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Torque and angulated retaining screw preload in implant supported prostheses

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Torque and Angulated Retaining Screw Preload in Implant Supported Prostheses



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A research report submitted for partial fulfilment for the degree of of Masters in Dentistry in Prosthodontics

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Declaration

I, JOHANNES HENDRIK SCHOEMAN declare that this research report is my own work. It is being submitted for the degree of Master of Dentistry in the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University

Signed …………..

This 17th day of August 2020

Dedication

I dedicate this research report to my loving wife, An-Suzanne, for her continued love and support and to my two beautiful boys, Monrich and Estefan, who always put a smile on my face.

Acknowledgements

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Abstract

Purpose

Angulated screw channel systems provide for screw-retained implant restorations in cases of leass than ideal implant positioning. Theoretical calculations predict a loss in abutment screw preload when the screw is torqued at an angle to the long axis of the implant. This *in-vitro* study aimed at measuring the loss in preload with a change in the angle of the applied torque and to determine to what value the torque should be increased to minimise the loss in preload for any specific angle.

Method

A custom built preload measurement device (Southern Implants, Irene, South Africa) was used to measure the preload achieved in the abutment screw (Dynamic Abutment® Solutions, Spain). A manual torque wrench applied torques ranging from 20 to 40 Ncm in 5 Ncm intervals at each angulation interval between 0° and 30° in 5° increments. Each test combination of angle and applied torque was repeated 4 times. Comparison of the preload between angles at a given torque were made by one-way ANOVA. Post-hoc comparisons were done using the Tukey-Kramer adjustment for multiple comparisons. The preload data were modelled using Ordinary Least Squares (OLS) regression.

Results

For all angles up to 20°, the preload had a positive linear relationship with all torques applied and was close to the value of the applied torque. At angles >20° a statistically significant loss in preload ($p < 0.5$) occurred for all torque values between 25 and 35 Ncm. At a torque of 20 Ncm, a significant loss in preload ($p = 0.023$) was seen at 30° whereas at 40 Ncm, a significant loss ($p = 0.015$) first occurred at 15°. Thus at higher angles a non-linear relationship appeared between preload and angle. The data allowed the use of a non-linear regression model to predict the change in preload as a function of both applied torque and

angle. At the recommended torque value of 25 Ncm, a predicted 12.1% and 20.7% loss in preload occurred at angles 25° and 30° respectively.

Conclusions

In angulated screw channel systems, when the angular correction is >20° a significant loss in preload occurred when applying the recommended torque of 25 Ncm. To minimise the loss in preload a recommended increase in applied torque of 11% (torque to 28Ncm) for angles ranging between 20° and 25° and 24% (torque to 31Ncm) for angles greater than 25° should be applied.

1. Introduction

1.1 The dental implant: survival and success

The process of osseointegration aims to "*create a firm, intimate, and long lasting connection between the implant and the vital host bone*" (Adell et al., 1981). The development of the osseointegrated dental implant (Brånemark, 1983) has created an extra dimension in our ability to replace missing teeth and restore oral function and aesthetics. Following osseointegration, the implant fixture provides a platform onto which a transmucosal abutment together with a tooth-like prosthetic restoration can be placed. The latter is known as an implant-supported prosthesis (ISP) and can be cement-retained or screw-retained.

Longitudinal studies have shown the long-term survival of implants (Adell et al., 1981; Moraschini et al., 2015), however, it has long been recognised that implant success constitutes much more than implant survival and the mere measurement of bone loss around implants (Attard and Zarb, 2004). The implant-osseous connective interface, unyielding material properties, and uni-axial design of implants reduce the biomechanical adaptation and clinical application of implants (Howes, 2017). This can impact implant success at a prosthesis, soft tissue, and patient satisfaction level (Papaspyridakos et al., 2012).

The prevention and/or maintenance of technical and biological complications has become an important aspect in the long-term success and survival of ISPs (Goodacre et al., 2003; Monje et al., 2016). Among the prosthetic variables that can influence the success of implant-supported restorations, abutment screw loosening is one of the most common technical complications (Lazzara et al., 1996 ; Schwarz, 2000 ; Misch, 2005). Screw loosening can lead to screw fractures, abutment fractures, superstructure damage and/or dislodgement as well as implant fracture or peri-implant bone loss (Katsuta and Watanabe, 2015).

1.2 The rationale for a screw-retained ISP

The three-dimensional positioning of the implant fixture in bone should promote both the biomechanical needs of the bone and surrounding soft tissues, as well as satisfy the functional and aesthetic demands of tooth replacement. However, bone resorption patterns following tooth extraction, as well as the natural form of the teeth such as the angulation of the crown to the root, may compromise the ideal position of the implant in the bone to satisfy functional and aesthetic demands (Howes, 2017).

For ease of retrievability, a screw-retained ISP is often preferred for the maintenance of the prosthesis and peri-implant tissues over time. In order for the ISP to be screw-retained the long axis of the implant should be aligned such as to accommodate the screw access hole to be in the centre of the cingulum area of anterior teeth and the central fossa of posterior teeth (Howes, 2017). Failure to comply with this implant-restoration alignment complicates the aesthetic restoration of the implant (Sadid-Zadeh et al., 2015). In cases where the implant angulation does not permit a screw-retained ISP, cement-retained ISPs can be used, in conjunction with custom made abutments, to accommodate the aesthetic restoration of the implant. Cement-retained ISPs are, however, associated with increased technical as well as biological complications particularly in the presence of augmentation materials and procedures (Browaeys *et al.*, 2013). Technical complications relate to the difficulty in retrieving the ISP when abutment screw loosening has occurred; and biological complications relate to subgingival cement remnants that risk the integrity of the peri-implant tissues and underlying bone health (Linkevicius *et al.*, 2013; Pesce et al., 2015).

