Measurement and Comparison of Retention Load Values between Three Implant Overdenture Attachment Systems

by

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Measurement and Comparison of Retention Characteristics between Three Implant Overdenture Attachment Systems

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in Craniofacial Science

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Abstract

Objective: To measure retention load values for Locator Legacy, Locator R-Tx and Novaloc attachment systems after two thousand multiple pulls test, and compare the retention load values at initial cycles, in addition to cycles equivalent to six months, one year and a year and a half between the three groups.

Material and methods: Three acrylic models were fabricated. Two implants were embedded into each block. Three attachment systems were tested in this study: Locator Legacy, Locator R-Tx and Novaloc attachments. Using an Electrodynamic Fatigue Test Machine (EFTM), two thousand multiple pulls test was performed at a crosshead speed of 50.8mm/min. Retention values were recorded for each of the two thousand cycles. One-way analysis of variance was carried out to compare the difference in retention load values between groups LL, R, NV at cycle numbers 1, 10, 548, 1096 and 1644. A post-hoc Tukey's test was subsequently used to identify the difference between the groups.

Results: The results revealed a statistically significant difference between the three groups at all the cycles ($p<.001$). Further, the post-hoc Tukey's test analysis showed a significantly higher retention values for Locator Legacy and R-Tx at the initial cycles, while R-Tx and Novaloc are significantly higher at cycles 548 and 1096. There was no statistical significance difference between Locator Legacy and R-Tx at cycles 1 and 10; and between R-Tx and Novaloc at cycles 548 and 1096. Furthermore, the Novaloc group was significantly higher than both groups at cycle 1644.

Conclusion: It can be concluded that LL and R groups showed an initial large reduction in retention values, 44.5% and 41.1%, respectively, from cycle 1 to cycle 10. NV and R groups exhibited significantly higher retention load values at cycles 548 and 1096 when compared to LL group. The NV group had the highest retention load values at the completion of the tested number of cycles in comparison to LL and R groups. The Novaloc attachments potentially may prove to provide some clinical advantages due to the prolonged duration of retention but there are potential complications that may also arise as a result.

Lay Summary

Due to relatively reduced denture-bearing area and mobility of the floor of the mouth, mandibular complete dentures are at higher risk of instability and lack of retention. As such, two implant supported mandibular overdentures are now considered a commonly accepted method for restoring edentulous mandible. In the past years, there has been constant new development in attachment systems that connect overdentures to implants. However, attachment systems suffer from constant wear and loss of retention which require periodic maintenance. The objective of this study is to measure and compare the retention load values of three commonly used attachment systems namely Locator Legacy, Locator R-Tx and Novaloc after multiple pulls test.

Preface

The research question was identified initially by Dr. Vincent Lee and modified subsequently by the supervisory committee. This research project was conducted under the supervision of Dr. Vincent Lee and the committee members: Dr. Caroline Nguyen, Dr. Ricardo Carvalho and Dr. Ross Bryant.

The block wax ups and implant placement were done chairside by the author, Mohammed Alqarni. Processing the blocks to heat cured acrylic resin was done at Uninature dental laboratory. The components of the project were completed by the author including the literature review, sample preparation, testing and data acquisition. The data analysis was performed by the author with guidance from the statistics department at the University of British Columbia.

As there was no human or animal or biohazards involvement in this project, ethical approval was not required from the Ethics Board of the University of British Columbia.

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List of Abbreviations

ANOVA – Analysis of variance

EFTM – Electrodynamic Fatigue Test machine

IT – Insert tool

LB – Lower acrylic block

LCT – Locator core tool

LL – Locator Legacy

MDT – Mounting and demounting tool

N – Newton

NV – Novaloc

OHIP-14 – Oral Health Impact Profile

PEEK – Polyetheretherketone

R – R-Tx

UB – Upper acrylic block

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My immense gratitude goes to my parents for their unconditional love and support throughout my journey. Great thanks to my family for always believing in me.

Finally, I must express my very profound gratitude to the government of Saudi Arabia for financially supporting my education for the past three years.

Dedication

I dedicate my thesis to my caring parents, Hathla and Nasser alqarni

Chapter 1: Introduction

In the past, conventional complete dentures were the only choice available for edentulous patients. Mandibular conventional complete dentures are often a disappointment for edentulous patients, especially for individuals who lost their teeth at a younger age.[1] Due to floor of mouth mobility and a relatively reduced denture-bearing area, mandibular dentures are at increased risk of instability. Stability of complete dentures are often based on the amount of retention and stability the denture exhibits while under functional loads. Retention is defined as the resistance in the movement of a denture away from the soft tissue when a vertical force is applied; whereas, stability is defined as the resistance in the movement of a denture away from the soft tissue when a horizontal force is applied.[2]

With the introduction of dental implants in late 1970s, treatment options for managing complete edentulism significantly evolved.[3] One such treatment option is the implant assisted overdenture. An overdenture is defined as any dental prosthesis that covers and rests on one or more natural teeth, root of natural teeth or dental implant(s).[2] Several designs of implant overdentures have been implemented so far with different number of implants and different attachment system designs, which connect the denture base to osseointegrated implants.[4,5]

Several techniques have been utilized for incorporating matrices into overdenture base. Generally, they can be categorized as a direct technique that is performed by clinician in a clinical settings, or an indirect technique that is accomplished in a laboratory.[6] Various factors can affect the technique of choice to incorporate attachments to overdenture bases such as: prosthetic design (solitary or splinted attachments), number of implants, implant positioning, angulation of the

implants, chronological implant placement in relation to prosthesis fabrication, and clinician preference.[7]

As the stability and retention of implant mandibular complete overdenture increased after using dental implants, patient satisfaction also significantly increased.[3,8,9]

1.1 Attachment systems

Attachments systems are devices that are generally comprised of two components: one that is connected to the implant (usually the patrix), and one that is incorporated into the definitive denture base (the matrix). These two components play an important role in improving overdenture stability and retention by achieving an intimate connection between the matrix and patrix.

Attachment systems can be divided into two main categories: splinted and solitary. Solitary attachments come in the form of individual studs or rare-earth magnets, whereas a splinted attachment presents in the form of bars.[10] A solitary stud attachment is a mechanical device that consists of a patrix, which is screwed to the implant, and a matrix that is incorporated within the denture base. Magnetic attachments consist of ferromagnetic metal keepers attached to the implants and magnets of opposite charge embedded in the denture base. They are made either of aluminum-nickel-cobalt alloys or rare earth elements such as samarium and neodymium.[11]

A bar attachment is also a mechanical attachment device where a milled or cast metal alloy beam is screwed to multiple implants thereby splinting and connecting the implants together. The

metal bar can be designed to receive individual attachments on top of it, or it could be designed to engage directly with matrix systems such as the Hader clip to improve retention and stability.

1.1.1 Locator Legacy

The Locator Legacy attachment system (Zest Anchors, Escondido, CA) is a solitary attachment that can be used to connect a denture directly to an implant or natural tooth root, or indirectly to multiple implants via a metal bar overdenture framework. Locator patrix (abutment) is made of titanium alloy and coated with titanium nitride that comes in gold color. On the external surface of the patrix there is a slight undercut, and on the top, there is a recessed socket. The undercut and socket features facilitate the mechanical retention mechanism. Further, the inside of the retention insert has a protuberance which plays a role in self-alignment and retention during placement over the patrix. The connection between the patrix and matrix incorporates a dual mechanism of interaction when standard retention inserts used. The dual mechanism is achieved through the engagement of the retention insert into the external undercut and the top socket of the patrix. The Locator Legacy standard inserts can compensate up to a maximum of 20 degree angulation between two implants in situations where implants are not positioned parallel to each other. The retention inserts come in three different retentive force values: extra light, light and regular and they are color coded as blue, pink and clear, respectively. The matrix metal housing of this system is made out of titanium alloy and is designed with external horizontal grooves that provides mechanical retention once embedded in denture bases (Figure 1).[12]

Figure 1: Locator Legacy patrix *(Gold)*, Retention insert *(Blue)*, Metal housing matrix *(Grey)*.

1.1.2 Locator R-Tx

In an attempt to improve the physical and aesthetic properties of the previously introduced Locator Legacy attachment system, a more recent Locator R-Tx attachment system was introduced by Zest Dental Solutions®. The patrix of the newer R-Tx attachment system is coated with DuraTec® which consists of multiple layers of titanium nitride and titanium carbon nitride that according to the manufacturer provides 30% increase in strength, around 65% surface roughness reduction and 25% higher wear resistance when compared to Locator Legacy. Additionally, the narrower coronal geometry leading edge of the R-Tx patrix was intended to allow for easier overdenture placement by patients via a taper-like effect external surface. Furthermore, in situations where implants are angulated, it can compensate for angular discrepancies of up to 60 degree between two implants instead of the maximum of 20 degree angulation correction offered by Locator Legacy standard inserts. The greater angulation compensation is achieved through the inside channel of the metal housing that allow for increased range of pivoting motion. The metal

matrix is made out of anodized titanium with a pink appearance that provides more aesthetic results compared to Locator Legacy (Figure 2).[12]

Similar to the Locator Legacy attachment, the mechanism of retention in this attachment system is dual and accomplished through the engagement of retention insert to the two slight undercuts in the external surface of the patrix. The retention inserts in this attachment system are zero, low, medium and high which are color coded as black, blue, pink and clear, respectively.[13]

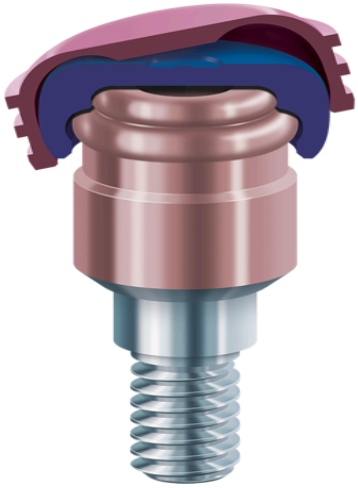

Figure 2: Locator R-Tx patrix *(Pink)*, Retention insert *(Blue)*, Metal housing matrix *(Pink)*.

1.1.3 Novaloc

Novaloc is also a solitary stud type attachment system that is manufactured by Straumann® Group (Figure 3). The patrix is made out of titanium alloy and coated with an amorphous diamond-like carbon. The manufacturer claims that this coating reduces surface roughness in comparison to other systems, increases the hardness and increases sliding characteristics which reduces abrasion to the abutment and wear to retention inserts. Novaloc is able to compensate up to 40 degrees divergence between two implants. The matrix housing on the other hand made of titanium or polyether ether ketone (PEEK), while the retention inserts is also made of PEEK plastic. Retention inserts vary in retentive force values from extra light, light, medium, strong, extra strong and ultra-strong that are color coded as red, white, yellow, green, blue and black, respectively.[13]

Due to its excellent properties, PEEK has become more common nowadays in dentistry.[14] PEEK is a semi-crystalline thermoplastic polymer material. Since its original introduction in the 1980s, it has exhibited great physical properties and has been used widely in medicine. The reason behind its widespread use are its great physical properties including: high wear resistance, corrosion resistance, biocompatibility with surrounding tissue, high modulus of elasticity and strength.[15]

Figure 3: Novaloc patrix *(Black)*, Retention insert *(Blue)*, Metal housing matrix *(Grey)*.

1.1.4 Ball

The ball attachment system is a solitary stud type attachment consisting of a patrix with a spherical shape that is screwed to implants, and a metallic or nylon based matrix that is embedded in denture bases and has different range of retention strength.

