

**COMPARATIVE EVALUATION OF THE EFFECT
OF CYCLIC LOADING ON THE ABUTMENT
SCREW LOOSENING OF PREMACHINED AND
CUSTOM CAST ANGLED IMPLANT ABUTMENTS
– AN *IN VITRO* STUDY**

Dissertation Submitted to

THE TAMILNADU Dr. M.G.R. MEDICAL UNIVERSITY

In partial fulfillment for the Degree of

MASTER OF DENTAL SURGERY



**BRANCH I
PROSTHODONTICS AND CROWN & BRIDGE
APRIL 2016**

**THE TAMILNADU Dr. M.G.R. MEDICAL UNIVERSITY
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DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation titled
“COMPARATIVE EVALUATION OF THE EFFECT OF
CYCLIC LOADING ON THE ABUTMENT SCREW
LOOSENING OF PREMACHINED AND CUSTOM CAST
ANGLED IMPLANT ABUTMENTS – AN *IN VITRO* STUDY”
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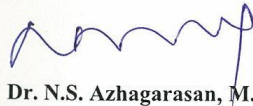
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CERTIFICATE

This is to certify that the dissertation titled "COMPARATIVE EVALUATION OF THE EFFECT OF CYCLIC LOADING ON THE ABUTMENT SCREW LOOSENING OF PREMACHINED AND CUSTOM CAST ANGLED IMPLANT ABUTMENTS – AN *IN VITRO* STUDY", is a bonafide record work done by Dr. SYED ERSHAD AHMED under our guidance and to our satisfaction during his post graduate study period between 2013 – 2016.

This dissertation is submitted to THE TAMILNADU Dr. M.G.R. MEDICAL UNIVERSITY, in partial fulfillment for the Degree of MASTER OF DENTAL SURGERY – PROSTHODONTICS AND CROWN & BRIDGE, BRANCH I. It has not been submitted (partial or full) for the award of any other degree or diploma.

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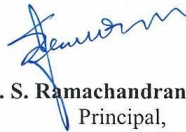
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CONTENTS

S.NO	TITLE	PAGE NO.
1.	INTRODUCTION	1
2.	REVIEW OF LITERATURE	9
3.	MATERIALS AND METHODS	16
4.	RESULTS	44
5.	DISCUSSION	57
6.	CONCLUSION	69
7.	SUMMARY	71
8.	BIBLIOGRAPHY	73
9.	ANNEXURES	

LIST OF TABLES

TABLE NO.	TITLE	PAGE NO.
1.	Basic and mean pre-cyclic loading Reverse Torque Values (pre-RTV ₁) of Group I test samples (25 ⁰ angled premachined titanium abutments)	45
2.	Basic and mean post-cyclic loading Reverse Torque Values (post-RTV ₁) of Group I test samples (25 ⁰ angled premachined titanium abutments)	46
3.	Basic and mean Reverse Torque Differences (RTD ₁) of Group I test samples (25 ⁰ angled premachined titanium abutments)	47
4.	Basic and mean pre-cyclic loading Reverse Torque Values (pre-RTV ₂) of Group II test samples (25 ⁰ angled custom cast cobalt chromium abutments)	48
5.	Basic and mean post-cyclic loading Reverse Torque Values (post-RTV ₂) of Group II test samples (25 ⁰ angled custom cast cobalt chromium abutments)	49
6.	Basic and mean Reverse Torque Differences (RTD ₂) of Group II test samples (25 ⁰ angled custom cast cobalt chromium abutments)	50
7.	Comparative evaluation of the mean pre- and post-cyclic loading Reverse Torque Value of Group I test samples using Paired 't' test (25 ⁰ angled premachined titanium abutments)	51

8. Comparative evaluation of the mean pre- and post-cyclic loading Reverse Torque Value of Group II test samples using Paired 't'test (25⁰ angled custom cast cobalt chromium abutments) 52
9. Comparative evaluation of the mean pre-cyclic loading Reverse Torque Values of Group I test samples (25⁰ angled premachined titanium abutments) (pre-RTV₁) and Group II test samples (25⁰ angled custom cast cobalt chromium abutments) (pre-RTV₂) using Independent 't' test 53
10. Comparative evaluation of the mean post-cyclic loading Reverse Torque Values of Group I test samples (25⁰ angled premachined titanium abutments) (post-RTV₁) and Group II test samples (25⁰ angled custom cast cobalt chromium abutments) (post-RTV₂) using Independent 't' test 54
11. Comparative evaluation of the mean Reverse Torque Difference values of Group I test samples (25⁰ angled premachined titanium abutments) (RTD₁) and Group II test samples (25⁰ angled custom cast cobalt chromium abutments) (RTD₂) using Independent 't' test 55

ANNEXURE I

METHODOLOGY- OVERVIEW

ANNEXURE II

CALIBRATION CERTIFICATE FOR CYCLIC LOADING MACHINE

ANNEXURE III

LIST OF FIGURES

Fig.No.	Title
Fig.1	: Titanium dental implant, standard platform, internal hexagon, 3.75mm diameter,10mm length
a	: Manufacturer packaging
b	: Vial containing implant
c	: Dental implant
Fig.2	: 25 ⁰ angled premachined titanium abutment, standard platform, internal hexagon
a	: Manufacturer packaging
b	: Abutment
Fig.3	: Titanium abutment screw for 25 ⁰ angled premachined titanium abutment
Fig.4	: Plastic cylinder (abutment) internal hex
a	: Manufacturer packaging
b	: Abutment
Fig.5	: Titanium abutment screw for Plastic cylinder (abutment)
Fig.6	: Hex driver

- Fig.7** : Spirit level indicators
- Fig.8** : Clear autopolymerising acrylic resin (monomer and polymer)
- Fig.9a** : Putty consistency – Polyvinylsiloxane impression material
- Fig.9b** : Light body consistency - Polyvinylsiloxane impression material
- Fig.9c** : Dispensing gun
- Fig.9d** : Auto mixing spiral
- Fig.9e** : Intra oral tips
- Fig.10a** : BP handle
- Fig.10b** : BP blade
- Fig.11** : Pattern resin (monomer and polymer)
- Fig.12a** : Sprue wax
- Fig.12b** : Silicone investment ring
- Fig.12c** : Crucible former
- Fig.12d** : Surfactant spray
- Fig.12e** : Colloidal silica
- Fig.12f** : Phosphate bonded investment material for Cobalt Chromium alloy
- Fig.13** : Cobalt chromium alloy (Co-Cr) pellets
- Fig.14** : Aluminum oxide powder - 110µm
- Fig.15a** : Carborundum separating discs and mandrel
- Fig.15b** : Tungsten carbide metal trimming burs
- Fig.15c** : Silicon rubber finishing wheels
- Fig.16** : Die lubricant
- Fig.17** : Inlay casting wax

- Fig.18** : PKT instruments
- Fig.19a** : Sprue wax
- Fig.19b** : Silicone investment ring
- Fig.19c** : Crucible former
- Fig.19d** : Surfactant spray
- Fig.19e** : Colloidal silica
- Fig.19f** : Phosphate bonded investment material for Nickel-Chromium alloy
- Fig.20** : Nickel chromium alloy(Ni-Cr)
- Fig.21** : Type I Glass Ionomer luting cement
- Fig.22a** : Mixing pad
- Fig.22b** : Agate spatula
- Fig.22c** : Plastic instrument
- Fig.22d** : Hand scaler, anterior
- Fig.23** : Fast setting epoxy compound
- Fig.24** : Dental surveyor
- Fig.25** : Milling unit with surveyor
- Fig.26** : Vacuum mixer
- Fig.27** : Burnout furnace
- Fig.28** : Induction casting machine
- Fig.29** : Sandblasting unit
- Fig.30** : High speed lathe (alloy grinder)
- Fig.31a** : Digital torque meter
- Fig.31b** : Torque meter adapter for attaching hex driver

- Fig.31c** : Interconnecting tool for attaching adapter to the torque meter
- Fig.32** : Line diagram of digital torque meter
- Fig.33** : Custom made Cyclic Loading machine
- Fig.34** : Custom made positioning jig
- Fig.35** : Line diagram of custom made Cyclic Loading machine
- Fig.36a** : Custom made stainless steel block
- Fig.36b** : Line diagram of custom made stainless steel block
- Fig.37** : 25⁰ angled premachined titanium abutment connected to implant
- Fig.38** : Surveying platform made parallel to floor using spirit level indicators
- Fig.39** : Positioning of implant-25⁰ angled premachined titanium abutment assembly in stainless steel block
- Fig.40a** : Implant with 25⁰ angled premachined titanium abutment secured in acrylic resin (Group I)
- Fig.40b** : Verification of level of secured implant
- Fig.41** : Milling of abutment
- Fig.42a** : Milled 25⁰ angled premachined titanium abutment
- Fig.42b** : 25⁰ angled premachined titanium abutment before and after milling
- Fig.43a** : Fabrication of silicone index over milled 25⁰ angled premachined titanium abutment
- Fig.43b** : Completed silicone index
- Fig.44a** : Attachment of plastic abutment on the implant
- Fig.44b** : Trimming of plastic abutment with BP Blade up to height of abutment screw
- Fig.45a** : Pattern resin applied in the silicone index

- Fig.45b** : Positioning of silicone index with pattern resin on the plastic abutment
- Fig.45c** : Retrieval of silicone index after setting of pattern resin
- Fig.46** : Duplicated 25⁰ angled plastic abutment with pattern resin
- Fig.47** : Spruing of pattern resin abutment
- Fig.48** : Investing the pattern resin abutment
- Fig.49** : Invested pattern resin abutment
- Fig.50** : Burnout of pattern resin abutment
- Fig.51** : Casting done with Co-Cr alloy pellets using induction casting machine
- Fig.52** : Divested casting
- Fig.53** : Sandblasting of the casting
- Fig.54** : Trimming of the cast abutment
- Fig.55** : Finished abutment
- Fig.56** : 25⁰ angled custom cast Co-Cr abutment connected to implant
- Fig.57** : Surveying platform made parallel to floor using spirit level indicators
- Fig.58** : Positioning of implant-25⁰ angled custom cast abutment assembly in stainless steel block
- Fig.59a** : Implant with 25⁰ angled custom cast abutment secured in acrylic resin (Group II)
- Fig.59b** : Verification of level of secured implant
- Fig.60** : Application of die lubricant on the 25⁰ angled milled premachined titanium abutment
- Fig.61** : Wax pattern of central incisor with screw access hole on labial side for Group I sample
- Fig.62** : Fabrication of silicone index over wax pattern

- Fig.63a** : Completed silicone index for duplicating the wax pattern
- Fig.63b** : Sectioned silicone index for duplicating the wax pattern
- Fig.64a** : Pouring molten inlay into the silicone index
- Fig.64b** : Positioning of silicone index with inlay wax on the abutment
- Fig.64c** : Retrieval of silicone index after setting of wax
- Fig.64d** : Wax pattern on sample
- Fig.65** : Spruing the wax pattern
- Fig.66** : Investing the wax pattern
- Fig.67** : Invested wax pattern
- Fig.68** : Burnout of wax pattern
- Fig.69** : Casting of wax pattern with Ni-Cr alloy pellets using induction casting machine
- Fig.70** : Divested castings
- Fig.71** : Sandblasting
- Fig.72** : Trimming of crowns
- Fig.73** : Finished crown
- Fig.74** : Checking the fit of crown
- Fig.75** : Sealing the abutment screw access with wax
- Fig.76** : Mixed cement loaded in to crown of Group I and Group II samples
- Fig.77** : Crown cementation for Group I and Group II samples
- Fig.78** : Unscrewing the cemented crowns
- Fig.79** : Removal of excess cement from the crown abutment margin
- Fig.80a** : Group I test samples

- Fig.80b** : Group II test samples
- Fig.81** : Hex driver secured into the adapter of digital torque meter
- a** : Hex driver and adapter of digital torque meter
 - b** : Fast setting epoxy compound – base and catalyst
 - c** : Mixed Fast setting epoxy compound
 - d** : Hex driver secured into the adapter of digital torque meter with fast setting epoxy compound
- Fig.82** : Torquing of abutment screws to 35 Ncm
- Fig.83a** : Measurement of reverse torque values before cyclic loading in Group I test sample
- Fig.83b** : Measurement of reverse torque values before cyclic loading in Group II test sample
- Fig.84** : Retorquing of abutment screw to 35 Ncm prior to cyclic loading
- Fig.85a** : Cyclic loading in custom made cyclic loading machine
- Fig.85b** : Cyclic loading at 30⁰ angulation
- Fig.86a** : Measurement of reverse torque values after cyclic loading in Group I test sample
- Fig.86b** : Measurement of reverse torque values after cyclic loading in Group II test sample

ANNEXURE IV

LIST OF GRAPHS

GRAPH. NO	TITLE
1.	Basic pre-cyclic loading Reverse Torque Values (pre-RTV ₁) of Group I test samples (25 ⁰ angled premachined titanium abutments)
2.	Basic post-cyclic loading Reverse Torque Values (post-RTV ₁) of Group I test samples (25 ⁰ angled premachined titanium abutments)
3.	Basic Reverse Torque Differences (RTD ₁) of Group I test samples (25 ⁰ angled premachined titanium abutments)
4.	Basic pre-cyclic loading Reverse Torque Values (pre-RTV ₂) of Group II test samples (25 ⁰ angled custom cast cobalt chromium abutments)
5.	Basic post-cyclic loading Reverse Torque Values (post-RTV ₂) of Group II test samples (25 ⁰ angled custom cast cobalt chromium abutments)
6.	Basic Reverse Torque Differences (RTD ₂) of Group II test samples (25 ⁰ angled custom cast cobalt chromium abutments)
7.	Comparative evaluation of the mean pre- and post-cyclic loading Reverse Torque Values of Group I test samples (25 ⁰ angled premachined titanium abutments) using Paired 't' test
8.	Comparative evaluation of the mean pre- and post-cyclic loading Reverse Torque Values of Group II test samples (25 ⁰ angled custom cast cobalt chromium abutments) using Paired 't' test

9. Comparative evaluation of the mean pre-cyclic loading Reverse Torque Values of Group I test samples (25^0 angled premachined titanium abutments) (pre-RTV₁) and Group II test samples (25^0 angled custom cast cobalt chromium abutments) (pre-RTV₂) using Independent 't' test
10. Comparative evaluation of the mean post-cyclic loading Reverse Torque Values of Group I test samples (25^0 angled premachined titanium abutments) (post-RTV₁) and Group II test samples (25^0 angled custom cast cobalt chromium abutments) (post-RTV₂) using Independent 't' test
11. Comparative evaluation of the mean Reverse Torque Difference values of Group I test samples (25^0 angled premachined titanium abutments) (RTD₁) and Group II test samples (25^0 angled custom cast cobalt chromium abutments) (RTD₂) using Independent 't' test

Introduction

INTRODUCTION

The successful treatment of patients with implants during the past twenty five years has significantly influenced restorative dentistry treatment planning.^{3,18,27,29,46,54,58} Clinical evidence has shown excellent long term results for osseointegrated implants with a success rate above 90%.^{5,17,37,50} Despite such high success rates, clinical complications do occur as reported in the literature.^{1,2,4, 5, 6, 9, 18, 19, 21,22,27 -30,33- 44,57,60, 64}

Mechanical complications are the most common complications that can lead to implant failure^{15,19,21,27,29,30,33-37,44,47,52,57,58} and include preload reduction, rotational misfit, fracture of the abutment screw and screw loosening among others. Of the above, the most common problem is loosening and fracturing of screws.^{6,9,19,21,22,27,29,33,34,37,41,42,48} Screw loosening may be an early warning of inadequate biomechanical design and/or occlusal overloading. Screw loosening can cause complications like formation of granulation tissue between loose abutment and implant, leading to soft tissue infection.^{19,60}

In order to overcome this problem, the mechanics involving with the screw joint has to be understood first. Clinicians must recognize the possible forces that will be acting on the screw joint, so that screw loosening and the other possible complications are minimized or avoided.

The important mechanical factor that prevents abutment screw loosening is screw joint preload.^{8,9,60,63,64} Dental implant screw joint consists of 3 components, namely, implant body, abutment and abutment screw as defined by McGlumphy et al.⁴⁶ The screw is tightened by applying torque which develops a force within the screw called the “preload”.^{8,9,21,34,46,61} When the screw is tightened, there is elongation in the screw thereby producing tension from the elastic recovery of the screw. This elastic recovery of the screw pulls the other two parts together creating a clamping force. This preload is equal in magnitude to the clamping force and keeps the screw threads tightly secured to the screw’s mating counterpart.^{2,5,6,19,25,28,34,52,56,60,63} Too little or too high torque may allow separation of joint, resulting in screw fatigue, loosening and failure or may lead to stripping of threads respectively.^{60,61}

The screw loosens only if outside forces trying to separate the parts are greater than the force keeping the components together. Forces attempting to disengage the parts are called joint separating forces. These forces must remain below the threshold of the established clamping force. Clinically, the screw joint within an implant prostheses is constantly subjected to external joint separating forces such as, off axis occlusal contacts, interproximal contacts between natural teeth and implant restoration, protrusive contacts, parafunctional forces and non passive framework that attaches to the implant.^{22,27,29,34,56,60}

Preload must be maintained and should fluctuate as little as possible to prevent the joint from separating and can be influenced by component and screw materials, torque delivery systems, manufacturer quality control, screw joint design, surface roughness and fatigue. It has been reported that 2-10% of the initial preload is lost as result of settling effect of the abutment screws.^{22,25,29,33,34,56,61}

Settling effect (embedment relaxation) plays a critical role in screw stability and it is a significant mechanism that causes loss of preload leading to screw loosening.^{56,61} Friction on the screw threads also results in loss of preload⁶. Settling occurs when the micro rough areas of the abutment screws flatten under load resulting in loss of contact between screw and implant.^{34,56,61} To compensate the preload loss from settling effect, several researchers have studied the screw tightening methods to regain the preload. Most of them have recommended that one time retightening of the abutments, 10 minutes after initial torque applications should be performed routinely during abutment implant connection and this is routinely followed protocol in most clinical and *in vitro* studies.^{22,34,56,61} Specific torque is recommended for abutment screws of different implant systems by different manufactures to maintain adequate contact between the screw and the implant, thereby reducing screw loosening.^{22,56,61}

Screw loosening has been reported for all types of prostheses including single and multiple unit restorations, irrespective of whether the connection is

external or internal.^{19,33,37-44,47,48} It is mainly caused due to inadequate tightening and other factors such as nature and design of the screw, wide occlusal table, poorly fitting components, bone remodeling, non-axial loading and bruxism.^{19,56} In the anterior region, regardless of occlusal philosophy, the palatal surfaces of the maxillary teeth provide a vertical ramp for the mandibular anterior teeth through protrusive and lateral excursions. Thus, most occlusal loads applied are at an angle to the long axis of implants which can result in screw loosening.^{10,27,29,56}

When the anterior teeth are lost in maxillary arch, the change in bone morphology often dictates placement of implants with long axis in exaggerated angulations to satisfy space and esthetic needs. Anatomic constraints such as the width, height and angle of residual bony ridge, the presence of bony undercuts, the shape of the arch and the maxillomandibular arch relationships influence placement of implants in less than ideal positions. Angled abutments are considered as a suitable option in such situations and are commonly seen in anterior single implant restorations in maxillary arch.^{1,10,22,23,24,29-32,56} Angled abutments can be either pre machined or custom cast. A variety of pre machined angled abutments are available at predetermined divergence angle ranging from 0 to 45 degrees and selection of a particular angled abutment is primarily governed by the angulations of the implant and available inter occlusal space.^{10,22,23,28-30,32,56,59} Clinicians can restore the implant either with premachined angled abutments or custom cast

angled abutments and these custom cast abutments can be cast in a variety of alloys such as titanium, gold, palladium, nickel-chromium, cobalt-chromium.^{29,33,37} A previous study comparing premachined and cast straight abutments concluded that machined abutments retain a significantly greater percentage of torque compared with cast abutments and casting procedures decrease the percentage of applied torque, which may influence final screw joint stability.³⁷ Some of the photo elastic and 3-D finite element studies have shown the various degrees of stress pattern in the bone around the implants placed in the anterior maxilla when restored with angled abutments but the evidence of mechanical failures were lacking in these studies.^{11,13,14,27} Studies comparing the screw loosening of premachined angled and custom cast angled abutments before and after cyclic loading in single implant situations in the anterior maxilla are lacking.