1.3 Biomechanical factors affecting the implant-abutment connection

1.3.1 Stress distribution

Stress distribution along the body of the implant, the restoration, and the surrounding bone as a function of load direction has been measured using mathematical studies and three-dimensional finite element analysis (FEA). Although the heterogeneity of these studies makes comparison difficult, it seems that the highest concentration of compressive and tensile stresses occurs in the region of the alveolar crest (cortical bone) and the neck of the implant when subject to non-axial forces (Weinberg and Kruger, 1995; Naveau et al., 2009; Maminskas et al., 2016). A significant increase in stress was reported as the angle of force was increased relative to the long axis of the implant (Martini et al., 2012; Kumar et al., 2013). Similar stress values have been reported for both straight and angulated abutments (Martini et al., 2012), but as angulated abutments are used in cases of less than ideal implant placement, it is logical that the oblique force applied to the long axis of the implant would in general result in an increased strain on the cortical bone, the cervical region of the implant, the implant abutment connection and the retention screw.

1.3.2 The screw joint and its behaviour in function

The integrity of the implant abutment connection plays an important role in the biomechanical stability of this interface and is influenced, *inter alia*, by the type of abutment connection, the passivity of the fit of its matching components, and the force created by the abutment screw as it 'clamps' the abutment onto the implant fixture (Schwarz, 2000). The term, *screw joint*, is used to describe this connection (Misch, 2005).

Torque is a twisting force that tends to cause rotation of an object and is a function of both force magnitude and direction. The point around which the object rotates is called the axis of rotation. When torqued, tension is created within the screw as it elongates. The tension

generated is a function of the amount of torque applied to the abutment screw and creates a clamping force between the components of the screw joint that is also called 'preload'(Winkler et al., 2003).

The magnitude of the torque is responsible for achieving a clamping force and is directly related to the amount of preload achieved (Misch, 2005). There is, however, a limit to this relationship. The behaviour of a screw under tension can be described by means of a stress-strain curve (see figure 1.1)

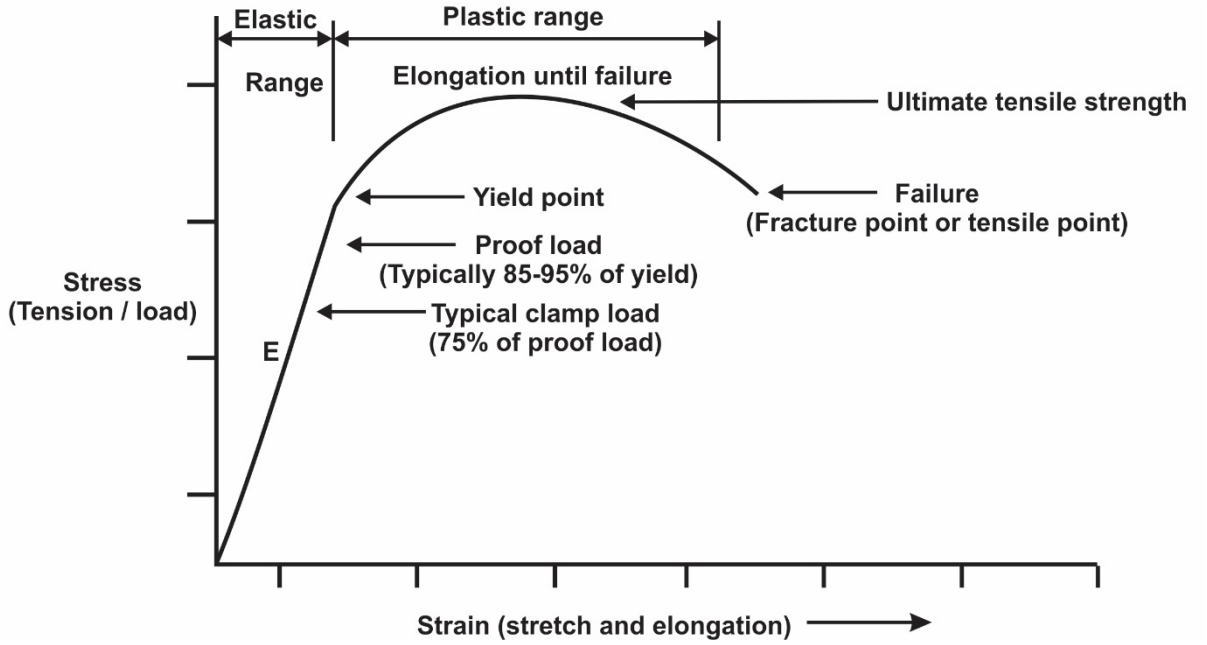


Figure 1.1 Tensile stress/strain diagram of the behaviour of a screw while it is being torqued (after https://www.fastenal.com/en/69/bolted-joint-design).

The straight line E (Fig. 1.1) represents the elastic deformation (change in length) of the screw as stress (torque) is increased. The change in the length of the screw for any value of stress along the straight line E will not result in permanent deformation: the screw will always return to its original length if the screw is unscrewed. The proof load is the maximum tensile force that can be applied to a bolt that will not result in plastic deformation.The screw

will behave elastically until it reaches the Yield Point. The Yield Point represents the end of the screw's elastic behaviour and the beginning of plastic behaviour (Bickford, 1995).

In order to create preload, the friction in the screw-joint assembly needs to be overcome. Preload and friction have an inverse relationship so that preload would increase as the coefficient of friction decreases (Oliver and Jain, 2006). Therefore, the higher the torque and the lower the friction, the better the joint will perform. However, this is limited by the material properties of the abutment screw and driver as it will not be ideal for the materials to be strained beyond their yield strength. The aim is therefore to torque the abutment screw to a level that will optimise joint stability (Bickford, 1995). The lower limit of this torque has to be enough to effectively overcome the friction in the screw joint, but the upper limit should not surpass 75% of the torque value necessary to reach the yield point of the material. The remaining 25% allows for fatigue resistance in the screw and provides a safety margin to prevent the tension in the screw from reaching the stage of plastic deformation when in function (Cantwell and Hobkirk, 2004; Misch, 2005).

Bolted joints are fasteners that capture and join other parts, and are secured with screw threads, and their behaviour is unfortunately very difficult to predict and many variables have been recognised that affect the control and accuracy of this assembly (Bolt Science, 2018). Any factor that can reduce the amount of stored energy in the joint will affect the predictability of the clamping force. Amongst these are 1) insufficient torque applied, 2) friction (heat), 3) bending and twisting moments, 4) surface irregularities, 5) screw head design, 6) thread design parameters, 7) composition of the metal and its modulus of elasticity, and 8) embedment of the screw and implant threads (Bickford, 1995; Misch, 2005). The latter is a process where high spots/ irregularities on the threads and screw head are flattened after

initial contact, and where the material would creep as a result of the pressure created. This creep or "settling effect" can reduce the clamping force as the joint is said to "relax" (Bickford, 1995).