There are several designs of ball attachment, one of them is made by Nobel Biocare™. The patrix in this design is made of titanium alloy, while the Gold Cap (matrix) and retention insert is made out of gold alloy. The retention force of the Gold Cap retention inserts can by adjusted to the desired retention by turning the lamellae retention insert clockwise (increasing) or counter-

clockwise (decreasing) using screwdriver/activator for the Gold Cap. This ball attachment design can compensate up 30 degree between two unaligned implants.[16]

1.1.5 Magnet

Magnet attachment (Figure 4) is a solitary type attachment that utilize magnetism to attract and secure denture in place and reduce instability. It consists of two components: ferromagnetic metal keeper (or magnetic abutment) that is attached to teeth or implants, and a magnet that is embedded in denture bases. The metal keeper is usually made of stainless steel or titanium that is laser welded to prevent corrosion. Several designs are available for magnetic abutments such as: conical, rounded surface, flat type, and dome type. Magnet attachments have the ability to self-align dentures during insertion which make it easier for patients when wearing their dentures. The retention strength range between 1.6 N to 3 N.[17]

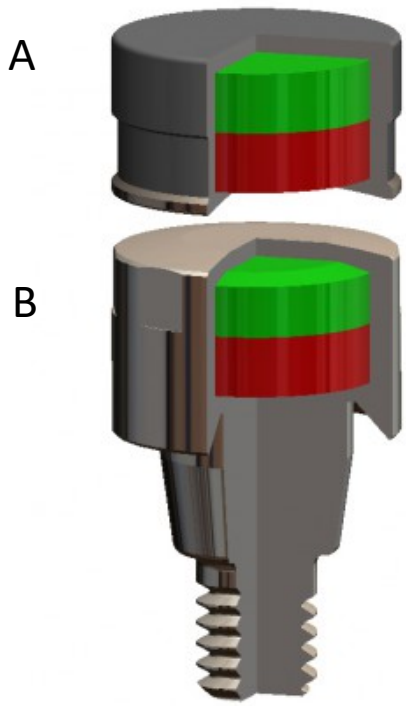

Figure 4: (A) Magnet. (B) Ferromagnetic keeper (abutment).

1.1.6 Hader bar attachment system

The Hader bar attachment system (APM-Sterngold, Attelboro, MA) is a splinted type attachment where a cast metal alloy bar is used to connect a denture to two implants or more via its abutments. The attachment system consists of three components: metal bar, retention insert (rider) and metal housing. The bar is connected to osseointegrated implants via abutments, while the metal housing and rider are embedded in denture bases. The cross section of the bar is round and it is 1.8mm in diameter, which is equivalent to 13 gauge. Furthermore, the rider is made of nylon and come in three color-coded retentive strengths: white (light), yellow (moderate) and red (heavy). The mechanism of retention in this attachment is achieved through mechanical snap

retention of the rider on the bar. Hader bar attachment allows for a hinging movement when patients are functioning with their overdenture intraorally.[18]

1.2 Implant Overdenture Attachment Systems Outcomes

Implant overdenture bars, studs, and magnets are reported to be the three most commonly used attachment systems for implant overdenture.[19] The type of attachment system used is based on clinician personal experience and patient considerations, such as digital dexterity. However, other factors should be considered, including the number of supporting implants, type and size of attachment and the degree of residual ridge resorption.[20]

Any outcome event could be categorized to an expected or unexpected event. Complications in the medical literature are defined as unanticipated problems arising following, and as a result, of a procedure, treatment or illness. Whereas a maintenance event is a problem that is expected and occurs within reasonable frequency.[21,22]

1.2.1 Magnet Attachment System Outcomes

Magnet attachment systems have been recommended for elderly frail patients with decreased manual dexterity that may limit their ability to insert and remove a dental prosthesis.[23,24] The outcomes of magnet attachment systems have been reported in the literature with comparison to other attachment systems. Cristache *et al*. [25] compared three attachment systems (Locator, ball,

and magnet) outcomes over five years of function. Success was based on criteria such as patrix/matrix activation, repair, or replacement. The results showed superior outcomes for magnet attachment with the highest success rate (82.6%). However, magnet attachments corrode and wear over time, which is associated with the reduction of the attachment strength.[26] Furthermore, in a 10-years randomized clinical trial, magnet attachments required substantially more maintenance, such as replacement of magnets, in comparison to mechanical attachments.[27]

1.2.2 Bar Retained Attachment System Outcomes

In comparison to the other outcomes of prosthetic complications and maintenances events, the most common prosthetic maintenance issues encountered with ball or bar attachments involved reactivation or tightening of the metal matrices. Furthermore, wear or fracture of the retentive components in a bar attachment systems can happen, which will require replacement of the affected components.[19,28] The outcome of the different clinical studies were inconsistent in terms of prosthetic maintenance needs. For example, in a randomized clinical trial, [29] a significant increase in maintenance was found for ball attachments compared to bar attachment systems over three years of function.[29] In contrast, another study [30] showed an increased need for prosthetic maintenance in bar attachments compared to ball attachments after five years. However, variability in the ball attachments utilized, the number of years of follow up, and the number of recall appointments in the two studies make it difficult to compare the results and may explain the difference in outcomes.

1.2.3. Stud Attachment System Outcomes

Locator® and ball attachments are among the most commonly used solitary stud implant overdenture attachment systems.[19,31] Due to their ability to compensate for implant angulation; resiliency; and simplicity of design, the Locator overdenture attachment system has become one of the preferred attachment systems.[31]

Many studies have been conducted to compare the different solitary attachment systems to each other. [25,32,33] Again, variation in outcomes were noted in the different studies that compared locator and other attachment designs. In a randomized clinical trial, Cristache *et al.* [25] showed that locator had less prosthetic complications compared to ball attachment after five years of function.[25] On the other hand, a study conducted by Kleis *et al.*, [32] compared three types of attachment systems over one year: locator, Dal-Ro, and TG-O-Ring. They found significantly more maintenance needs for locators, which mainly included the replacement of nylon matrices.[32] In agreement with the findings of the latter study [33], a recent study was conducted comparing ball attachments with locator attachments over five years. Significantly more prosthetic maintenance and complications were found with locator attachments, including adjustment of retention and ulceration. On the other hand, ball attachments had infrequent retention intervention in the first three years, as well as less frequent pain and ulceration issues.[33] However, a major complication with ball attachment is the high wear of ball in the long term which renders it useless requiring replacement of the patrix which was particularly prevalent when metal matrices were used.[34]

In the literature, many *in-vitro* studies have been conducted on the retentive characteristics of commonly used attachment systems. An *in-vitro* study was conducted by Sia and colleagues [35] using a pair of pink locator retention inserts with four different abutment height discrepancies

between the two abutments of each pair. Vertical discrepancies in abutment height tested were 0, 2, 4, and 6 mm between each pair of abutments. The four groups underwent simulated function for a period corresponding to 6 months of clinical service. The results showed statistically significant lower retention for the 0 and 2 mm groups in comparison to the 6 mm height group. However, these differences were small and may not be clinically detectable.[35] Another study was carried out by Evtimovska and co-authors [36] where a multiple pulls test was performed for Hader clips and Locator Legacy clear and green retention inserts. After 20 consecutive multiple pulls tests, locator attachments demonstrated higher retention values than the Hader clip attachments. However, the Hader clips exhibited a lower percentage of retention reduction between the first and last pulls as compared to the Locator attachments.[36] A different study that also investigated the attachment systems retentive characteristics was performed by Kobayashi *et al.* [10] They compared three attachment systems *in-vitro*: Locator Legacy, Spherical Dalbo – PLUS, and SFI-Bar for up to 14,600 insertion-removal cycles. The Locator Legacy attachment showed the highest loss of retention between the three groups.[10] Another study by Maniewicz *et al.* [37] compared retentive force changes in Novaloc, Locator R-Tx and CM LOC before and after 10, 100, 1,000, 5000 and 10,000 multiple pulls test. Novaloc showed an increase in retention force until 1,000 cycles, then diminished in retention force towards the end of the test, while R-Tx did not show a significant reduction in retention before 5,000 pulls.

1.3 Patient Based Outcomes

Studying patients' responses toward dental conditions or dental management is achieved through outcomes of patient-based assessments. The assessment of dental management is the outcome comparison by the patient prior and after treatment or comparing different treatment

approaches. It is essential to have studies that compare patient-based outcomes since it helps to facilitate the decision-making process for health care practitioners and patients in understanding the psychological and social impact for specific dental conditions or management.[38,39] One of the methods to quantify patient-related outcomes is the Oral Health Impact Profile (OHIP-14) questionnaire, which consists of 14 questions. The answers are ranked using a Likert scale where 4 is a very negative and 0 is a very positive outcome. The sum of all scores is referred to as the OHIP-total, where 0 indicates a high appreciation of quality of life and 56 indicates a low quality of life.[38]

It has been reported in the literature that patients with mandibular implant overdentures have experienced higher satisfaction compared to having conventional complete removable dentures.[3,8,9] Connecting an overdenture to two implants requires attachments, which can be splinted as bar/clip or non-splinted, such as ball, telescopic, magnetic or stud abutments. Currently, there are multiple studies that support the preference of one attachment system over the other based on the prosthetic success and maintenance. Recently, a five year follow-up study was conducted for mandibular two implant overdentures outcomes using ball and locator attachments. Ninety edentulous patients were treated with two implant mandibular overdentures using either ball (n=34) or Locator Legacy (n=56) attachment systems. Many variables were assessed in this study, including the OHIP-14 score at baseline before implant placement, 1 year and 5 years following implant overdenture insertion. The results showed that irrespective of the attachment system used, the OHIP-14 score ranged from 18.1 at baseline without implant attachments to 2.7 at the five years post-implant overdenture insertion follow up.[33] Another study [40] compared the outcome and patient satisfaction of different number of implants placed and different attachment systems for

mandibular overdentures. The three groups in the study were: 36 patients with ball attachments over two implants, 37 patients with a bar attachment over two implants, and 37 patients with a triple bar over 4 implants. At 1.5 year post-insertion, patient satisfaction was assessed using a questionnaire, and it was found that all groups had a positive satisfaction score in comparison to the baseline before treatment.[40] Eight years later, patients with ball attachments were found to be less satisfied with the retention and stability of their overdenture in comparison to the two other groups. However, the two-implant bar overdentures and four-implant triple-bar overdentures stayed at the same satisfaction level over 1.5 years from the baseline.[41]

The performance of a particular attachment system and patient satisfaction is dictated markedly by the amount of perceived retention. The coating on the patrix and the material composition of the retention inserts may also play a role in maintaining retention levels over time. It is not a straightforward task to quantity the minimum retentive force necessary for implant overdentures and patients satisfaction. It has been reported that 20 N is considered sufficient retention for mandibular overdenture[42]; however, lower retentive forces (8-10 N) have recently reported in the literature[43]. The required clinical retentive force rely largely on patients frailty and manual dexterity hence lower retentive forces are usually required for geriatric patients.[44]

1.4 Implant overdenture maintenance:

Individuals seeking prosthodontics treatment usually present with a loss of tooth structure, substantial dental treatment history, and complex etiological factors leading to tooth loss.[45] Therefore, complex treatments are needed to address functions and esthetics.[45] It is essential to

understand that regular patient recall and professional and home maintenance regimens are paramount for long-term success of the treatment.[46,47] In 2015, the American College of Prosthodontists reviewed the available literature and published consensus documents that proposed clinical practice guidelines for maintenance of tooth and implant borne prostheses. With regards to implant overdenture maintenance protocols, the guide consisted of three major components.

First, patient recall which includes obtaining dental examination visits at least every 6 months (lifelong). Patients at higher risks of based on age, ability to perform oral self-care, mechanical and biological complication of implant borne restorations should attend dental examination visits more frequently than every 6 months.

Secondly, professional maintenance which subsequently divides into biological and mechanical maintenance. Biological maintenance includes dental examination, oral and prosthesis hygiene instructions and providing chlorohexidine gluconate rinse if antimicrobial effect is needed. Professionals should use hygiene instrumentation that is compatible with implants and implant prostheses. Furthermore, implant removable prostheses should be cleaned extraorally and oral topical agents and oral hygiene aids should be recommended or prescribed by professionals for patient's home maintenance needs. Professional mechanical maintenance should include examination of intra- and extraoral prosthesis components. Adjustment, repair, replacement or remake of prosthesis or any of its components should be recommended or performed when needed.

Lastly, home maintenance where patients should be advised to clean the implant's intraoral components twice daily and clean their prosthesis with a soft brush and recommended cleansing agent. Additionally, patients should be advised to remove their prosthesis while sleeping and store it in a recommended cleansing solution.

