Displacement of Screw-Retained Single Crowns into New Generation Narrow Diameter Implants with Conical and Conical/Hex Internal Connections and their Performance when Cyclically Loaded

Thesis

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Abstract

Purpose: Previous studies have shown that internal conical implant-abutment connections without platforms can have axial displacement of crowns during screw tightening. This displacement may affect proximal contacts, incisal edge position, and/or occlusion. An implant design incorporating a conical/hex internal connection with a positive vertical stop could potentially prevent this unwanted axial displacement. This displacement could also occur during functional loading creating unsettling forces within the abutment-screw-implant complex potentially leading to torque dissipation, loss of pre-load and resulting loss of clamping force. This study aimed at confirming these previous findings and comparing these results to measured three-dimensional axial displacement of screw-retained single abutments with conical/hex internal connections into narrow diameter implants (NDI). Additionally, measured torque values before and after cyclic loading were compared to determine if torque dissipation results following repeated cyclic loading simulating 5 years of function.

Materials and Methods: Six narrow diameter implants (NDI) with conical internal connections (Astra Tech Osseospeed EV 3.0mmD - AST) and six NDIs with conical/hex internal connections (Zimmer Biomet Eztetic™ 3.1mmD - ZIM) were embedded in resin rods. Six prefabricated titanium abutments with conical internal connections and six with

conical/hex internal connections were used during testing. The spatial relationship of the abutments to the implant platforms after hand tightening was determined using three-dimensional digital image correlation (3D DIC), an optical measurement technique. The abutments were then tightened to the manufacturers' recommended torque values prior to recording the abutments' relative position again. The three-dimensional displacement of the abutment was compared between the hand-tightened and torqued states. At the conclusion of the 3D DIC measurements, the implants/abutments were retrieved, mounted at a 30 degree angle with respect to their long axes, and subjected to $5x10^6$ cycles at 2 Hz and 200N of mechanical loading in a chewing simulator to simulate 5 years of functional loading. Following completion of the cyclic loading, a digital torque device was used to measure the resulting removal torque values of each sample. The resulting torque values following loading were compared to those recommended by the manufacture to calculate preload efficiency of each system.

Statistical Analysis: ANOVA statistical analysis was used to compare the differences in implant/abutment displacement following torqueing and to compare differences in torque values before and after cyclic loading across the two groups ($\alpha = 0.05$).

Hypothesis:

H_{o1}: There would be no statistically significant difference in the axial displacement of abutments as measured by 3D DIC between the conical internal connection and conical/hex internal connection narrow diameter implants.

H_{o2}: There would be no statistically significant difference in the manufacturer recommended tightening torque delivered to the implant/abutment complex before cyclic loading and the reversal or removal torque values obtained after cyclic loading for either the conical internal connection or conical/hex internal connection narrow diameter implant systems.

Results: The mean displacement in the U direction (X-axis) for the AST group and ZIM Group were -0.7 µm (±8.7) and -4.7 µm (±11.0), respectively with no statistical difference between the groups in the U direction (P=.7253). The mean displacement in the V direction (Y-axis) for the AST group and ZIM Group were -37.0 µm (±29.0) and -150.0 µm (±33.0), respectively, with statistical difference between the groups (P<.0001). The mean displacement in the W direction (Z-axis) for the AST group and ZIM Group were -0.9 µm (±14.0) and -23.0 µm (±33.0) respectively with no statistical difference between the groups (P=.3472).

The mean torque value delivered by the Astra torque-limiting device with a concentration on the manufacturer recommended torque value setting of 25 Ncm (Dentsply Sirona/Astra Tech) was 31.11 Ncm (n=10, std error=1.19) with a lower 95% CL of 28.42 Ncm and an upper 95% CL Ncm of 33.79. The mean torque value delivered by the Zimmer torque-limiting device with a concentration on the manufacturer recommended torque value setting of 30 Ncm (Zimmer Biomet) was 34.29 Ncm (n=10, std error=0.05) with a lower 95% CL of 34.17 Ncm and an upper 95% CL Ncm of 34.41

During cyclic loading, 3 AST samples sustained catastrophic fractures and were not able to be used during reversal torque value measurements. A least squares mean of -8.77 Ncm (standard error = 1.78, DF = 4) representing the reversal torque values for the AST group was found following cyclic loading at 200 N at a rate of 2 Hz for 5 million cycles. A least squares mean of -14.24 Ncm (standard error = 1.28, DF = 7) representing the reversal torque values for the ZIM group was found after cyclic loading at 200 N at a rate of 2 Hz for 5 million cycles. Calculation of the preload efficiency yielded 28.1% for the AST group and 41.52% for the ZIM group.

Conclusions: Part I. Displacement

Within the limitations of this study, it can be concluded that:

1. Greater Abutment/Loading Cap Complex displacements were observed with the Internal Conical/Hex Connection Implant System (Eztetic™, Zimmer Biomet).
2. Greater Abutment/Loading Cap Complex displacements were observed with the internal connection system that required higher torque value (Eztetic™, Zimmer Biomet) to secure the abutment into the implant.
3. The Abutment/Loading Cap Complexes displaced significantly more in the V-axis in both implant systems (Osseospeed™ EV, Dentsply Sirona/Astra Tech and Eztetic™, Zimmer Biomet) with the Internal Conical/Hex Connection Implant System (Eztetic™, Zimmer Biomet) demonstrating statistically greater axial displacement.

Part II. Cyclic Loading and Preload Efficiency

Within the limitations of this study, it can be concluded that:

1. The implant made out of Ti Grade 5 Alloy (6Al-4V) (Eztetic™, Zimmer Biomet) had a higher survival than the implant made out of Ti Grade 4 (CP) (Osseospeed™ EV, Dentsply Sirona/Astra Tech) during cyclic loading.
2. Following cyclic loading of both internal conical and internal conical/hex connection implants the abutment screw lost a portion of its original torque value.
3. The internal conical/hex connection implant (Eztetic™, Zimmer Biomet) maintained preload more efficiently during cyclic loading than the internal conical connection implant (Osseospeed™ EV, Dentsply Sirona/Astra Tech).