The in-service behaviour of the screw joint is also affected by various factors such as temperature changes, vibration, shock, corrosive fluids, tension, etc. Torsional forces applied to the abutment implant interface are a major cause of clinical abutment screw loosening (Bickford, 1995). In the past clinical studies reported a high rate of abutment screw loosening within the first three years of function (Jemt and Pettersson, 1993; Henry et al., 1996). However, the more recent developments of improved anti-rotational features, screw materials, and the use of higher torque values, have resulted in a reported significant decrease in the percentage of abutment screw loosening. A systematic review by Theoharidou et al. (2008) predicted that an estimated 97% of single implant restorations would be complication-free after 3 years in service. The literature, however, has not provided evidence that this has been the case.

The 'settling effect' plays an important role in the loss of preload. An *in vitro* study by Siamos et al. (2002) reported a loss of up to 28% of preload after only a few hours following screw tightening. A cyclic torsional loading test, simulating only one month's functional load, revealed a loss of preload of between 2.4%-13.5% depending on the type of implant abutment connection (Katsuta and Watanabe, 2015). Although laboratory testing does not mimic the clinical scenario it can provide an indication of the behaviour of the screw joint and the loss in preload that can be expected. As such, these and similar results from other laboratory studies have resulted in recommendations to retighten abutment screws 10 minutes

after initial torque application and at regular intervals to overcome the loss in preload due to embedment relaxation (Bakaeen et al., 2001; Siamos et al., 2002).

1.4 Angular correction and its theoretical relationship with a reduction in preload

In an effort to accommodate screw-retained ISPs, dual-axis implants that allow for sub-crestal angular correction with conventional abutments were developed (Howes et al., 2004), as well as angled implant abutments for supra-crestal angular correction (Berroeta et al., 2015; Rutten et al., 2017). The disadvantage of angled abutments is the additional prosthetic space that is needed as the restorative platform is shifted from implant level to abutment level. In order for the metal abutment to be consealed, the implant must be placed more apically, or it must be maked by thick gingival mucosa to hide the components (Cavallaro and Greenstein, 2011). In order to obviate these aesthetic limitations, angular corrected abutments have been developed to facilitate a screw-retained ISP at the level of the implant head. Abutment systems that currently provide this alternative include the Dynamic abutment® (Dynamic Abutment® Solutions, Spain), the Angulated Screw Channel (Nobel Biocare®, Sweden), the castable angled abutment with Cr-Co base (IPD™, Spain*), and the Angulated Screw Access Solution (Neoss®, UK). These systems rely on an angulated screw channel and abutment screws with specially designed screw heads (e.g. TPA screw, IPD™*) to accomodate a screw driver with a special rounded omnidirectional/elliptical driver head (Fig. 1.2) that can turn the abutment screw at an angle relative to the long axis of the implant. Manufacturers claim that these screw/driver systems can provide adequate abutment screw preload at angles of up to 25° - 30° to the long axis of the implant.



Figure 1.2 A) Omnidirectional screw driver. (IPD™, Spain*); **B)** Elliptical Angulated Screw Channel driver (Nobel Biocare®, Sweden); **C)** Omnidirectional screw driver (Dynamic abutment®, Spain)

* IPD - <https://ipd2004.com/featured-products/Castable-angled-abutment-with-CoCr-base-d3. Accessed 2018/11/12>

1.5 Theoretical effect of angular change on input torque

The optimal manner in which to apply torque to an abutment screw is to turn the screw directly along its long axis, at 90° to the radius of the screw. Theoretical calculations indicate that as soon as the driver is angled relative to the screw axis, the torque transferred by the driver will be reduced by the target torque multiplied by the cosine of the driver angle (Fig. 1.3).

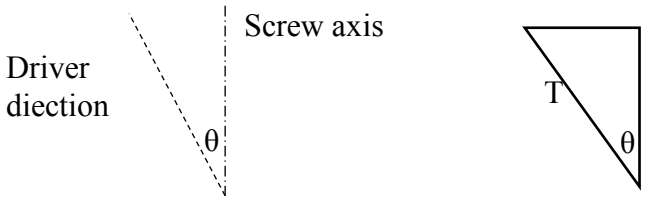


Figure 1.3 Torque is reduced if the driver is angled relative to the screw axis by Tcos θ where T is the target torque and θ the angle of the driver to the screw axis.

Table 1 illustrates this theoretical reduction in screw input torque with angular changes for a constant input or target torque of 40 Ncm (Pitman, 2017).

Table 1.1 Table of theoretical input torque reduction as a result of angulating the axis of torque application relative to the screw axis (Pitman 2017).

Angle (θ) in degrees	Theoretical input torque in Ncm	% of input torque reduction
0	40.0	100.00
5	39.8	99.62
10	39.4	98.48
15	38.6	96.59
20	37.6	93.97
25	36.3	90.63
30	34.6	86.60

1.6 Conclusion

Directing functional forces along the long axis of an implant provides the best biomechanical advantage for the implant to withstand them. However, bone resorption patterns and anatomical constraints often dictate the position of the implant, which can lead to an implant orientated in a compromised position which can be compounded by the fact that chewing patterns are not uniform.

As the majority of stress is concentrated at the neck of the implant, the screw joint will also be subjected to stress. The stress increases as the angle of the implant increases relative to the direction of the forces that act on it (Maminskas et al., 2016). This together with abutment screw loosening, reported to have the highest complication rate in single ISPs (Hanif et al., 2017), increases the risk of technical and biological complications when angulated or angular screw channel abutments are used.

Supra-crestal angular correction systems such as the Dynamic abutment, have become a popular choice for providing a screw-retained ISP in cases of less than ideal implant placement. The theoretical decrease in abutment screw preload with an increase of the angle at which the torque is applied has not been validated and very few studies have attempted to measure and predict the behaviour of these angulated screw channel systems (Pitman, 2017 ; Goldberg et al., 2019 ; Hu et al., 2020 ; Opler et al., 2019).