During function, clinical loading may result in micro motion in the stable implant screw joint, which contributes to screw loosening and subsequent loss of preload.^{22,63} Reverse torque value (RTV) is a measure of resistance offered by the torqued abutment screw to loosening. It is the measure of the remaining preload in the abutment screw after torque tightening and /or loading. Measurement of reverse torque value has been accomplished using torque meters which can be either analog^{4,5,22} or digital^{8,9,15,42} types. The digital type has better accuracy levels coupled with the advantage of data storage compared to the analogue type.

Cyclic loading tests have been employed in in vitro studies to simulate clinical loading conditions and their possible impact on the preload of abutment screw.^{4,5,21,22,29,42,43,57} Cyclic loading tests have been conducted using axial^{4,5,60} and non axial^{21,22,29,41,42,43} loads. Clinically, the off axial loading often experienced in the anterior maxillary incisal region leads to more stresses than axial loading, leading to more stress around implant ultimately resulting in micro motion of screw joint assembly, screw loosening and micro gapformation.^{29,31,39,55,56,57,64} Thus off axial cyclic loading is a logical means of testing the abutment screw loosening in vitro.

In the light of the above, the aim of the present in vitro study was to comparatively evaluate the effect of cyclic loading on abutment screw loosening of 25° angled premachined titanium abutments with that of 25° angled custom cast cobalt chromium (Co-Cr) abutments.

The null hypothesis for the present study was that abutment screw loosening will remain equal despite differences in mode of abutment fabrication for a given angulation of abutment.

The objectives of the present study included the following:

1. To measure the Reverse Torque Values of abutment screws for 25⁰ angled premachined titanium abutments before cyclic loading. (Group I pre-RTV₁)
2. To measure the Reverse Torque Values of abutment screws for 25⁰ angled premachined titanium abutments after cyclic loading. (Group I post-RTV₁)
3. To obtain the Reverse Torque Difference (RTD) of abutment screws for 25⁰ angled premachined titanium abutments. (Group I RTD₁)
4. To measure the Reverse Torque Values of abutment screws for 25⁰ angled custom cast cobalt chromium abutments before cyclic loading. (Group II pre-RTV₂)
5. To measure the Reverse Torque Values of abutment screws for 25⁰ angled custom cast cobalt chromium abutments after cyclic loading. (Group II post-RTV₂)
6. To obtain the Reverse Torque Difference (RTD) of abutment screws for 25⁰ angled custom cast cobalt chromium abutments. (Group II RTD₂)
7. To compare the mean Reverse Torque Value of abutment screws for 25⁰ angled premachined titanium abutments before and after cyclic loading. (Group I pre-RTV₁ with post-RTV₁)

8. To compare the mean Reverse Torque Value of abutment screws for 25⁰ angled custom cast cobalt chromium abutments before and after cyclic loading. (Group II pre-RTV₂ with post-RTV₂)
9. To compare the mean Reverse Torque Value of abutment screws for 25⁰ angled premachined titanium abutments with 25⁰ angled custom cast cobalt chromium abutments before cyclic loading. (pre-RTV₁ with pre-RTV₂)
10. To compare the mean Reverse Torque Value of abutment screws for 25⁰ angled premachined titanium abutments with 25⁰ angled custom cast cobalt chromium abutments after cyclic loading. (post-RTV₁ with post-RTV₂)
11. To compare the mean Reverse Torque Difference of abutment screws for 25⁰ angled premachined titanium abutments with 25⁰ angled custom cast cobalt chromium abutments. (RTD₁ with RTD₂)

Review of Literature

REVIEW OF LITERATURE

Lewis et al (1992)⁴⁴ reviewed the use of UCLA abutments in the Branemark implant system. It was concluded that UCLA abutment had various advantages over conventional titanium transmucosal abutment by overcoming problems of limited inter occlusal distance, inter proximal distance, implant angulations and soft tissue response with a good improvement in esthetics.

Burguete et al (1994)⁸ studied the significance of tightening characteristics for screwed joints in osseointegrated dental implants. Bickford's detailed description of screw loosening was quoted in the study. The necessity and means of achieving optimum torque to ensure a reliable joint in clinical practice was discussed.

Goheen et al (1994)²² evaluated the torque generated by handheld screwdrivers and mechanical torquing devices for osseointegrated implants in the Branemark implant system. It was concluded that care must be taken to ensure that components are not over or under tightened and concluded that calibrated torquing devices are mandatory if proper torquing procedures are to be accomplished.

Celletti et al (1995)¹¹ evaluated histologically, the forces acting on implants restored with pre angled abutments. They concluded that on histological

evaluation, the implants exhibited no adverse effects on surrounding bone. But due to non axial and bending forces acting on the prostheses of the implants, loss of components was seen by mechanical failure of abutment screws.

Dixon et al (1995)¹⁹ compared screw loosening, rotation and deflection among three implant designs: external hexagon, internal hexagon and internal octagon. Micro movements and torque levels required to loosen abutment screws were examined. Results showed no significant difference between the straight and angled abutments.

Balshi et al (1997)¹ conducted a three year evaluation of Branemark implants connected to angulated abutments. They highlighted need for angulated abutments to overcome compromised esthetic and functional results in site of complicated anatomy, especially in maxillary arch.

Sethi et al (2000)⁵⁵ studied the use of angulated abutments on patients who required replacing single and multiple teeth. Angulated abutments of 0 and 15 degrees in one group and between 20 and 45 degrees in other were used. They concluded saying that good aesthetics and functional outcomes were observed for both the groups.

Vigolo P et al (2000)⁶⁴ highlighted that vertical and horizontal misfits apply loads to the various restorative components which can result in abutment

screw loosening. The study demonstrated no significant alteration and they suggested that the risk of screw loosening could be reduced, if all laboratory procedures are observed carefully for castable UCLA type abutment.

Eger et al (2000)²¹ compared the clinical success of implants restored with angled abutments to implants restored with standard abutments and found that implants restored with angled and standard abutments, yielded no significant differences for any parameter at any time period.

Martin W et al (2001)⁴⁶ evaluated the effect of materials and surfaces of abutment screws on preload generation. The results showed that abutment screw removal torque values decrease with reduction in the coefficient of friction. Thus, a reduction in removal torque results in an increase in clamping forces.

Siamos G et al (2002)⁵⁶ determined whether varying the preload on the implant-abutment complex would affect screw loosening under simulated loading conditions. Retightening abutment screws 10 minutes after the initial torque applications and increasing the torque value for abutment screws above 30 Ncm could be beneficial for abutment-implant stability and to decrease screw loosening.

Winkler et al (2003)⁶¹ reviewed the mechanics of the implant screw and the concept of settling effect. The review emphasized the importance of optimal

abutment screw tightening and the importance of settling effect associated with the screw tightening procedure, it was concluded that to reduce the settling effect, implant screws should be retightened 10 minutes after the initial torque application as routine clinical procedure.

Michalakis et al (2003)⁴⁸ compared screw retained and cement retained prostheses based on the literature. Advantages, disadvantages and limitations of both the types were discussed and it was found out that several factors were needed for long term success of the implant prostheses, such as: ease of fabrication and cost, passivity of the framework, retention, occlusion, esthetics, delivery and retrievability.

HsuMing et al (2005)²⁸ reviewed the various clinical applications of angled abutments. Based on the literature, several conclusions were concluded, the stresses/strains generated through off axis loading increases as the abutment angulation increases, but there is no consensus as to what extent of angle increase implant and bone failure. Hence the authors opined that the clinical performances of angled abutments have been mostly satisfactory.

Kano et al (2006)³² compared the loss of applied torque (detorque) values in machined titanium and in cast UCLA type abutments. SEM analysis of the contact surface was conducted and it showed that cast abutments presented more roughness and irregularities than the machined abutments. They concluded that

the machined titanium abutments retained significantly greater percentage of applied torque than cast abutments values compared with all cast groups.

Theoharidou et al (2008)⁵⁹ did a systematic review on abutment screw loosening in single-implant restorations with different implant-abutment connection geometries and the results of the review showed that abutment screw loosening is a rare event in single - implant restoration regardless of the implant-abutment connection geometry, provided that proper anti rotational features and torque are employed.

Ha CY et al (2011)²⁵ compared the removal torque values (RTVs) of different abutments (straight, angled, and gold premachined UCLA-type) in clinical situation of the anterior maxilla. The angled abutment group showed significantly higher RTVs than the straight abutment and gold premachined UCLA-type abutment groups in external-hex implants. However, no significant difference in RTVs was found among abutments in internal-hex implants.

Cavallaro et al (2011)¹⁰ assessed the practicality of using angled abutments and also evaluated the damage caused by increased stress on implant prostheses and adjacent bone using photo elastic stress assessments, finite element analysis and strain gauge. There were complications arising when angled abutments are used to align prosthetic position. However, survival rates did not have significant clinical difference.

Kanchanapoomi T et al (2011)³¹ compared the effect of 3 screw tightening methods on screw loosening resistance for the implants. The abutment screws were tightened to the torque of 35Ncm. The fatigue loading (60N) was applied for 106 times. The reverse torque values were measured and they suggested the importance of the screw retightening method after 10 minutes of initial tightening.

Yao KT et al (2011)⁶³ studied the The effect of clockwise and counterclockwise twisting moments on abutment screw loosening.. The surface of the abutment hexagon corners were examined with SEM after loading. No abutment screw loosening was found after loading. It was concluded that there was little effect of twisting moment direction on the total torque loss of an internal hexagon connection implant system. This could be attributed to the anti-twisting mechanism of the internal hexagon connection

Junqueria M et al (2013)³⁰ evaluated the loss of applied torque (detorque) values in cast and pre-machined abutments for external hex abutment/implant interface of single implant-supported prostheses subjected to mechanical cycling. Detorque values were measured using the digital torque gauge. The difference of the initial (torque) and final (detorque) measurement was registered; it was be concluded that the mechanical cycling, reduced the torque of the samples regardless if cast or pre-machined UCLA abutments were used.

Kim et al (2013)⁴⁰ examined the effects of the abutment types and dynamic loading on the stability of implant prosthesis with three types of implant abutments prepared using different fabrication methods - stock abutments, gold cast abutments and CAD/CAM custom abutment, Removal torque both before and after dynamic loading were evaluated. They found that the abutment types did not have a significant influence on screw loosening for a loading time period of 10^5 cycles.

Chung et al (2015)¹⁷ examined the abutment screw stability of screw and cement retained implant supported dental prostheses after simulated cement washout as well as the stability of SCP cements after complete loosening of abutment screws. It was concluded, that the stabilities of SCP abutment screws and cement were not significantly changed after simulated cement wash out or screw loosening.

Materials and Methods

MATERIALS AND METHODS

The present *in vitro* study was conducted to comparatively evaluate the effect of cyclic loading on the abutment screw loosening of premachined and custom cast angled implant abutments.

The following materials and equipments were used for the study:

MATERIALS EMPLOYED

- Titanium dental implant, standard platform, internal hexagon, 3.75mm diameter, 10mm length (ADIN Dental Implants., Israel) (Fig.1)
- 25⁰ angled premachined titanium abutment, standard platform, internal hexagon (ADIN Dental Implants., Israel) (Fig.2)
- Titanium abutment screw for 25⁰ angled premachined titanium abutment (ADIN Dental Implants., Israel) (Fig.3)
- Plastic cylinder internal hex (ADIN Dental Implants, Israel) (Fig.4)
- Titanium abutment screw for plastic cylinder (ADIN Dental Implants., Israel) (Fig.5)
- Clear autopolymerizing acrylic resin (RR Cold Cure., DPI, India) (Fig.8)
- Polyvinylsiloxane impression material (Aquasil, Dentsply, Germany)
 - Putty consistency, regular set (Fig.9a)
 - Light body consistency, regular set (Fig.9b)

- Dispensing gun (Heraeus Kulzer, Dormagen, Switzerland) (Fig.9c)
- Auto mixing spirals (Yellow-70 mm, Adenta, USA) (Fig.9d)
- Intra oral tips (Yellow, Adenta, USA) (Fig.9e)
- Bp Blade (Glassvan India) (Fig.10b)
- Pattern Resin (GC Corporation, Tokyo, Japan) (Fig.11)
- Sprue wax (Ref 40085,Bego, Germany) (Fig.12a and 19a)
- Silicone investment ring (Sili Ring., Delta labs, Chennai, India) (Fig.12b and 19b)
- Crucible former (Sili Ring., Delta labs, Chennai, India) (Fig.12c and 19c)
- Surfactant spray (Aurofilm., Bego, Germany) (Fig.12d and 19d)
- Colloidal silica (Begosol., Bego, Germany) (Fig.12e and 19e)
- Phosphate bonded investment material for Cobalt Chromium alloy (Wirovest., Bego, Germany) (Fig.12f)
- Cobalt Chromium (Co-Cr) alloy pellets (Wironit., Bego, Germany) (Fig.13)
- Aluminum oxide powder, 110 μm (Korox, Alpha bond,Australia) (Fig.14)
- Die lubricant (Yeti Dental, Germany) (Fig.16)
- Inlay casting wax (GC Corporation, Tokyo, Japan) (Fig.17)
- Phosphate bonded investment material for Nickel Chromium alloy (Bellasun., Bego, Germany) (Fig.19e)

- Nickel Chromium (Ni-Cr) alloy pellets (Bellabond plus., Bego, Germany)
(Fig.20)
- Type I glass ionomer luting cement (powder and liquid) (GC Corporation.,
Tokyo, Japan) (Fig.21)
- Fast curing epoxy compound (Mseal, Pidilite Industries Ltd., India)
(Fig.23)

INSTRUMENTS USED:

- Hex driver (ADIN Dental Implants., Israel) (Fig.6)
- Spirit level indicators (Jinhua Hengda tools., China) (Fig.7)
- BP Handle (Hebbar surgical, Chennai, India) (Fig.10a)
- PKT instruments (Delta Labs, Chennai, India) (Fig.18)
- Carborundum separating discs and mandrel (Dentorium., New York,
U.S.A) (Fig.15a)
- Tungsten carbide metal trimming burs (Edenta., Switzerland) (Fig.15b)
- Silicon rubber finishing wheels (Dentsply., Germany) (Fig.15c)
- Mixing pad (GC Corporation., Tokyo, Japan) (Fig.22a)
- Plastic spatula (GC Corporation., Tokyo, Japan) (Fig.22b)
- Plastic instrument (API, Manipal, India) (Fig.22c)
- Hand scaler, anterior (API., Manipal, India) (Fig.22d)

EQUIPMENTS USED:

- Dental surveyor (Saeshin Precision Ind. Co., Korea) (Fig.24)
- Milling unit with surveyor attached (Bredent GmbH & Co.,Germany) (Fig.25)
- Vacuum mixer (Whipmix., Kentucky, U.S.A.) (Fig.26)
- Burnout furnace (Technico laboratory products Pvt. Ltd., Chennai, India) (Fig.27)
- Induction casting machine (Fornax, Bego, Germany) (Fig.28)
- Sandblaster (Delta labs., Chennai, India) (Fig.29)
- Alloy grinder (Demco., California, U.S.A.) (Fig.30)
- Digital torque meter (Screw Torque Checker., Model STC50CN, Tonichi Corporation, Tokyo, JAPAN) (Fig.31a)
- Torque meter adapter for attaching hex driver (Fig.31b)
- Interconnecting tool for attaching adapter to the torque meter (Fig.31c)
- Custom-made cyclic loading machine (Designed & Manufactured by Lokesh Industries, Chennai) (Fig.33)
- Custom-made positioning Jig (Designed & Manufactured by Lokesh Industries, Chennai) (Fig.34)

Description of the Digital Torque Meter (Fig.31)

In this study, a digital-type torque meter (Screw Torque Checker, Model STC50CN, Tonichi Corporation, and JAPAN) was used (Fig.31a). This device is shaped like a screw driver and is suitable for easy and accurate measurements in various inspection and tightening applications (ratchet function). The wireless Digital torque meter has a built in digital display which eliminates personal error. This device has the capacity to record from 10 to 50 Ncm. It has a high accuracy level of 0.05 Ncm, which helps to detect even small changes in torque values and has an inbuilt memory to store up to 100 readings. The stored data can be transferred to another storage device via a USB cable. The stored data is not deleted even if the power is turned off since it has an auto memory function from 0.5 to 5.0 seconds. It has an auto-power off function after 3 minutes. The above model was chosen based on its user-friendly design. A custom-made adapter (Fig.31b) was fabricated to attach the hex driver to the interconnecting tool of the torque meter (Fig.31c).

Description of the custom-made cyclic loading machine: (Fig.33)

In the present study, a cyclic loading machine was custom-made to simulate the components in function, which permitted analysis of possible interaction between the Reverse Torque Value and loading. It consisted of a motor with gearbox, which when rotated, compressed a spring. The spring applied

a load, which was transmitted to the test sample. The individual components and the calibration are described below:

Specification of motor:

90 watts, Single phase 230V, Continuous rating, motor giving 1350 RPM with gear reduction box of 1:18 giving a final RPM of 75(Swipe Industries, Pune, India).

Specification of spring:

Spring load spring ISO 10243:2010 (Special Springs, Rosa, Italy)

Hole diameter – 16 mm, Rod diameter – 8 mm

Free Length of spring – 38 mm

Spring constant – 48.5 N/mm

Specification of timer:

999 minutes timer with time memory (K-Pas, Chennai, India)

The motor was connected to an eccentric cam of 2.5 mm, which rotated when the motor was turned on. The 2.5 mm eccentric cam compressed a spring to the same length as it rotated generating a load of approximately 120N. The spring

transmitted the load to the stylus (3 mm diameter), which transmitted a lesser load of approximately 109 N to the sample due to energy loss.

Calibration of custom-made cyclic loading device:

The maximum and minimum loads delivered by the custom-made cyclic loading device were calibrated by a professional load calibration agency (Hi Tech Calibration Services, Chennai, India) (Annexure I).

Calibrated Results:

Auto mode : Max. Load: 105.8 N, Min. Load: 0.2N

Manual mode : Max. Load: 109.2 N, Min. Load: 0.2N

Description of Custom-made positioning Jig: (Fig.34)

The custom-made positioning jig was used to orient the sample for loading in the cyclic loading machine. The custom-made jig consists of a platform and bolt. The sample when placed in the jig platform is positioned at 30° angulation to the platform and can be secured in place with the help of a bolt.

METHODOLOGY

The present *in vitro* study was conducted to comparatively evaluate the effect of cyclic loading on the abutment screw loosening of premachined and custom cast angled implant abutments.