1.4.1 Attachments and Cleansing Agents.

On a routine basis, it is recommended for patients wearing overdentures to keep a high standard of hygiene by using mechanical or chemical cleansing agents.[48-51] Mechanical cleansing usually involves brushing with water and soap/toothpaste or ultrasonic cleaning. The chemical cleansing agents may be alcohol-based disinfectant, alkaline hypochlorite, alkaline peroxides or other cleansing agents.[48] It has been shown that mechanical brushing is not enough to remove debris, plaque, and dental calculus on overdenture surfaces.[52] Therefore, it was recommended to use chemical cleaning agents to maintain standard hygiene.[48,52-55]

If used incorrectly, denture cleansing agents may have adverse effects on overdentures, such as bleaching of the acrylic resin, metal corrosion or deterioration of attachment components.[48,56-58] Nguyen *et al.*[59] conducted an *in-vitro* study where pink retention insert for locator attachments were soaked in six different cleansing agents: Polident Regular, Efferdent®, sodium hypochlorite (NaOCL, 1:10 dilution), Polident Overnight, Cool Mint Listerine® mouthwash, and water as the control group. Twenty pink retention inserts for each group were soaked for a period of time equivalent to 6 months of use according to manufacturer instructions. A one pull test was performed using a universal testing machine and the peak-to-dislodgment values were recorded for each group after being soaked in the different solutions. Compared to the control group [60],

sodium hypochlorite was found to significantly reduce the retention of the locator attachment. However, the Polident Regular and Polident Overnight group was not found to be statistically different when compared to the control group. Cool Mint Listerine mouthwash increased the retentive values of the attachments when compared to the control group, although this might be accompanied with added brittleness, while Efferdent decreased retention slightly.[59] In another *in-vitro* study conducted by You *et al.*, [61] pink locators were soaked in sodium hypochlorite (NaOCL, 1:10 dilution) and other cleansing agents. An initial peak-to-dislodgment pull test was conducted for each group. 548 insertion and removal cycles (equal to 6 months of use) were completed for each group. After 6 months of use, all groups showed significant reduction in the retention of the pink Locator retention inserts. Sodium Hypochlorite showed significantly lower retention compared to the other groups.[61] Ayyildiz *et al.* [62] results also showed that Sodium Hypochlorite significantly reduced the retention of pink locator attachments after 6 months of immersion in comparison to their remaining study groups.[62] On the other hand, another study compared the Hader clip retention using a one pull test after soaking for a period equivalent to 6 months according to manufacturer instructions in one of the following solutions: Polident regular, Polident overnight, Efferdent, Sodium Hypochlorite (1:10 diluted) 15 mins/day, Sodium Hypochlorite (1:10 diluted) for 8 hours/day, water or dry. Sodium Hypochlorite (1:10 diluted) for 15 mins/day showed a significant increase in retention compared to the other groups.[63] This increase in retention, may indicate an increase of Hader clip rigidity due to immersing in Sodium Hypochlorite.

1.5 Implants Overdenture Complications

Complications in the medical literature is when unanticipated problem arises following, and as a result, of a procedure, treatment or illness, whereas maintenance is when a problem is

expected and happened within reasonable frequency.[21] Complications may arise from any prosthodontic treatment.[64] Many authors have looked into implant overdenture complications. [25,29,64,65] There are a wide range of complications that can be encountered in the three main components of implants overdenture prostheses: the attachment, the implant or the prothesis.[28] Attachment components complications could be a loosening of the attachment, attachment fracture, the need to replace the matrix/patrix, or the need to change the entire attachment system to a different one. Furthermore, implant related complications can include fracture of the implant, failure of the implant or jaw fracture. Lastly, various prostheses related complications can be found such as the need to adjust the denture tissue surface, adjustment of interferences, or full denture remake. [28,66,67]

Implant overdenture complications have been reported in the literature. Complication prevalence vary greatly between the different components of implant overdentures. In 2003, a literature review was published for clinical implant and implant prosthesis complications between 1981 and 2001[28]. Implant overdenture complications include overdenture reline of 19% (represent 114 out of 595 prostheses) incidents for the included studies. Overdenture attachment or clip fracture composed 17% (represent 80 out of 468 prostheses) and overdenture fracture were present in 12% (representing 69 out of 570 prostheses) of the studies included in the literature review. Implant loss occurred in 19% (representing 206 out of 1103 implants) of maxillary overdentures and 4% (representing 9 out of 242 implants) of mandibular overdentures. In 2018, another literature review [68] reported implant prosthesis complications between 2001 and 2017. Implant overdenture complications included mucosal hyperplasia (31%), overdenture reline (26%),

opposing prosthesis reline (25%), and attachment loss or fracture (5% of incidents for the included studies).

Chapter 2: Project Rationale, Specific aims and Hypothesis

Patients with substantial alveolar bone resorption may experience problems with the use of conventional complete dentures. These problems arise from impaired load-bearing area capacity, such as pain during mastication and insufficient stability and/or retention of dentures.[69] For many years, the only available option was to replace missing teeth with complete dentures. However, based on the McGill Consensus statement on overdentures, the standard of care should now be two-implants supported overdentures for the edentulous mandible.[8] Many attachment systems are currently available in the marketplace, and all retentive attachment systems suffer from ongoing wear and require continuous maintenance.

In the literature, many *in-vitro* studies have been conducted on the retentive characteristics of commonly used attachment systems, where most of them were over a predetermined number of cycles. However, there is a lack of studies conducted on the pattern of retention loss of commonly utilized implant overdenture attachments systems. Therefore, it would be advantageous to measure retention force values for each cycle under multiple pulls test for common clinically utilized retentive attachment systems, and compare them at any specific cycle. Furthermore, no study has yet compared the Legacy Locator, Locator R-Tx, and Novaloc together under multiple tests. Hence, it would be beneficial to compare retention force values between the three attachment systems.

2.1 Specific aims:

- To measure retention force values for Locator Legacy, R-Tx and Novaloc attachment systems during 2,000 multiple pulls test.
- Observe graphically the trends plots of the continuous retention load values measurements of Locator Legacy, Locator R-Tx and Novaloc for two thousands multiple pulls test.
- To compare the retention force values between the three attachment systems at cycles 1, 10, 548, 1096, and 1644.

2.2 Null Hypothesis

- H_0: There is no statistically significant difference in retention force values between Locator Legacy, Locator R-Tx and Novaloc attachment systems at cycles 1, 10, 548, 1096, and 1644 after multiple pulls test.

Chapter 3: Materials and Methods

3.1 Sample Size Calculation:

The sample size calculation of the current study was based on means of Sia *et al.* study[35], where a power analysis was performed. The results showed that a sample size of 14 in each group is required to detect significance mean differences between the groups. For this study's power analysis, α was set at 0.01 and effect size of 0.89, to allow for 0.99 power. The sample size calculation was performed using G*Power software for Mac, Version 3.1.9.6 (Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany).

Since there were multiple comparisons performed simultaneously at the selected cycles (1, 10, 548, 1096, and 1644) between the three groups, the multiple comparison must be ameliorated, to avoid the issue of multiple comparisons (recommendation of Statistics Department, UBC). One common method is to apply Bonferroni correction, which is reduces the level of significance by dividing it to the number of tests. In the current study, we run five comparison at the five selected cycles, hence the corrected level of significance set at = 0.05/5 = 0.01.

3.2 Model Fabrication:

This research project implemented methods similar to those described by Varghese *et al*.[63] and Nguyen *et al.*[59] Initially, 3 pairs of wax blocks were fabricated to be used in this research project, one pair for each group. The armamentarium used for shaping the wax blocks were measuring ruler, wax knife, blade handle, blade number 15 and Beale wax carver (Figure 5). Using the aforementioned tools, the first block of each pair was constructed using Metrowax wax base plates (Metrodent, Huddersfield HD3 4EP, United Kingdom) into a rectangular block with

dimensions of 2” × 1” × 1.5” in length, width and height, respectively (Figure 6). The second block of each pair was then constructed with the same dimensions.

Figure 5 Wax block fabrication armamentarium.

Figure 6 Wax block with dimensions of 2” × 1” × 1.5” (length, width and height, respectively).

Two implants (Bone level, RC, 4.1 mm, 10 mm length; Institut Straumann AG,Basel, Switzerland) were then placed in the first wax block of each one of the three pairs of wax blocks. The implants were placed 22mm apart from each other being consistent with the previously reported average distance between mandibular canines.[70] The entire implants were embedded in the wax block. Parallelism and depth were maintained the same during the implants placement. In order to achieve parallelism and depth a wax guide pin was attached to a Ney surveyor (Dentsply, Bloomfield, CT). The wax guide pin was then attached to each implant individually and placed in a perpendicular manner to the wax block and the floor (Figure 7). Two impression posts (Institut Straumann AG,Basel, Switzerland) were inserted and hand tightened to the implants to ensure of the implants stability during subsequent steps of investing, wax boil out and acrylic packing (Figure 8).

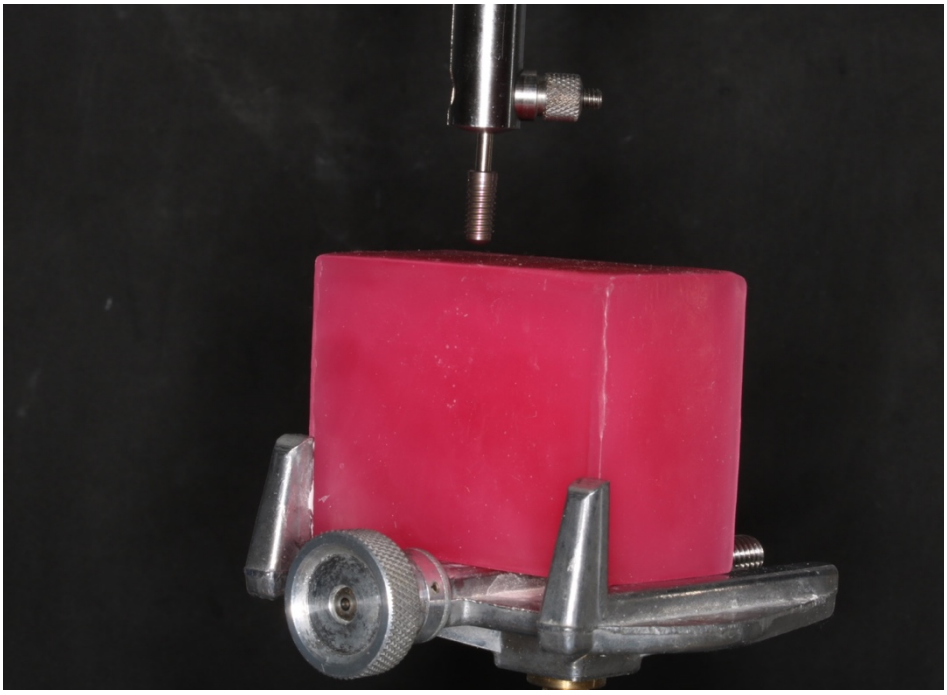

Figure 7 implant attached to wax guide pin and Ney surveyor during placement into the wax block.

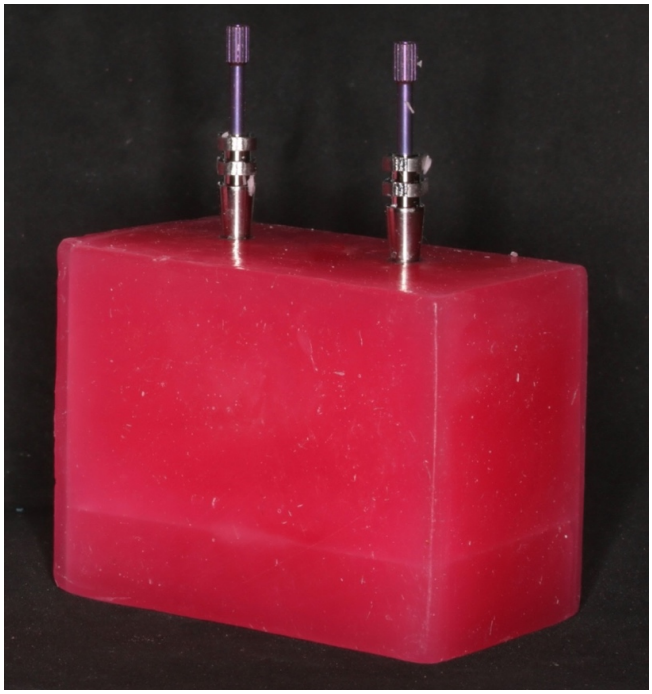

Figure 8 Wax block with two implants embedded and attached to impression posts.