A recent *in vitro* study (Goldberg et al., 2019) tested dynamic abutment screws (Dynamic Abutment Solutions) at 3 different angles (0°, 20°, and 28°) by measuring the difference in the removal torque value (ΔRTV) at baseline and the removal torque after subjecting the screws to cyclic fatigue testing simulating 5 years of function. The ΔRTV of the 0° group was the smallest and that of the 28° group the largest, but no significant differences ($p>0.5$) in the mean ΔRTV within and between the different angulation groups were measured. The authors concluded that the larger ΔRTV of the 28° group was as a result of the increased tensile stresses created from the non-axial loading of the abutment. They did, however, fail to compare the mean torque removal values between the different groups. The RTVs were also measured at the same angle as that used to torque the abutment screw and not at an angle parallel to the implant. For the same reasons that preload is said to be lost with an increase in the angle at which torque is applied, so the removal torque value might be influenced by the angle of retrieval. The values might as a result be skewed as theoretically more force is required to undo the screw with an increase in angle. The true value of the removal torque should be measured at an angle parallel to the the long axis of the implant.

Hu et al. (2020) compared the mean RTV of an angulated screw channel system using angles of 0°, 10°, and 20 degrees. Unlike the previous study (Goldberg et al 2019) the

authors reported a significant difference ($p<0.001$) in the mean RTV between the different groups and that the values were significantly influenced by the screw driver angulation. In this study the authors correctly tested the mean removal torque values by removing the screws parallel to the long axis of the implant analogue. Limitations to the study included that laboratory implant analogues were used, which have distinct differences in metallurgic behaviour and machining tolerances compared with implants, and they failed to use a new implant analogue for each screw tested. One implant analogue and abutment were repeatedly used perangle tested. Sixteen screws were torqued at each angle and as such the results could be skewed due to distortion of the internal threads of the implant analogue. Also, the maximum angle tested was 20 degrees which falls short of manufacturer's recommendations for torqueing screws up to angles of 30 degrees.

Opler et al. (2019) confirmed the results of Hu et al. (2020) and found a significant difference ($p < 0.5$) between the mean RTV of abutment screws torqued at 0 degrees and 28 degrees with a 23% reduction in RTV measured at the 28° angle. The authors also measured the difference in the input torque value (ITV) and the resultant output torque value (OTV) at angles 0°, 15°, 25°, and 28 degrees. No statistically significant differences ($p>0.5$) were found between 0° and 15° angulations, but a significant difference ($p<0.5$) was noted at angles 25° and 28 degrees. The study was unfortunately limited by the large interval in angles that were tested, making it difficult to determine exactly at which angle between 15- and 25 degrees a clinical significant loss in the OTV occurred.

Studies that aim to measure the preload achieved in abutment screws of angulated screw channel systems are therefore few and have limitations to their methodology. According to

the author's knowledge there are no studies measuring the relationship between target torque and preload using a wide range of accepted torque values at the full range of angles recommended by manufacturers.

2. Aims and Objectives

2.1 Aims

1. To determine the effect of the angle at which torque is applied on the preload achieved in the abutment screw of the Dynamic abutment® system (Dynamic Abutment® Solutions, Spain)
2. To determine which value of applied torque will produce the least reduction in preload for any given angle.

2.2 Objectives

1. To measure the preload at different angles to the long axis of the implant with each applied value of torque
2. To determine the range of applied torque values that will reduce the loss in preload to a minimum for each angle within the properties of the screw.

3. Method and Materials

3.1 Method

A custom built preload measurement device (Southern Implants, Irene, South Africa) (Fig. 3.1) was used to test the preload achieved in the abutment screw (Dynamic Abutment® Solutions, Spain) when a specific torque was applied at various angles relative to the long axis of the screw. The device consisted of a load cell (LT400, Loadtech Load Cells (Pty) Ltd, South Africa) together with an implant analogue clamping system, an abutment analogue and specifically designed guide rings (Fig.3.2) that fitted into the preload tester head (Fig.3.3) to ensure the driver was orientated at the correct angle at all times during the tests. Six different guide rings with angles ranging from 0-30° in intervals of 5° were used.

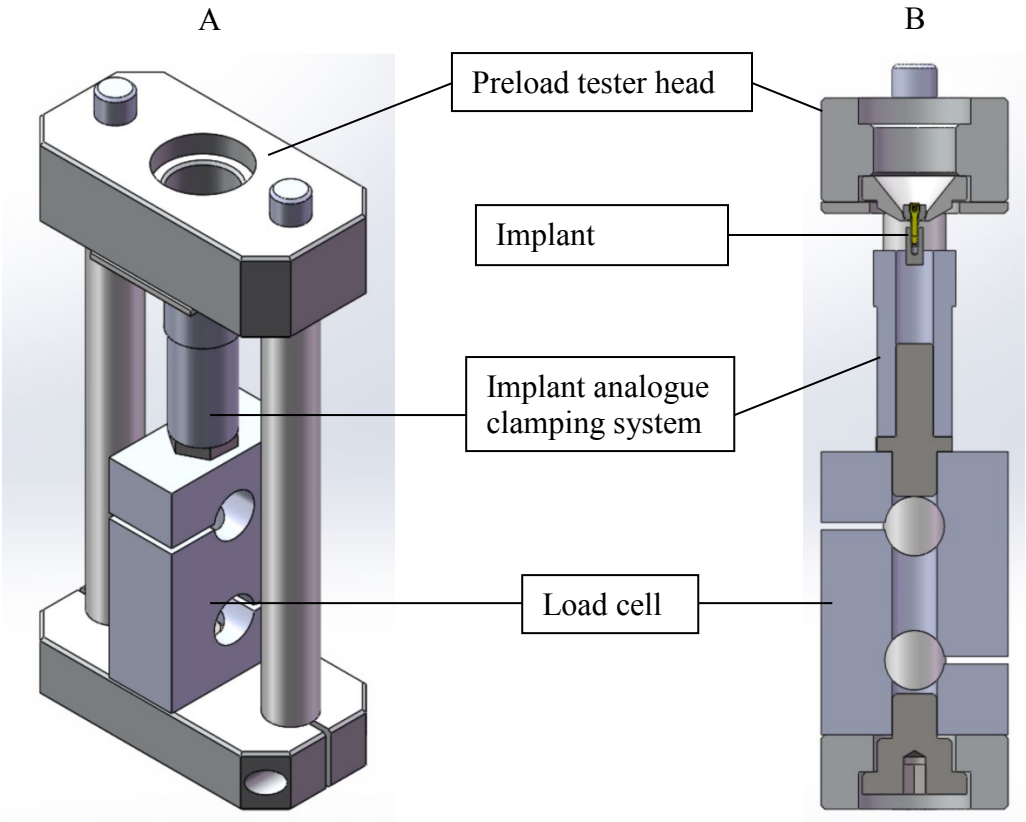


Figure 3.1 Custom built preload measurement device. A) Oblique view; B) Cross section.