The methodology adopted in the present study is described under the following sections:

- I Preparation of stainless steel blocks
- II Connection of 25⁰ angled premachined titanium abutments to implants
- III Placement of implant-25⁰angled premachined titanium abutment assembly in stainless steel block [Group I]
- IV Milling of 25⁰ angled premachined titanium abutments
- V Custom fabrication of 25⁰ angled custom cast cobalt chromium (Co-Cr) abutments:
 - a Fabrication of putty index on 25⁰ angled premachined titanium abutment
 - b Connecting and trimming of plastic abutment
 - c Duplication of the shape and dimensions of the milled premachined titanium abutment
 - d Casting, Divesting, and Finishing of modified plastic abutment with Co-Cr alloy

- VI Connection of 25⁰ angled custom cast cobalt chromium (Co-Cr) abutments to implants
- VII Placement of implant-25⁰ angled custom cast cobalt chromium (Co-Cr) abutment assembly in stainless steel block [Group II]
- VIII Fabrication of cement-cum-screw retained Ni-Cr cast crowns
 - a Fabrication of wax pattern
 - b Spruing of wax pattern
 - c Investing the wax pattern
 - d Burnout of wax pattern
 - e Casting procedure
 - f Divesting and finishing the cast crowns
- IX Cementation of cement-cum-screw retained Ni-Cr cast crowns
- X Grouping of test samples
- XI Measurement of the Reverse Torque Values before cyclic loading
- XII Retorquing of the abutment screw
- XIII Cyclic loading of test samples
- XIV Measurement of the Reverse Torque Values after cyclic loading
- XV Data tabulation and statistical analysis

I. Preparation of stainless steel blocks: (Fig.36 a and b)

Twenty (20) stainless steel blocks (Fig.36a) (Raja Industries, Chennai) of dimensions 27mm x 27mm x18mm with a cylindrical mold space of diameter 23mm and depth of 16mm were custom-made (Fig.36b). Grooves were made on the internal surfaces of the cylindrical mold space to help retain the auto polymerizing acrylic resin. Four holes each with a diameter of 3mm and depth of 2mm were drilled at the four corners of each block to act as reorientation guides.

II. Connection of 25⁰ angled premachined Titanium abutments to implants: (Fig.37)

Twenty titanium implants with standard platform, internal hexagon, tapered, 3.75 diameter, 10mm length (ADIN Dental Implants, Israel) were used. Each of the ten implants were randomly selected and connected to one randomly selected premachined titanium 25⁰ angled abutment (ADIN Dental Implants, Israel) by hand torquing the abutment screw with a hex driver (ADIN Dental Implants, Israel) (Fig.37)

III. Placement of implant-25⁰ angled premachined titanium abutment assembly in the stainless steel block [Group I]: (Fig.38-40b)

One custom-made stainless steel block was randomly selected and placed on the surveying platform of a dental surveyor (Saeshin Precision Ind. Co., Korea)

with the mold space facing up and stabilized. The surveying platform was made parallel to the floor using spirit level indicators (Jinhua Hengda tools, China) (Fig.38). The angled abutment connected to the implant was used as a carrier to orient the implant and it was attached to the surveying mandrel and positioned in the center of the mold space of the custom-made stainless steel block such that the implant was submerged completely in the mold space, except for 1 mm at the crest module (Fig.39). Auto polymerizing clear acrylic resin (Cold Cure, DPI, India) was mixed as per the manufacturer's recommendations and poured into the mold space and then allowed to polymerize. This procedure was repeated to obtain 10 stainless steel blocks having one implant and secured to one 25⁰ angled premachined titanium abutment embedded using self cure acrylic resin in each block (Fig.40a). After polymerization of the acrylic resin, the abutment was removed from the implant by detorquing of the abutment screw using the hex driver. The secured implant level was then visually verified (Fig.40b). The abutments were reconnected to the respective implants. These ten implant-abutment assemblies secured in the stainless steel blocks were categorized as Group I.

IV. Milling of 25⁰angled premachined titanium abutments: (Fig.41,42a,b)

To standardize the abutment height, taper, mucosal collar thickness and to facilitate the access for the abutment screw channel, the abutments were custom

milled. One implant-abutment assembly with the stainless steel block was placed at a time on the model support platform of milling unit attached to the surveyor (Bredent GmbH & Co., Germany) and oriented to 0° . Model support platform was locked in this horizontal position (Fig.41). High precision milling with variably adjustable speed range from 0 to 30,000 rpm was done using a 6° tapered tungsten carbide bur for overall reduction and round end tungsten carbide bur for finishing of mucosal collars in order to obtain uniform height of 8mm with mucosal collar width standardized to 0.8mm leaving supra gingival, heavy chamfer margin. A total occlusal convergence of approximately 6° was given and the abutments were finished and polished (Fig.42a, b). A total of 10 uniformly milled 25° angled premachined titanium abutments were obtained in this manner.

V. Custom fabrication of 25° angled custom cast Cobalt-Chromium (Co-Cr) abutments: (Fig.43-Fig.55)

The custom cast cobalt chromium abutments were fabricated to match the shape and dimensions of the milled premachined abutments. The following steps were carried out:

a) Fabrication of putty index on 25° angled premachined titanium abutment: (Fig.43 a, b)

One milled 25° angled premachined titanium abutment-implant assembly was taken. An index was obtained of the milled abutment using addition

polyvinylsiloxane impression material of putty and light body consistency. (Aquasil, Dentsply, Germany) in a single step procedure. The putty was hand mixed with equal quantities of base and catalyst to obtain a homogenous dough. Light body material in a cartridge was attached to the automixing gun. A spiral mixing tip was attached to the cartridge tip and the material was injected gently over the milled abutment. The mixed putty was then pressed and shaped over the light body material such that it covered the top of the stainless steel block and flowed completely into the four reorientation holes present in the stainless steel block. It was left undisturbed until set. After setting, the index was removed with a single snap movement and inspected for acceptability. The putty index thus obtained was used to standardize the dimensions of the custom cast abutments with that of premachined abutments. (Fig. no 43 a, b)

b) Connecting and trimming of plastic abutment: (Fig.44a)

Following the retrieval of the putty index, the premachined abutment was unscrewed and removed from its implant. One plastic abutment (ADIN Dental Implants, Israel) was then connected to the implant by hand torquing the abutment screw using the hex driver (Fig.44a).

c) Duplication of the shape and dimensions of the milled premachined titanium abutment: (Fig.44b, 45 a, b, c and 46)

The connected plastic abutment was then trimmed to the level of the abutment screw using a BP blade (Glassvan, India) attached to BP Blade Handle (Hebbar surgicals, Chennai, India) (Fig.44b). Pattern resin (GC Corporation, Tokyo, Japan) was mixed as per manufacturer's instructions and poured into the putty index previously obtained (Fig.45a). The index was positioned over the trimmed plastic abutment such that the putty projections at the four corners of the index were seated completely into the four reorientation holes of the stainless steel block (Fig.45 b,c). This ensured similar orientation of the putty index over the plastic abutment as it was over the milled premachined abutment. The index was left undisturbed to allow the pattern resin to set. After setting the index was removed with a single snap and the pattern formed over the trimmed plastic abutment was inspected for acceptability. In this manner the plastic abutment was customized similar to the shape and dimensions of the milled 25° angled premachined titanium abutment. The customized pattern was then unscrewed and removed from the implant. The same protocol was followed to obtain ten customized plastic abutment patterns of uniform dimensions which were ready for casting. The milled premachined titanium abutment was now reconnected to the implant in the stainless steel block (Fig.46)

d) Casting, Divesting, and Finishing of modified plastic abutment with Co-Cr alloy: (Fig.47-56)

The modified plastic abutment was then carefully unscrewed and removed from the implant. Each pattern was covered with a thin layer of wax to avoid deterioration of the investment surface during heating up in the burnout furnace as per the manufacturer's recommendations. The patterns were sprued with a preformed wax sprue (Bego, Germany) of 2.5mm diameter. The wax sprue was attached to the tip of the pattern and a reservoir was placed 1.5 mm away from the pattern. The pattern was directly sprued to the crucible former of the ring less casting system (Sili Ring, Delta labs, Chennai, India) (Fig.47). All the 10 modified plastic abutment patterns were sprued individually in an identical manner. All the 10 modified plastic abutment patterns were invested individually using graphite free, phosphate-bonded investment material specially meant for cobalt chromium alloys (Wirovest, Bego, Germany). A 6mm distance was provided between the pattern and the top of the ring. All patterns were sprayed with surfactant spray (Aurofilm, Bego, Germany) to aid in better wetting of the investment material. As per the manufacturer's recommendations, 400gm of the phosphate-bonded investment was mixed with 60ml of investment liquid, which was prepared by mixing 40 ml of colloidal silica (Begosol, Bego, Germany) and 20 ml of distilled water in the ratio of 3:1. The investment powder was first hand

mixed with a spatula until the entire material was wetted thoroughly followed by vacuum mixing for 30 seconds using vacuum power mixer (Whipmix, Kentucky, U.S.A.). The entire pattern was painted with a thin layer of mixed investment using a small paintbrush and the remainder of investment was poured and vibrated slowly into the ring (Fig.48). All the 10 samples were invested in a similar manner.

The invested patterns were allowed to bench set for 20 minutes, and the silicone ring was removed (Fig.49). The invested patterns were labeled for future identification. All the individually invested patterns were allowed to completely set for 1 hour and then placed individually in a burnout furnace (Technico, Technico laboratory products Pvt. Ltd., Chennai, India) for pattern elimination. During the first hour, the temperature was raised from room temperature to 250⁰C; in the second hour, the temperature was raised to 570⁰C and during the last hour the temperature was sustained at 950⁰C – 1050⁰C. The burnout procedure was extended for another extra 10 -15 minutes to accomplish complete burnout of the pattern without any residue. The same procedure was followed for all 10 patterns (Fig.50).

Casting was accomplished individually with Co-Cr alloy (Wironit, Bego, Germany) melted in an induction casting machine (Fornax, Bego, Germany). The casting procedure was performed quickly to prevent heat loss resulting in thermal

contraction of the mold. The Co-Cr alloy was heated to 1300⁰C according to manufacturer's recommendation for melting the alloy ingot and the crucible was released. The centrifugal force ensured the complete flow of the molten metal into the mold space (Fig.51). The same procedure was followed for all the ten samples.

The casting was allowed to cool to room temperature. A knife was used to trim the investment at the bottom end of the ring. It was then broken apart and the remaining investment was slowly removed (Fig.52). Adherent investment was removed from the casting by air abrasion using 110 μ m alumina (Korox, Chennai, India) at 80 psi pressure in a sand blasting machine (Delta labs, Chennai, India) (Fig.53). Sprue was cut using a 0.7mm thin carborundum separating disc (Dentorium, New York, U.S.). The casting was inspected under magnification for casting defects. External surfaces were relieved of any irregularities with a round carbide bur. All the 10 cast abutments were trimmed using metal trimming burs (Edenta, Switzerland) and polished using silicon rubber wheels (Dentsply, Germany) (Fig.54). In this manner ten custom cast cobalt chromium 25⁰ angled abutments were obtained (Fig.55)

VI. Connection of 25⁰angled custom cast cobalt chromium abutments to implants: (Fig.56)

Each of the 25⁰angled custom cast Co-Cr abutments were randomly selected and connected to one randomly selected implant by hand torquing the abutment screw with a hex driver (Fig.56). Each abutment was visually checked for proper seating on its respective implant.

VII. Placement of implant-25⁰ angled custom cast cobalt chromium abutment assembly in the stainless steel block [Group II]: (Fig.57-59b)

One custom-made stainless steel block was randomly selected and placed on the surveying platform of a dental surveyor with the mold space facing up and stabilized. The surveying platform was made parallel to the floor using spirit level indicators (Fig.57). The angled custom cast abutment connected to the implant was used as a carrier to orient the implant and it was attached to the surveying mandrel and positioned in the center of the mold space of one custom-made stainless steel block such that the implant was submerged completely in the mold space, except for 1 mm at the crest module (Fig.58). Auto polymerizing clear acrylic resin was mixed as per the manufacturer's recommendations and poured into the mold space and then allowed to polymerize. This procedure was repeated to obtain 10 stainless steel blocks each having one implant embedded using self cure acrylic resin and secured to one 25⁰ angled custom cast Co-Cr abutment (Fig.59a). After polymerization of the acrylic resin the abutment was removed

from the implant by detorquing of the abutment screw using hex driver. The secured implant level was then visually verified (Fig.59b). The abutments were reconnected to the respective implants. These ten implant-abutment assemblies secured in the stainless steel block were categorized as Group II.

VIII. Fabrication of cement cum screw retained Ni-Cr cast crowns: (Fig.60-74)

The following procedures were carried out:

Cement -cum -screw retained Ni-Cr single crowns of uniform dimensions for each of the Group I and Group II abutments

a) Preparation of wax pattern:(Fig.60-64d)

One implant-abutment assembly was randomly selected from Group I. The screw access hole of the angled, milled abutment was initially filled and sealed off with wax. The abutment was coated with die lubricant (Yeti Dental, Germany) and excess lubricant was removed using a gentle stream of compressed air (Fig.60). Wax-up was done with inlay casting wax (GC Corporation, Tokyo, Japan) to obtain a single unit crown resembling a maxillary central incisor. The cingulum area was over contoured to create a flat surface at a 30 degree inclination to the long axis of the tooth. After the wax pattern fabrication, abutment screw access channel was reopened to facilitate access to the screw.

Screw access hole was placed in the middle third region of the labial side of the crown (Fig.61). To achieve uniformity in the shape and size of all the crowns in the study, a putty index was formed over the wax pattern. Polyvinylsiloxane (Aquasil, Denstply, Germany) light body impression material in an automixing gun was injected over the wax pattern. Putty consistency material was mixed homogenously and adapted over the light body to obtain an index. (Fig.62, 63a, b).The index was allowed to set undisturbed and then removed and inspected for acceptability. The index was sectioned transversely to obtain two equal halves to facilitate retrieval during wax pattern fabrication. Molten inlay wax was poured into the index which was then positioned over one abutment. It was left undisturbed until set. After the wax had hardened the two halves of the index were removed and the pattern was inspected for acceptability (Fig.64a-d). A total of 20 standardized wax patterns, ten for each group, were obtained in this manner.

b) Spruing the wax patterns: (Fig.65)

Each wax pattern was sprued with a preformed wax sprue (REF 40085, Bego, Germany) of 2.5 mm diameter. The wax sprue was attached to the incisal edge of the pattern and a reservoir was placed 1.5 mm away from the pattern. The pattern was directly sprued to the crucible former of the ringless casting system (Sili Ring, Delta labs, Chennai, India) (Fig.65). All the 20 wax patterns were sprued individually in a similar manner.

c) Investing the wax patterns: (Fig.66)

All the 20 wax patterns were invested individually using graphite free, phosphate-bonded investment material (Bella sun, Bego, Germany) suitable for Ni-Cr alloy casting. A 6mm distance was provided between the pattern and the top of the ring. All patterns were sprayed with surfactant spray (Aurofilm, Bego, Germany) to aid in better wetting of the investment material. As per the manufacturer's recommendation, 160 gm of the phosphate-bonded investment was mixed with 38 ml of investment liquid, which was prepared by mixing 30 ml of colloidal silica (Begosol, Bego, Germany) and 8 ml of distilled water in the ratio of 3:1. The investment powder was first hand mixed with a spatula until the entire material was wetted thoroughly followed by vacuum mixing for 30 seconds using vacuum power mixer (Whipmix, Kentucky, U.S.A.). The entire pattern was painted with a thin layer of investment using a small paintbrush. The silicone ring was positioned on the crucible former and the remainder of investment was poured and vibrated slowly in to the ring (Fig.66). All the 20 wax patterns were invested in a similar manner. The invested patterns were allowed to bench set for 20 minutes, and the silicone ring was removed. The invested patterns were labeled for future identification.

d) Burnout of wax patterns: (Fig.67 and 68)

All the individually invested patterns were allowed to completely set for 1 hour (Fig.67) and then placed individually in a burnout furnace (Technico, Technico laboratory products Pvt. Ltd., Chennai, India) for pattern elimination. Investments with the patterns were left in the burnout furnace for a period of three hours. During the first hour, the temperature was raised from room temperature to 380°C; in the second hour, the temperature was raised to 900°C and during the last hour the temperature was sustained at 900°C to accomplish complete burnout of the pattern without any residue. The investment mold was initially placed in the furnace such that the crucible end was in contact with the floor of the furnace for the escape of molten material. The investment mold was reversed later near the end of burnout cycle with the sprue hole facing upward to enable escape of the entrapped gases and also to allow oxygen contact to ensure complete burnout of the wax pattern (Fig.68). The same procedure was followed for the burnout of all twenty patterns.

e) Casting procedure: (Fig.69)

Casting was accomplished with Ni-Cr alloy (Bellabond plus, Bego, Germany) melted in an induction casting machine (Fornax, Bego, Germany). The casting procedure was performed quickly to prevent heat loss resulting in thermal contraction of the mold. The Ni-Cr alloy was heated to 1300°C according to manufactures recommendation for melting the alloy ingot and the crucible was

released. The centrifugal force ensured the complete flow of the molten metal into the mold space (Fig.69). The same procedure was followed for casting all the twenty Ni-Cr crowns.

f) Divesting and finishing the cast crowns: (Fig.70-74)

The hot casting was allowed to cool to room temperature. A knife was used to trim the investment at the bottom end of the ring. It was then broken apart and the remaining investment was slowly removed (Fig.70). Adherent investment was removed from the casting by air abrasion using 110 μ m alumina (Korox, Chennai, India) at 80 psi pressure in a sand blasting machine (Delta labs, Chennai, India) (Fig.71). Sprue was cut using a 0.7mm thin carborundum separating disc (Dentorium, New York, U.S.). The casting was inspected under magnification for casting defects. Casting with irregularities in the internal margin, distorted surfaces were discarded. External surfaces were relieved of all nodules with a round carbide bur. All the 20 cast crowns were trimmed using metal trimming burs (Edenta, Switzerland) and polished using silicon rubber wheels (Fig.72) (Dentsply, Germany). Twenty finished Ni-Cr cast crowns with labial screw access for each implant-abutment assembly were obtained. Each finished crown was seated on its respective abutment (Fig.73) and checked for proper fit and marginal accuracy (Fig.74).

IX. Cementation of cement cum screw retained Ni-Cr cast crowns: (Fig.75-79)

Type I Glass ionomer cement (GC Corporation, Tokyo, Japan) in a powder and liquid system was used for cementation of the cast crowns to their respective abutments. Before cementing the copings, it was ensured that the screw access hole was sealed off with cotton covered with a layer of wax (Fig.75). Equal amounts of powder and liquid were dispensed on a mixing pad. Both the powder and liquid were mixed by the folding technique using an agate plastic spatula (GC Corporation, Tokyo, Japan) for 30 seconds. The mixed cement was carried to the inner surface of the cast crowns with a plastic filling instrument (API, Manipal, India) and painted on the walls (Fig.76). The cast crowns were then seated on their respective abutments and pressed down with finger pressure for 5 minutes until the initial set (Fig.77). After setting of the luting cement, each cast crown along with its respective abutment was unscrewed and removed from their respective implant, using a hex driver (Fig.78). The excess cement was carefully removed from the crown abutment margin using an anterior hand scaler (API, Manipal, India) without scratching the surface of the abutment (Fig.79). A total of twenty Ni-Cr cast crowns were thus cemented to twenty individual samples.

X. Grouping of test samples: (Fig.80 a, b)

Following cementation of the Ni-Cr crowns, the test samples were ready for testing. Group I test samples were 25⁰ angled premachined titanium abutments connected to their respective implants and they were labeled randomly from GI 1 to GI 10 (n=10) (Fig.80a). Group II test samples were 25⁰ angled custom cast Cobalt Chromium alloy abutments connected to their respective implants and were labeled randomly from GII 1 to GII (10 n=10) (Fig.80b).

XI. Measurement of the Reverse Torque Values before Cyclic Loading: (Fig.81a-81b)

24 hours after the cementation of the crowns, the reverse torque value of each of the Group I and Group II test samples was recorded and noted. The hex driver (ADIN Dental Implants., Israel) was secured to the custom made adapter of the digital torque meter using fast setting curing epoxy compound (Mseal, Pidilite Industries Ltd., India) (Fig.81a). After the complete setting of the epoxy compound the adapter was secured to the interconnecting tool of the torque meter (Fig.81 b,c and d). The torque gauge was held firm, carefully oriented in the long axis of the implant with the driver seated in the screw head and rotated clockwise until the abutment screw was tightened to 35Ncm. A ten minute settling time was allowed, following which it was retightened to 35Ncm to minimize embedment

relaxation between the mating threads and to achieve the optimal “preload”. This procedure was repeated for all ten samples. After a waiting period of five minutes, Reverse Torque Value (RTV) for each of the Group I test samples was measured individually using the digital torque meter. The torque required to loosen the abutment screw was the quantum of preload remaining in the screw joint as against the tightening torque applied. This was designated as the pre-cyclic loading Reverse Torque Value (pre-RTV₁) (Fig.83a) for that test sample. Similarly for the Group II test samples, the Reverse Torque Values were measured and designated as the pre-cyclic loading Reverse Torque Values (pre-RTV₂) (Fig.83b). The Reverse Torque Value for each sample was displayed in the LCD screen of the digital torque meter and was saved in its memory. The pre-cyclic loading reverse torque values of both Groups I and II test samples were recorded and tabulated separately.