Dedication

Dedicated to those who taught me to

Never Give Up

and more importantly to those who

Never Gave Up On Me

Acknowledgments

I would first like to thank The Ohio State University College of Dentistry and my program Director, Dr. Damian Lee, for giving me the opportunity to train, practice, and define myself as a Prosthodontist. These past three years have far exceeded my expectations and provided me with a foundation of knowledge that I look forward towards expanding upon in the future. Next, I would like to thank my advisor, Dr. Burak Yilmaz, for providing invaluable support throughout this project and always pushing me towards achieving more than I thought I was capable of. A special thank you to Dr. Edwin McGlumphy for his advice and guidance during my transition away from academics and into the workplace. I would like to thank Dr. Jeremy Seidt for his support, knowledge and resources during experimental testing. Additionally, I would like to that Dr. William Johnston and Dr. Robert Seghi for their statistical analysis, work ethic and tremendous support. Finally, I would like to thank David Kiser from Slagle-Kiser Dental Ceramics Inc. for his mastery of metal work and help during fabrication of custom loading caps.

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Fields of Study

Major Field: Dentistry

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Chapter 1. Introduction

The use of osseointegrated dental implants as a treatment option for the partially edentulous and completely edentulous patient has been extensively studied with long-term clinical data to support their high success rates (Zarb and Schmit, 1990, Adell et al., 1990, Hultin et al., 2000). These high success rates, especially in the edentulous jaws, have provided clinicians and researchers with the confidence needed to begin confronting more challenging clinical situations, namely the replacement of the single teeth (Jemt T, 1986). In today's practice the highly successful and predictable use of dental implants to replace a single missing tooth has made this the treatment option of choice for clinicians and patients all over the world (Hultin, 1997 , Jemt T., 1986, Fugazzotto PA., 1997, Henry, 1996).

Narrow-Diameter Implants (NDI)

Narrow-diameter implants range from 2.0 mm to 3.5 mm and should not be confused with the 1.8 to 2.0 mm diameter, machined-surfaced, "mini-implants" introduced in the 1990s for use as temporary, transitional devices to stabilize immediate prosthesis. Narrow-diameter implants (NDIs) are intended for placement in narrow alveolar ridges, anterior incisor tooth sites, between convergent tooth roots or restricted interdental spaces, and in sites with a thin alveolar crest (Polizzi et al., 1999 and Andersen et al., 2001). Recent evidence from systematic reviews shows survival rates for narrow-diameter implants that are comparable to those of standard diameter implants (Klein et al., 2014 and Sohrabi et al., 2012).

Complications

One common complication of the single unit implant-supported prosthesis is screw loosening, which can lead to prosthesis loosening and potential wear of the implant abutment connection (IAC). After 5 years the reported cumulative incidence of screw or abutment loosening is 12.7% (Jung, et al., 2008). Screw loosening of 37% of the Astra Osseospeed (conical connection) implants at 5 years was reported by Cha, et al., 2013, with 23/43 IACs loosening in the first 6 months. Introduction of an anti-rotational component within the conical IAC changes the biomechanical relationship compared to non-rotational conical IAC (Villarinho, et al., 2015). While some studies support the use of conical interfaces due to decrease micro-gap and inflammatory markers between the implant-abutment interface, other evidence suggests an increase in the micro-gap after cyclic loading (Blum, et al., 2015). Significant clinical issues including screw loosening, microbial invasion, and subsequent bone loss has sparked interest in exploring abutment settling and residual torque values after cyclic loading.

Screw Mechanics

As mentioned above, screw loosening continues to be one of the major complications encountered with implant restorations. An understanding of screw mechanics is necessary to help comprehend what contributes to this commonly encountered clinical situation. When an abutment is fixed to an implant by means of a screw, the resulting unit is referred to as a *screw joint* (McGlumphy et. al, 1998). By applying a torque to the screw, the screw elongates and produces a tension in the shank and threads of the screw. The *clamping force* is a result of the elastic recovery of the screw pulling the two parts together. *Preload* is defined as the initial load on the screw when a torque is applied and is equal in magnitude to the clamping force (McGlumphy et al., 1998). Within the oral cavity the screw joint is constantly under assault, and forces that attempt to separate the components are called *joint separating forces* (McGlumphy et al., 1998). Screw loosening occurs when the joint separating forces are greater than the clamping force. By minimizing joint separating forces, a maximal clamping force can be sustained preventing the screw from loosening.

The design of the conical IAC may be one of the causative factors promoting screw torque reduction and vertical settling with single tooth restorations (Yilmaz, et al., 2013). Vertical displacement, rotational freedom and angular deflection have all been identified as causative agents. All conical implant abutment connections (IAC) exhibit some degree of angular deformation and vertical displacement (Yilmaz et al., 2013). Studies report microgap changes, screw loosening, peri-implantitis, and potential bone loss with conical IAC's (Blum, et al., 2015). Studies have also shown that crestal cortical bone loss is reciprocal to dental implant diameter, with greatest stress at diameters below 3.5mm (Klein, 2014). The decreased side wall thickness of narrow platform implants makes them less able to withstand masticatory forces creating a higher risk of IAC movement and decreased residual tightening torque.

Zimmer Biomet – Eztetic™

The implant used in this study, the 3.1mm Eztetic™ Dental Implant System, features a new and unique implant-abutment connection. The Eztetic™ implant-abutment connection is a double internal "Friction-Fit" conical-and-hexagon connection with platform switch abutments. Previous studies evaluating Zimmer Biomet Tapered Screw Vent (TSV) implants with their proprietary MTX® coating placed primarily in maxillary jaws and under a variety of clinical conditions, report high survival rates demonstrating long-term integration. The 10-year cumulative survival rates as reported by Ormianer and Palti, 2012, were 99.3% for 137 TSV implants placed in periodontal patients and 100% for 35 TSV implants in healthy patients. Harel et al., 2013, reported in a 10-year retrospective study survival rates of 100% for 57 immediately loaded implants and 98.1% for 53 delayed-loaded implants. A third retrospective analysis of TSV implants (Ormianer et al., 2012) reported 100% survival for 65 implants immediately placed in extraction sockets compared to 99.1% for 108 implants placed into healed extraction sites. This series of studies established a successful history of use for the MTX® Surface as demonstrated by the TSV implant, a system which also features the conical "Friction Fit" connection. This conical connection has been subjected to dynamic loading in a comparative bench study and was shown to prevent bacterial leakage at the implant-abutment interface (Steinbrunner et al., 2005). The incorporation of a conical/hex "double friction fit" connection provides new opportunities to study this unique connection and evaluate whether or not it will help contribute to Zimmer Biomet's history of success.