The completed wax block pairs ready for the investment step (Figure 9). Each wax block was invested in a flask using type II stone (Kulzer, South Bend, IN). Each flask was then placed in a boil-out tank for seven minutes to melt down the wax and create the mold for acrylic packing at a later stage. The flasks were then removed from the boil-out tank and the flask were separated. The remaining wax inside the flasks were removed and cleaned with hot steam to ensure complete wax removal. The flasks were then bench cooled at room temperature for 30 minutes (Figure 10). Two layers of separating medium (Ivoclar Vivadent Inc.) were applied to facilitate the separation of the acrylic block during the divesting step (Figure 11). Heat polymerized clear ProBase acrylic (Ivoclar Vivadent Inc.) was mixed according to manufacturer instructions and packed into the flasks in the doughy stage.

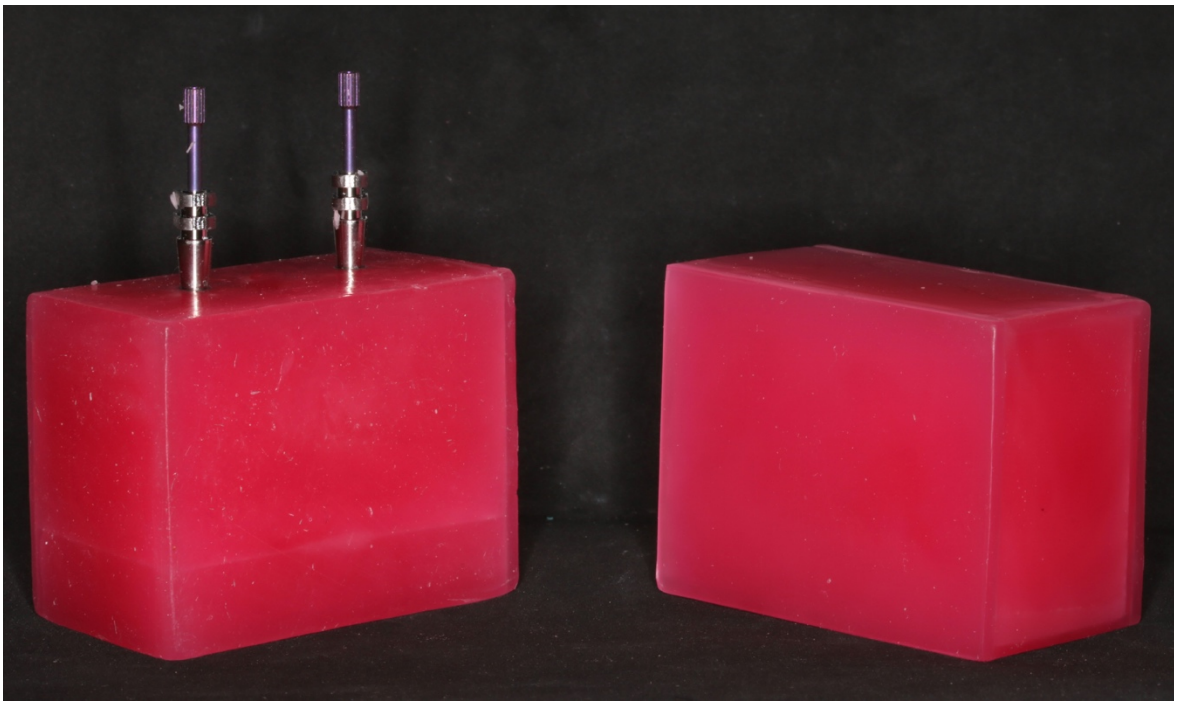

Figure 9 Finished wax blocks. *(Left)* First wax block with attached impression copings. *(Right)* Second wax block.

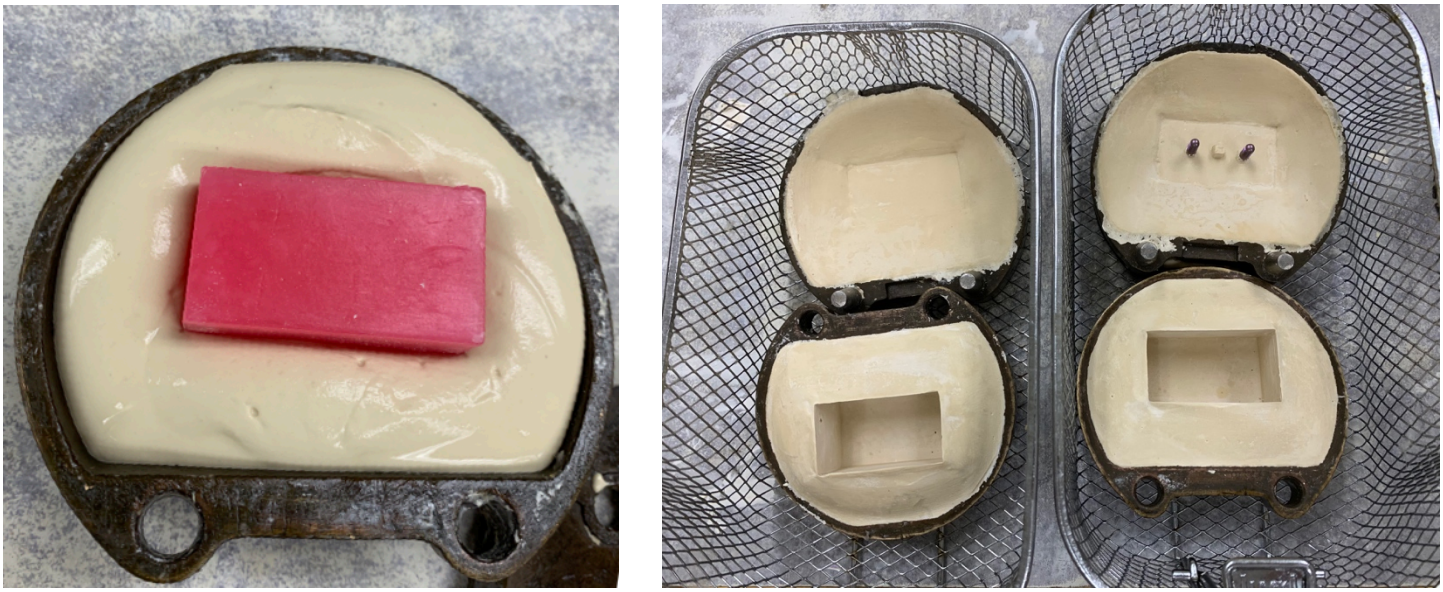

Figure 10 Wax block flask investing and cool down process.

The flasks were then inserted into a flask press to pack the acrylic. A pressure of 1500 psi was applied three times for each flask and a final pack at 3000 psi. The flasks were then heat activated in a hot water tank at 165F^{o} for 9 hours for one cycle. Once the cycle was completed, the flasks were divested and the acrylic blocks were finished and polished (Figure 12).

The same fabrication process was followed for the second block with the exception that no implants were placed. The second block was merely solid acrylic block at this stage.

Figure 11 application of separating medium.

Figure 12 Finished and polished acrylic block pair. *(Bottom)* Lower acrylic block (LB), *(Top)* Upper acrylic block (UB)**.**

3.3 Model-Machine Connection Preparation

In this study, an Electrodynamic Fatigue Test machine (EFTM) (TestResources, Shakopee, MN, USA) was utilized to perform the multiple pulls test which will be discussed in the following section. Each acrylic block needed to be fixed to the EFTM in order to perform the multiple pulls test. The connection between the acrylic block and the machine is achieved through special fixtures (Figure 13). Modifications of the acrylic blocks bases were needed to allow the blocks to be connected to the fixture. The fixtures consisted of screw threads at one end which were hand tightened to the machine and body and key-channel on the other end. In order to attach the acrylic blocks to the other end of the fixture, a hollow space was prepared in the block bases to

accommodate the fixture's body. Afterward, two additional holes were prepared on either side of the acrylic blocks to complement the key-channel components (Figure 14).

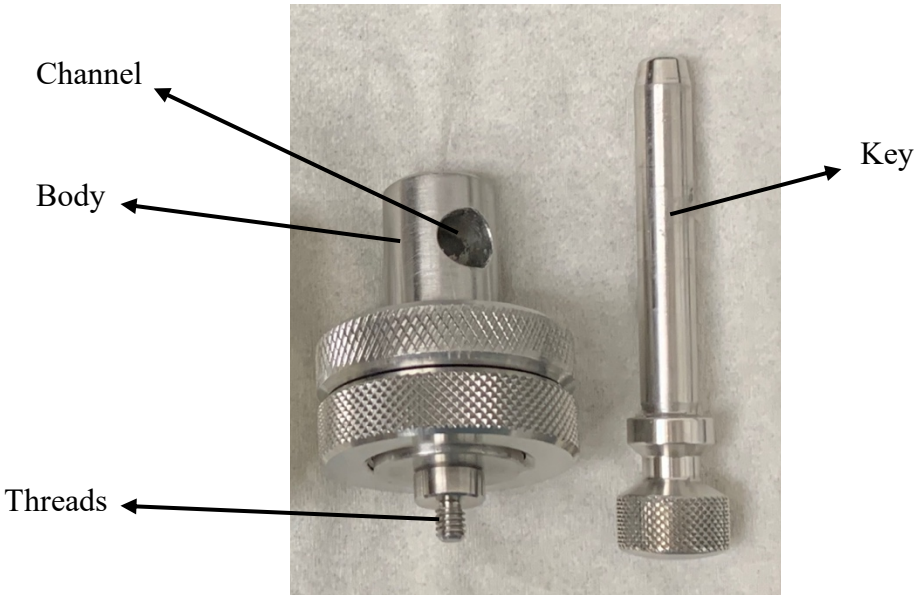

Figure 13 Block-Machine connection Fixture

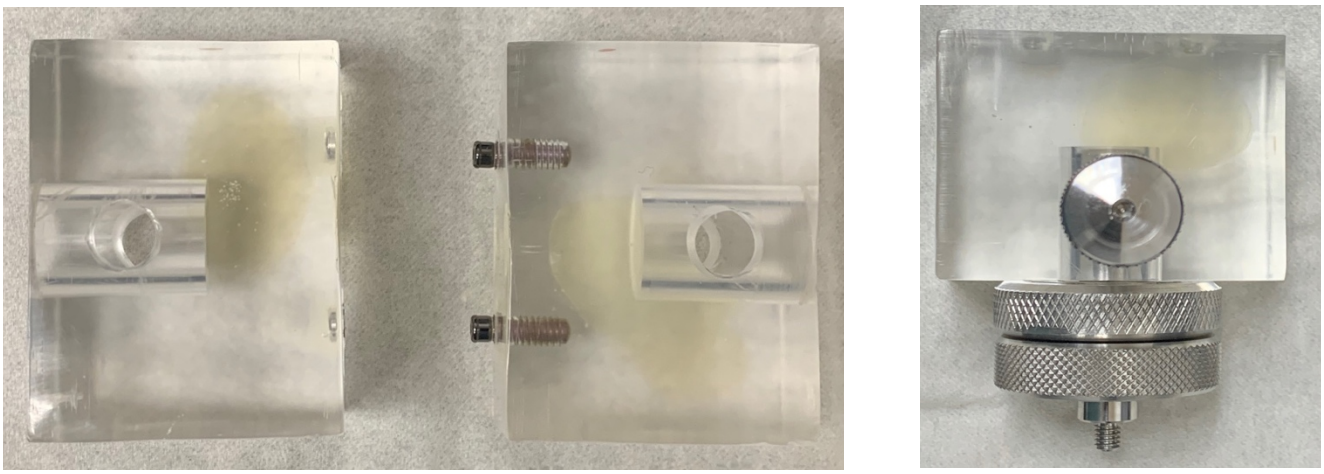

Figure 14 *(Left)* Blocks with fixture prepared spaces. *(Right)* Acrylic block attached to the fixture.

3.4 Electrodynamic Fatigue Test machine

In this study, an Electrodynamic Fatigue Test Machine (EFTM) was the device of choice to perform the multiple testing procedure. EFTM is a tabletop machine system that performs several mechanical tests including static, dynamic and fatigue load testing that can range between 0.5 Newton and 50,000 Newton load capacity. Dynamic testing includes tensile, compression, change in strain and load, and collect an accurate time-dependent measurement of different material utilizing a computerized test software. It has the ability to report and analyze dynamic properties of polymers, elastomers and other biomaterials. In term of hardware components, the machine consists of metal dual column load frame, electrodynamic actuators, load cell, test software, computer and other accessories.