XII. Retorquing of the abutment screw: (Fig.84)

Subsequent to the pre-RTV₁ measurements, the abutment screws of all ten Group I test samples (GI 1 to GI 10) were torqued to 35Ncm and then retorqued after allowing a settling period of 10 minutes as described previously to ensure optimal preload prior to cyclic loading (Fig.84). The same procedure was followed for all ten test samples of Group II (GII 1 to GII 10).

XIII. Cyclic loading of the test samples :(Fig.85a, b)

Cyclic loading was performed for all twenty test samples individually, with a custom-made cyclic loading machine (Lokesh Industries, Chennai) to simulate oral loading conditions (Fig.85a). The test sample with the cement cum screw retained cast restoration was placed in a custom-made positioning jig (Fig.85b) (Lokesh Industries, Chennai), which positioned and secured the sample at a 30 degree angle to the floor to simulate the direction of forces at the maxillary anterior region. This jig with the test sample was attached to the cyclic loading machine. The stylus of the cyclic loading machine was placed on the flattened cingulum portion of the cast Ni-Cr central incisor crown. The test sample was subjected to cyclic loading. A sinusoidal waveform at 1.25Hz for load up to 109N (approximately) simulating human masticatory frequency and loads was applied. This cycle was continued for 42hrs (2520 mins with a break of 2hrs, every 21hrs) simulating 1,89,000 cycles which was approximately 6 months of function. The cyclic loading was performed in a dry environment. This procedure was repeated for all the twenty test samples.

XIV. Measurement of the Reverse Torque Values after cyclic loading: (Fig.86a, b)

At the completion of the cyclic loading period, the respective test sample was removed from the custom-made cyclic loading machine. The test sample was

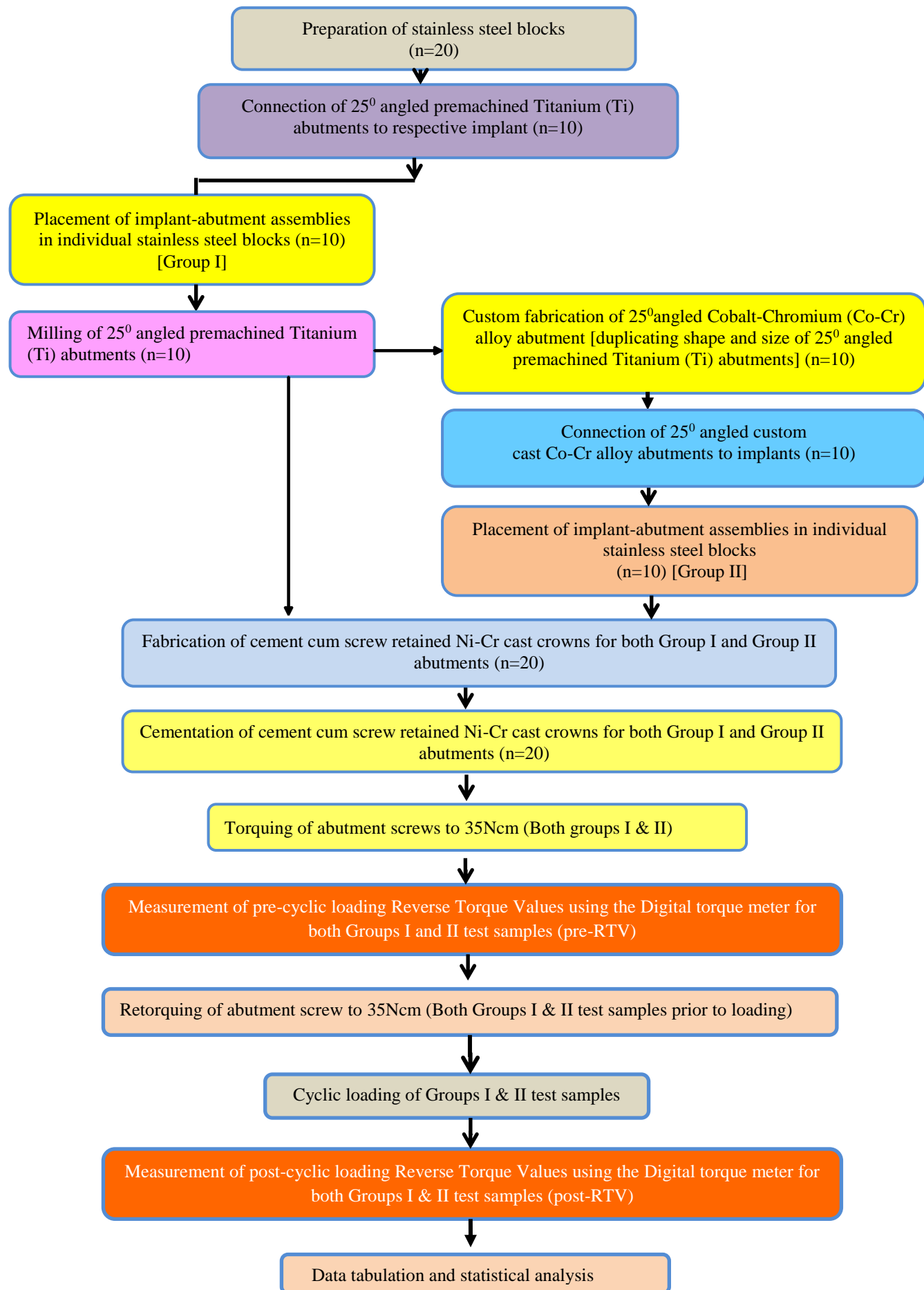
subjected to visual and tactile inspection for any deformation, decementation and/or abutment rotation or loosening. The Reverse Torque Value after cyclic loading for each of the Group I and Group II test samples was measured with the digital torque meter similar to that described before and recorded as the post-cyclic loading Reverse Torque Values. The post-cyclic loading reverse torque values of Group I (Fig.86a) and Group II (Fig.86b) samples were designated as post-RTV₁ and post-RTV₂ respectively. The reverse torque difference (RTD) for each test group was then calculated individually by finding the difference between the respective post cyclic loading reverse torque value and pre cyclic loading reverse torque value of each test sample of that test group [RTD = post-RTV (-) pre-RTV] The mean Reverse Torque Difference (RTD) for Group I and Group II test samples were labeled as RTD₁ and RTD₂ respectively. The data thus obtained were subjected to statistical analysis.

XV. Data tabulation and statistical analysis:

The data obtained were tabulated using Microsoft Excel (Microsoft, USA) and SPSS (SPSS for Windows 10.0.5, SPSS Software Corp., Munich, Germany) software. Paired 't' test was used to compare the mean pre and post RTV within both test groups. Independent 't' test was used to compare the respective mean pre and post cyclic loading reverse torque values and the respective mean reverse torque difference between both test groups.

ANNEXURE I

METHODOLOGY - OVERVIEW



ANNEXURE II

Calibration certificate for cyclic loading machine



Hi Tech Calibration Services

No. 130, Second Floor, VGP Nagar, Mugappair West, Chennai - 600 037
 Phone : 044 - 2656 9696 / 2656 8696 / 4385 1234, Mobile : 98402 40990
 Mail : enquiry@hitechcalibration.com, www.hitechcalibration.com

CALIBRATION CERTIFICATE			
Certificate No.	HT/456/001	Issue Date	5-Sep-2015
CUSTOMER DETAILS		TEST INSTRUMENT DETAILS	
Name	Dr. Syed Ershad Ahmed,	Description	Cyclic Loading Machine
Address	Ragas Dental College, Utthandi, Chennai.	Make	--
		Range	--
		Leastcount	--
Job No	456	Mode	Compression
Job Date	4-Sep-2015	Serial No	1134006
Calibration done at	Site	Identification	--
Instrument Received Condition	Satisfied	Location	--
ENVIRONMENTAL CONDITION		Calibration On	4-Sep-2015
Temperature	25°C±5°C	Due On	3-Sep-2016
Humidity	35 %RH to 70%RH	Calibrated By	V.Prabu
STANDARD DETAILS			
Description	Load Cell with Indicator		
Certificate No.	SICC/CC/1195/11/2013-2014		
Valid Till	28-Nov-2015		
Traceability	SICC (NABL)		

CALIBRATION RESULT

Manual Mode :-

Max Load : 109.2 N
 Min Load : 0.2 N

Auto Mode :-

Max Load : 105.8 N
 Min Load : 0.2 N

Ershad
 Checked By
 ERSHAD - CALIBRATION ENGINEER
 HT / FT / 538 / 01

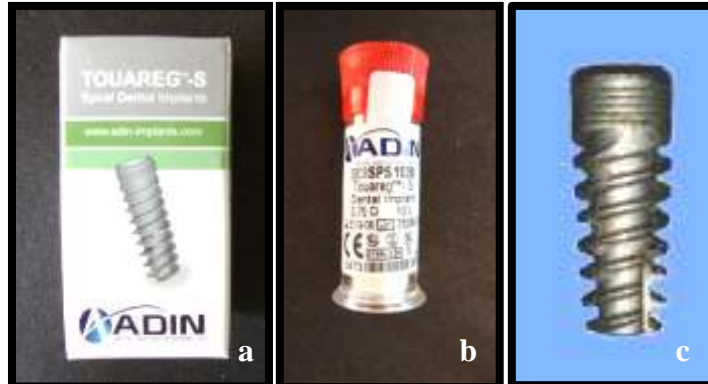


R. Menaka
 Approved By
 R.MENAKA - CALIBRATION ENGINEER
 Page 1 of 1

• The Calibration certificate shall not be reproduced except in full without written approval of Hi Tech Calibration Services.
 • The Calibration certificate are valid only for the condition of the received test instrument at the time under the stated conditions of calibration

ANNEXURE III

MATERIALS



**Fig.1: Titanium dental implant, standard platform,
internal hexagon 3.75 mm diameter, 10 mm length**

1a: Manufacturer packaging

1b: Vial containing implant

1c: Dental implant



Fig.2: 25⁰ angled premachined titanium abutment

2a: Manufacturer packaging

2b: 25⁰ angled abutment



Fig.3: Titanium abutment screw for 25° angled premachined titanium abutment



Fig.4: Plastic cylinder (abutment) internal hex
4a: Manufacturer packaging
4b: Plastic abutment



Fig.5: Titanium abutment screw for plastic cylinder (abutment)



Fig.6 :Hex driver



Fig.7: Spirit level indicators



Fig.8: Clear autopolymerising acrylic resin (monomer and polymer)



Fig.9 a: Putty consistency -Polyvinylsiloxane impression material
b: Light body consistency -Polyvinylsiloxane impression material
c: Dispensing gun
d: Auto mixing spiral
e: Intra oral tips



Fig.10 a: BP Handle
b: BP Blade



Fig.11: Pattern resin(monomer &polymer)



Fig.12a: Sprue wax

b: Silicone investment ring

c: Crucible former

d: Surfactant spray

e: Colloidal silica

**f :Phosphate bonded investment material for
Co-Cr alloy**



Fig.13: Cobalt-Chromium (Co-Cr) pellets



Fig.14: Aluminum oxide powder-110 μ m

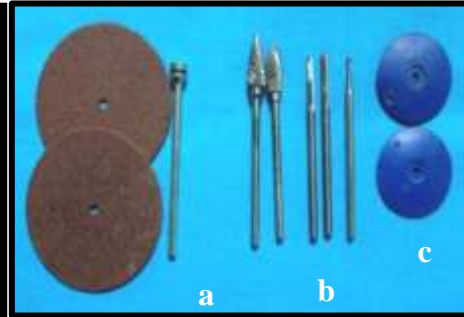


Fig.15a: Carborundum separating discs and mandrel

b: Tungsten carbide metal trimming burs

c: Silicon rubber finishing wheels



Fig.16: Die lubricant



Fig.17: Inlay casting wax

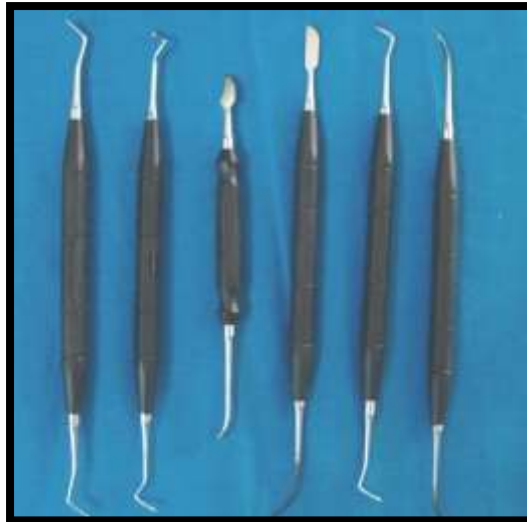


Fig.18:PKT Instruments



Fig.19a: Sprue wax

b: Silicone investment ring

c: Crucible former

d: Surfactant spray

e: Phosphate bonded investment material for Ni-Cr alloy

f: Colloidal silica



Fig.20: Nickel Chromium (Ni-Cr) alloy pellets



Fig.21: Type I Glass ionomer Luting cement

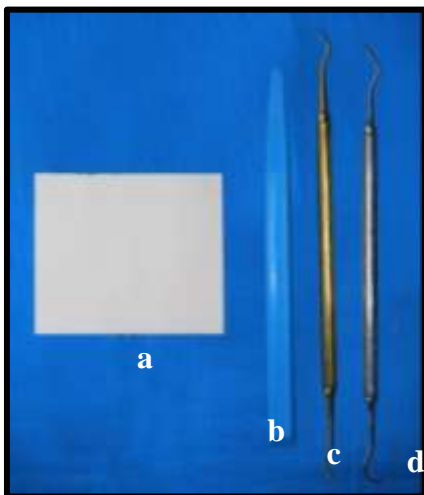


Fig.22a: Mixing pad
b: Agate spatula
c: Plastic instrument
d: Hand scaler



Fig.23: Fast setting epoxy compound

EQUIPMENTS EMPLOYED



Fig.24: Dental Surveyor



Fig.25: Milling unit with Surveyor



Fig.26: Vacuum Mixer



Fig.27: Burnout Furnace



Fig.28: Induction Casting Machine



Fig.29: Sandblasting Unit



Fig.30: High Speed Lathe(Alloy Grinder)