Previous studies have shown that internal conical implant-abutment connections without platforms can have axial displacement of crowns during screw tightening (Yilmaz et al., 2013). This displacement may affect proximal contacts, incisal edge position, or occlusion. An implant design incorporating a conical/hex internal connection with a positive vertical stop could potentially prevent this unwanted axial displacement. This displacement could also occur during functional loading creating unsettling forces within the abutment-screw-implant complex potentially leading to torque dissipation, loss of pre-load and resulting loss of clamping force. The displacement and performance under loading of this recently introduced NDI (Eztetic™, Zimmer Biomet) currently has not been investigated. The purpose of this study was twofold. The first aim was to confirm previous finding and compare these results to the newly measured three-dimensional axial displacement of screw-retained single abutments with a recently introduced conical/hex internal connection NDI. The second aim was to compare applied clockwise or tightening torque values before and counter clockwise or reversal torque values after cyclic loading to calculate the preload efficiency of the systems following cyclic loading simulating 5 years of function (Gratton et al., 2001 and Cibirka et al., 2001).

H_{o1}: There would be no statistically significant difference in the axial displacement of abutments as measured by 3D DIC between the conical internal connection and conical/hex internal connection NDI.

H_{o2}: There would be no statistically significant difference in the manufacturer recommended tightening torque values obtained before cyclic loading and the reversal or removal torque values obtained after cyclic loading for either the conical internal connection or conical/hex internal connection NDIs.

Chapter 2. Materials and Methods

Implants, Abutments, and Hemispherical Loading Cap

Six 3.0 mm x 13 mm narrow diameter implants (NDI) with conical internal connections (Osseospeed EV, Dentsply Sirona/Astra Tech - AST) and six 2.9 mm x 13 mm narrow diameter implants (NDI) with conical/hex internal connections (Eztetic™, Zimmer Biomet - ZIM) were selected as test groups. Six corresponding prefabricated titanium abutments with conical internal connections (TiDesign™ EV 3.0mm, Dentsply Sirona/Astra Tech) and six with conical/hex internal connections (Contour Abutment Eztetic™ 2.9mm NP, Zimmer Biomet) were acquired from the original manufacturer. One abutment from each group was scanned using a Trios 3 intraoral scanner (3Shape, Copenhagen, Denmark) creating a standard tessellation language (.stl) file that was used for computer aided design (CAD)(MeshMixer, Autodesk, San Rafeal, CA, USA) of the hemispherical loading cap in accordance to ISO standard 14801:2007. The hemispherical loading cap was designed to be the combination of a screwable and cementable option ("screw-mentable"), which offered the advantages of firm fixation to the abutment while maintaining clear access to the abutment retaining screw. The loading caps were printed using castable resin (FormLabs 2, Somerville, MA, USA) and cast with base metal using traditional lost wax techniques (Slagle-Kiser Dental Ceramics, Inc., Reynoldsburg, OH, USA). Following casting, the fit of the loading cap onto the abutments was assessed using a vinyl polyether silicone material (Fit Checker Advanced, GC America, Alsip, IL, USA), and adjustment were made to assure full seating prior to luting. The finished hemispherical loading caps were luted to the prefabricated titanium abutments using a self-adhesive self-curing dental resin cement (SpeedCEM, Ivoclar Vivadent, Buffalo, NY, USA) and excess cement was removed and cleaned.

Implant Embedment

Twelve 10 mm x 15 mm glass-cloth reinforced epoxy resin rods (G10, National Electrical Manufactures Association, Rosslyn, Virgina, USA) were fabricated for embedment of each implant sample. G10 has an elastic modulus of 1,600 Mpa approximating published estimates for cancellous bone (1,507 Mpa) (Takahashi, et al., 1978). Osteotomy preparations corresponding to the respected implant diameters were made in the center of each rod to a depth of 10 mm and a vent hole placed at the apex. All implants were embedded into the G10 rod to a depth of 10 mm leaving the coronal most 3 mm of each implant exposed in accordance to ISO standard 14801:2007. Implants were fixated within the osteotomy preparations using a duel cured foundation material (Rock Core; Danville Materials, Anaheim, CA, USA) with a modulus of elasticity similar to that of bone mimicking osseointegration by filling in the spaces between the prepared sites and the implant surface (Passos, et al., 2013) (Figure 1).