Figure 3.2 Guide rings with angles ranging from 0-30° in intervals of 5°

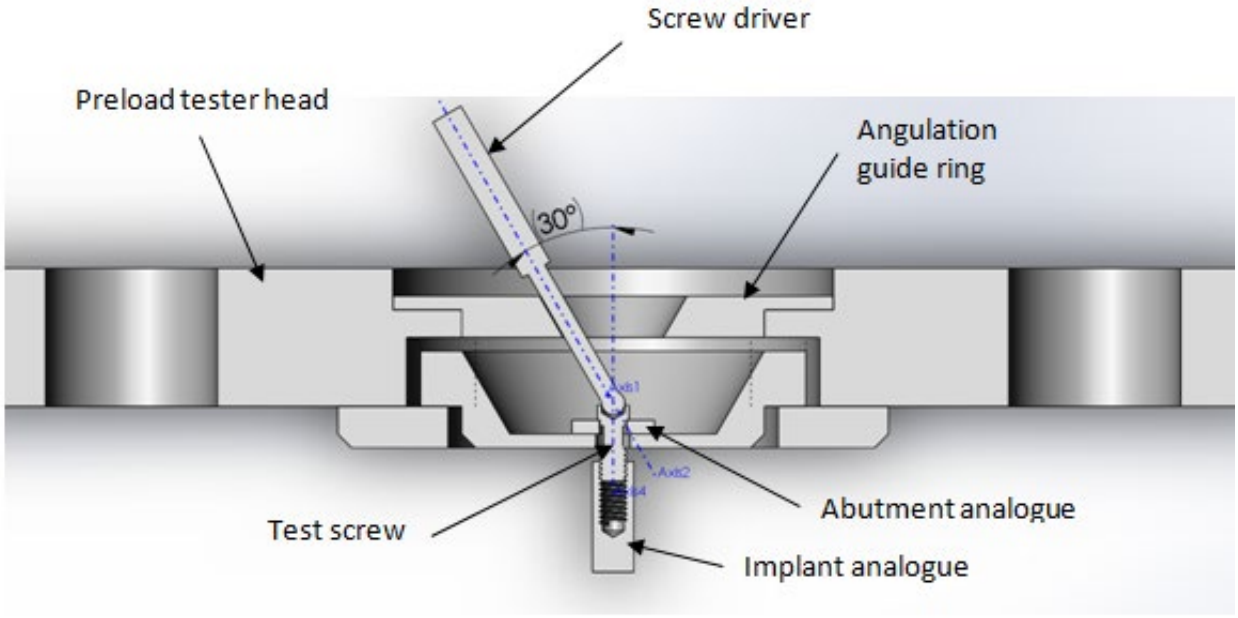


Figure 3.3 Cross section of preload tester head.

A manual torque wrench (QSN 40 SD, Torqueleader®, UK) was used to apply torques ranging from 20 to 40Ncm in 5Ncm intervals at each of the target angulation intervals. After each application of the target torque, the preload achieved by the screw was measured by the load cell.

The data were entered into a spreadsheet (Excel® Microsoft Corp). Each test at each combination of angle and applied torque was repeated 4 times, making a total number of 140 tests. Experiments were carried out in random order (generated by randomising a list of the experiments in Excel). There are no recommendations from the manufacturers as to how many times the screw driver can be used. But because these tests involved torquing the screws beyond the manufacturers' recommended torque values, it was considered prudent to

change driver as often as possible to ensure a pristine working interface. There was, however, a limit to the number of drivers available due to cost constraints. It was therefore decided to use a new driver after every 35 tests to optimise material quality and surface interaction between the driver and the abutment screw head. Because of the time-consuming nature of the tests, they were performed over two days. Day one consisted of the randomised experiments 1 to 35, whereafter experiments 36 to 140 were completed on Day 2.

The same operator performed all the tasks (test assembly, torque applied, and collection of data). The load cell and torque wrench was calibrated and was fully operational as verified by the Design Engineer of Southern Implants, the owners of the devices. The calibration of the torque wrench was again verified after test day one before commencing to tests day two.

3.2 Sample Size

Sample size estimation was based on the ability to determine significant differences, should they exist, in preload measurements between different angles and different levels of torque. Estimations were based on data from a previous study (Pitman, 2017), where the mean preload varied from 18.8 to 24.7 N between 7 angles and from 15.1 to 29.2 N between 5 levels of torque. Given a within-experiment standard deviation of 2.1 and 5.5 N respectively, these corresponded to effect sizes of 0.36 and 0.91 respectively. With a significance level of 5%, and 80% power, total sample sizes of 119 and 20, respectively, would be required. The minimum sample size requirement was thus 119, i.e. 119/35 experimental combinations = 3.4 experiments per combination, which was rounded up to 4, giving 4*35 = 140 experiments per system.

Sample size calculations were carried out in G*Power (Faul, 2007).

3.3 Data Analysis

Measured preload data were summarised by the mean, standard deviation, median, and interquartile range.

Comparison of the preload between angles at a given torque were made by one-way Analysis of Variance (ANOVA). Post-hoc comparisons were done using the Tukey-Kramer adjustment for multiple comparisons.

The preload data were then modelled as follows using Ordinary Least Squares (OLS) regression:

$$\text{Preload} = k_0 + k_1(\text{angle}) + k_2(\text{angle}^2) + k_3(\text{torque}) + k_4(\text{torque}^2) + k_5(\text{angle*torque})$$

Where $k_0 \ldots k_5$ are regression coefficients to be estimated.

Data analysis was carried out using SAS version 9.4 for Windows. The 5% significance level was used.