Fig.31a: Digital torque meter

b: Torque meter adapter for attaching hex driver

c: Interconnecting tool for attaching adapter to the torque meter

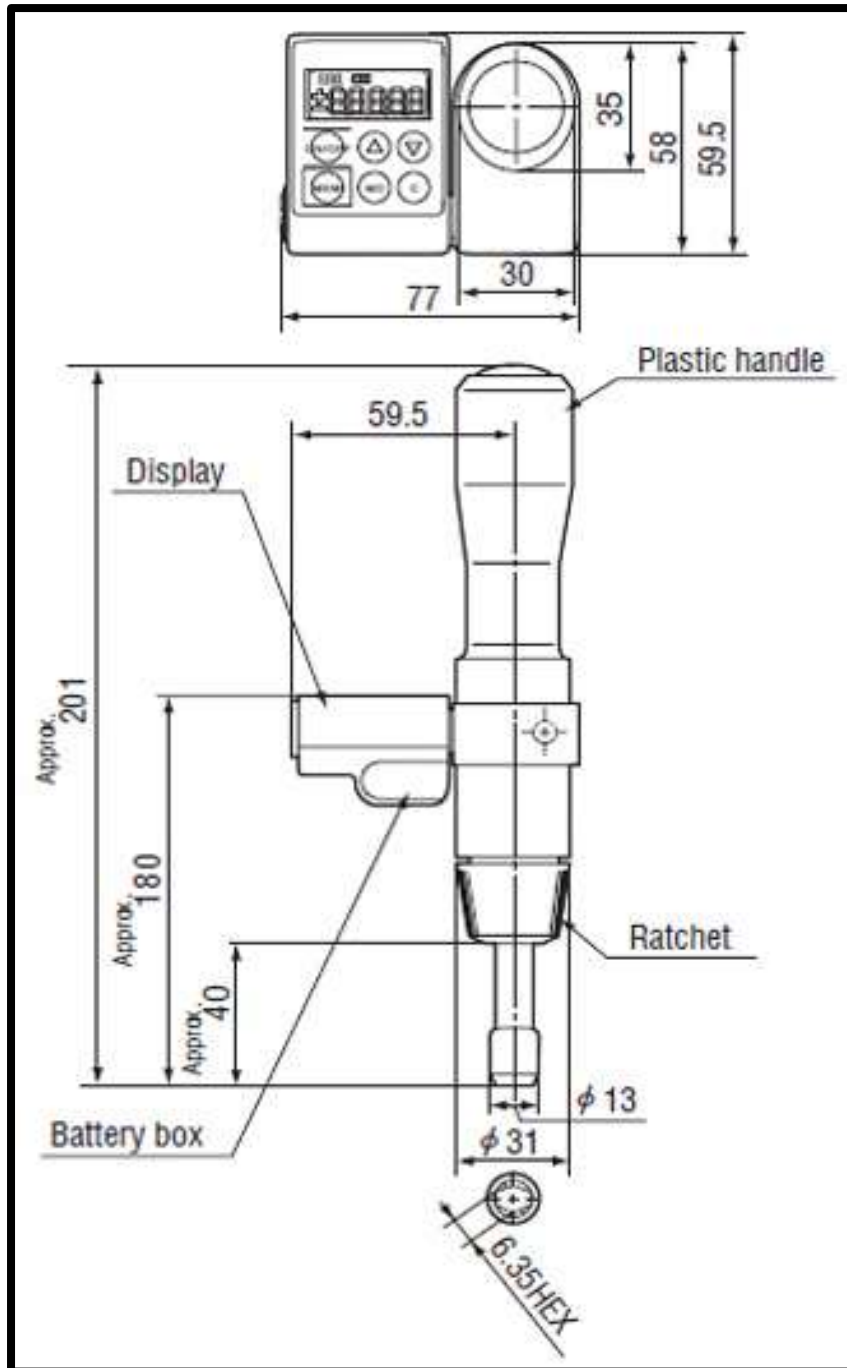


Fig.32: Line diagram of Digital torque meter

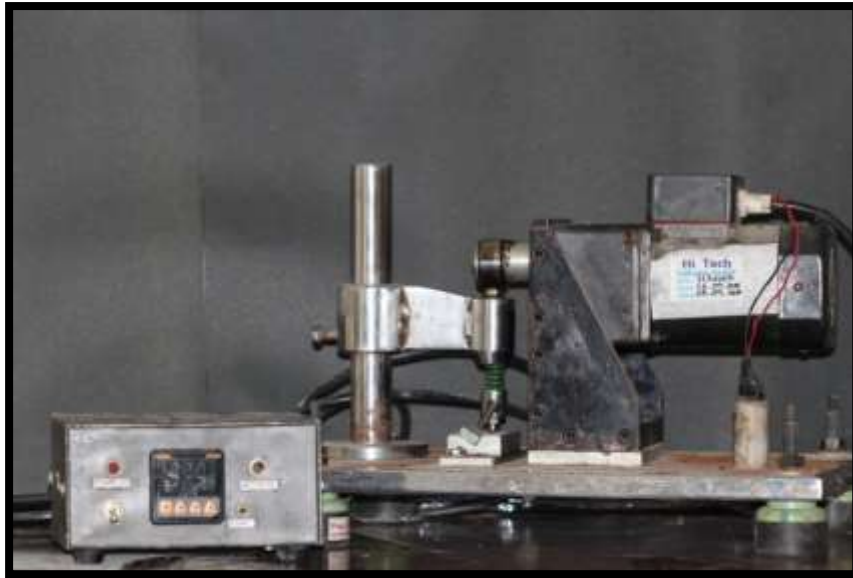


Fig.33: Custom-made Cyclic Loading Machine



Fig.34: Custom-made positioning jig

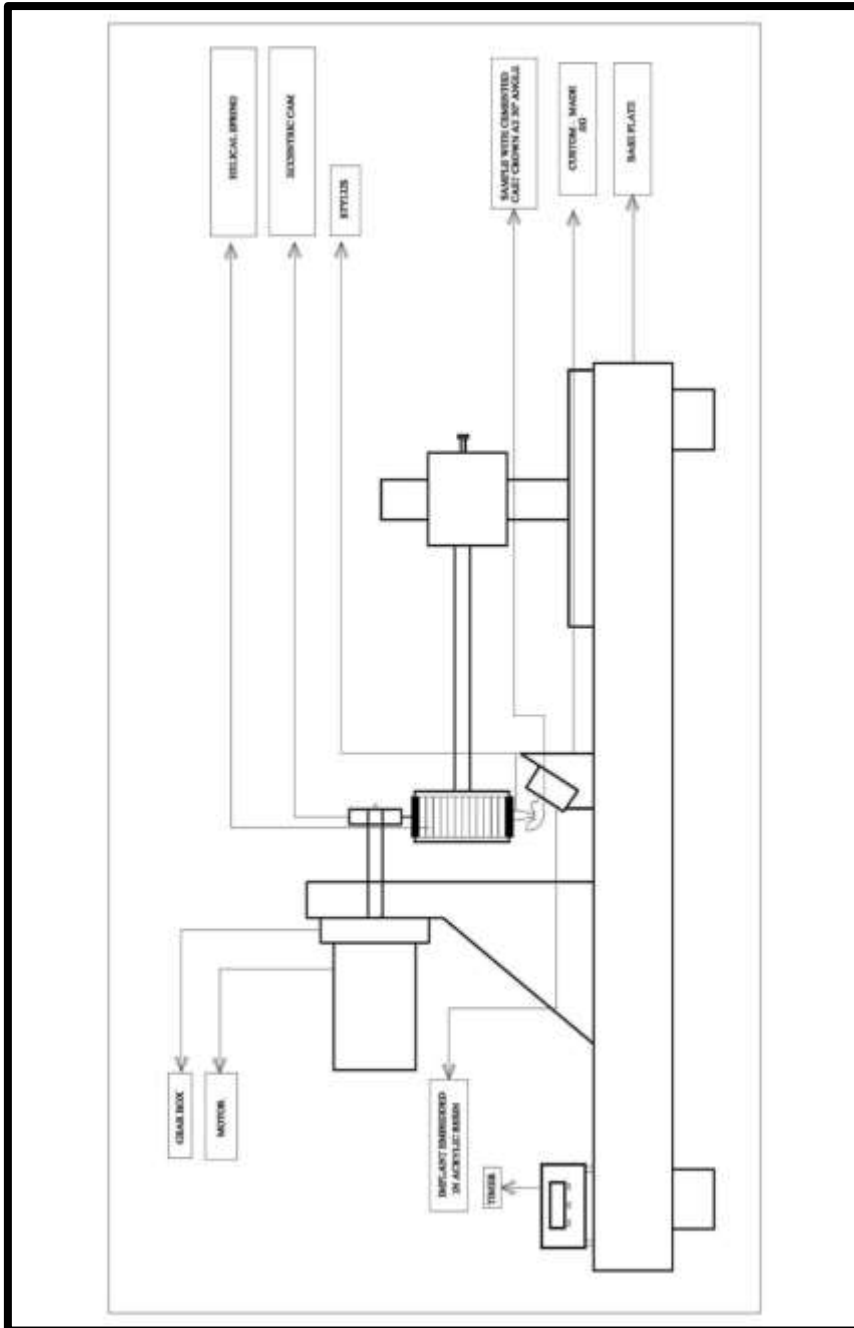


Fig.35: Line diagram for custom-made cyclic loading machine and positioning jig

METHODOLOGY

PREPARATION OF STAINLESS STEEL BLOCK

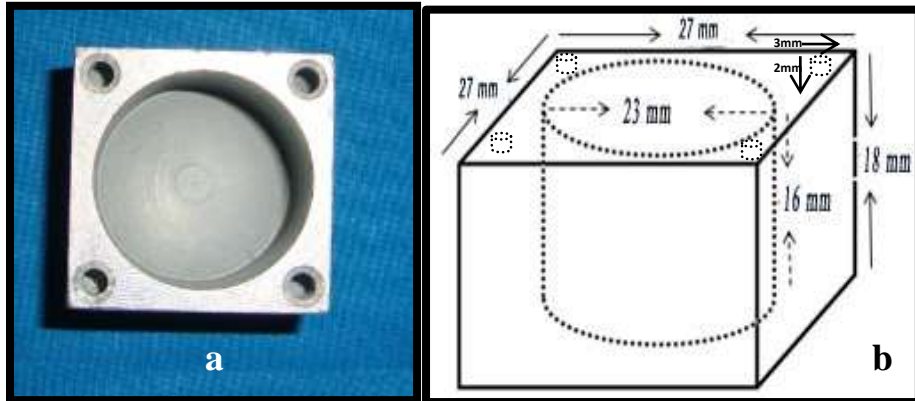


Fig.36a: Custom-made stainless block

b: Line diagram of custom-made stainless steel block

CONNECTION OF 25° ANGLED PREMACHINED ABUTMENTS TO IMPLANTS



Fig.37: 25° angled premachined titanium abutment connected to implant

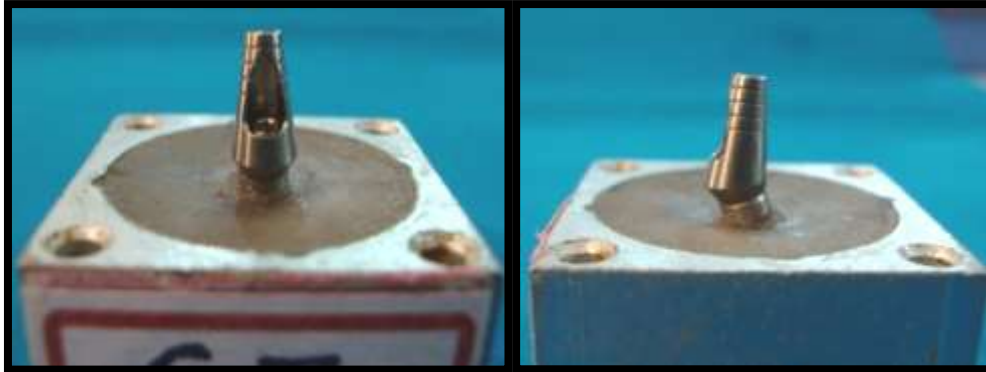
**PLACEMENT OF IMPLANT-25° ANGLED PREMACHINED
TITANIUM ABUTMENT ASSEMBLY IN STAINLESS
STEEL BLOCK**



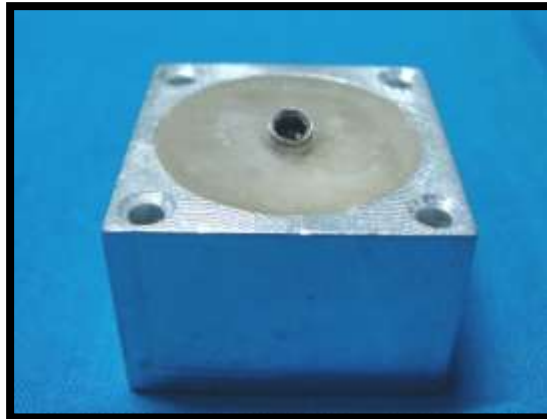
Fig.38: Surveying platform made parallel to floor using Spirit level indicators



Fig.39: Positioning of implant-25° angled premachined titanium abutment assembly in stainless steel block



a



b

Fig.40a: Implant with 25⁰ angled premachined titanium abutment secured in acrylic resin (Group I)

40b: Verification of level of secured implant

MILLING OF 25° ANGLED PREMACHINED TITANIUM ABUTMENTS



Fig.41: Milling of abutment



Fig.42a: Milled 25° angled premachined titanium abument

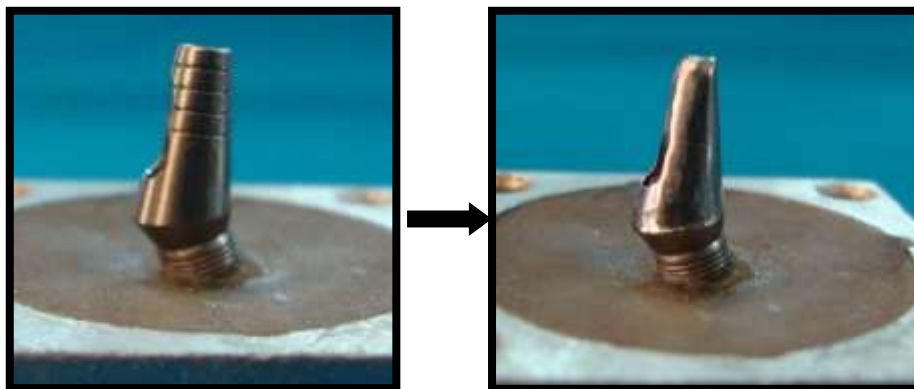


Fig.42b: 25° angled premachined titanium abument before and after milling

CUSTOM FABRICATION OF 25° ANGLED CAST COBALT-CHROMIUM ABUTMENT

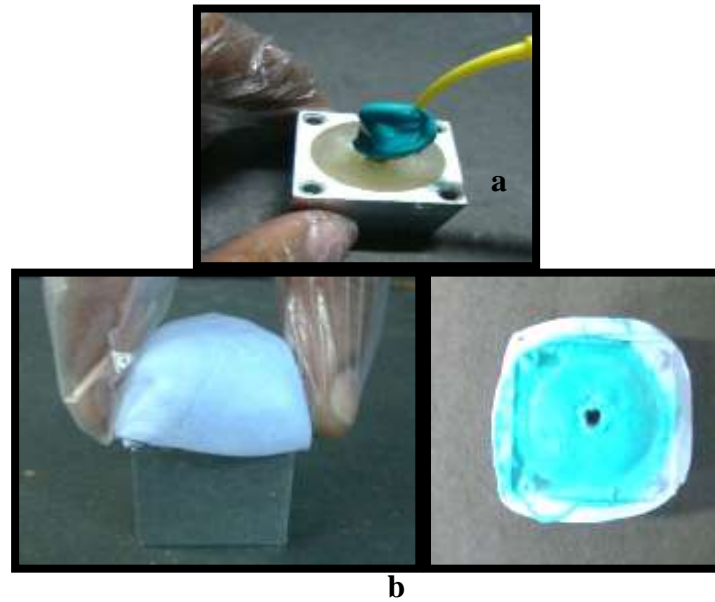


Fig.43a: Fabrication of silicone index over milled 25° angled premachined titanium abutment

b: Completed silicone index

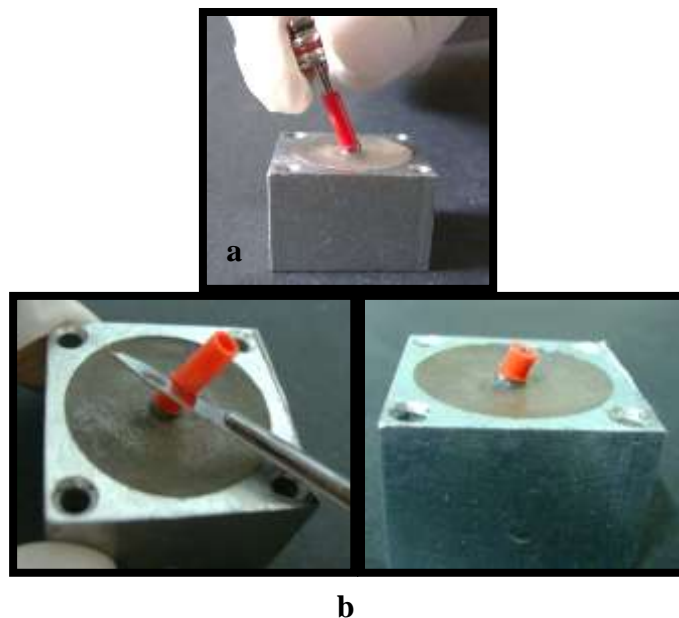


Fig.44a: Attachment of plastic abutment on the implant

b: Trimming of plastic abutment with BP Blade upto height of abutment screw

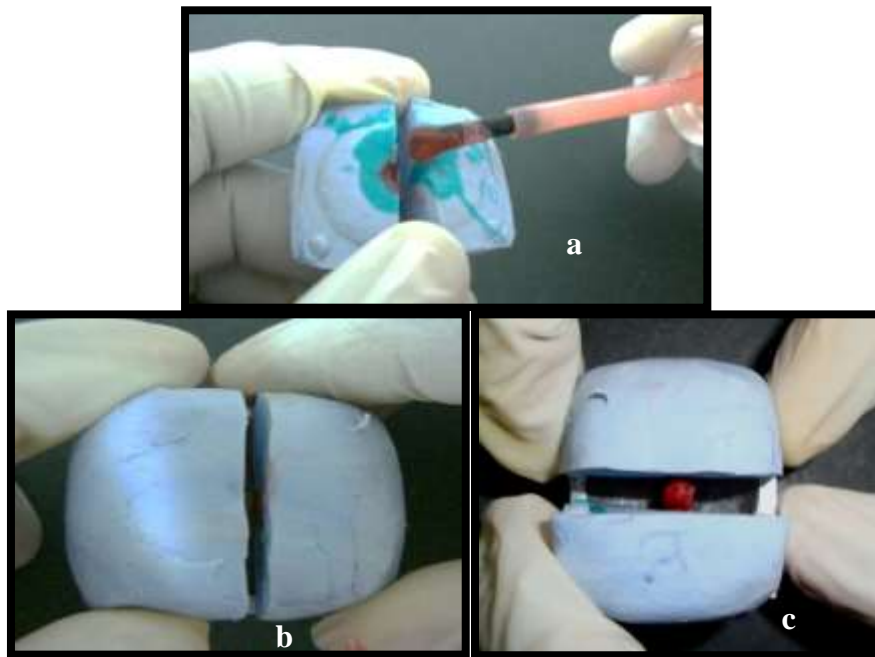


Fig.45a: Pattern resin poured in the silicone index
b: Positioning of silicone index with pattern resin on the plastic abutment
c: Retrieval of silicone index after setting of pattern resin

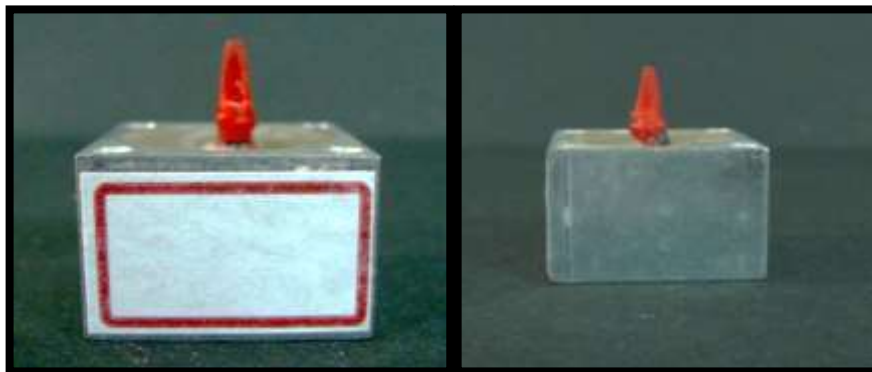


Fig.46: Duplicated 25° angled plastic abutment with pattern resin



Fig.47: Spruing of pattern resin abutment



Fig.48: Investing the pattern resin abutment



Fig.49: Invested pattern resin abutment



Fig.50: Burnout of pattern resin abutment



Fig.51: Casting done with Co-Cr alloy pellets using induction casting machine



Fig.52: Divested casting



Fig. 53: Sandblasting of the casting



Fig.54: Trimming of cast abutment



Fig.55: Finished abutment

**CONNECTION OF 25° ANGLED CUSTOM CAST
COBALT-CHROMIUM ABUTMENTS TO IMPLANTS**



**Fig.56: 25° angled custom cast Co-Cr abutment
connected to the implant**

**PLACEMENT OF IMPLANT-25⁰ ANGLED CUSTOM CAST COBALT
CHROMIUM ABUTMENT ASSEMBLY IN STAINLESS STEEL
BLOCK**



Fig.57: Surveying platform made parallel to floor using spirit level indicators



Fig.58: Positioning of implant-25⁰ angled custom cast cobalt chromium abutment assembly in stainless steel block



a

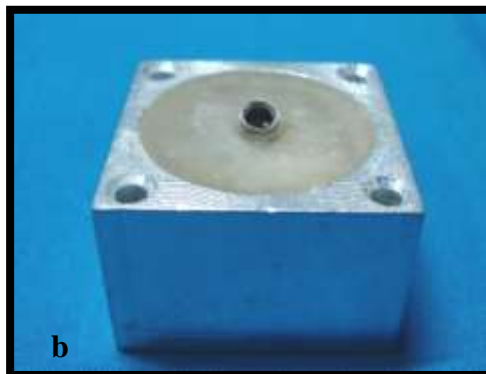


Fig.59a: Implant with 25⁰ angled custom cast cobalt chromium abutment secured in acrylic resin (Group II)

59b: Verification of level of secured implant

**FABRICATION OF CEMENT CUM SCREW RETAINED
CAST Ni-Cr CROWNS**



Fig.60: Application of die lubricant on the 25⁰ angled milled premachined titanium abutment



Fig.61: Wax pattern of central incisor with screw access hole on labial side for Group I test sample

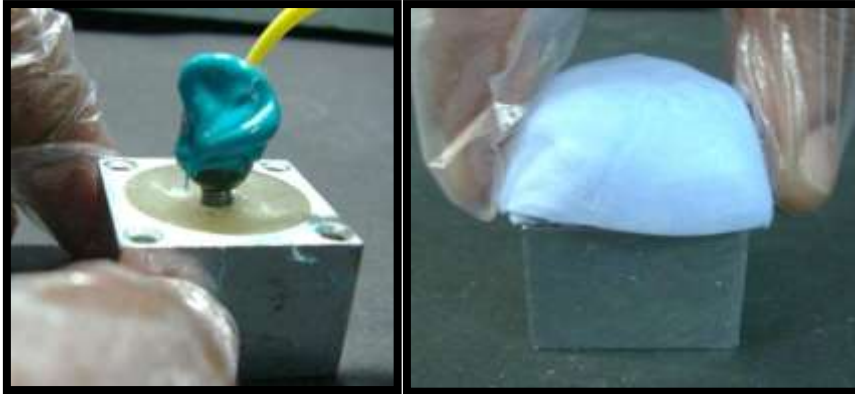


Fig.62: Fabrication of silicone index over wax pattern

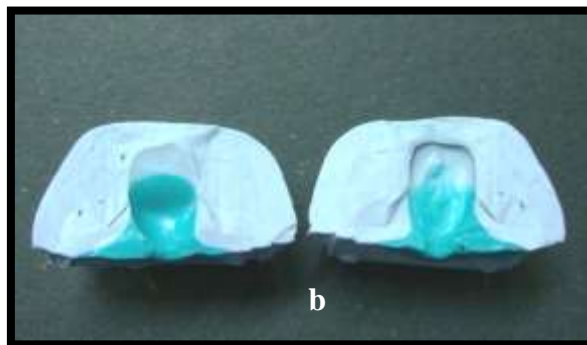
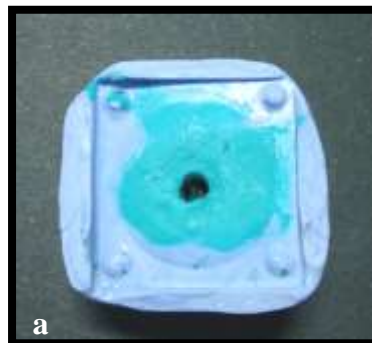