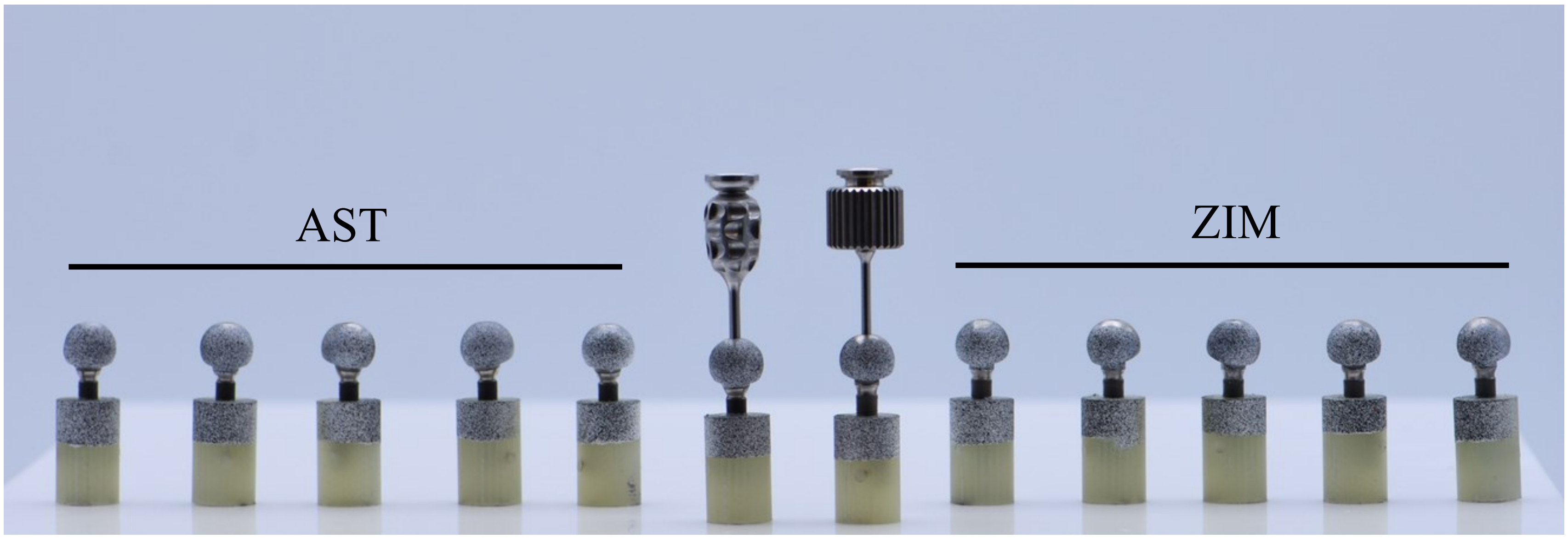


Figure 1. AST and ZIM sample preparations embedded in G10 resin rod with "screw-mentable" hemispherical loading cap and high contrast, non-repetitive, random dot pattern used during 3D DIC measurements.

Three-Dimensional Digital Image Correlation (3D DIC)

The spatial relationship of the abutment/hemispherical loading cap complex to the implant platforms was measured using three-dimensional digital image correlation (3D DIC). This optical measurement technique relies on calibrated digital images taken with two 1624 x 1224-pixel resolution cameras (GRAS-20S4 M) equipped with 35-mm lenses (Schneider-Kreuznach; Jobs. Schneider Optische Werke). The digital cameras were mounted on a custom fixation device on a tripod, fixed and focused on the abutment/hemispherical loading cap complex. The incorporation of two high-resolution cameras provided a synchronized stereo view of the test subjects during the experiment. Initial calibration of each camera was performed independently by taking images of the same 1-in. glass calibration grid from different views to establish a common world coordinate system. This world coordinate system was used as the basis for relating the image positions in both cameras to a common 3D location (Seidt, JD, 2010 & Yilmaz, Et al., 2018). A high contrast, non-repetitive, random dot pattern was applied to the surfaces of the abutment/hemispherical loading cap complex and G10 resin rod in order to create measuring points for the image correlation software (Vic-3D, 2009 Digital Image Correlation Version 2009.1.0, build RC 2009.448, Correlated Solutions, Inc. Columbia, SC, USA). Finally, by measuring this spatial relationship after hand tightening and then again after manufacture recommended final torque value the relative displacement between the two states could be derived (Figure 2).

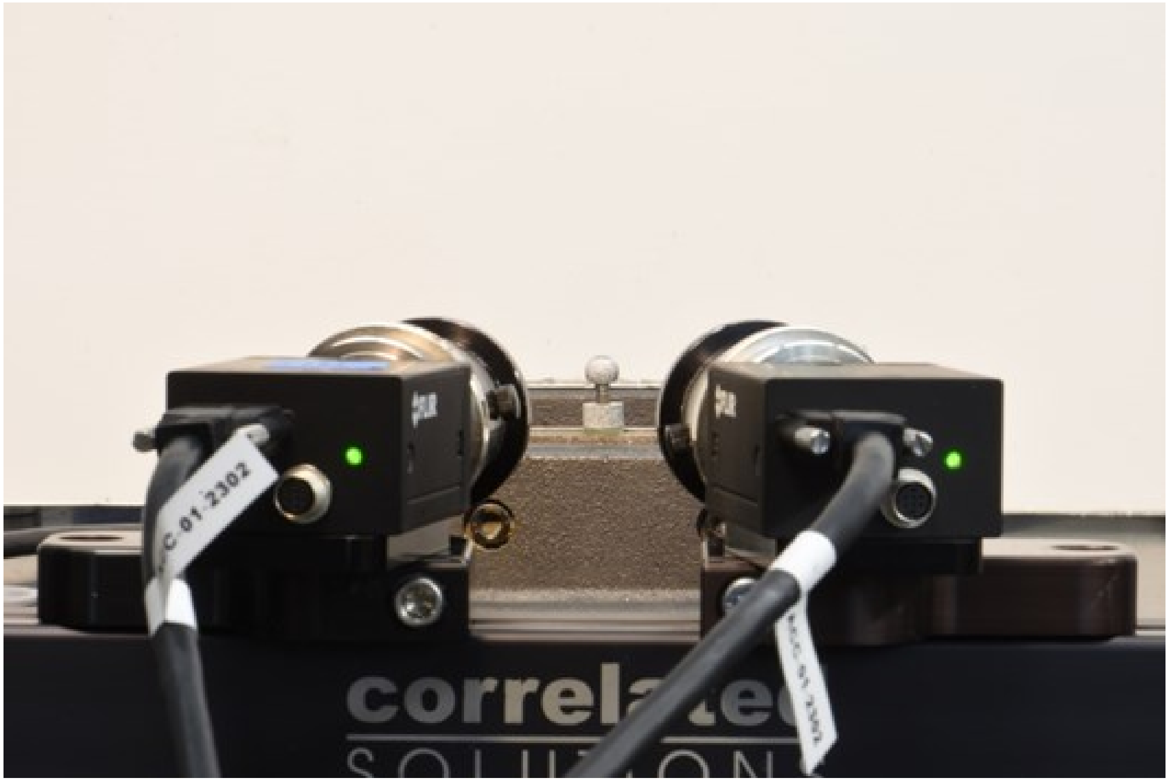


Figure 2. 3-Dimensional digital image correlation (3D DIC) test apperatus.

Torque Protocol

Adjustable torque-limiting devices from the original implant manufacturer (Lot # AST 0710196, Dentsply Sirona/Astra Tech and Lot # ZT0319, Zimmer Biomet) were used to deliver torque during testing to both groups (Figure 3). Both torque-limiting devices used were friction-style or toggle-type with a minimum value of 10 Ncm and adjustable with 5 Ncm demarcations. Based on previous studies, it has been shown that the average torque value a clinician can apply by hand is 15 Ncm and this served as the baseline hand torqued state and was delivered using the calibrated torque-limiting devices mentioned above (Alikhasi et al., 2016, Hill et al., 2007, and Kanawati et al., 2009). Following hand tightening to 15 Ncm, the first set of digital images were taken for the 3D DIC measurements. Each abutment/loading cap complex was then tightened to the manufacturer's recommended torque value (25 Ncm for Osseospeed EV, Dentsply Sirona/Astra Tech and 30 for Ncm Eztetic™, Zimmer Biomet) prior to capturing another set of digital images.