3.5 Model Set Up in the Electrodynamic Fatigue Test Machine

EFTM has a lower member that is always fixed and does not move in any direction, and an upper member that moves in a vertical up or down direction. The Upper Block (UB) and Lower Block (LB) were securely fixed to the upper and lower members, respectively. The experimental setup in this study is based on moving the upper member in a vertical direction along an axis parallel to the placed implants, which is also parallel to the path of insertion and removal of the tested attachment systems.

Initially, the one fixture was screwed to the lower member of the EFTM and hand tightened. The lower acrylic block (LB) was then inserted to the lower fixture and securely tightened to ensure stability and prevent any movement of the acrylic block during the experiment. Similarly, the upper fixture was hand tightened to the upper member of the machine and UB inserted to it and hand tightened.

After securing the acrylic blocks in the EFTM, two abutments were screwed and hand tightened to the implants in the LB. Each abutment was then torqued using a corresponding screwdriver and torque wrench according to the manufacturer instructions torque force values. The upper member was then lowered down carefully using the computer software to identify sites on the lower surface of UB that correspond to the abutments embedded in LB. The identified sites on UB will be used to drill hollow spaces for the metal matrices for each corresponding attachment system. The upper member was then lifted up carefully and UB was then removed from the upper member and hollow spaces were drilled in the indicated sites. After drilling the hollow spaces, UB was replaced and hand tightened to the upper member. Heat activated clear acrylic resin was then applied around the metal housing and inside the hollow spaces followed by dragging the upper member down again. Following the initial setting of the acrylic resin, the upper member was dragged up where the metal housings were picked up inside UB. Further curing process for the recently added acrylic resin was performed by placing UB in hot water and applying pressure in a pressure cooker. UB was removed from the pressure cooker, finished, polished and replaced to the upper member (Figure 15).

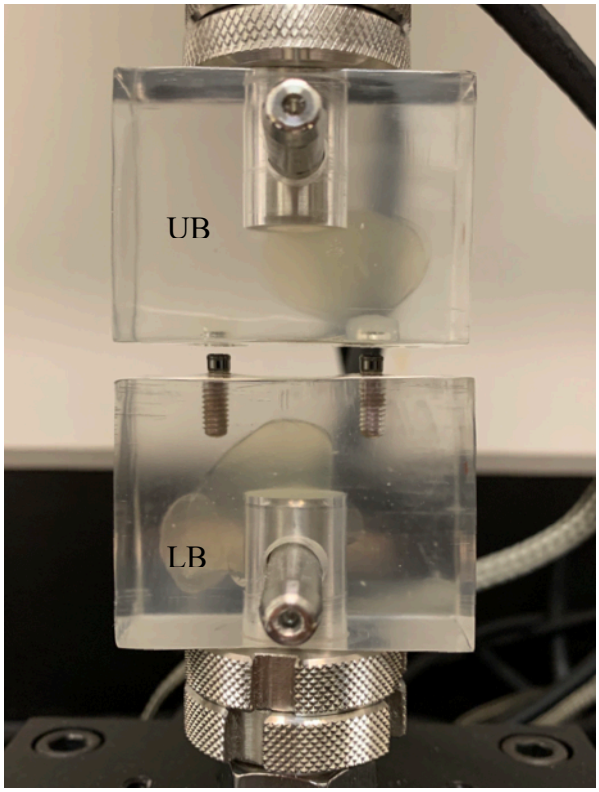

Figure 15 LB (Bottom) and UB (Top) attached to the lower and upper member of the machine, respectively**.**

3.6 Machine validation

A validation process was performed for EFTM to ensure data collection reliability. The validation process was achieved by testing different retention insert types other than the retention insert type that was used in this *in-vitro* study. As pink retention insert (medium strength) is the most commonly used by dentists [59], the chosen retention inserts in this study were medium, hence strong and light retention inserts types were utilized for the validation process. Following multiple pulls testing procedure (Detailed testing procedure is explained in the following section) of the strong, medium and light retention inserts, data was collected. The data showed higher, medium

and lower values corresponding to strong, medium and light retention inserts, respectively. The results of this validation process indicated the EFTM reliability.

3.7 Experimental Groups

The experimental groups in the current study comprised three attachment systems groups, Group 1: Locator Legacy, Group 2: R-Tx, Group 3: Novaloc (Figure 16).

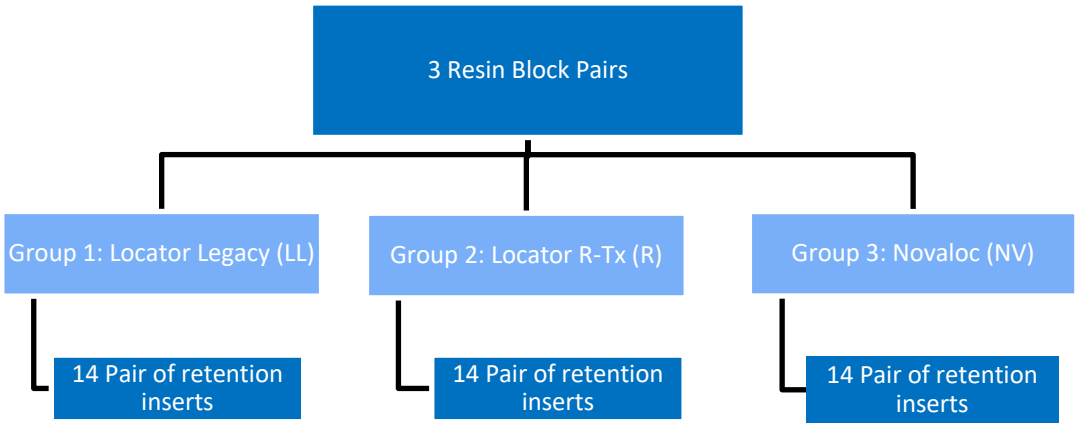

Figure 16 Experimental groups

Each attachment system involved in this study consisted of titanium abutments, titanium metal housings and retention inserts (Figure 17). Efforts were made to focus testing the medium retention inserts in all involved attachment systems in this study (Figure 18).

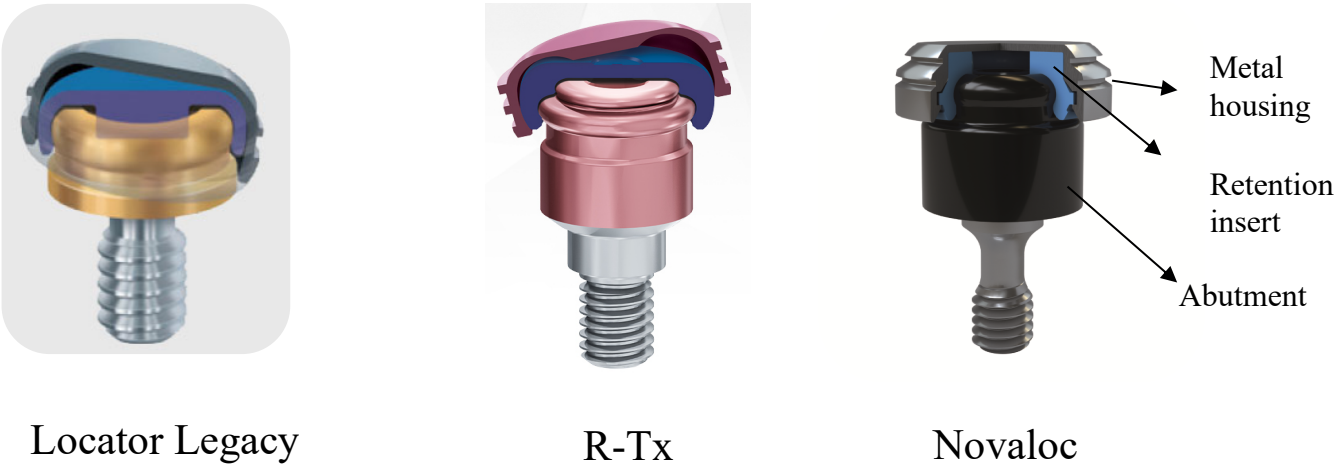

Figure 17 Attachment systems: Locator Legacy *(Left),* R-Tx *(Middle),* Novaloc *(Right).*

Figure 18 Retention inserts for: Locator Legacy *(Left),* R-Tx *(Middle),* Novaloc *(Right).*

3.8 Testing Setup Procedure

In this *in-vitro* study, each attachment pair underwent two thousand multiple pulls cycles. The test starts first by fully seating the matrix over the patrix making sure that there is no loading applied when fully seated. Each cycle started by displacing the engaged attachments moving the

upper block upward and ending the cycle by inserting it to the same full seating position. Each removal-insertion cycle was considered as one cycle. The EFTM was programmed to measure a load parallel to the path of insertion and removal at a crosshead speed of 50.8 mm/min (0.16 Hertz, 1 cycle per 6 seconds) and 2.5mm displacement distance. Several load force values were recorded with each removal-insertion cycle and exported to the computer. At the end of two thousand cycles, the retention inserts were replaced 14 times with a new retention inserts in each group.

Different special removal tools were used for replacement of the retention inserts in each attachment system group. For instance, the Locator Core Tool (LCT) was used for removing and placing the Locator legacy retention inserts (Zest Anchors, Escondido, CA) (Figure 19). Meanwhile, the Locator R-Tx Insert Tool (IT) was used to remove and place retention inserts in the R-Tx attachment system (Zest Anchors, Escondido, CA) (Figure 20). Finally, the Novaloc Mounting and Demounting Tool (MDT) was used for removal and placing NV retention inserts (Institut Straumann AG; Valoc AG) (Figure 21).

Figure 19 Locator Legacy core tool (LCT)

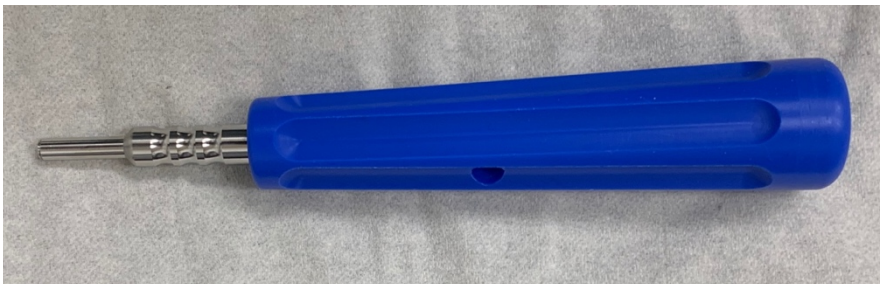

Figure 20 Locator R-Tx insert tool (IT)

Figure 21 Novaloc Mounting and demounting tool (MDT)

3.9 Statistical Analysis

Raw data in this *In-vitro* experiment was initially generated toward an excel files. The desired data was obtained subsequently and arranged in SPSS statistical software (SPSS, Chicago, IL, USA). In order to perform the appropriate statistical analysis test, the initial goal was to determine whether the data is normally distributed or not ($p<0.01$). Shapiro-Wilk test and Z-values calculation were performed to test the normal distribution of the collected data. It was noted that the Shapiro-Wilk test results of all the groups at all the cycles numbers were not significant ($P>0.01$). Additionally. All the Z-values were within ± 1.96. Hence it was concluded that the data sets are approximating normality and a parametric statistical test (One-way analysis of variance)

was used to perform the statistical analysis. A One-way analysis of variance (ANOVA)[71] test was carried out to determine if there is any statistical significance difference between groups LL, R, NV. A post-hoc Tukey's test was used afterward to identify the difference between the specific groups.

Chapter 4: Results

Based on the present experiment, the retention load values were obtained for the three groups at each cycle for two thousand cycles. A continuous plotted lines graphs were subsequently drawn for each system individually in order to study the retention pattern of each attachment continually along the entire multiple pulls test. The figures as shown in Figure 22 & 23 were made in relation to the cycle number and load value that are represented in the X axis and Y axis, respectively.