Fig.63a: Completed silicone index for duplicating the wax pattern

b: Sectioned silicone index for duplicating the wax pattern

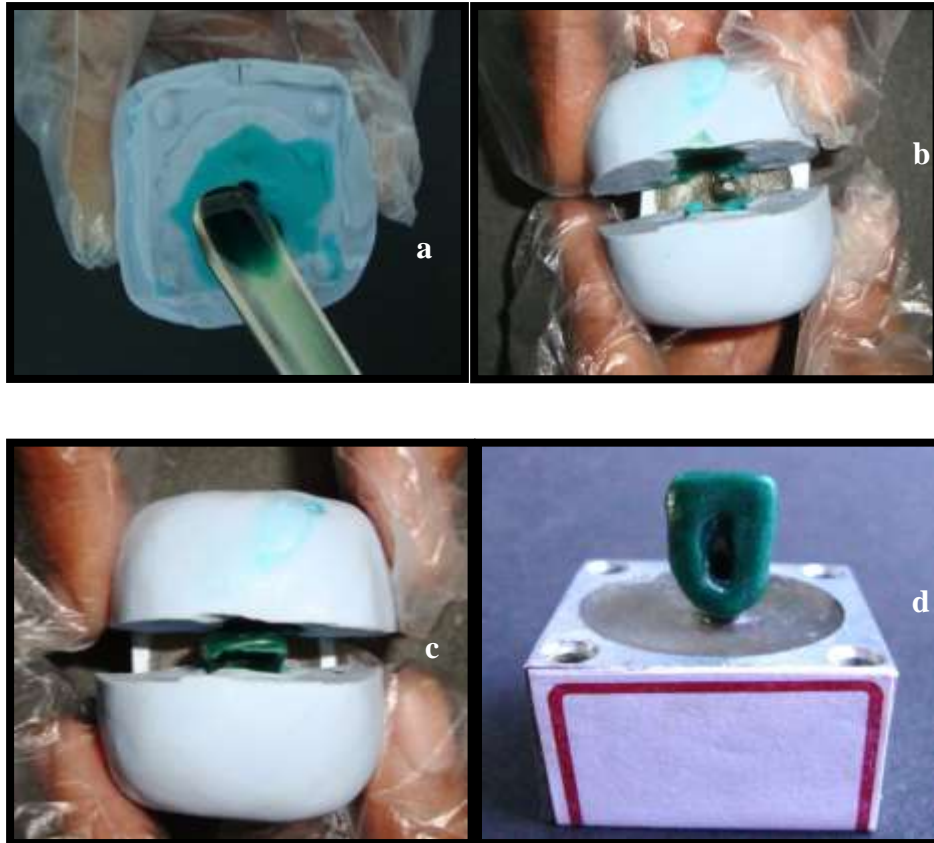


Fig.64a: Pouring molten inlay into the silicone index

b: Positioning of silicone index with inlay wax on the abutment

c: Retrieval of silicone index after setting of wax

d: Wax pattern on sample



Fig.65: Spruing the wax pattern



Fig.66: Investing the wax pattern



Fig.67: Invested wax pattern



Fig.68: Burnout of wax pattern



Fig.69: Casting of wax pattern with Ni-Cr alloy pellets using induction casting machine



Fig.70: Divested casting



Fig.71: Sandblasting



Fig.72: Trimming of crown



Fig.73: Finished crown

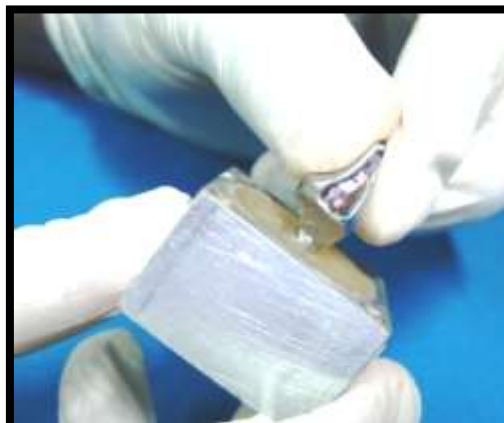


Fig.74: Checking the fit of crown

CEMENTATION OF CEMENT CUM SCREW RETAINED CAST Ni-Cr CROWNS



Fig.75: Sealing of abutment screw access with wax for Group I and Group II abutment



Fig.76: Mixed cement loaded in to crown



Fig.77: Crown cementation for Group I and Group II sample



Fig.78: Unscrewing the cemented crown



Fig.79: Removal of excess cement from crown abutment margin

GROUPING OF TEST SAMPLES



Fig.80a: Group I test Samples

80b: Group II test Samples

TORQUING OF ABUTMENT SCREWS



Fig.81: Hex driver secured into the adapter of digital torque meter

a: Hex driver and adapter of digital torque meter

b: Fast setting epoxy compound – base and catalyst

c: Mixed fast setting epoxy compound

d :Hex driver secured into the adapter of digital torque meter with fast setting epoxy compound.

TORQUING OF ABUTMENT SCREWS TO 35Ncm



Fig.82: Torquing of abutment screws to 35Ncm

MEASUREMENT OF REVERSE TORQUE VALUES BEFORE CYCLIC LOADING



Fig.83 a: Measurement of reverse torque value before cyclic loading in Group I test sample

b: Measurement of reverse torque value before cyclic loading in Group II test sample

RETORQUING OF ABUTMENT SCREWS



Fig.84: Retorquing of abutment screw to 35Ncm prior to cyclic loading

CYCLIC LOADING OF TEST SAMPLES

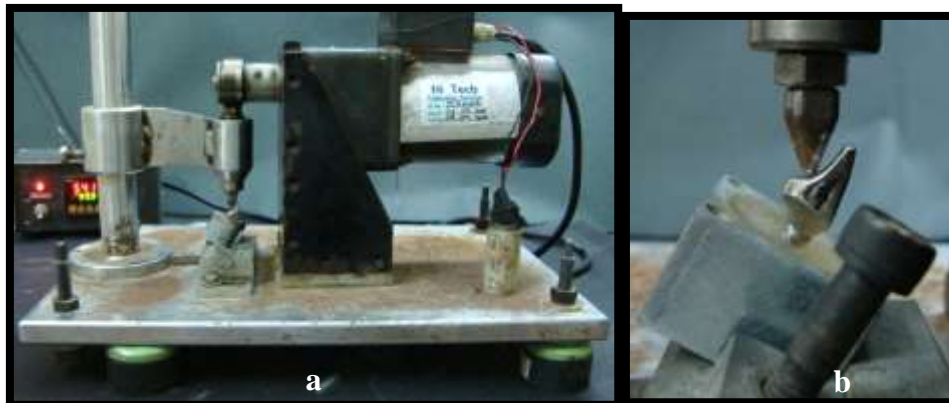


Fig.85a: Cyclic loading in custom made cyclic loading machine

b: Cyclic loading at 30° angulation

MEASUREMENT OF REVERSE TORQUE VALUES AFTER CYCLIC LOADING



a



b

Fig.86a: Measurement of reverse torque value after cyclic loading in Group I test sample

b: Measurement of reverse torque value after cyclic loading in Group II test sample

Results

RESULTS

The present *in vitro* study was conducted to evaluate the effect of cyclic loading on the abutment screw loosening in premachined and custom cast angled implant abutments.

Ten 25⁰ angled premachined (Group I) titanium abutments and ten 25⁰ angled custom cast (Group II) cobalt-chromium abutments were connected to their respective titanium implants which were then mounted in stainless steel blocks. Cement-cum-screw retained nickel-chromium cast crowns were fabricated. Abutment screws were torqued to 35Ncm to their respective implants. Reverse Torque Values were measured using a Digital torque meter before cycling loading and all the twenty samples were subjected to cyclic loading simulating 6 months of function. Reverse torque values were measured after cyclic loading. The basic and mean data of each test group was tabulated separately (refer Tables I - VI; Graphs I - VI) and statistically analyzed using Paired 't' test (refer Tables VII and VIII; Graphs VII and VIII) and Independent 't' test (refer Tables IX - XI; Graphs IX - XI).

Table I: Basic and mean pre-cyclic loading Reverse Torque Values (pre-RTV₁) of Group I test samples (25⁰ angled premachined titanium abutments)

Sample No.	Pre- RTV₁(Ncm)
GI 1	29.55
GI 2	27.42
GI 3	29.47
GI 4	29.07
GI 5	28.12
GI 6	29.76
GI 7	28.23
GI 8	29.29
GI 9	28.83
GI 10	29.85
Mean/S.D	28.96/±0.80

Inference:

For Group I test samples, the maximum pre-cyclic loading Reverse Torque Value was 29.85Ncm and the minimum pre-cyclic loading Reverse Torque Value was 27.42Ncm. The mean pre-cyclic loading Reverse Torque Value (pre- RTV₁) was 28.96Ncm.

Table II: Basic and mean post-cyclic loading Reverse Torque Values (post-RTV₁) of Group I test samples (25⁰ angled premachined titanium abutments)

Sample No.	Post- RTV₁(Ncm)
GI 1	27.75
GI 2	24.64
GI 3	26.01
GI 4	26.13
GI 5	24.70
GI 6	26.18
GI 7	25.08
GI 8	26.27
GI 9	25.53
GI 10	26.13
Mean/S.D	25.84/±0.92

Inference:

For Group I test samples, the maximum post-cyclic loading Reverse Torque Value was 27.75Ncm and the minimum post-cyclic loading Reverse Torque Value was 24.64Ncm. The mean post-cyclic loading Reverse Torque Value (post-RTV₁) was 25.84Ncm.

Table III: Basic and mean Reverse Torque Differences (RTD₁) of Group I test samples (25⁰ angled premachined titanium abutments)

Sample no.	Pre-RTV₁ (Ncm)	Post-RTV₁ (Ncm)	Post-RTV₁(-) Pre-RTV₁ =RTD₁ (Ncm)
GI 1	29.55	27.75	-1.80
GI 2	27.42	24.64	-2.78
GI 3	29.47	26.01	-3.46
GI 4	29.07	26.13	-2.94
GI 5	28.12	24.70	-3.42
GI 6	29.76	26.18	-3.58
GI 7	28.23	25.08	-3.15
GI 8	29.29	26.27	-3.02
GI 9	28.83	25.53	-3.30
GI 10	29.85	26.13	-3.72
Mean/ S.D	28.96/ ±0.80	25.84/ ±0.92	-3.117/ ±0.548

Inference:

For Group I test samples, the maximum Reverse Torque Difference was -3.72Ncm and the minimum Reverse Torque Difference was -1.80Ncm. The mean Reverse torque Difference (RTD₁) was -3.117Ncm.

Table IV: Basic and mean pre-cyclic loading Reverse Torque Values (pre-RTV₂) of Group II test samples (25⁰ angled custom cast cobalt chromium abutments)

Sample no.	Pre-RTV₂ (Ncm)
GII 1	26.40
GII 2	25.60
GII 3	26.77
GII 4	25.22
GII 5	25.52
GII 6	26.91
GII 7	26.62
GII 8	25.70
GII 9	25.20
GII 10	26.15
Mean/ S.D	26.01/±0.64

Inference:

For Group II test samples, the maximum pre-cyclic loading Reverse Torque Value was 26.91Ncm and the minimum pre-cyclic loading Reverse Torque Value was 25.20Ncm. The mean pre-cyclic loading Reverse torque Value (pre-RTV₂) was 26.01Ncm.

TableV: Basic and mean post-cyclic loading Reverse Torque Values (post-RTV₂) of Group II test samples (25⁰ angled custom cast cobalt chromium abutments)

Sample no.	Post-RTV₂ (Ncm)
GII 1	23.75
GII 2	23.50
GII 3	23.10
GII 4	22.70
GII 5	24.30
GII 6	24.10
GII 7	24.75
GII 8	23.80
GII 9	24.25
GII 10	24.45
Mean/ S.D	23.82/±0.63

Inference:

For Group II test samples, the maximum post-cyclic loading Reverse Torque Value was 24.75Ncm and the minimum post-cyclic loading Reverse Torque Value was 22.70Ncm. The mean post-cyclic loading Reverse torque Value (post-RTV₂) was 23.82Ncm.

Table VI: Basic and mean Reverse Torque Differences (RTD₂) of Group II test samples (25° angled custom cast cobalt chromium abutments)

Sample no.	Pre-RTV₂ (Ncm)	Post-RTV₂ (Ncm)	Post-RTV₂(-) Pre-RTV₂ =RTD₂ (Ncm)
GII 1	26.40	23.75	-2.65
GII 2	25.60	23.50	-2.10
GII 3	26.77	23.10	-3.67
GII 4	25.22	22.70	-2.53
GII 5	25.52	24.30	-1.22
GII 6	26.91	24.10	-2.81
GII 7	26.62	24.75	-1.87
GII 8	25.70	23.80	--1.90
GII 9	25.20	24.25	-1.25
GII 10	26.15	24.45	-1.70
Mean/SD	26.01/0.64	23.82/0.63	-2.17/±0.757

Inference:

For Group II test samples, the maximum Reverse Torque Difference was -3.67Ncm and the minimum Reverse Torque Difference was -1.22Ncm. The mean Reverse torque Difference (RTD₂) was -2.17Ncm.

Table VII: Comparative evaluation of the mean pre- and post-cyclic loading Reverse Torque Value of Group I test samples (25⁰ angled premachined titanium abutments) using Paired ‘t’ test

GROUP I	Number of samples	Mean RTV₁(Ncm)	p – value
Pre-cyclic loading (pre-RTV₁)	10	28.96	0.001
Post-cyclic loading (post-RTV₁)	10	25.84	

*p value < 0.001; significant at 1 level

Inference:

On statistical analysis using Paired ‘t’ test, it was found that the mean post-cyclic loading Reverse Torque Value of Group I test samples (post-RTV₁) was lesser than the mean pre-cyclic loading Reverse Torque Value (pre-RTV₁) and this was found to be statistically significant. (p value < 0.001)

Table VIII: Comparative evaluation of the mean pre- and post-cyclic loading Reverse Torque Value of Group II test samples (25⁰ angled custom cast cobalt chromium abutments) using Paired ‘t’ test

GROUP II	Number of samples	Mean RTV₂(Ncm)	p – value
Pre- cyclic loading (pre-RTV₂)	10	26.01	0.001
Post- cyclic loading (post-RTV₂)	10	23.82	

*p value < 0.001; *significant at 1% level

Inference:

On statistical analysis using Paired ‘t’ test, it was found that the mean post-cyclic loading Reverse Torque Value of Group II test samples (post-RTV₁) was lesser than the mean pre-cyclic loading Reverse Torque Value (post-RTV₁) and this was found to be statistically significant.(p value < 0.001)

Table IX: Comparative evaluation of the mean pre-cyclic loading Reverse Torque Values of Group I test samples (25⁰ angled premachined titanium abutments) (pre-RTV₁) and Group II test samples (25⁰ angled custom cast cobalt chromium abutments) (pre-RTV₂) using Independent ‘t’ test

GROUP	Number of samples	Mean / S.D Pre-cyclic loading RTV (Ncm)	p – value
I (pre-RTV₁)	10	28.96/±0.80	0.001
II (pre-RTV₂)	10	26.01/±0.64	

*p value < 0.001; * significant at 1% level

Inference:

On statistical analysis using Independent ‘t’ test to compare the respective mean pre-cyclic loading Reverse Torque Values of Group I and II test samples, it was found that the mean pre-cyclic loading Reverse Torque Value of Group II test samples was lesser than that of Group I test samples and this was found to be statistically significant (p value <0.001).

Table X: Comparative evaluation of the mean post-cyclic loading Reverse Torque Values of Group I test samples (25⁰ angled premachined titanium abutments) (post-RTV₁) and Group II test samples (25⁰ angled custom cast cobalt chromium abutments) (post-RTV₂) using Independent ‘t’ test

GROUP	Number of samples	Mean / S.D Post-cyclic loading RTV (Ncm)	p – value
I (post-RTV₁)	10	25.84/±0.92	0.001
II (post-RTV₂)	10	23.82/±0.63	

*p value < 0.001; * significant at 1% level

Inference:

On statistical analysis using Independent ‘t’ test to compare the respective mean post-cyclic loading Reverse Torque Values of Group I and II test samples, it was found that the mean post-cyclic loading Reverse Torque Value of Group II test samples was lesser than that of Group I test samples and this was found to be statistically significant (p value <0.001).

Table XI: Comparative evaluation of the mean Reverse Torque Difference values of Group I test samples (25⁰ angled premachined titanium abutments) (RTD₁) and Group II test samples (25⁰ angled custom cast cobalt chromium abutments) (RTD₂) using Independent ‘t’ test

GROUP	Number of samples	Mean / S.D RTD (Ncm)	p – value
I (RTD₁)	10	-3.11/±0.548	0.001
II (RTD₂)	10	-2.17/±0.757	

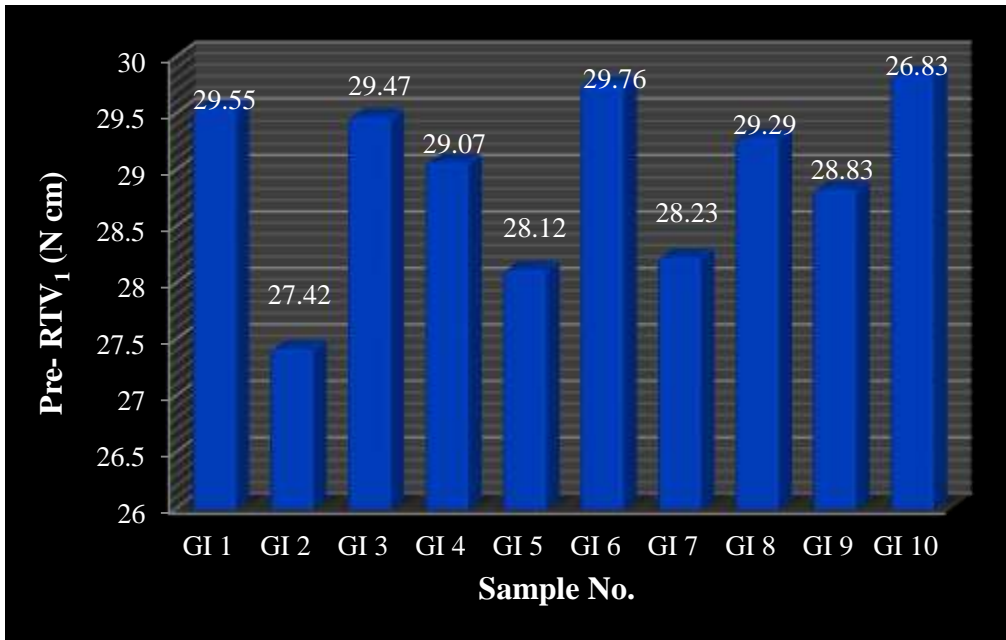
*p value < 0.001; * significant at 1% level

Inference:

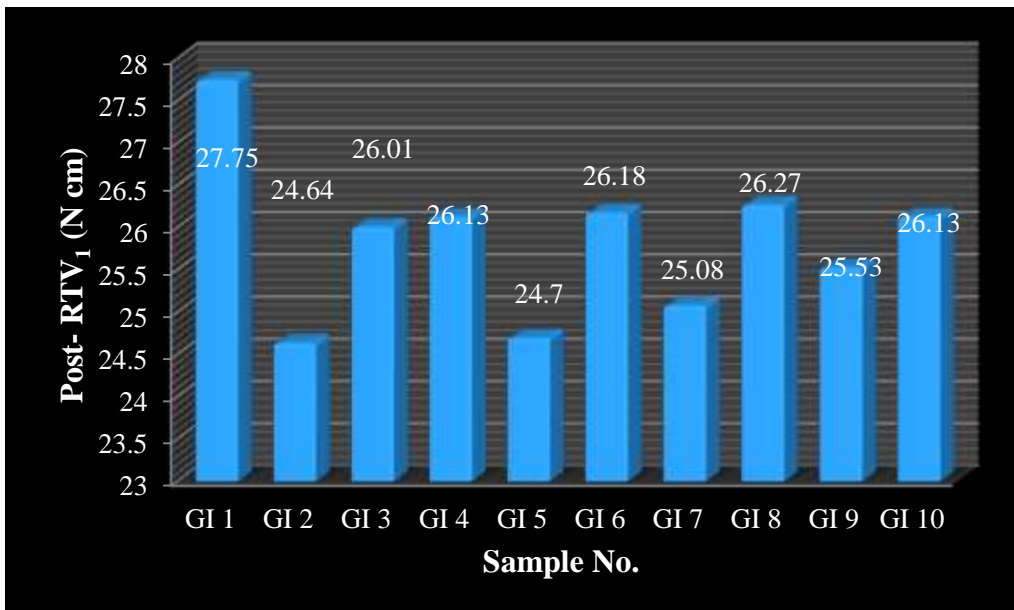
On statistical analysis using Independent ‘t’ test to compare the respective mean Reverse Torque Difference of Group I and II test samples, it was found that the mean Reverse Torque Difference of Group II test samples was lesser than that of Group I test samples and this was found to be statistically significant (p value <0.001).