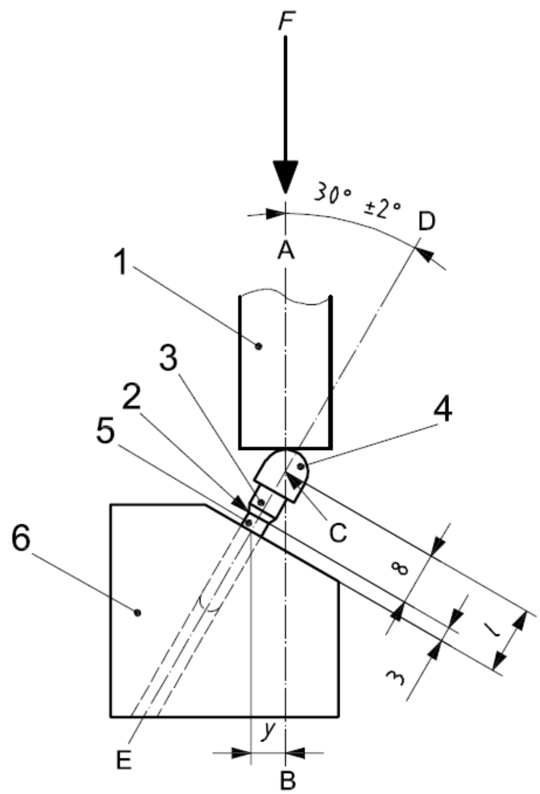
Figure 3. Astra (AST) and Zimmer (ZIM) adjustable friction-style torque limiting devices.

Digital Image Correlation Data Analysis

To analyze the data collected from the digital images taken by the two cameras, a commercial digital image correlation software (Vic-3D, 2009 Digital Image Correlation Version 2009.1.0, build RC 2009.448, Correlated Solutions) was used. This software used a preset data set that was defined on both the abutment/loading cap complex and the G10 resin rod based off of the random dot pattern generated. Then, two points were selected, one approximately in the middle of the abutment data set and the other on the G10 resin rod data set, approximately 11 mm directly below the first point. The 3-dimensional coordinates of these two points were extracted from the data following hand tightening to 15 Ncm and then again when the abutment/loading cap complex was torqued to manufacture recommended values, 25 NCm and 30 NCM for Osseospeed EV and Eztetic™ respectively. Relative displacement was calculated by subtracting the abutment/loading cap point coordinates from the G10 resin rod point coordinates to account for any possible movement between the camera setup and the table fixing the resin block during the test. The displacements were analyzed in the U, V, W coordinates. U direction represented a horizontal displacement along the x-axis or the abutment/loading cap displacing side-to-side, V represented a vertical displacement along the y-axis, or the abutment/loading cap displacing up-and-down, and the W direction represented displacement along the z-axis, or the abutment/loading cap displacing closer or further from the cameras.

Chewing Simulator

At the conclusion of the 3D DIC measurements, all samples were retrieved and mounted in 30 degree angled steel holder in accordance to ISO standard 14801:2007 (Figure 4) for cyclic loading on the *Seghi-matic Universal Chewing Simulator*. Cyclic loading was carried out on all specimens in air, at room temperature, at 2 Hz for 5 million cycles under a load of 200N simulating 5 years of functional loading (Gratton et al., 2001 and Cibirka et al., 2001).



Key

1 loading device [shall be allowed free movement transverse to loading direction (see 5.2.6)]

2 nominal bone level (see 5.3.2)

3 connecting part

4 hemispherical loading member

5 dental implant body

6 specimen holder

Figure 4. Schematic of ISO standard 14801:2007 test set-up for systems with no pre-angled parts.

Torque Wrench Setting Vs. Actual

Adjustable torque-limiting devices from the original implant manufacturer (Lot # AST 0710196, Dentsply Sirona/Astra Tech and Lot # ZT0319, Zimmer Biomet) were used to deliver torque during testing of both groups. To assess the reliability of the manufacturer recommended setting vs. the actual torque delivered to the screw both torque-limiting devices were tested using a digital torque gauge (Chatillon Model DFS2-R-ND, Ametek, Largo, Fla). Each torque-limiting device was tested for a total of ten observation at the manufacturer recommended torque values (25 Ncm and 30 Ncm for Osseospeed EV and Eztetic™), 1.25 Ncm below the recommended setting, and 1.25 Ncm below the recommended setting for a total of 30 observations per device.

Reversal/Removal Torque Value Measurement

Following completion of the cyclic loading all samples were retrieved and a digital torque gauge (Chatillon Model DFS2-R-ND, Ametek, Largo, Fla) was used to measure the peak counter-clockwise torque value that was needed to loosen the abutment screw (Figure 5). This peak counter-clockwise torque value, also known as the removal torque, was compared to the manufacture recommended initial torque values that were applied to the screw during the 3D DIC testing, to calculate “the pre-load efficiency.” Paepoemsin et al., 2016 defined and used the following formula for calculating “the preload efficiency.”

Preload Efficiency (%) = (Removal Torque / Tightening Torque) x 100

Figure 5. Measurement of peak counter-clockwise torque value (ie. removal or reversal torque).

Statistical Analysis

The displacement dataset was analyzed by a repeated measures ANOVA using the maximum likelihood estimation and the Satterthwaite methods (PROC MIXED, SAS® Proprietary Software 9.4, SAS Institute Inc., Cary, NC) with significant sources of variation involving more than 1 total degrees of freedom resolved by Student's t-tests corrected by the step-down Bonferroni method ($\alpha=0.05$). Only pairwise comparisons in each direction were considered relevant.