4. Results

4.1 Descriptive analysis of the study data

The data for experiment 135 were excluded due to screw head failure.

The box-and-whisker plot shown in Fig 4.1 shows a quantitative analysis of the results and reveals the effect that torque and angle had on preload. It is evident that for all angles, preload followed a positive linear relationship with an increase in the amount of torque that was applied to the screw. The preload achieved appeared to be close to the value of the applied torque for all angles up to 20 degrees after which a noticeable loss in preload was observed at angles greater than 20 degrees.

Figure 4.1 Box-and-whisker plots: preload achieved as a function of the applied torque/angle combination.

A within-group (applied torque) comparison of the preload measured at different angles was made to determine whether or not a statistically significant difference in preload existed between the various angles.

Table 4.1 Comparison of the Preload between angles at a given torque

Applied Torque (NCm)	Significant differences in mean Preload in relation to Angle
20	0 and 15 deg > 30 deg (p=0.029, 0.023)
25	0 deg > 25 and 30 deg (p=0.0013, 0.022) 5, 10, 15, 20 deg > 25 deg (p=0.022,0.018,0.016,0.010)
30	0 deg > 25 and 30 deg (p<0.0001, 0.0002) 5 deg > 25 and 30 deg (p=0.0006, 0.0023) 10 deg > 25 and 30 deg (p<0.0001, <0.0001) 15 deg > 25 and 30 deg (p<0.0001, 0.0003) 20 deg > 25 and 30 deg (p=0.0004, 0.0015)

35	0 deg > 25 and 30 deg (p<0.0001, 0.0006) 5 deg > 25 and 30 deg (p=0.0090, 0.047) 10 deg > 25 and 30 deg (p=0.0086, 0.045) 15 deg > 25 and 30 deg (p=0.0011, 0.0071) 20 deg > 25 and 30 deg (p=0.0061, 0.033)
40	0 deg > 25 and 30 deg (p=0.0024, 0.0005) 5 deg > 25 and 30 deg (p=0.020, 0.0046) 10 deg > 25 and 30 deg (p=0.0062, 0.0014) 15 deg > 25 and 30 deg (p=0.015, 0.0033)

Table 4.1 represents the quantitative relationship between the preload achieved from different angles at which the various torque values were applied. Significant losses in preload occurred at angles greater than 20 degrees for all applied torques ranging between 25 and 35 Ncm. At an applied torque of 20 Ncm, a significant loss in preload ($p = 0.023$) was only seen at 30 degrees whereas at 40 Ncm, a significant loss ($p = 0.015$) occurred at 15 degrees. An unexplained anomaly was seen in the 25 Ncm torque group where a significant loss in preload occurred between angles 20 and 25 degrees, but not between the 20 and 30 degree angles.

4.2 Regression model

Because of the variability of the data and the non-linear relationship that was seen between preload and angle at the higher angles, a non-linear regression model was used to quantify the effect that both a change in angle and torque (as the independent variables) would have on preload (as the dependent variable) and to create a model to best predict the change in preload as a result of both of these effects. The relationship between these variables is described by means of a mathematical equation that would estimate the value of the dependent variable with any changes in the independent variables. For each outcome:

$$\text{Outcome} = k_0 + k_1(\text{angle}) + k_2(\text{angle}^2) + k_3(\text{torque}) + k_4(\text{torque}^2) + k_5(\text{angle*torque})$$

Where $k_0 \ldots k_5$ are regression coefficients to be estimated.

In order to model this relationship quadratic terms were used for the independent variables to create a model that would best fit the data in order to reduce the standard error. The final model was calculated as:

Preload = -0.410 + 0.378(angle) - 0.010(angle^2) + 1.019(torque) – 0.010(angle*torque).

The source table for the full model is shown in Table 4.2

Table 4.2 Source table for full Preload model

Source	DF	Type III SS	Mean Square	F Value	p-value
Angle	1	63.48	63.48	13.04	0.0004
Angle²	1	106.06	106.06	21.78	<.0001
Applied torque	1	80.05	80.05	16.44	<.0001
Applied torque²	1	0.48	0.48	0.10	0.76
Angle x Applied torque	1	68.46	68.46	14.06	0.0003

The effect of Applied torque^2 was not significant so it was removed from the model. The source table for the revised model is shown in table 4.3.

Table 4.3 Source table for revised Preload model

Source	DF	Type III SS	Mean Square	F Value	p-value
Angle	1	63.55	63.55	13.14	0.0004
Angle²	1	106.16	106.16	21.95	<.0001
Applied torque	1	2232.04	2232.04	461.52	<.0001
Angle x Applied torque	1	68.51	68.51	14.17	0.0002

All effects were significant. The model explains 90.5% of the variability in preload, which makes it able to predict the loss in preload with a change in angle. Using this model, the predicted preload, with its 95% confidence interval, is tabulated in Table 4.4 for every

torque-angle combination. The fit of the data to the model is illustrated in Figure 4.2, which shows the predicted preload from the model (lines), along with the experimental points.

Table 4.4 Model prediction for Preload for any combination of Applied torque and Angle

Angle (deg)	Applied torque (Ncm)	Preload (Ncm)			
		Predicted	95% CI		% change from Applied torque
0	20	20.0	15.4	24.5	0
0	25	25.1	20.6	29.5	0.2
0	30	30.2	25.7	34.6	0.5
0	35	35.3	30.8	39.7	0.7
0	40	40.3	35.8	44.9	0.9
5	20	20.6	16.2	25.1	3.1
5	25	25.5	21.1	29.9	1.8
5	30	30.3	25.9	34.7	1.0
5	35	35.1	30.8	39.5	0.4
5	40	40.0	35.6	44.4	0.0
10	20	20.7	16.3	25.2	3.7
10	25	25.3	21.0	29.7	1.4
10	30	29.9	25.6	34.3	-0.2
10	35	34.5	30.2	38.9	-1.3
10	40	39.1	34.7	43.6	-2.2
15	20	20.4	16.0	24.8	1.9
15	25	24.7	20.3	29.1	-1.1
15	30	29.1	24.7	33.5	-3.1
15	35	33.4	29.0	37.8	-4.5
15	40	37.8	33.4	42.2	-5.6
20	20	19.5	15.1	23.9	-2.5
20	25	23.6	19.2	28.0	-5.6
20	30	27.7	23.3	32.1	-7.7
20	35	31.8	27.4	36.2	-9.1
20	40	35.9	31.5	40.3	-10.2
25	20	18.1	13.7	22.6	-9.4
25	25	22.0	17.6	26.4	-12.1
25	30	25.8	21.4	30.2	-13.9
25	35	29.7	25.3	34.1	-15.2
25	40	33.5	29.1	38.0	-16.2
30	20	16.2	11.7	20.8	-18.9
30	25	19.8	15.4	24.3	-20.7
30	30	23.4	19.0	27.9	-21.9