ANNEXURE IV

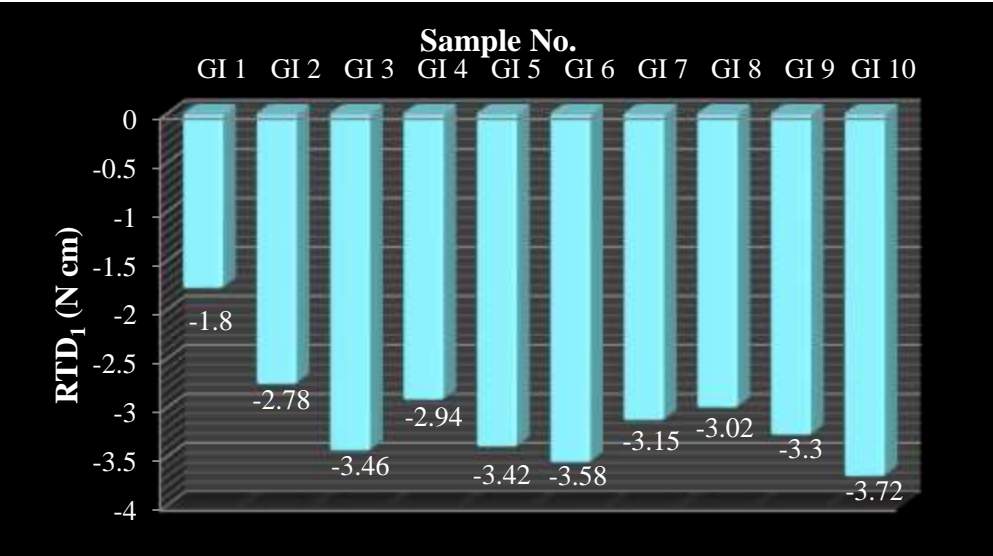
Graph I: Shows basic pre-cyclic loading Reverse Torque Values (pre-RTV₁) of Group I test samples (25° angled premachined titanium abutments)



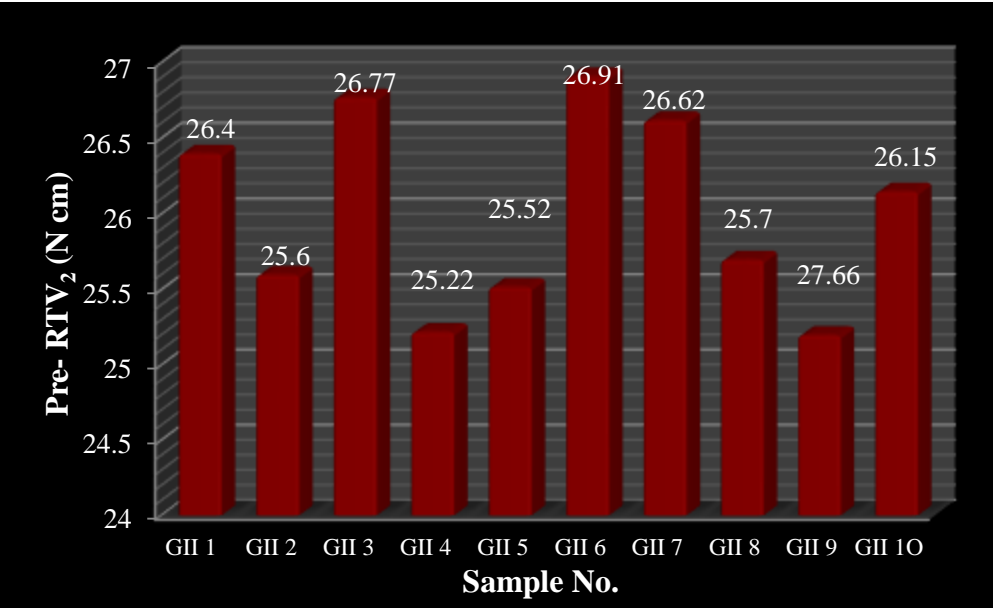
Graph II: shows basic post-cyclic loading Reverse Torque Values (post-RTV₁) of Group I test samples (25° angled premachined titanium abutments)



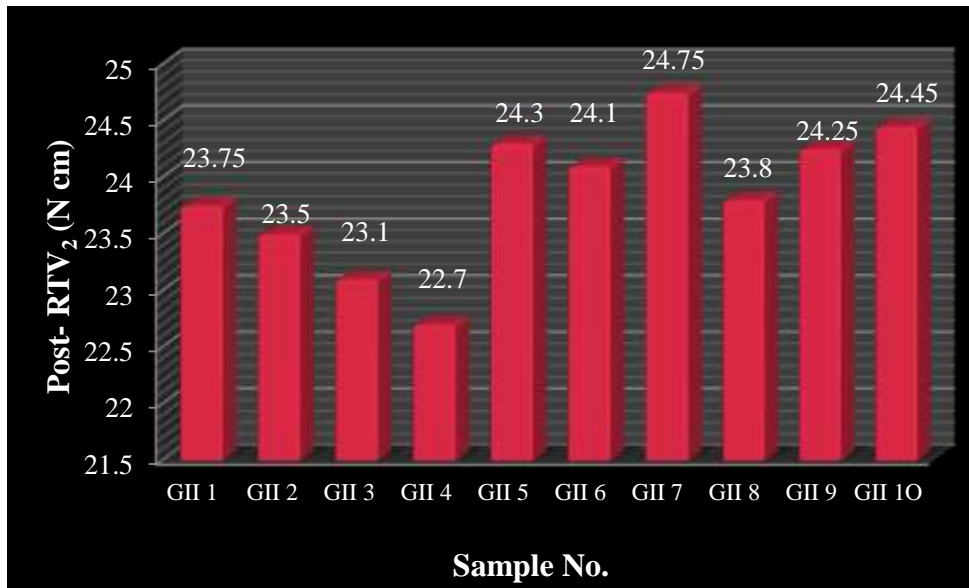
Graph III: Shows basic Reverse Torque Differences (RTD₁) of Group I test samples (25° angled premachined titanium abutments)



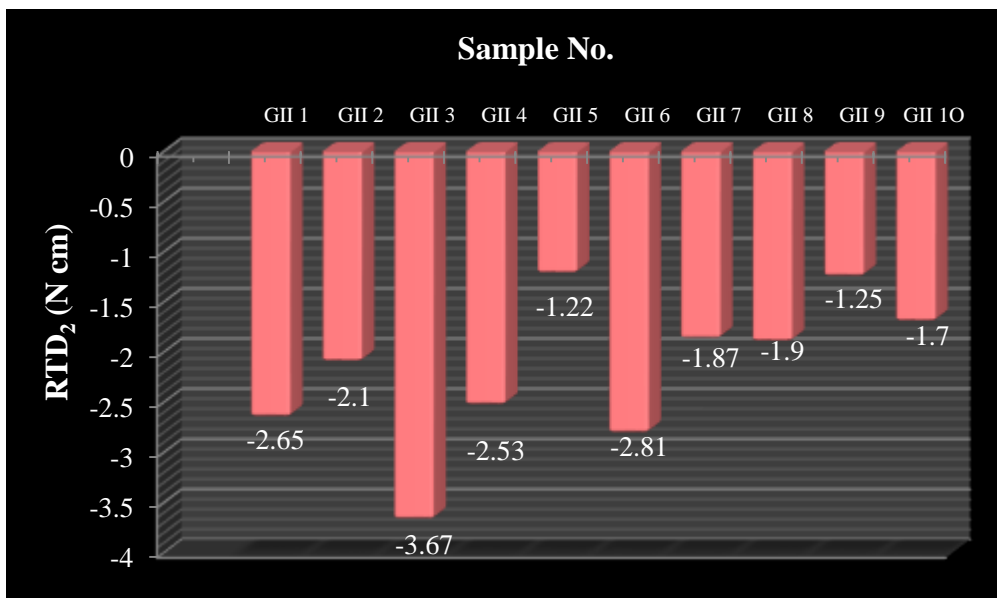
Graph IV: Shows basic pre-cyclic loading Reverse Torque Values (pre-RTV₂) of Group II test samples (25° angled custom cast cobalt chromium abutments)



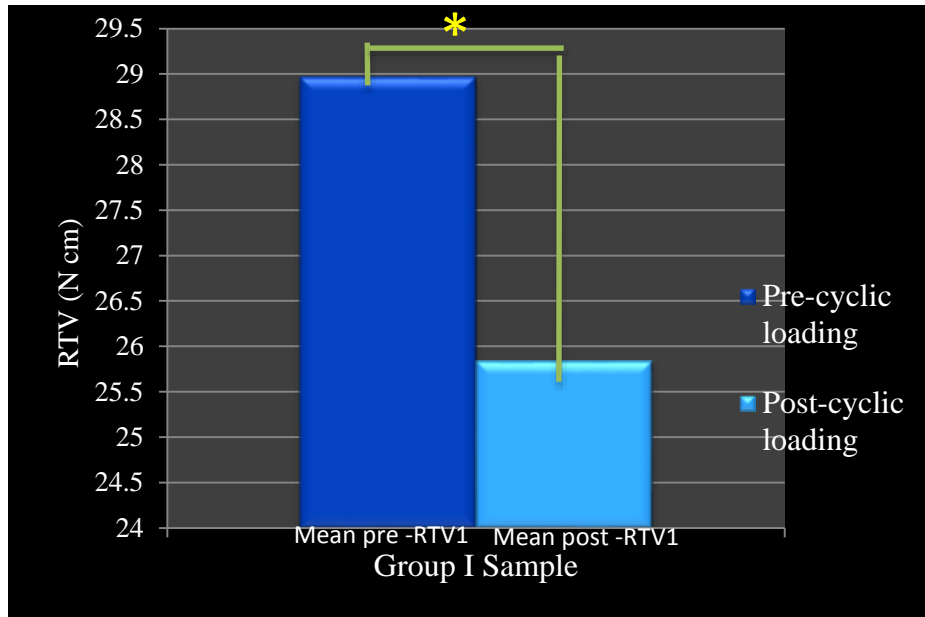
Graph V: Shows basic post-cyclic loading Reverse Torque Values (post-RTV₂) of Group II test samples (25° angled custom cast cobalt chromium abutments)



Graph VI: Shows basic Reverse Torque Differences (RTD₂) of Group II test samples (25° angled custom cast cobalt chromium abutments)

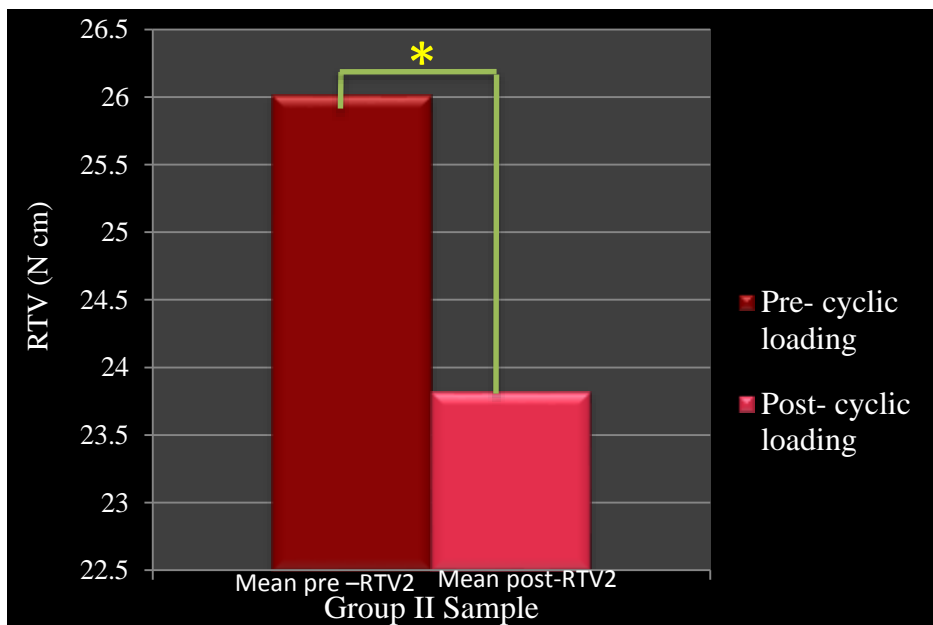


Graph VII: Shows comparative evaluation of the mean pre- and post-cyclic loading Reverse Torque Values of Group I test samples (25° angled premachined titanium abutments) using Paired 't' test



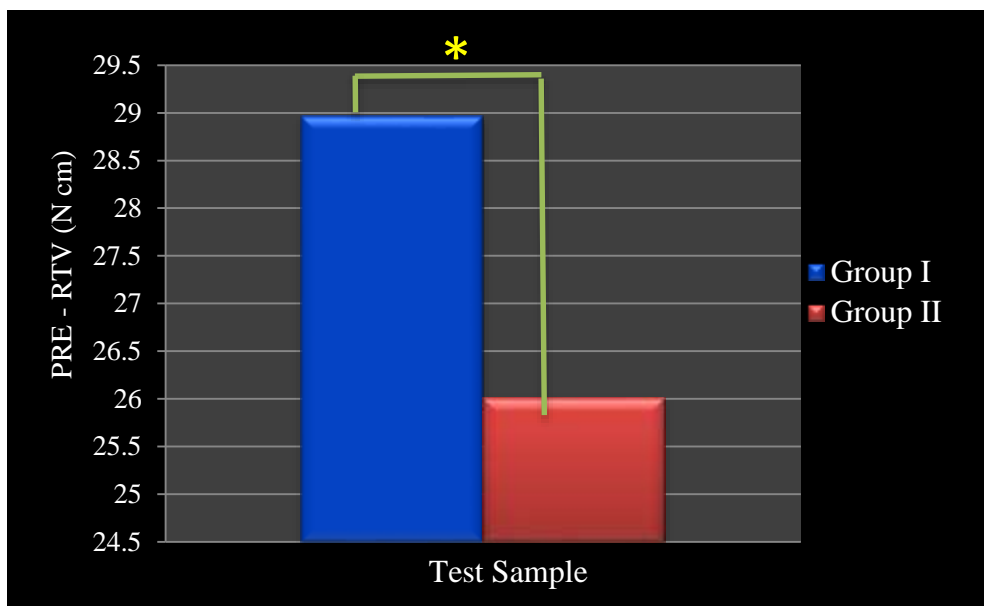
* Significant at 1% level

Graph VIII: Shows comparative evaluation of the mean pre- and post-cyclic loading Reverse Torque Values of Group II test samples (25° angled custom cast cobalt chromium abutments) using Paired 't' test



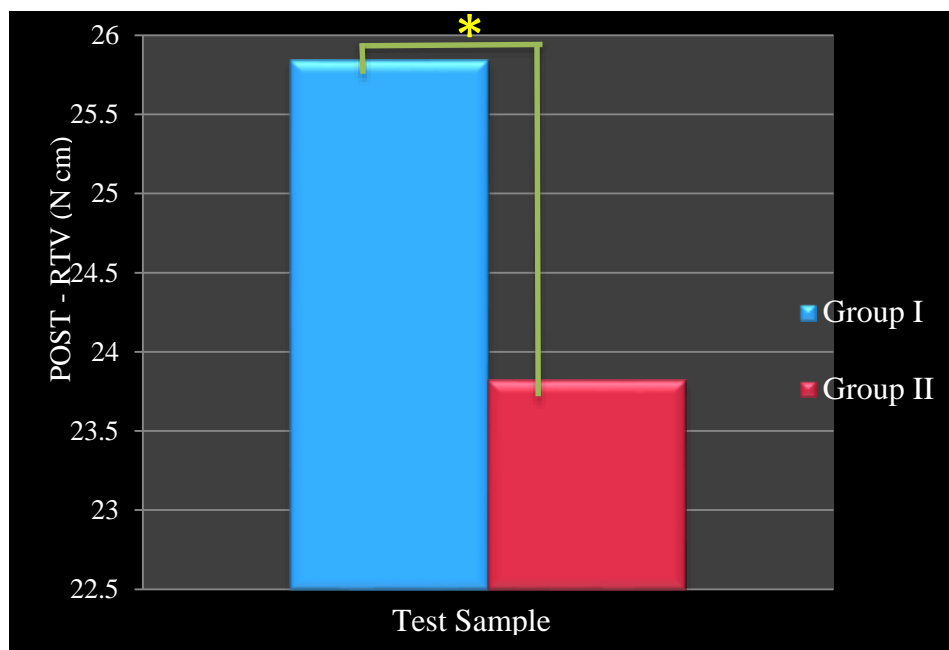
* Significant at 1% level

Graph IX: Shows comparative evaluation of the mean pre-cyclic loading Reverse Torque Values of Group I test samples (25⁰ angled premachined titanium abutments) (pre-RTV₁) and Group II test samples (25⁰ angled custom cast cobalt chromium abutments) (pre-RTV₂) using Independent 't' test



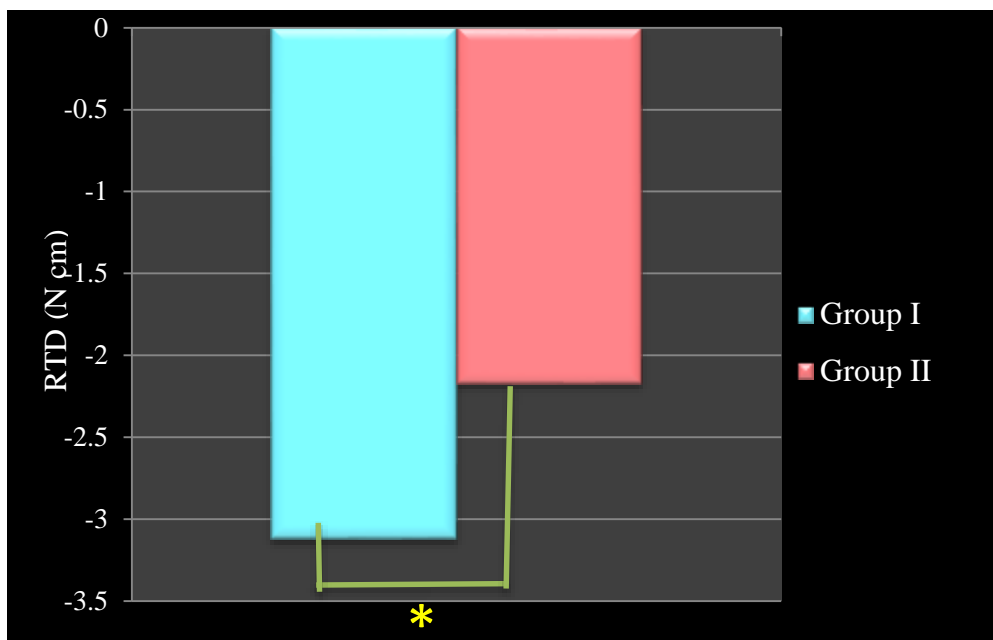
* Significant at 1% level

Graph X: Shows comparative evaluation of the mean post-cyclic loading Reverse Torque Values of Group I test samples (25⁰ angled premachined titanium abutments) (post-RTV₁) and Group II test samples (25⁰ angled custom cast cobalt chromium abutments) (post-RTV₂) using Independent 't' test



* Significant at 1% level

Graph XI: Shows comparative evaluation of the mean Reverse Torque Difference value of Group I test samples (25° angled premachined titanium abutments) (RTD₁) and Group II test samples (25° angled custom cast cobalt chromium abutments) (RTD₂) using Independent 't' test



* Significant at 1% level

Discussion

DISCUSSION

The present *in vitro* study was conducted to comparatively evaluate the effect of cyclic loading on the abutment screw loosening of premachined and custom cast angled implant abutments.