The torque wrench data was analyzed by a simple linear regression model viewing actual torque value registered on the digital torque meter as the dependent on torque wrench setting (PROC MEANS, SAS® Proprietary Software 9.4, SAS Institute Inc., Cary, NC) with a concentration on target manufacturer recommended torque values (25 Ncm and 30 Ncm for Osseospeed EV and Eztetic™).

The reversal torque values following cyclic loading were analyzed for least squares means using the restricted or residual maximum likelihood estimation (PROC MIXED, SAS® Proprietary Software 9.4, SAS Institute Inc., Cary, NC).

Chapter 3. Results

3D Digital Image Correlation – Displacement

The mean displacement for the Osseospeed EV (n=6) and Eztetic (n=6) NDIs were calculated following manufacturer recommended torque values, 25 Ncm and 30 Ncm respectively, in the U, V, and W directions.

The mean displacement in the U direction (X-axis) for the AST group and ZIM Group were -0.7 µm (±8.7) and -4.7 µm (±11.0), respectively with no statistical significance between the groups in the U direction (P=.7253).

The mean displacement in the V direction (Y-axis) for the AST group and ZIM Group were -37.0 µm (±29.0) and -150.0 µm (±33.0), respectively with statistical significance between the groups (P<.0001).

The mean displacement in the W direction (Z-axis) for the AST group and ZIM Group were -0.9 µm (±14.0) and -23.0 µm (±33.0), respectively with no statistical significance between the groups (P=.3472).

Mean displacement values and their associated confidence intervals for both groups, in the three directions, were presented in Figure 6. Statistical analysis using repeated ANOVA were presented in Table 1.

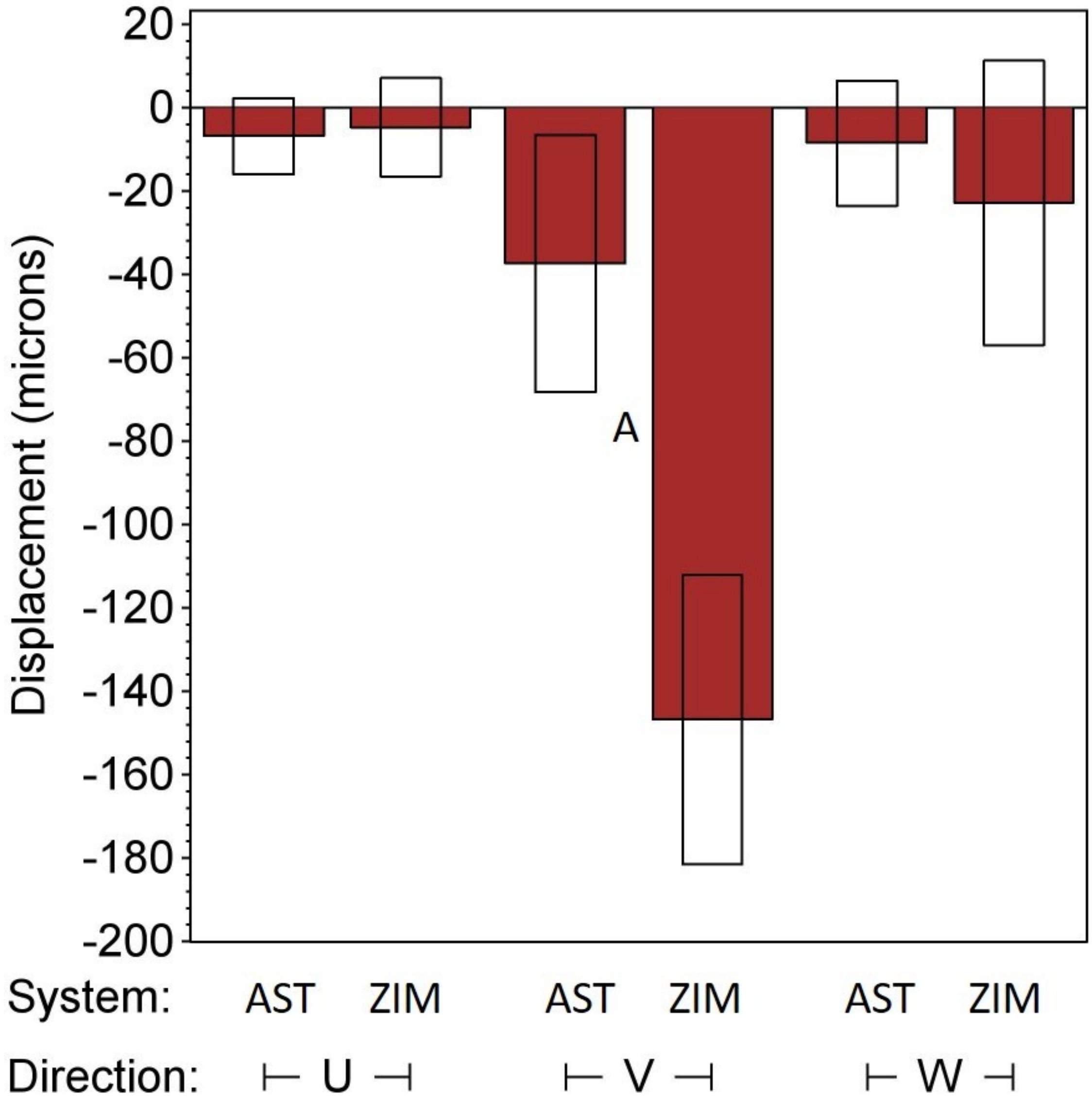


Figure 6. Mean Displacement of AST and ZIM Abutment/Loading Cap Complex with confidence intervals in U, V, and W directions in Osseospeed EV and Eztetic™ implant systems. A single uppercase letter indicates the two groups which were found to be significantly different (P<0.0001)

Source of Variation	Degrees of Freedom		F-ratio	P-value
	Numerator	Denominator		
System	1	10	21.44	0.0009
Direction	2	20	52.33	<.0001
System x Direction	2	20	21.23	<.0001

Table 1. ANOVA table showing interaction between the effects of the system and direction of displacement. A significant interaction was found (dfN=2, dfD=20, F=21.23, P,.0001).

Manufacturer Recommended Torque Value Verification

The mean torque value delivered by the Astra torque-limiting device with a concentration on the manufacturer recommended torque value setting of 25 Ncm (Dentsply Sirona/Astra Tech) was 31.11 Ncm (n=10, std error=1.19) with a lower 95% CL of 28.42 Ncm and an upper 95% CL Ncm of 33.79.

