up until failure, albeit to a lesser degree. The prototype PEEK matrices did, however, fail after approximately 1 year of prosthetic usage compared with the approximate 2 years' lifespan of the OT-Equator® attachment system. The expected increase in the number of matrix replacements for the prototype PEEK matrices is offset by the significantly easier process to replace the matrix irrespective of the level of experience or training of the operator. As such these replacements can conveniently be performed by the lay person in any environment, whether at home or in a care facility.

5.10 Limitations

As this is an *in vitro* study, conditions under which testing was performed could not completely simulate the clinical environment. Factors such as the purely vertical dislodging movement for the tensile tests, the elevated temperature and a continuous moist environment due to salivary coating, could have potentially affected the degree of friction to be overcome by each matrix system prior to separation from its abutment. The lack of continuous submersion during fatigue testing could also not account for the potential of surface degradation and breakdown of the matrices by oral fluids once continuously bathed.

It is further speculated that the measuring equipment used may also not have been sensitive enough to be able to distinguish between the maximum (peak) load and break load, a limitation which resulted in a lack of comparison to a previous study in which this was reported.

CHAPTER 6 . CONCLUSION

With statistically superior initial retention values and no significant difference in retention value at point of failure, the OBZ abutment with prototype PEEK matrix offers a valid alternative to the more commonly used OT-Equator® abutment with standard retention nylon matrix.

Estimated to have a longevity of approximately 1 year and 2 months versus 2 years for the OT-Equator® abutment with standard retention nylon matrix, the OBZ abutment with prototype PEEK matrix however proved easier to replace irrespective of participant experience. As such it can be performed by any individual without the need for a clinical visit to a trained dental professional.

Within the limitations of the study the OBZ abutment with prototype PEEK matrix can be considered a viable alternative to the OT-Equator® abutment with standard retention nylon matrix, specifically in the setting of a mandibular single implant-supported overdenture, now shown to be an acceptable treatment modality to the more common two implant-retained overdenture.

CHAPTER 7 . REFERENCES

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