Implant supported prostheses for replacing missing anterior teeth are an established treatment option with favorable success and patient acceptance rates, that are available to us today.^{1,3,23,55} Two piece dental implants are more popular than the single piece implant system owing to their versatility in various clinical situations. It consists of an implant fixture and an abutment carrying the prosthetic restoration. The abutment is connected to the implant fixture by an abutment screw via screw joint mechanism.^{31,56,61,63}

The abutment screw is responsible for two opposite tasks. One, the screw needs to be firmly fixed to withstand loading. Two, it also needs to be retrievable for servicing and /or replacement of components above the fixture and hence, needs to be loosened. Screw loosening is one of the commonest mechanical complications that can occur in the implant prostheses and it is even more noticed in unfavorably placed implant due to off-axial loading.^{9,25,33,38,40}

Important mechanical factor that prevents abutment screw loosening and fracture is to achieve optimal screw joint “preload” during tightening of components.^{8,9,18,19,31,61,63} Preload is responsible for the clamping force which keeps the screw joint components together.^{8,9,18,19,31} Burguete and colleagues³⁸

highlighted two major aims for tightening screwed joints in the implant system. First, the joint components must be clamped together by applying a recommended torque on the joint screw which is achieved by applying an optimum preload. Second, the screw's fatigue life should be prolonged. The screw loosens only if the external "joint separating forces" are greater than the forces keeping them together. Hence, the two primary factors involved in keeping implant screws tight are maximizing the clamping force and minimizing the joint separating forces.^{5,25,31,56,61}

The joint separating forces which act on the screw joint constantly may exceed preload in cases of non-axially placed implants where the implant-abutment assembly is under non axial loading, leading to excessive occlusal forces such as bending overload and shearing stress, ultimately leading to screw loosening^{22,25,28,29,34,56,60,61}.

Ideally, implants should be placed parallel to adjacent teeth and to the adjacent implant(s) and hence should be aligned vertically. But the morphology of existing bone in the premaxillary region often dictates that implants be placed at an angle. These implants are difficult to restore with conventional abutments and so in these situations these are restored using angled abutments to fulfill functional as well as esthetic requirements.^{1,10,19,25,28,52,54}

A variety of pre-angled titanium abutments are available at angulations ranging from 0° to 45°.^{10, 21,25,31,55} In order to address angulation and esthetic concerns, castable plastic burnout patterns that can be cast using various alloys

are also available.^{18,34,35} Noble metal alloys and titanium alloys have exceptional mechanical properties and excellent biocompatibility²⁶ and they provide excellent corrosion resistance to saline or acidic environments. But, casting them has a high production cost and they are highly technique sensitive,⁵¹ so base metal alloys like Nickel-Chromium (Ni-Cr) and Cobalt-Chromium (Co-Cr) which have acceptable mechanical properties are used for cast restorations nowadays. These alloys have also been used for fabricating both custom cast straight or angulated implant abutments.³⁵

Angulated abutments used in cases of non-ideal positioning of implants, are more vulnerable to non-axial forces that transfer unfavorable forces to implant and bone thereby compromising the prognosis of the treatment as shown by in vitro studies^{11,25,28} Clinical studies have also shown that the force directions were related to stress/strain elicited along the implant-abutment interface and screw loosening. Some of the photo elastic and 3-D finite element studies have shown the greater degrees of stress patterns in the bone around the implants placed in the anterior maxilla when restored with angled abutments.^{12,16,40}

Screw loosening can be measured at various time intervals by recording the reverse torque value or detorque value of the screw.^{4,5,9,19,25,31} It is measured by applying a counter clockwise twisting or loosening movement to a right handed threaded commercial implant.⁶⁰ It is a measurement of the remaining preload in the abutment screw.⁹ Measurement of reverse torque value of a screw

is significant because it gives us an idea about the torque required to loosen a tightened screw. The more closer it is to the applied torque, the better is the maintenance of preload.⁴⁵ Measurement of reverse torque value can be accomplished by using a torque meter which can be either an analog type^{4,5,19} or a digital type.^{8,9,12,37,39} The latter has the advantage of higher accuracy levels coupled with data storage and recall facility.

A cyclic loading test is intended to simulate components in function, which permits analysis of possible interaction between abutment screw and loading and has been used in various in vitro studies to evaluate the effect of simulated loading on test specimens.^{4,5,12,18,19,25,37-40,56}

There have been limited studies comparing the influence of varying abutment angulations on screw loosening before and after cyclic loading.^{19,25,30,32} Studies comparing the screw loosening of premachined and custom cast angled abutments before and after cyclic loading in single implant situations in the anterior maxilla are lacking.

In light of the above, the aim of the present in vitro study was to comparatively evaluate the effect of cyclic loading on the abutment screw loosening of 25⁰ angled premachined titanium abutments and 25⁰ angled custom cast cobalt chromium (Co-Cr) abutments. The null hypothesis for the present study was that abutment screw loosening will remain equal despite differences in mode of abutment fabrication.

All the steps discussed in the methodology for sample preparation and cyclic loading were performed by a single operator to avoid operator based errors and bias. Sterile, titanium dental implants of the same dimensions with an internal hexagon design were employed for standardization of the implant fixtures. The internal hexagon configuration has a reported advantage of reduced vertical height from implant platform to the top of the abutment, distribution of lateral loading deep within the implant leading to a better – shielded abutment screw and long internal wall engagement that creates a stiff, unified body to resist joint micro movement when compared to external hexagon connection implant systems.^{3,18,63}

A single abutment angulation of 25⁰ was selected for both test groups simulating clinical situation with angled placement of implants. 25⁰ angled premachined titanium abutments were chosen for Group I test samples (n=10). For Group II test samples, cobalt chromium alloy was used as material of choice for fabricating custom cast abutments (n=10), since the alloy has good mechanical properties. Both the pre machined angled titanium as well as the plastic abutments used for casting were from the same manufacturer as that of the implant, to avoid the potential impact of interchangeably used abutments of other systems on the screw loosening as recommended by Kim SK et al.³⁹

Implant-abutment assembly positioning was standardized using dental surveyor. Auto polymerizing methyl methacrylate resin was used for embedding the implants in stainless steel blocks, as it exhibits an elastic

modulus similar to that reported for trabecular bone (1.95 Gpa).¹⁹ The entire implant was submerged except for 1mm at the crest module to allow easy visualization. Milling of the premachined abutments was done for standardization of abutment height, taper, mucosal collar thickness. A silicone index made over a milled 25⁰ angled premachined titanium abutment aided in standardization of the angulation and dimensions of all the plastic abutments prior to casting.

A cement-cum-screw retained maxillary central incisor restoration cast in Ni-Cr alloy, fabricated with an over contoured cingulum area was done to accommodate the stylus of the cyclic loading apparatus. A cement -cum-screw retained crown was chosen in the present study because it combines the ‘passivity’ feature of cement-retained prostheses along with the ‘retrievability’ feature of a screw retained prostheses and provides an esthetic restoration in the anterior region.^{15,47} A silicone index fabricated over one prototype wax pattern for the crown ensured uniformity and standardization among all the test restorations as reported in a previous study.⁵ All the twenty cast crowns were luted with the help of glass ionomer Type I luting cement, since this is one of the recommended luting agents for these types of restorations.²⁶

Following cementation, torque tightening of the abutment screws was done based on the protocol as recommended in the literature^{5,8,37,56,61} Prior to cyclic loading the remaining preload of the abutment screws was measured using a digital torque checker. These values were designated as the pre-cyclic

loading reverse torque values, namely, pre-RTV₁ and pre-RTV₂ for Group I and Group II test samples respectively. The mode of torque application by the clinician, namely, manual or mechanical, is an important clinical consideration.^{4,5,8,9,12,19,37,39} It has been shown that the average torque delivered by a manual driver is within 10Ncm.^{56,63} To ensure consistent tightening of implant components to torque values recommended by implant manufacturers mechanical torque gauges should be used instead of hand drivers. A digital torque meter was used in the present study because of the advantages previously described for these devices over analog types.

A cyclic loading test was performed to simulate the components in function, which permitted the analysis of possible interaction between loading and the change in preload with the aid of a custom made cyclic loading machine. A cyclic load between 0 to 109N was applied at a loading rate of 1.25Hz to simulate the force acting on anterior teeth. Loading was done simulating 6 months of clinical loading based on previous literature on cyclic loading study.²⁸ Breeding et al reported that mechanical failures like screw loosening tend to occur early, usually within the first month of function and hence,⁵ a 6 month simulation of loading was considered sufficient for the present study.

Non-axial forces were applied at a 30⁰ inclination to the crown to simulate the functional stresses along the central incisor root angulation, which arise due to its esthetic and functional requirements. In vitro studies pertaining to maxillary anterior region have used non-axial loading forces, delivered at

angulations ranging between 30° - 45° .^{19,25,30,37,38,39,60} This was achieved by the custom fabricated positioning jig in the present study.

Following cyclic loading, each test sample was subjected to visual and tactile inspection for any deformation, decementation and/or abutment rotation or loosening as recommended in the previous study.²⁵ The post-cyclic loading Reverse Torque Values were measured and were designated as post-RTV₁ and post-RTV₂ respectively for Group I and Group II samples. Further, the mean Reverse Torque Difference (RTD) was obtained for both test groups to assess the range in loss of preload. The data was analyzed statistically using SPSS software.

The mean pre- and post-cyclic loading Reverse Torque Values for Group I (25° angled premachined titanium abutments) test samples were 28.96Ncm and 25.84Ncm respectively and their mean Reverse Torque Difference was -3.11Ncm (Tables I, II, III respectively). The mean pre- and post-cyclic loading Reverse Torque Values for Group II (25° angled custom cast cobalt chromium abutments) test samples were 26.01Ncm and 23.82Ncm respectively and their mean Reverse Torque Difference was -2.17Ncm (Tables IV, V, VI respectively).

Tightened abutment screws undergo some relaxation resulting in loss of preload even without loading.^{2,6,20,57,58} This is indicated by the respective mean pre-RTV values obtained for both abutment types as against the tightening torque applied in the present study. Kano et al³² studied loss of preload in

tightened abutments screws for premachined and custom cast straight abutments. They reported a significant loss of preload in the custom cast abutments irrespective of the type of casting alloy, compared to the premachined titanium abutments. This is line with the results obtained in the present study, where there is significant loss of preload even before cyclic loading for the custom cast abutments compared to the premachined abutments (Table IX).

In previous studies, Dixon et al¹⁹, Ha et al²⁵ and Jenquiera et al³⁰ studied the effects of cyclic loading on abutment screw loosening by comparing between straight and 17⁰ angled premachined titanium abutments, straight and 25⁰ angled premachined titanium abutments and straight premachined and custom cast abutments, respectively for both internal and external connections. They concluded that irrespective of whether the connection was internal or external there is a significant decrease in the reverse torque value after cyclic loading within each abutment type. This decrease has been attributed to settling effect which is otherwise called “embedment relaxation”, which occurs when the rough contacting spots flatten under load. The extent of settling depends on the initial surface roughness, surface hardness and magnitude of the loading forces.^{56,61} The results in the present study are in line with those obtained with the above studies. When viewed with the results of these studies, it indicates that cyclic loading induces significant screw loosening in both premachined and custom cast angled abutments (Tables VII and VIII).

On comparison of the mean post-cyclic loading reverse torque values of both Group I and Group II in the present study, it was found that the mean post-cyclic loading reverse torque value for the angled custom cast cobalt chromium abutments were significantly higher as compared to that of the angled premachined titanium abutments. Angled premachined titanium abutments showed significantly lesser screw loosening compared to the angled custom cast cobalt chromium abutments after cyclic loading.

In a previous study by Jenqueira et al³⁰, the effect of cyclic loading on abutment screw loosening was compared between premachined and custom cast Ni-Cr straight abutments. They reported no significant difference in the post-cyclic loading reverse torque values between the premachined and custom cast straight abutments. This is in variance with the results obtained in the present study, where there is a significant reduction in post cyclic reverse torque values for custom cast angled abutments compared to premachined abutments (Table X). This could probably be due to differences in study design, test materials employed and the study environment. Since studies similar to the present study are lacking, further direct comparisons of the results obtained in the present study cannot be done.

Kano et al³² observed the abutment mating surfaces under Scanning Electron Microscope for interpretation of screw loosening results and suggested that the casting procedures render the abutment mating surfaces irregular compared to that of the premachined abutments. This could be a reason for the

significantly greater loss of preload seen in the custom cast abutment group in the present study and needs further evaluation.

The Reverse Torque Difference between the two groups was compared (Table XI). Reverse torque difference is the difference between pre-cyclic loading reverse torque value and the post-cyclic loading reverse torque value. The value was calculated to assess the range of torque loss in Group I and Group II samples, thereby to quantify the screw loosening.^{2,25,37,38} Custom cast 25⁰ angled abutments had significantly lesser reverse torque difference between pre- and post- cyclic loading reverse torque values. This indicated that the range of torque loss was significantly greater for the premachined abutments as compared to the custom cast abutments. However this could also be due to the limited sample size, employed in the present study. An increased sample size could also give different interpretations. This needs to be investigated further in future studies.

Within the limitations of the present study, both premachined and custom cast angled abutments had a significant loss in preload after cyclic loading. This preload loss which is indicative of abutment screw loosening was significantly greater for the custom cast angled cobalt chromium abutments than the premachined angled titanium abutments after cyclic loading. Thus the null hypothesis was rejected because of the significant differences in screw loosening values between both test groups.

The present study had some limitations. The duration of cyclic loading was only a 6 month simulation performed under dry conditions. A longer loading period may affect the screw joint differently. A reduced magnitude of torque that loosens abutment screws may not be detrimental to the screw joint unless it is progressive and if the remaining preload is sufficient to prevent slippage of joint components.¹⁹ This can be assessed when longer loading periods are employed. Further, the presence of moisture in the oral cavity may also impact the results differently. Accurately simulating the normal human functional parameters in *in vitro* studies is both time consuming and technically challenging.

Further *in vitro* and clinical studies are required to understand the different influences that can cause loss of torque values in implant-abutment screw joints. Future studies incorporating the above limitations along with a higher sample size are recommended to add merit to the findings obtained with the present study.

Conclusion

CONCLUSION

The following conclusions were drawn based on the results obtained in the present in vitro study, which was conducted to comparatively evaluate the effect of cyclic loading on the abutment screw loosening of premachined and custom cast angled implant abutments.

1. The mean pre-cyclic loading Reverse Torque Value (pre-RTV₁) of Group I test samples (25⁰ angled premachined titanium abutments) was found to be **28.96Ncm**.
2. The mean post-cyclic loading Reverse Torque Value (post-RTV₁) of Group I test samples (25⁰ angled premachined titanium abutments) was found to be **25.84Ncm**.
3. The mean Reverse Torque Difference (RTD₁) of Group I test samples (25⁰angled premachined titanium abutments) was found to be **-3.117Ncm**.
4. The mean pre-cyclic loading Reverse Torque Value (pre-RTV₂) of Group II test samples (25⁰ angled custom cast cobalt chromium abutments) was found to be **26.01Ncm**.
5. The mean post-cyclic loading Reverse Torque Value (post-RTV₂) of Group II test samples (25⁰ angled custom cast cobalt chromium abutments) was found to be **23.82Ncm**.

6. The mean Reverse Torque Difference (RTD₂) of Group II test samples (25° angled custom cast cobalt chromium abutments) was found to be **-2.17Ncm**.
7. On comparison, between the pre-cyclic loading (**28.96Ncm**) and post-cyclic loading Reverse Torque Values (**25.84Ncm**) of Group I test samples, the post-cyclic loading RTV was found to be significantly lesser than pre-cyclic loading RTV (p<0.001).
8. On comparison, between the pre-cyclic loading (**26.01Ncm**) and post-cyclic loading (**23.82Ncm**) Reverse Torque Values of Group II test samples, the post-cyclic loading RTV was found to be significantly lesser than pre-cyclic loading RTV (p<0.001).
9. On comparison, the mean pre-cyclic loading Reverse Torque Values of Group I test samples (**28.96Ncm**) was higher than that of Group II test samples (**26.01Ncm**) and this difference was found to be statistically significant. (p<0.001).
10. On comparison, the mean post-cyclic loading Reverse Torque Values of Group I test samples (**25.84Ncm**) was higher than that of Group II test samples (**23.82Ncm**) and this difference was found to be statistically significant. (p<0.001).
11. On comparison, the mean Reverse Torque Difference (RTD) of Group I test samples (**-3.117Ncm**) was significantly higher than that of Group II test samples (RTD₂) (**-2.17Ncm**) and this difference was found to be statistically significant. (p<0.001).

Summary

SUMMARY

The present *in vitro* study was conducted to evaluate the influence of the effect of cyclic loading on the abutment screw loosening of premachined and custom cast angled implant abutments.

Twenty titanium implants (standard platform) of dimension 3.75mm x 10mm were embedded individually using autopolymerizing acrylic resin in custom made stainless block and randomly divided into two groups of ten each. In Group I, ten 25⁰ angled premachined titanium abutments were connected to their corresponding implants (n=10). In Group II, ten 25⁰ angled custom cast cobalt chromium abutments were connected to their corresponding implants (n=10). Milling of abutments for standardization of the height, taper and mucosal collar thickness were done. Nickel-chromium cement cum screw retained cast crowns were fabricated for all the twenty samples and cemented with type I Glass ionomer cement with an access to the screw channel. All the abutment screws were torqued to 35Ncm using the Digital torque meter. Pre-cyclic loading Reverse Torque Values were measured individually for the samples of Group I and Group II using the Digital torque meter.

Each test sample was subjected to cyclic loading with loads up to 109N for 1,89,000 cycles simulating 6 months of function. The post-cyclic loading

Reverse Torque Values were measured for all the test samples. The Reverse Torque Difference was calculated from the pre-cyclic and post-cyclic loading Reverse Torque Values for each test sample respectively for both Groups I and II. The results obtained were tabulated and statistically analyzed.

The results of the present study yield the following conclusions:

There was loss of preload for both Groups I and II as against the applied tightening torque before cyclic loading as exhibited by the mean pre-RTV₁ and pre-RTV₂ respectively. This loss of preload in the tightened abutment screw was significantly greater for the custom cast angled abutments than the premachined titanium angled abutments. The mean post-cyclic loading Reverse Torque Values of abutment screws for both Groups I and II test samples were significantly lesser than their respective mean pre-cyclic loading Reverse Torque Values indicating that screw loosening occurs after cyclic loading for both premachined as well as custom cast angled abutments. On comparison between the two abutment types, the mean Reverse Torque Value of abutment screws for Group II was significantly lesser than that of abutment screws of Group I, after cyclic loading indicating greater screw loosening for custom cast angled abutments than the premachined titanium angled abutments.

Future studies incorporating higher sample sizes with a longer loading duration and simulating the oral environment are recommended to enhance the results obtained in the present study.

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