The mean torque value delivered by the Zimmer torque-limiting device with a concentration on the manufacturer recommended torque value setting of 30 Ncm (Zimmer Biomet) was 34.29 Ncm (n=10, std error=0.05) with a lower 95% CL of 34.17 Ncm and a upper 95% CL Ncm of 34.41.

Survival

During cyclic loading three of the AST samples sustained catastrophic fractures (Figure 7). Sample 4 was the first to fracture at approximately 256,260 cycles, followed by sample 3 at approximately 278,600 cycles, and finally sample 5 at approximately 788,650 cycles. All ZIM samples survived the cyclic loading portion of the study as shown in survival curves shown in figure 8. No statistically significant difference was found between groups ($P = 0.0578$).

Figure 7. Fractured AST samples and approximate cycle number when fracture was sustained.

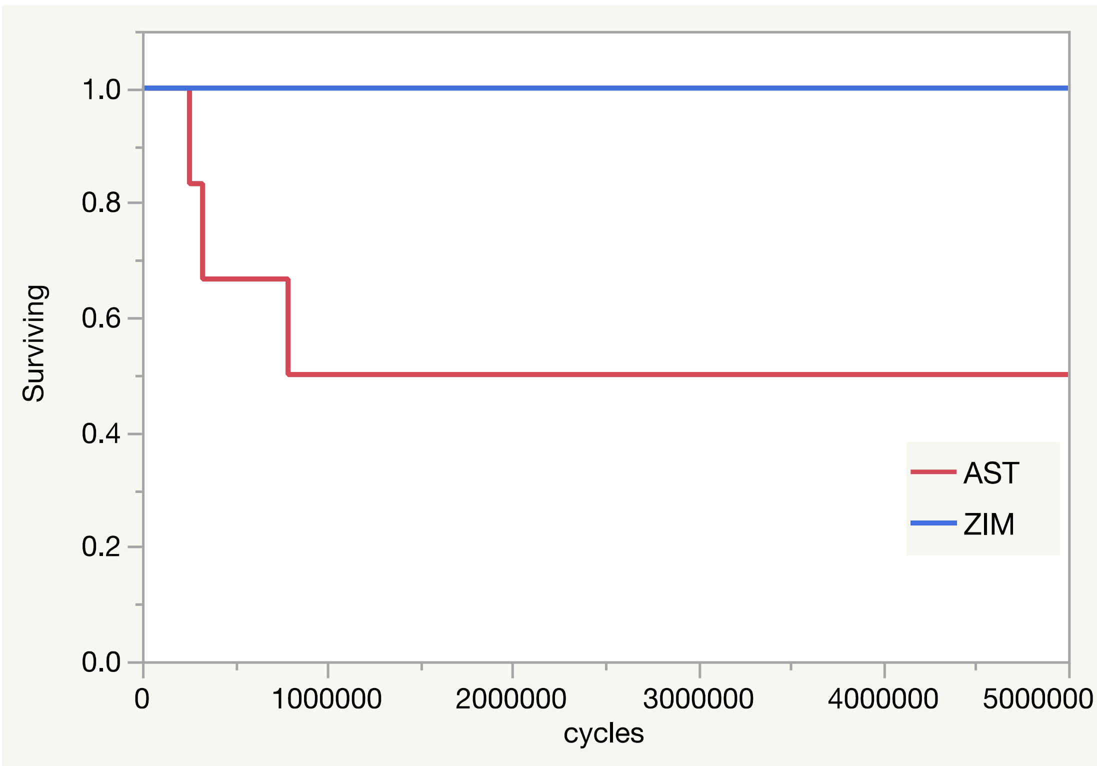


Figure 8. Survival curves following cyclic loading of AST and ZIM samples. No statistically significant difference was found between groups (P = 0.0578).

Reversal Torque

A least squares mean of -8.77 (standard error = 1.78, DF = 4) representing the reversal torque values for the AST (n=3) group was found following cyclic loading at 200 N at a rate of 2 Hz for 5 million cycles.

A least squares mean of -14.24 (standard error = 1.28, DF = 7) representing the reversal torque values for the ZIM (n=6) group was found following cyclic loading at 200 N at a rate of 2 Hz for 5 million cycles.

Preload Efficiency Calculations

Paepoemsin et al., 2016 defined and used the following formula for calculating "the preload efficiency:"

Preload Efficiency (%) = (Removal Torque / Tightening Torque) x 100

AST Preload Efficiency (%) = (8.7667 Ncm / 31.108 Ncm) x 100

AST Preload Efficiency = 28.18%

ZIM Preload Efficiency (%) = (14.24 Ncm / 34.29 Ncm) x 100

ZIM Preload Efficiency = 41.52%

Chapter 4. Discussion

The first part of this in vitro study evaluated the 3-dimensional displacement of prefabricated abutments between the hand tightened state and final manufacturer recommended torque value state of two different implant systems. The null hypothesis, which stated that there would be no statistically significant difference in the axial displacement of abutments as measured by 3D DIC between the conical internal connection and conical/hex internal connection narrow diameter implant was rejected.

The rejection of this hypothesis was based on the results of the multi-factorial ANOVA, which showed a significant interaction between the effects of the System (Astra and Zimmer) and the Direction (U, V, and W) of the Displacement. Further analysis on the effect of the System in each of the 3 Directions, also found a statistically significant difference in the V direction (axial) between the 2 Systems (Astra and Zimmer) studied.

These findings have been previously reported in studies by Yilmaz B, et al., 2013, 2014, and 2017, which evaluated the displacement of implant superstructures into internal connection implants using a variety of different torque values, abutment materials and splinted vs. non-splinted designs. These studies demonstrated that a mean vertical displacement of $\approx 43\mu m$ was found between the hand tightened and torqued states in a conical connection system. Furthermore, it was stated that a displacement of this magnitude could result in esthetic and functional deficits. Yilmaz B, et al., 2015 also evaluated the displacement of internal hex friction fit abutments following initial and repeated torqueing. This study failed to show a statistically significant differences for mean vertical displacement between abutments tested with the largest mean vertical displacement $\approx 5\mu m$ and smallest mean vertical displacement $\approx 3\mu m$ being reported.