It can be noted in the figures below (Figure 22, 23) that the retention values of LL and R groups had decreased dramatically at the beginning of the multiple pulls test during the first 10 cycles. The LL group continued to decrease gradually until the end of the test. However, the R group had increased slightly and gradually after the initial dramatic decrease until cycle 900, and then had a gradual decrease again for the remaining of the multiple pulls test. On the other hand, NV group had a slight initial decrease of the retention load values and then increased at cycle 10 and continued to increase gradually till the end of the two thousandth cycle.

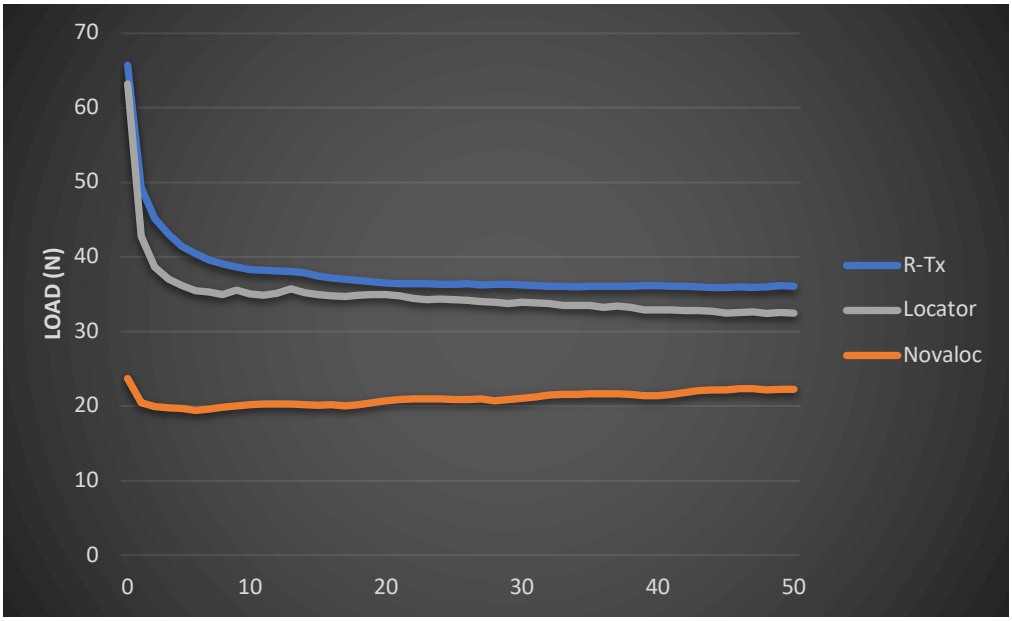

Figure 22 Time dependent mean retention load values for the first 50 cycles of the multiple pulls test for Locator Legacy *(Grey)*, R-Tx *(Blue)* and Novaloc *(Orange)*. This figure is showing the dramatic initial decrease in retention for Locator legacy and R-Tx, and the slight decrease for Novaloc. *N – *Newton;* Cycle – *cycle number.*

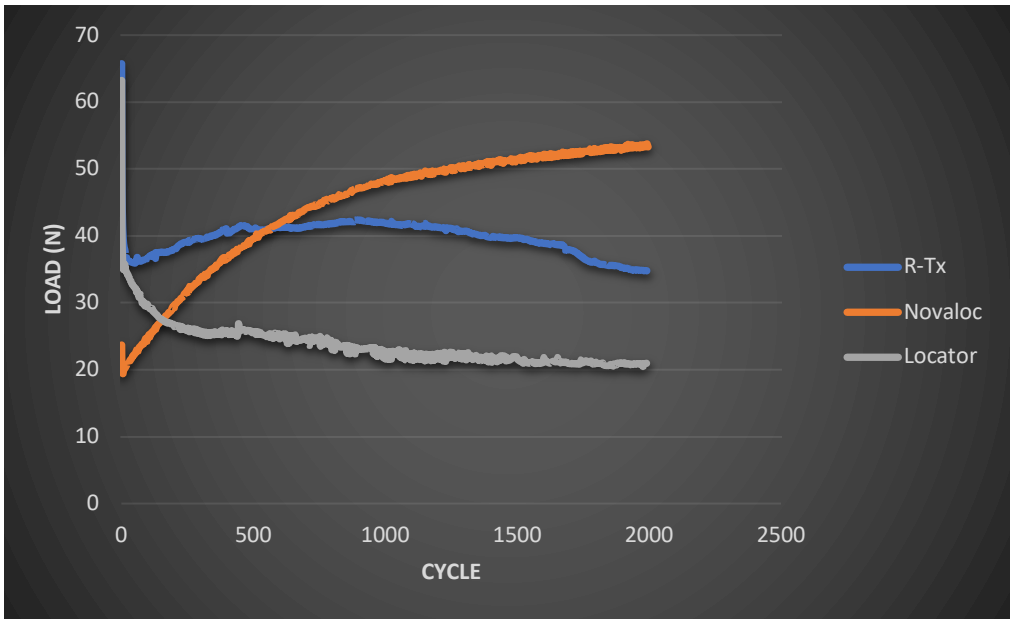

Figure 23 Time dependent mean retention load values for Locator Legacy *(Grey)*, R-Tx *(Blue)* and Novaloc *(Orange)* during two thousand multiple pulls test. *N – *Newton;* Cycle – *cycle number.*

For statistical comparison between the three groups, several cycle points were chosen along the two thousand cycles of the multiple pulls test. Mean retention, standard deviation and difference in retention load values were obtained for each attachment at cycles 1, 10, 548, 1096, and 1644 (Table 1). These cycles were chosen based on the initial placement of the retention inserts in the implant overdenture, and an estimated usage time period of 6 months (548), one year (1,096) and a year and a half (1,644) assuming that patients are placing and removing their implant overdenture an average of three times a day. Furthermore, cycle 10 was chosen to relate it to a previous study that perform simulated function, as well as 10 cycles multiple pulls test.[35]

Table 1 Mean retention values, standard deviations and difference in retention load values for LL, R and NV at cycles 1, 10, 548, 1096 and 1644.

Cycle Number	Group	Mean (N ±SD)	Difference in Retention Load Values (%)
1	Locator Legacy (LL)	63.21 ± 27.17	N/A
	R-Tx (R)	65.71 ± 14.00	N/A
	Novaloc	23.68 ± 4.88	N/A
10	Locator Legacy (LL)	35.04 ± 11.53	- 44.57 %
	R-Tx (R)	38.63 ± 5.88	- 41.21 %
	Novaloc	20.19 ± 3.84	-14.73 %

548	Locator Legacy (LL)	25.24 ± 8.22	- 60.06 %
	R-Tx (R)	43.40 ± 7.34	-33.95 %
	Novaloc	40.76 ± 8.52	72.12%
1096	Locator Legacy (LL)	21.58 ± 5.86	- 65.85 %
	R-Tx (R)	41.76 ± 4.52	- 36.44 %
	Novaloc	48.83 ± 8.90	106.2 %
1644	Locator Legacy (LL)	21.18 ± 5.34	- 66.49 %
	R-Tx (R)	38.73 ± 4.20	- 41.05 %
	Novaloc	51.81 ± 8.66	118.79 %

N – *Newton;* SD – *standard deviation;* Difference in Retention Load Values (%) – *difference in retention in comparison to cycle 1.*

For the comparison of data between the three groups at cycle 1, the obtained data was compared by means of an ANOVA test. The overall result showed a statistically significant difference between the three groups at cycle number 1 with $p<0.001$. Further post-hoc Tukey statistical analysis demonstrated statistically significant difference between groups LL and NV ($p<0.001$); and between groups NV and R ($p<0.001$). No statistical significance difference was found were between groups LL and R ($p=1.00$). As shown in (Table 2 and 3), a summary of the ANOVA and post hoc Tukey test are presented. Figure 24 shows a simple boxplot for the data at cycle number 1.

Table 2 Analysis of variance comparing Locator, R-Tx and Novaloc at cycle 1 between and among groups.

		Sum of Squares	df	Mean square	F	Sig.
Cycle 1	Between Groups	15567.75	2	7783.87	24.35	<0.001
	Within Groups	12461.90	39	319.53		
	Total	28029.65	41			

. ** df – degrees of freedom; F – ANOVA F-value; Sig. – significance level*

Table 3 Post-hoc Tukey comparison between the groups at cycle 1

		Mean Difference	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
LL	R	-2.50	6.75	1.00	-19.40	14.39
	NV	39.53	6.75	<0.001	22.62	56.43
R	LL	2.50	6.75	1.00	-14.39	19.40
	NV	42.03	6.75	<0.001	25.13	58.93
NV	LL	-39.53	6.75	<0.001	-56.43	-22.62
	R	-42.03	6.75	<0.001	-58.93	-25.13

**LL – Locator Legacy; R – R-Tx; NV –Novaloc; Sig – significance.*

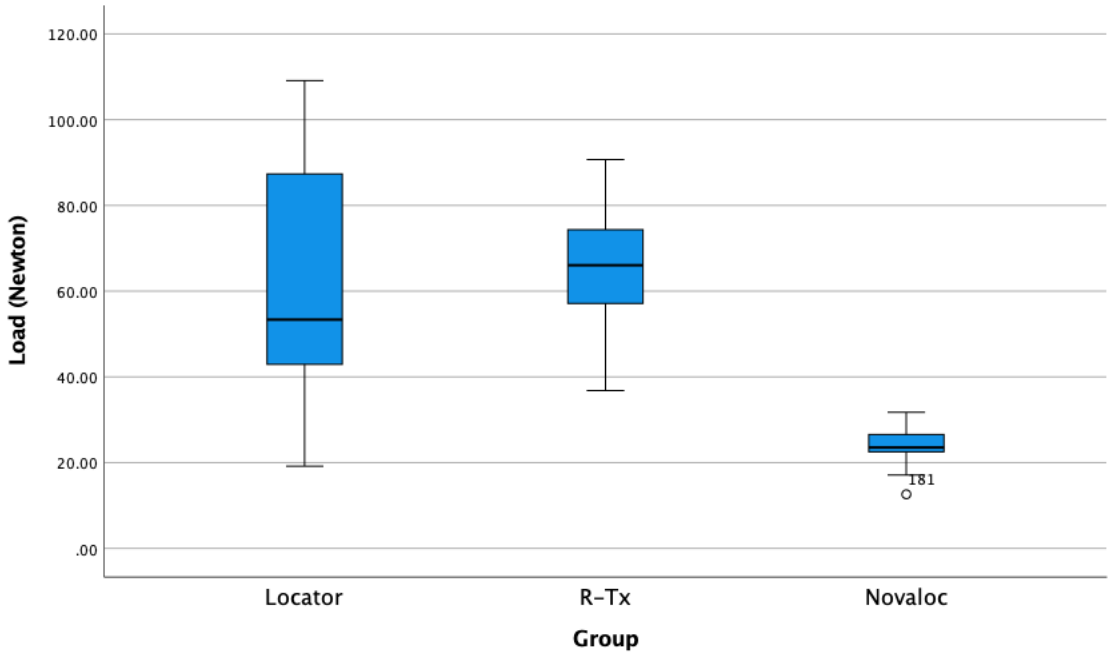

Figure 24 Boxplot and whiskers to represent retention load values for groups Locator Legacy (LL), R-Tx (R) and Novaloc (NV) at cycle 1. The lines extending parallel from the boxes (whiskers) indicate upper and lower values. Lines in the middle of the boxes present median. (° - indicates outliers)

With the same statistical analysis tests used in cycle 1, one way ANOVA showed a statistically significant difference among the three groups ($p<0.001$) at cycle number 10. A post-hoc Tukey test revealed a statistically significant difference between groups LL and NV ($p<0.001$); and between groups NV and R ($p<0.001$); however, there was no statistical significance between groups LL and R ($p=0.69$). Summary of the both statistical analysis tests are presented in (Table 4 and 5). Additionally, a simple boxplot (Figure 25) shows the data at cycle number 10.

Table 4 Analysis of variance comparing Locator, R-Tx and Novaloc at cycle 10 between and among groups.