Angle (deg)	Applied torque (Ncm)	Preload (Ncm)			
		Predicted	95% CI		% change from Applied torque
30	35	27.0	22.6	31.5	-22.7
30	40	30.6	26.1	35.2	-23.4

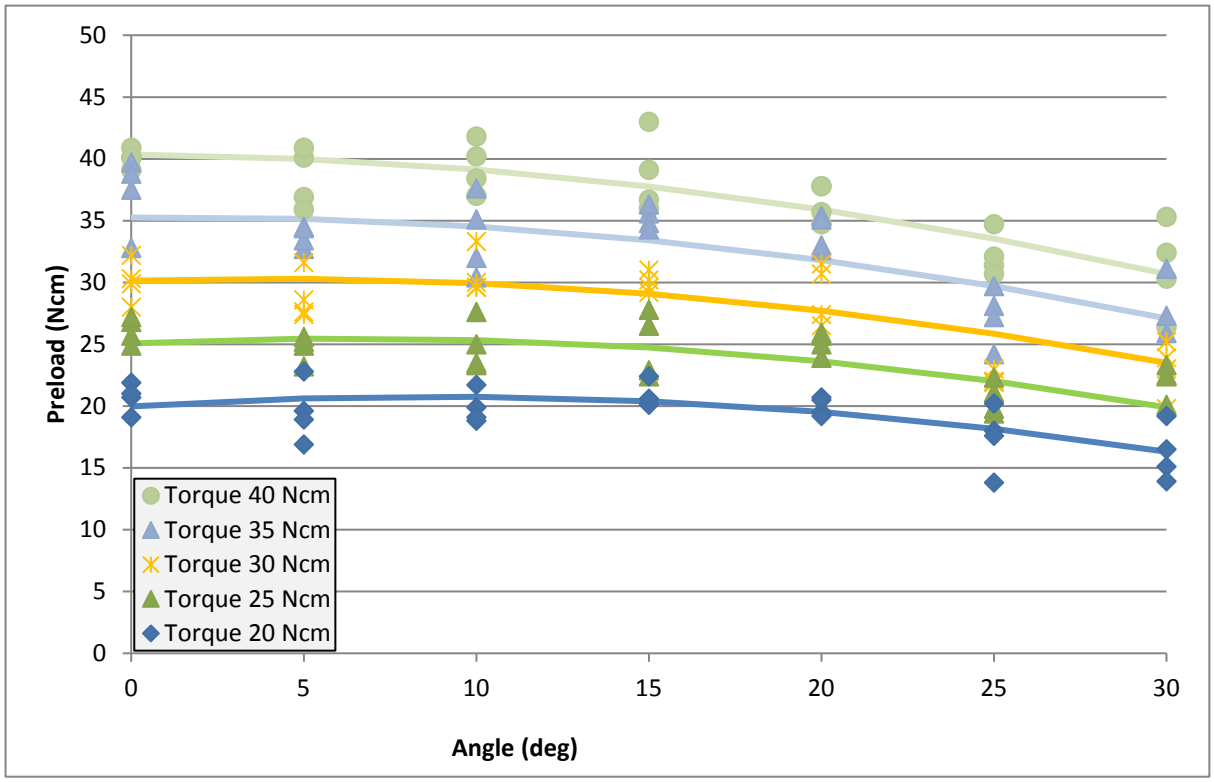


Figure 4.2 Predicted Preload as a function of a specific applied torque/angle combination

5. Discussion

5.1 Rationale for the study

The angulated screw channel abutment is most often used in restoring anterior implants with a less than ideal position in order to provide a screw retained ISP. Studies have shown that the non-axial nature of the forces applied on the anterior dentition will result in increased tensile force vectors being applied to the abutment screw joint. (Martini et al., 2012; Kumar et al., 2013). In addition, functional tensile stresses will increase the tensile load on the screw, causing the joint to separate and reducing the clamping force on the joint. It is therefore

important to torque the abutment screw sufficiently to provide adequate joint stability during function, but not to a level that the additional functional loads will stretch the joint components beyond their yield strength.

Abutment screw loosening is one of the most frequent clinical complications in single implant supported prostheses and is well documented (Jemt and Pettersson, 1993; Henry et al., 1996; Theoharidou et al., 2008), however, no clinical studies have reported on the incidence of screw loosening in using angulated screw channel systems. Clinical experience and anecdotal evidence seems to indicate that abutment screw loosening of angulated screw channel systems occurs more frequently. Theoretical calculations predict a loss in preload with an increase in the angle at which the screw is torqued (Pitman, 2017). It was therefore important to test this theory and to determine its clinical implications.

Several *in-vitro* studies have investigated the possible loss in preload with a change in the angle at which the abutment screw is torqued (Goldberg et al., 2019 ; Hu et al., 2020).

A well designed *in-vitro* study by Opler et al. (2019), reported a statistically significant loss ($p < 0.05$) in preload at a 25 degree angle. The study included interval sizes between the angles of 0°, 10°, 15°, 25°, and 28° at which a removal torque was measured. The authors concluded that although a statistically significant difference was measured between angles 15- and 25 degrees, the true angle at which a significant loss in removal torque occurred could not be accurately determined due to the irregular intervals in angles that were used. The present study made use of 5° increments in the angles at which the preload was measured, and was able to more accurately determine the critical angle at which a significant loss in preload occurred.