One of the goals of this study was to investigate the displacement of the newly introduced conical/hex internal connection design to see if the incorporation of an internal hexagon would provide a vertical stop limiting the amount of vertical displacement previously reported in studies evaluating conical connection implants. Interestingly, the mean displacements in the V direction (Y-axis) for the samples tested was -150 μm (±33.0) for the internal conical hex and -37.0 μm (±29.0) for the internal conical connections. The displacement results for the internal conical connection implants corresponded well with previous studies evaluating this system (Yilmaz et al., 2012), however the mean vertical displacement of the conical hex internal connection reported was many orders of magnitude greater than previously reported displacement values (Yilmaz et al., 2015).

One possible explanation for this finding could be the different manufacturer recommended final torque values delivered to each system. The internal conical connection system required 25Ncm. Whereas, the internal conical hex connection required 30Ncm. Displacement as it relates to torque values have been previously reported by Dailey B, et al., 2009 who found a continuous vertical (axial) displacement of abutments into the implant occurred as the torque value on the abutment screw increased. Furthermore, Yilmaz B, et al., 2017, found that internal connection systems that require higher torque value to secure the abutment into the implant demonstrate greater abutment displacement. Finally, the connection design features a “double friction fit.” Due to multiple mating surfaces in close frictional contact with one another it is possible that the hand tightened state was not able to overcome this friction and seat the abutment vertically as much as a standard conical connection. This could possibly have created space that the abutment could be displaced axially as the final manufacturer recommended torque value was applied.

The second part of this in vitro study evaluated the performance of these two different connections during cyclic loading and the ability of their abutment screws to maintain preload. The second null hypothesis, which stated that there would be no statistically significant difference in the manufacturer recommended tightening torque values obtained before cyclic loading and the reversal or removal torque values obtained after cyclic loading for either the conical internal connection or conical/hex internal connection narrow diameter implant systems, was also rejected.

There were concerns regarding the accuracy of the manufacturer recommended torque limiting device used during this study. Previous studies suggested that the torque delivered by a torque wrench should be within ±10% of the target value (Mahshid M et al., 2012), which was also support by Standlee et al., 2002, who reported the mean torque values of new friction-style and spring-style torque wrenches were found to be within 10% of their target torque values. The mean torque value delivered by the Astra torque-limiting device with a concentration on the manufacturer recommended torque value setting of 25 Ncm (Dentsply Sirona/Astra Tech) was 31.11 Ncm and the mean torque value delivered by the Zimmer torque-limiting device with a concentration on the manufacturer recommended torque value setting of 30 Ncm (Zimmer Biomet) was 34.29 Ncm. Mean torque values for both systems exceeded the 10% threshold previous reported as an acceptable range, but this measurement was taken in hopes of providing a more accurate representation of the torque value delivered to the abutment screw during experimental testing.

As a quantitative way of comparing torque values before and after cyclic loading Paepoemsin et al., 2016 defined the term "preload efficiency" and calculated it using the following formula:

Preload Efficiency (%) = (Removal Torque / Tightening Torque) x 100

This group tested three different implant systems with three different abutment screws and concluded that the preload efficiency in all groups decreased significantly (Paepoemsin et al., 2016). The results from the current study showed that the internal conical/hex system (ZIM) more efficiently maintained its preload when compared to the internal conical system (AST).

Within the two groups tested during this study, there were variations between the abutment screw design. Previous studies by Shetty et al., 2014 and Caselli MA, 2013 evaluated tapered-head and flat-head screws ability to maintain preload. Their results demonstrated that flat-head screws were preferable for preload maintenance due to more even force distribution within the screw and head of the screw. Additionally, previous studies by Binon PP, 2000, evaluated screw stem length and concluded that long stem length provided more favorable elongation during preload development. The two attributes mentioned above are found within the Zimmer abutment screw and not the Astra abutment screw. Finally, the newly designed "double friction fit" Zimmer Eztetic^{TM} connection could also potentially provide for a more stable joint, which was able to resist unsettling forces during cyclic loading that would be unfavorable for preload maintenance in the screw joint complex.

There were several limitations within this current in vitro study that deserve discussion. The first being the small sample size, which got reduced even further due to catastrophic fractures of 3 of the AST samples. A larger sample size would aid in further strengthening the statistical analysis and reported results. A second limitation was the uncertainty regarding accuracy and validity of the torque-limiting device setting and actual delivered torque value. This required extra attention and statistically derived mean values that were used for calculation. Repeating this experiment and utilizing a standardized device to deliver more precise manufacturer recommended final torque values would aid in strengthening the results obtained. Finally, results derived from this in vitro study should be interpreted with caution and corroborated with clinical prospective/retrospective evaluations to further observe the effects of internal connection designs within implant restorations.

Chapter 5. Conclusions

Part I. Displacement

Within the limitations of this study, it can be concluded that:

1. Greater Abutment/Loading Cap Complex displacements were observed with the Internal Conical/Hex Connection Implant System (Eztetic™, Zimmer Biomet).
2. Greater Abutment/Loading Cap Complex displacements were observed with the internal connection system that required higher torque value (Eztetic™, Zimmer Biomet) to secure the abutment into the implant.
3. The Abutment/Loading Cap Complexes displaced significantly more in the V-axis in both implant systems (Osseospeed™ EV, Dentsply Sirona/Astra Tech and Eztetic™, Zimmer Biomet) with the Internal Conical/Hex Connection Implant System (Eztetic™, Zimmer Biomet) demonstrating statistically greater axial displacement.

Part II. Cyclic Loading and Preload Efficiency

Within the limitations of this study, it can be concluded that:

1. The implant made out of Ti Grade 5 Alloy (6Al-4V) (Eztetic™, Zimmer Biomet) had a higher survival than the implant made out of Ti Grade 4 (CP) (Osseospeed™ EV, Dentsply Sirona/Astra Tech) during cyclic loading.
2. Following cyclic loading of both internal conical and internal conical/hex connection implants the abutment screw lost a portion of its original torque value.
3. The internal conical/hex connection implant (Eztetic™, Zimmer Biomet) maintained preload more efficiently during cyclic loading than the internal conical connection implant (Osseospeed™ EV, Dentsply Sirona/Astra Tech).

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