		Sum of Squares	df	Mean square	F	Sig.
Cycle 10	Between Groups	2676.24	2	1338.12	21.99	<0.001
	Within Groups	2372.79	39	60.84		
	Total	5049.03	41			

** df – degrees of freedom; F – ANOVA F-value; Sig. – significance level*

Table 5 Post-hoc Tukey comparison between the groups at cycle 10

		Mean Difference	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
LL	R	-3.59	2.94	0.69	-10.96	3.78
	NV	14.84	2.94	<0.001	7.47	22.22
R	LL	3.59	2.94	0.69	-3.78	10.96
	NV	18.44	2.94	<0.001	11.06	25.81
NV	LL	-14.84	2.94	<0.001	-22.22	-7.47
	R	-18.44	2.94	<0.001	-25.81	-11.06

**LL – Locator Legacy; R – R-Tx; NV –Novaloc; Sig – significance.*

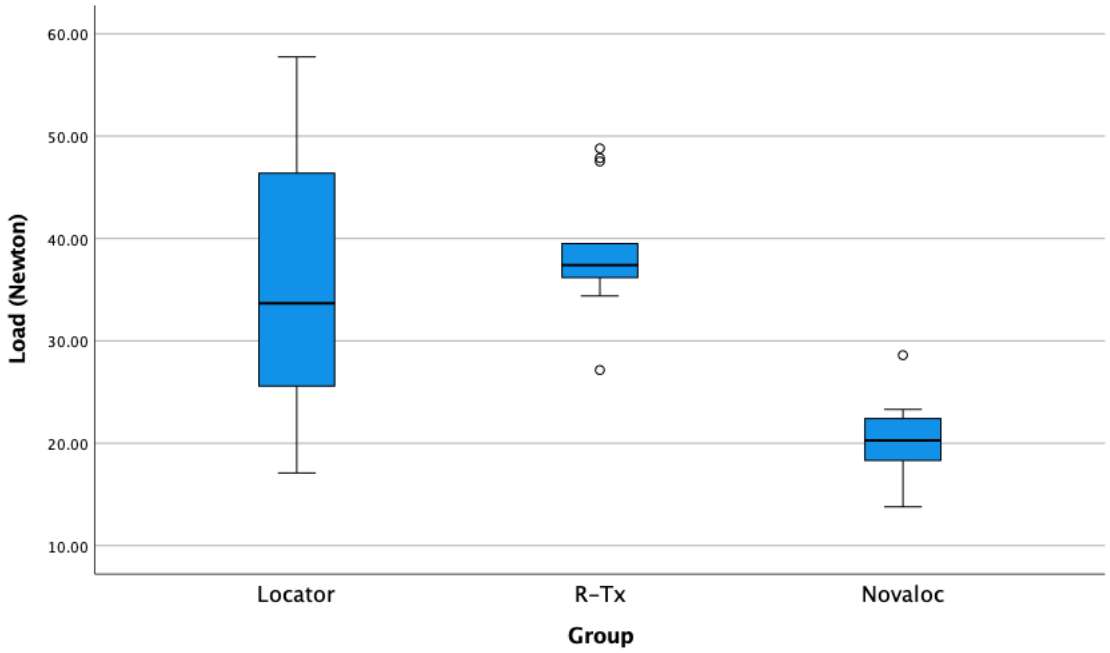

Figure 25 Boxplot and whiskers to represent retention load values for groups Locator Legacy (LL), R-Tx (R) and Novaloc (NV) cat cycle 10. The lines extending parallel from the boxes (whiskers) indicate upper and lower values. Lines in the middle of the boxes present median. (° - indicates outliers)

There was a statistical significant difference among the three groups at cycle number 548 ($p<0.001$). A post-hoc Tukey test revealed statistically significant differences between groups LL and R ($p<0.001$); and between groups LL and NV ($p<0.001$). No statistical significant difference between groups NV and R ($p=1.0$). Summary of the both statistical analysis tests are presented in Table 6 and 7. Below a simple boxplot (Figure 26) shows the data at cycle number 548.

Table 6 Analysis of variance comparing Locator, R-Tx and Novaloc at cycle 548 between and among groups.

		Sum of Squares	df	Mean square	F	Sig.
Cycle 548	Between Groups	2695.21	2	1347.60	20.82	<0.001
	Within Groups	2524.33	39	64.72		
	Total	5219.55	41			

** df – degrees of freedom; F – ANOVA F-value; Sig. – significance level*

Table 7 Post-hoc Tukey comparison between the groups at cycle 548

		Mean Difference	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
LL	R	-18.15	3.04	<0.001	-25.76	-10.55
	NV	-15.51	3.04	<0.001	-23.12	-7.911
R	LL	18.159	3.04	<0.001	10.55	25.76
	NV	2.64	3.04	1.00	-4.96	10.24
NV	LL	15.51	3.04	<0.001	7.91	23.12
	R	-2.64	3.04	1.00	-10.24	4.96

**LL – Locator Legacy; R – R-Tx; NV –Novaloc; Sig – significance.*

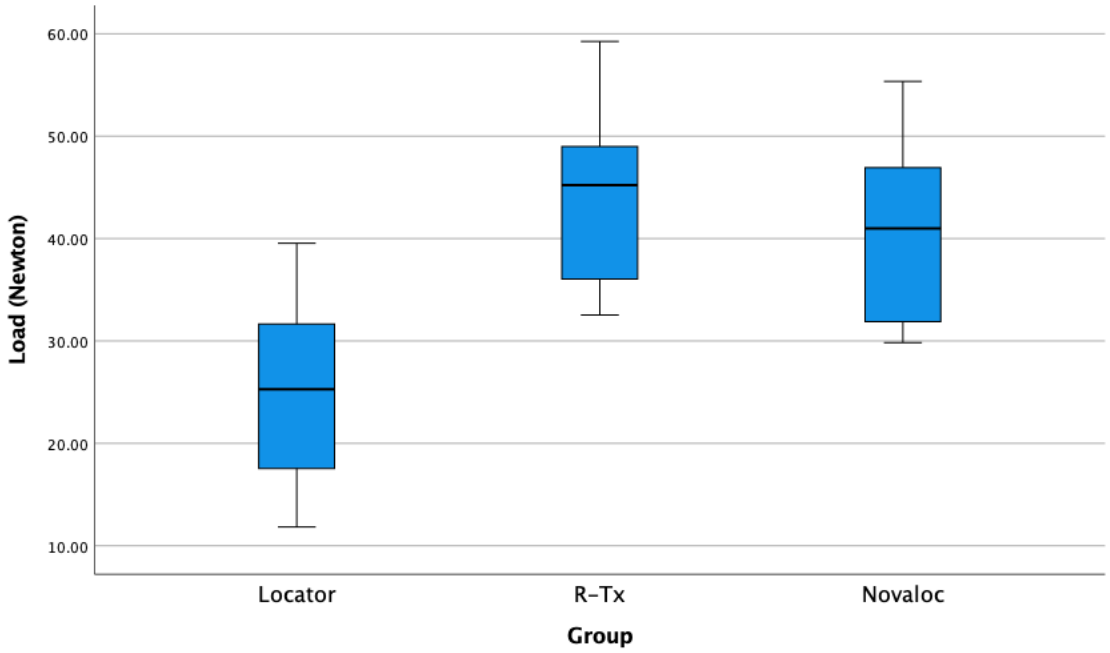

Figure 26 Boxplot and whiskers to represent retention load values for groups Locator Legacy (LL), R-Tx (R) and Novaloc (NV) at cycle 548. The lines extending parallel from the boxes (whiskers) indicate upper and lower values. Lines in the middle of the boxes present median.

The ANOVA test revealed a statistical significant difference between the groups at cycle 1,096 ($p<0.001$). Furthermore, there were statistically significant differences observed between groups LL and R ($p<0.001$); and between groups LL and NV ($p<0.001$). No statistical significant difference was observed between groups NV and R ($p=.024$). Summary of the both statistical analysis tests are presented in (Table 8 and 9). Figure 27 below shows a simple boxplot of the data at cycle number 1096.

Table 8 Analysis of variance comparing Locator, R-Tx and Novaloc at cycle 10 between and among groups.

		Sum of Squares	df	Mean square	F	Sig.
Cycle 1096	Between Groups	5599.45	2	2799.72	62.59	<0.001
	Within Groups	1744.34	39	44.72		
	Total	7343.79	41			

** df – degrees of freedom; F – ANOVA F-value; Sig. – significance level*

Table 9 Post-hoc Tukey comparison between the groups at cycle 1096

		Mean Difference	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
LL	R	-20.18	2.52	<0.001	-26.50	-13.86
	NV	-27.24	2.52	<0.001	-33.57	-20.92
R	LL	20.18	2.52	<0.001	13.86	26.50
	NV	-7.06	2.52	0.024	-13.38	-0.74
NV	LL	27.24	2.52	<0.001	20.92	33.57
	R	7.06	2.52	0.024	0.74	13.38

**LL – Locator Legacy; R – R-Tx; NV –Novaloc; Sig – significance.*

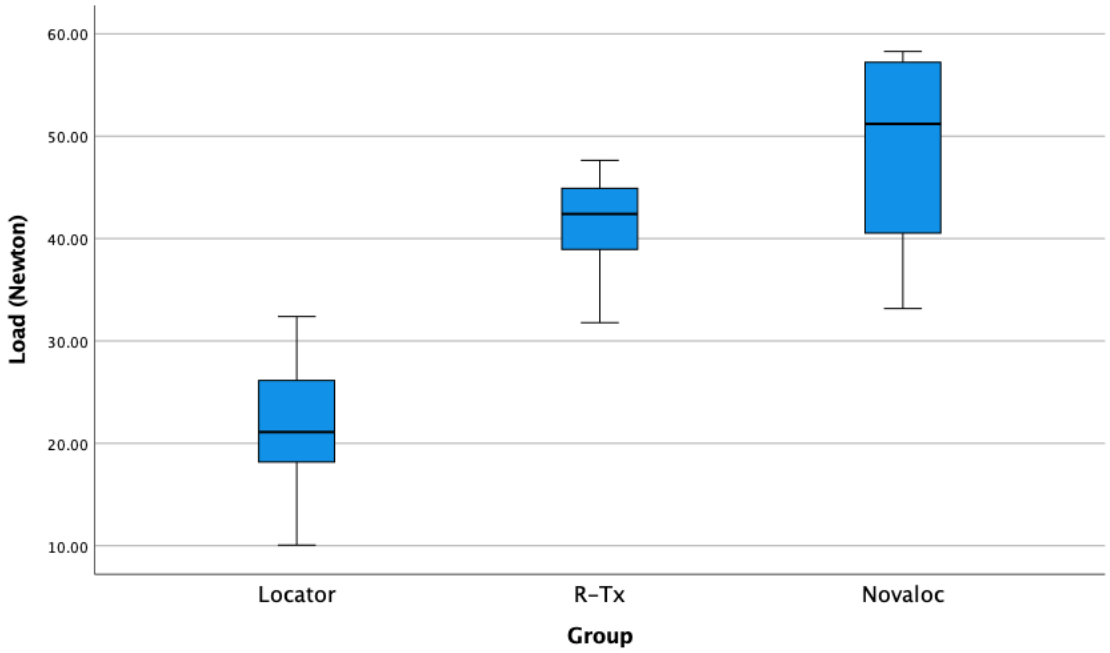

Figure 27 Boxplot and whiskers to represent retention load values for groups Locator Legacy (LL), R-Tx (R) and Novaloc (NV) at cycle 1096. The lines extending parallel from the boxes (whiskers) indicate upper and lower values. Lines in the middle of the boxes present median.

In cycle number 1,644 there was a statistical significance difference ($p<0.001$) between all groups when the one-way ANOVA and post hoc Tukey tests were utilized for comparison between the three groups. Data from both tests are presented in Table 10 and 11. Additionally, data of cycle 1,644 is presented in simple boxplot (Figure 28).

Table 10 Analysis of variance comparing Locator, R-Tx and Novaloc at cycle 1644 between and among groups.

		Sum of Squares	df	Mean square	F	Sig.
Cycle 1644	Between Groups	6613.84	2	3306.92	81.74	<0.001
	Within Groups	1577.72	39	40.45		
	Total	8191.57	41			

** df – degrees of freedom; F – ANOVA F-value; Sig. – significance level*

Table 11 Post-hoc Tukey comparison between the groups at cycle 1644

		Mean Difference	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
LL	R	-17.55	2.40	<0.001	-23.56	-11.54
	NV	-30.62	2.40	<0.001	-36.64	-24.61
R	LL	17.55	2.40	<0.001	11.54	23.56
	NV	-13.07	2.40	<0.001	-19.08	-7.06
NV	LL	30.62	2.40	<0.001	24.61	36.64
	R	13.07	2.40	<0.001	7.06	19.08

**LL – Locator Legacy; R – R-Tx; NV –Novaloc; Sig – significance.*

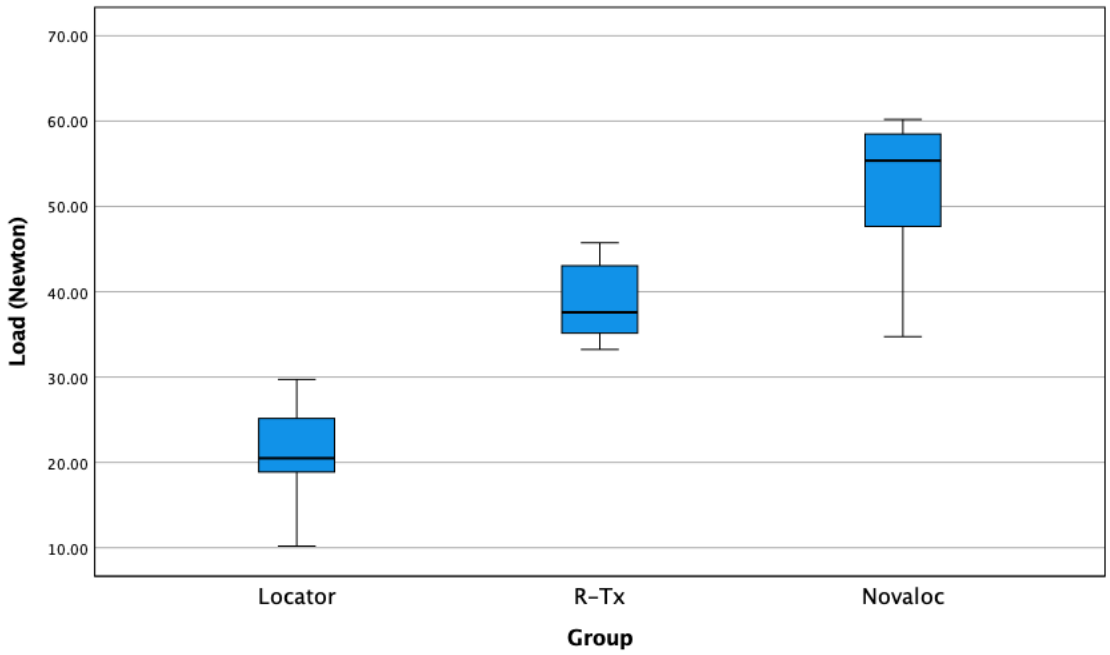

Figure 28 Boxplot and whiskers to represent retention load values for groups Locator Legacy (LL), R-Tx (R) and Novaloc (NV) at cycle 1644. The lines extending parallel from the boxes (whiskers) indicate upper and lower values. Lines in the middle of the boxes present median.

Chapter 5: Discussion

5.1 Comparison to Other Studies and Other Attachments

Two implants supported overdenture is considered as the standard of care for restoring the edentulous mandible.[8] Overdentures are attached to osseointegrated implants in an attempt improve the retention and stability of removable prosthesis. Attachment systems are affected by the daily use of the prosthesis as they undergo wear that require periodic maintenance.

There are several studies in the literature that studied the retention characteristics of the different attachment systems. However, and to our knowledge, there is a lack of studies related to the pattern of retention loss of different attachment systems over an extended period of simulated insertion and removal. Furthermore, it is beneficial to know more about those attachments as they are commonly used clinically due to their ability to compensate for unaligned implants, low abutment profile, resiliency, simplicity, in addition to the recent introduction of the Novaloc attachment system to the market. The objective of this *in-vitro* study is to continuously measure retention force values for medium retention inserts of Locator Legacy, Locator R-Tx and Novaloc attachment systems in each cycle of two thousand cycles. Moreover, the study also performed a comparison of the retention force values of the three aforementioned attachment systems at cycles 1, 10, 548, 1096, and 1644.

The data in Figure 23 is showing real time retention load value measurements for each group in each cycle along the two thousand multiple pulls test cycles. This is considered as novel data in comparison to the previously reported data where retention load values were measured at a specific cycle point rather than continuously measuring the load values throughout the multiple

pulls test. It can be noticed that there is a variation in the plotted curves of the mean retention values between the three attachment systems. For instance, NV retention load values are increasing gradually toward the end of the two thousand cycles, while LL was decreasing only toward the end. On the other hand, the R attachment retention load decreased dramatically initially, then increased slightly and gradually reaching to cycle 900 and then decreasing gradually toward the end of the two thousand cycles.

It was shown in the present study that the mean retention load value of the LL group was 35.04 ± 11.53 N at cycle 10, which was within the range of a previously conducted study by Sia *et al.*[36] who had a result of 32.3 ± 8.8 N. On the other hand, the mean retention load value at cycle 10 for the R group was 38.63 ± 5.88 N in our study. This finding was lower than Maniewicz *et al.*[37] results, which was 75.5 ± 24.9 N. However, it is difficult to compare the retention values between the present study and Maniewicz *et al*. study because of the differences in the experimental set up as wet testing medium and higher removal crosshead speed (120mm/min) were used by the latter study. Furthermore, the NV group mean retention load value was 20.19 ± 3.84 N at cycle 10. This was, again, lower than Maniewicz *et al.* findings of 57.7 ± 31.0 N. Again, it is difficult to compare the two findings because of the aforementioned differences in studies protocols.

The percentage of retention reduction after the initial pull (cycle 1) and pull number 10 (cycle 10) were different between the three experimental groups in the current study. For LL group, the mean retention load value dropped from 63.21 ± 27.17 N after the first pull to 35.04 ± 11.53 N after pull number 10, which represents a reduction of 44.5%. The R group showed slightly less

reduction with 41.2% (65.71 ± 14 N after the initial pull and 38.63 ± 5.88 N after pull 10), while the NV group showed 14.7% reduction (23.68 ± 4.88 N after the initial pull and 20.19 ± 3.84 N after pull 10). Evtimovska *et al.* showed that there was a retention reduction of 25.9 % for green locators and 21% of white locators after 20 multiple pulls.[36] It was recommended by this study to remove and place overdentures multiple times before delivery to patients. The LL and R results of our study would also benefit from the recommendation to remove and place overdentures multiple times before delivery to enable clinicians to clinically evaluate the retention of the attachments before delivery to patients. However, this recommendation might not be necessary for NV as there was a slight retention reduction of only 14.7%.

The mean retention load value of the LL group at 548 cycles (approximating six months) was 25.24 ± 8.22 N. This finding was higher than the finding of You *et al.*[61] 10.5 ± 2.9 N. The difference of mean retention values between the present study and You *et al.* could be attributed to the differences in the methodology as retention inserts were immersed in cleansing agents in the latter study. Additionally, pairs of implants were used in the present study versus using a single implant in You *et al.* study which also made it difficult to compare the findings of the two studies.

The mean retention load values of all of the groups at cycle 1096 (approximating one year) and cycle 1644 (approximating one and a half years) are presented in (Table 1). Due to a lack of studies on retention load values at those time periods, it was not possible to compare the current findings with other studies. In (Table 1), the difference in retention load values are presented between each cycle in comparison to cycle 1. It can be noticed that NV mean retention load value increased to 118.79 % compared to the initial retention load value, while there was a reduction in retention of 66.49 % and 41.06 % for LL and R, respectively.

In this study, a crosshead speed of 50.8 mm/min was used to displace the attachment matrices from their corresponding attachment abutments, which has been reported as the average speed at which patients remove their denture.[72] However, patient denture removal speed might be different and/or vary from one patient to another thus making our findings difficult to apply to a clinical situation.

The implants chosen in the current study were regular diameter platform (RC, 4.1 mm, 10 mm length; Institut Straumann AG,Basel, Switzerland). This implant diameter was chosen to be consistent with the literature [35,37,61,62] that reported the retention characteristics of the different attachment systems. It is unknown if the retention load values of the regular implants diameter used in the current study will be similar to narrower or wider implants diameters; however, we expect the results would be the same as the attachment matrices seating area over patrices are similar across the different implants platforms, and the implant diameter should therefore not impact on the retention values.

As it can be noted in the current project, two thousand cycles were chosen for the multiple pulls test. The decision to extend the testing to 2000 cycles was based on a pilot study performed prior to starting the main project. A set of five hundred multiple pulls tests were initially carried out in the pilot study and it was expected to see a decline and a plateau in the line graph at the end of the 500 cycles indicating a deterioration of the retention inserts. However, this was not observed and the decision was made to increase the number of cycles to two thousand cycles with the

expectation that we would be able to see a deterioration of the attachments retention at the end of the 2000 cycles. By increasing the number of cycles to 2000, we were able to observe a deterioration pattern in our samples of Locator Legacy and Locator R-Tx attachments; however, no deterioration of retention was noticed with the Novaloc attachment during our study.

5.2 Clinical implications

The current study revealed that the retention load values of NV attachment has increased gradually toward the end of the multiple pulls test. This increase in retention values may indicate that NV might require less periodic replacement of the retention inserts in comparison to LL and R which might need more frequent replacement as part of the attachment maintenance. This potential decrease in maintenance frequency might reduce the burden on patients via reducing the number of follow-up dental visits needed, especially for elderly individuals with reduced physical capabilities. Furthermore, reduction of maintenance frequency may reduce the economic burden on patients.

However, the gradual increase of NV retention load values over time may also lead to undesirable consequences. The increase in retention may lead to difficulty removing overdentures as the retention reach higher values over time from the mouth, especially for patients who have reduced manual dexterity. Furthermore, this increase in retention overtime may overload osseointegrated implants and cause bone loss around the implants and eventually implants failure.

As mentioned previously, the present study showed a reduction in retention from cycle 1 to cycle 10 of 44.5% and 41.1% for LL and R, respectively. Therefore, it is recommended to

remove and place overdentures made with these attachments multiple times before delivery to enable clinicians to evaluate the retention of the attachments before dismissing patients at the delivery appointment.

The findings of the current study should be taken with caution as the present project is an in-vitro study and the results might not be accurately applicable to the real clinical conditions due to the wet nature of the oral cavity, masticatory forces and alignment of the placed implants. Further clinical studies are necessary to validate the outcomes of the current study.

5.3 Limitation of the study

The present study was carried out in a dry *in-vitro* setting where the results might be not representative of the oral environment. Additional factors could play a role in the retention characteristics of the attachment systems including the temperature of the oral environment and presence of lateral loads in normal masticatory function, in addition to the vertical loads tested. Furthermore, the current project assumed that patients remove and insert overdenture three times a day; however, patients may remove and insert their overdenture more often than that. Therefore, the retention load values of the retention inserts will deteriorate faster than reported in the current study. Lastly, no denture cleansing solutions were used during the experiment set up of the current study, though it was reported that some cleansing solutions affected retention inserts characteristics.[59,61,62]

5.4 Future directions

The current study was designed in a dry condition which is very different to the condition of the oral environment. Further *in-vitro* studies in wet conditions such as artificial saliva could be considered to better approximate the oral environment.

Although the current study was performed with two thousand multiple pulls test, it did not show a decrease in NV retention load values at the end of the multiple pulls test. Longer than two thousand multiple pulls test perhaps could be considered to study how the Novaloc retention inserts ultimately behave once their retention limits are surpassed.

Lastly, the implants in each acrylic block were placed in a parallel manner to each other in our study. Divergent implants and attachments might yield different results after performing a multiple pulls test.

Chapter 6: Conclusion

The objective of this study was to measure the retention load values for LL, R and NV attachment systems under multiple pulls test, in addition to comparing the retention load values at cycles 1, 10, 548, 1096 and 1644. Based on the results of this study, and within the limitations of this study, the null hypothesis can be rejected as statistically significant differences in retention values were observed between the different attachment systems at all tested cycle durations.

- The LL and R groups showed an initial large reduction in retention load values, 44.5% and 41.1%, respectively, from cycle 1 to cycle 10.
- The NV and R groups exhibited significantly higher retention load values at cycle 548 when compared to the LL group.
- The NV group had the highest retention load values at the completion of the tested number of cycles in comparison to LL and R groups. The Novaloc attachments potentially may prove to provide some clinical advantages due to the prolonged duration of retention but there are potential complications that may also arise as a result.

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