5.2 Clinical significance

The recommended torque for the Dynamic abutment screw (TPDH2L6) is 25 Ncm. Table 4.1 reveals that for torque values of 25 and 30 Ncm a statistically significant loss in preload ($p < 0.05$) occurred at angles 25 and 30 degrees to the long axis of the implant. According to the model (Table 4.4) the predicted loss in preload is expected to be 12.1% and 20.7% respectively for an applied torque of 25 Ncm. As a further loss in preload can be expected due to embedment relaxation, the cumulative effect of these and other unknown variables can add to screw loosening (Bickford 1995; Cantwell and Hobkirk, 2004). Many factors have been recognised to affect the friction in the screw joint that have to be overcome in order to create tension in the abutment screw while it is being torqued. The minimum amount of torque that has to be applied to overcome the friction is therefore difficult to calculate. There is, however, some guidance and logical inference that can be drawn from the manufacturer's instructions.

According to Dynamic Abutment Solutions, the M2 dynamic abutment screw should be torqued to 25 Ncm. The screw driver is specifically designed to acts as a 'safety net' and will break at torque values of between 50-60 Ncm before the head of the abutment screw undergoes plastic deformation (Dynamic Abutment® Solutions, http://www.dynamicabutment.com/discover-safety-dynamic-abutment-solutions-system/, viewed December 1, 2019). This implies that the yield point for the abutment screw is even higher than 50 Ncm. The recommended 25 Ncm at which this specific abutment screw should be torqued is therefore at most 50% of the torque value that will reach the yield strength of the material. This allows for a potential increase in abutment screw torque of between 25-

30% before the recommended safety margin of 75% of the material's yield strength is reached (Cantwell and Hobkirk, 2004; Misch, 2005).

To minimise the loss in preload a regression model was used to calculate the torque value necessary at these angles to maintain an adequate amount of preload. For angles 25 and 30 degrees the torque values need to be increased to 27.8 Ncm and 30.9 Ncm respectively. At the 30 degree angle the increase in torque of 5.9 Ncm constitutes an increase of 23.6% of the recommended torque value of 25 Ncm. This increase (50% + 23.6% = 73.6%) is still within the safety margin of 75% of the material's yield strength.

The variability of the measured preload should also be taken into account. According to Table 4.4 the highest value expected for preload (95% confidence interval) when a torque of 30 Ncm is applied at a 30°angle is 27.9 Ncm. Both the applied torque and resultant preload values are therefore still within the safety margin of 75% of the material's yield strength for this specific screw driver/abutment screw combination. The torque value of 30.9 Ncm recommended for a 30° angle should therefore be within close range of these safe values.

5.3 Possible explanations for a loss in preload

1) The increase in angle at which torque is applied will theoretically have an effect on the resultant force vector. Mathematical calculations predict a reduction in torque output by Tcosϴϴϴϴϴ (Fig. 1.3). T represents the applied torque at a specific angle (θ) to the screw axis.
2) The drop in preload could be related to the degree of engagement of the omnidirectional screw driver head in the abutment screw. The surface area in contact

between these two components reduces as the angle of the driver increases. The force transferred from the screw driver to the screw head might as a result be reduced.

3) As the angle of torque applied on the abutment screw is gradually increased, so the change in the force vector can potentially result in a swivelling effect on the abutment screw as it is turned into the implant fixture. This swivelling of the screw can cause asymmetrical engagement with the implant fixture's internal threads that could result in a higher amount of friction created which has to be overcome before the screw can deform elastically, thus reducing the clamping force (Cumming L, 2019, personal communication, 15 November).

5.4 Limitations of the study

As this is an *in vitro* study, conditions were optimal and did not simulate the clinical environment where aspects such as cyclic loading, elevated temperature and moisture (saliva, blood, etc.) contamination of the implant and abutment screw threads can have an influence on the tensile strength of the materials, friction, and the quality of abutment screw thread engagement.

The tests performed are only applicable to the specific Dynamic abutment screw (TPDH2L6) with no direct correlation that can be drawn to any other implant-screw-driver combination. Although all the analogue components were pristinely milled from Grade 4 Titanium alloy, they did not reflect a true implant-abutment assembly. The results should therefore be viewed with caution when relating them to the clinical environment. However, the percentage change in preload at any given angle for any given applied torque is a principle that can be transferred to other systems and to the clinical scenario.

6. Conclusion

For the system and condition being tested, with a statistically significant loss in preload ($p < 0.05$) observed at angles greater than 20 degrees it is advisable to minimise this loss by increasing the applied torque.

As there are numerous angulated screw channel abutment systems available with different screwdriver and abutment screw combinations, the absolute values of this study cannot be transferred. However, due to the design of the study it is possible to adapt the recommended applied torque values prescribed by the manufacturers by using the mathematical model [Preload = -0.410 + 0.378(angle) - 0.010(angle^2) + 1.019(torque) – 0.010(angle*torque)] to calculate the torque value necessary at any angle to preserve the desired preload. This recommendation is, however, subject to the safety precautions set out by the manufacturer and/or the yield strengths of the materials used for any specific system.

Within the limitations of this study it is recommended that for this specific Dynamic abutment screw (TPDH2L6), the applied torque be increased by 11% (torque to 28Ncm) for angles ranging between 20 and 25 degrees and by 24% (torque to 31Ncm) for angles greater than 25 degrees.

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Appendix 1. Ethics waiver

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG	HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

Office of the Deputy Vice-Chancellor (Research & Post Graduate Affairs)

TO: Dr JH Schoeman
School: Oral Health Sciences
Department: Oral Rehabilitation
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CC: Supervisor: Professors CP/DG Owen/Howes <Peter.Owen@wits.ac.za>
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FROM: Iain Burns
Human Research Ethics Committee (Medical)
Tel: 011 717 1252

E-mail: Iain.Burns@wits.ac.za

DATE: 04/12/2018

REF: *R14/49*

PROTOCOL NO: W-CBP-181204-01 (This is your ethics application study reference number. Please quote this reference number in all correspondence relating to this study)

PROJECT TITLE: *Torque and angulated retaining screw preload in implant-supported prosthesis*

Please find attached the Clearance Certificate for the above project. I hope it goes well and that an article in a recognized publication comes out of it. This will reflect well on your professional standing and contribute to the Government funding of the University.

MSWorks2000/Iain0007/ClearScanWaiver.wps

Appendix 2. Turnitin report

Filters used:

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Exclude sources of less than 2%.

Report:

