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Graduate School Srinakharinwirot University

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ปริญญานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตร
วิทยาศาสตรมหาบัณฑิต สาขาวิชาทันตกรรมคลินิก
คณะทันตแพทยศาสตร์ มหาวิทยาลัยศรีนครินทรวิโรฒ
ปีการศึกษา 2562

COMPARISON OF RETENTION BETWEEN TWO IMPLANT ATTACHMENT SYSTEMS AFTER FATIGUE TEST

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A Thesis Submitted in partial Fulfillment of Requirements

for MASTER OF SCIENCE (Clinical Dentistry)

Faculty of Dentistry Srinakharinwirot University

2019

THE THESIS TITLED

BY

KITTITHORN LERTSURIYAKARN

HAS BEEN APPROVED BY THE GRADUATE SCHOOL IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE MASTER OF SCIENCE IN CLINICAL DENTISTRY AT SRINAKHARINWIROT UNIVERSITY

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Author	KITTITHORN LERTSURIYAKARN
Degree	MASTER OF SCIENCE
Academic Year	2019
Thesis Advisor	Assistant Professor Dr. Mali Palanuwech

The aim of this study was to compare retention after mechanical fatigue tests consisting of 5,400 cycles between two dental implant attachment systems, the Locator and the Locator R-Tx. There were samples of each system investigated for their retentive forces. The retentive forces before fatigue testing and subsequently after 900, 1,800, 3,600, and 5,400 cycles that simulated three years of functional life were recorded. The Instron universal testing machine was a measurement with a crosshead speed of 5cm per minute and a 3mm vertical range (0.14 Hz frequency). The descriptive statistics were represented by mean and standard deviation. The retentive forces of both systems across each cycle of the entire fatigue test were compared by independent t-tests (α = 0.05). The results of both systems revealed decreased retentive forces in overall fatigue testing. The retentive force of the Locator R-Tx exhibited from baseline to 5,400 cycles with 19.24 ± 1.12 N to 10.70 ± 1.75 N accordingly, and the Locator exhibited from 19.95 ± 0.78 N to 11.65 ± 0.94 N. Although, the retentive forces of the Locator in each cycle were higher than the Locator R-Tx through the entire fatigue test and both systems were not significantly statistically different ($P < 0.05$) in each cycle. In conclusion, the retention of the Locator R-Tx and Locator was not significantly different in terms of both initial retention and final retention within 5,400 cycle fatigue test represented a three-year functional life. The Locator R-Tx was an innovation to replace the Locator and improved geometry and design. This study supported the conclusion that Locator R-Tx could provide retention similar to the Locator, which is a standard and popular implant attachment in the international market.

Keyword : Retention, Implant attachment systems, Fatigue testing

ACKNOWLEDGEMENTS

First of all, I would like to express my profound respect to my advisor, Asst. Prof. Dr. Mali Palanuwech, for her useful advice and extensive support in guiding me during my research work. I also would like to express my deep appreciation to Mr. Anucharte Srijunbarl, scientist, Dental Material Science Research Center, Faculty of Dentistry, Chulalongkorn University, for giving me permission and suggestions to do my thesis especially for material testing. My special gratitude is impressed to my advisory committee, Assoc. Prof. Dr. Viritpon Srimaneepong and Lect. Dr. Jaruma Sakdee who always provided continuous support, comments, suggestions and recommendations on this study. My sincere thank is admired to Mrs. Kingkaew Boonphong for their valuable advice and guidance of thesis progression. I greatly appreciate to all lecturers, who taught me in these past few years, in order to improve my knowledge and clinical skill in prosthodontics and implantology, and to all staffs and friends who provided constant support and encouragement. In addition, I am particularly thankful to all participants who spent their valuable time attending this study. Finally, I would like to express my gratitude to my beloved family who has always unconditionally supported me. Without all of the precious advice, co-operation, encouragement and help, this thesis could not have been completed.

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Chapter 1
Introduction

1.1 Background of the study

Although public oral health care had been developed exponentially, total tooth loss had increased among elderly people. Loss of teeth was still a global issue, and there were more than 276 million edentulous people in the world.[1] Tooth loss and poor oral care affected to both oral and overall health of elderly people. Temporomandibular disease was a chronic condition which troubled masticatory system with tooth loss. Systemic diseases were relevant to loss of natural dentition, for example, cardiovascular disease, cerebrovascular disease, cancers, as well as mortality.[2-7] Conventional complete denture, as a traditional treatment option for edentulism, had been used to improve functions and esthetics since a long period. Fabrication of complete denture with similar materials and methods for a century had been practiced. Earl Pound's technique was established an ordinary approach which had been appreciated to a success of complete denture treatment, and this technique emphasized to communicate between dentist and patient. Metal health, attitude and willingness had been necessary to be evaluated before they were indicated a prognosis of the treatment. Moreover, this technique could be applied to fabrication of complete denture with dental implants.[8-15] Although both traditional technique and simplified technique of the denture fabrication were satisfying and acceptable, the simplified technique was currently used more cost-effective than the traditional technique. However, the simplified technique should be used precisely for the details of the denture fabrication and be careful to adapt in specialized cases such as displaceable upper ridges, patients with mobile fibrous, knife-edge lower ridges.[16-19] Both techniques regularly needed to be rechecked and adjusted following the complaints from patients. Most common complaints were loss of retention and stability after a period of maintenance.[20, 21]

In the 20th century, dental implant become an aided dental device in enhancement of denture retention and stability. Implant-supported overdenture allowed more effective chewing, less physical pain and less psychological discomfort compared with conventional complete dentures. An overwhelming number of studies assessing patients' quality of life showed that the implant overdenture was more desirable than the complete denture.[22, 23] These studies supported McGill Consensus 2002 which stated that conventional complete denture should no longer be the first-line treatment of choice for edentulous mandible, instead two-implant mandibular overdenture should be recommended.[24] In 2009, the York Consensus Statement reinforced same idea by supporting use of two-implant mandibular overdenture as a standard care for edentulous patients.[25] In contrary, there were few studies about maxillary implant-supported overdenture, and the studies comparing maxillary conventional complete denture and maxillary implant overdenture were still uncertain results. Further, long term studies needed to be evaluated these treatment options.[23]

Retentive components played an important role in implant-supported overdentures, and they were referred as an implant attachment. The attachment was ordinarily classified into splinted and unsplinted group. The splinted group used a rigid connecting bar and a retentive clip when interocclusal space for overdenture was enough, whereas the unsplinted group used a solitary stud (patrix and matrix) such as balls, caps, magnets. The splinted group was indicated to correct implant divergences. The splinted group was more retention and stability, while the unsplinted group (low-profile attachment) was commonly advocated for cases with limited restorative space. The unsplinted group was more popular because of ease of cleaning, technical simplicity and cost effectiveness. Cap attachment was the most common clinical use. It was divided into two principle structures: denture and implant site. The denture site was composed of housing and nylon insert which were important parts for overdenture retention. The implant site was composed of attachment head and screw. The attachment head was usually unique in that system. Although there were different geometry and design of the heads, their functions were same as a retentive head in

each system. The screw was specific in implant platform and connection following models of implant fixture.[26-28]

In 2001, Locator attachment system (Zest Anchors, USA) was launched as one of the most popular low-profile cap attachments. Retentive components composed of a patrix (male part) and a matrix (female part), using several color-coded retentive values in same nylon material. The color-coded retentions determined sequence of retention levels. Retention of nylon insert consisted of core and ring retention. Principally, the core was more retention than the ring, and different core sizes caused different retention levels. Core retention was created by attachment between larger diameter core of nylon patrix and smaller diameter central hole of metal matrix. Ring retention was created by attachment between ring of nylon patrix and undercut under the widest part of metal matrix. In addition, the nylon inserts had two ranges of choice that they compensated different implant angulations. For regular range, the core and ring were known as dual retention with limited 20 degrees of angulation. Whereas, extended range was only the ring that it compensated 40 degrees of angulation. So, the nylon inserts were used to correct 20 to 40 degrees total implant divergence depending on the type of range. Locator attachment system had been used the most stud attachment in the market and confirmed with high survival rate and good periodontal status along with patient satisfaction and promoted quality of life; however, the complications could occur. Many studies had been reported about the maintenance period, especially involving the loss of retention and nylon replacement that they concluded an annual follow-up as a critical requirement. There were plenty of performance studies on Locators both in vitro and in vivo.[29, 30]

In 2018, Locator R-Tx (Zest Anchors, USA) was launched as a novel attachment system. It was claimed by the manufacturer to exhibit dual engagement on external surface of the attachment, potentially improving overdenture retention. Furthermore, it was promoted a new DuraTec Titanium Carbon Nitride Coating that is 32% harder and had 26% greater wear resistance and a 64% reduction in roughness.[31] Locator R-Tx was designed with a dual retentive surface and a narrower coronal geometry that

allowed for an increase in pivoting capabilities of metal housing and allowed up to 60 degrees diversion between two implants. This was a great improvement over the legacy Locator that allowed up to 40 degrees diversion between the implants when extended range inserts were used. The pivoting capability also helped reduce damages to the nylon inserts when the implants were misaligned. With original Locator, clinicians were often faced with food debris being lodged in the tripod on top of the attachment, causing patients to complain about lack of retention and lack of ability to seat their dentures in place. Replacement of the tripod or drive mechanism with a small cavity of hex drive permitted simplified placement of the attachment and minimized an accumulation of food in recess of the top. The industry standard hex drive mechanism allowed treating dentists to use most brands of 0.050 inches screwdriver that they had in offices. The housing was redesigned and subjected to pink anodization to reduce chance of grey color of the housing showing through acrylic denture base. Flat grooves were added on cameo surface of the housing to resist vertical and rotational movements of the housing in dentures after they picked up.[32]

Retention was one of the most important requirement of implant attachments. Maximum tensile load (peak load dislodgement) had been created in laboratories to search for retentive forces. Besides, many types of fatigue test had been simulated to demonstrate functional life of the attachments over a long-term period. Mechanical cyclic fatigue test was the most common fatigue test to simulate wear of the attachments. The number of 1,080 - 15,000 cycles were determined approximately 3 - 10 years of use based on average of 3 - 5 insertions and removals per day. Retention of high-profile attachments (bar and clip), magnetic attachment, old-style stud attachment, and Locator was showed various values depending on attachment characteristic and laboratory design.[33-43]

However, there was no report of Locator R-Tx's performance both in vivo and in vitro. To our knowledge there was no study of single implant which compared differences between Locator and Locator R-Tx before and after long-term fatigue test.

Therefore, the authors would like to compare the retentive forces of these attachments in vitro after 5,400 cycles representing 3-year functional life.

1.2 Research Questions

Are retentive forces between Locator and Locator R-Tx after mechanical fatigue test 5,400 cycles similar?

1.3 Purposes of the study

To compare retentive forces of two implant attachment after mechanical fatigue test 5,400 cycles.

1.4 Scopes of the study

This study is a laboratory experimental design to compare retentive forces of two implant attachment systems.

1.4.1 Independent variables

Two implant attachment systems: Locator (pink, medium retention) and Locator R-Tx (pink, medium retention)

1.4.2 Dependent variables

Retentive forces (N) were measured by universal testing machine and its software following mechanical fatigue test.

1.4.3 Controlled variables

Samples are tested by same manufacturer (Zest Anchors, USA). The machine and software are calibrated as a standard protocol.

1.5 Research Hypothesis

H_0: Retentive forces after mechanical fatigue test 5,400 cycles of two implant attachment systems are equal.

H_1: Retentive forces after mechanical fatigue test 5,400 cycles of two attachment systems are different.

1.6 Definitions of terms

1. Retentive force (Peak load dislodgement, Maximum tensile load, Maximum retentive load) is a maximum retentive value of each sample during pulled out, then the maximum value is recorded in Newton (N).

2. Implant attachment is a prosthetic part of implants that is connected with an implant fixture. The attachment is composed of patrix (male) part and matrix (female) parts that the patrix are snapped in the matrix.

1.7 Significances of the study

1. Retention of implant-supported overdenture is concerned as patient's first impression. Thus, the result of this study will be informed as an up-dated clinical guideline of the overdenture.

2. Retentive loss is the most complication of implant-supported overdenture. Therefore, precise time for recall is important. In this study, retentive force within three years after fatigue test will be measure and then calculate as a retention loss.

Chapter 2
Literature Review

Retention of implant-supported overdentures was a topic that was frequently discussed. The major retentive component was an implant attachment. Many prior studies of the attachments proposed retention of high-profile attachments (bar and clip attachments) and low-profile attachments (magnetic attachments, ball attachments, cap attachments) including Locator attachment.[33-43] Unlike, there was no evidence of retention of Locator R-Tx attachment.

Retention of the attachments could be referred as other terms, for example, maximum tensile load, peak load dislodgement, or retentive force. The retention was set up in laboratory to determine removal force of the attachments, whereas mechanical fatigue test was the most common fatigue test to simulate retentive changes of the attachments. Laboratory design was fabricated to simulate retention of the attachments under oral conditions.

There were different directions of retention in laboratory test. Stud attachments could be displayed only vertical retention, but magnetic attachments could be displayed both vertical and horizontal retentions because its pole energy of the magnets were resistant to gripping or splitting. In vertical retention, the studs were even more retention than the magnets. The magnets were showed noticeably more vertical retention than horizontal retention. Especially, larger size of the magnet had more retention.[44] Vertical direction was from forces both axial and divergent implant positions. More divergent positions of single implant attachment were placed, less vertical retentions of the attachment were found. In addition, more divergent positions delivered more lateral forces to the attachments that the forces were harmful to the attachments.[45] However, axially vertical retention was related to ideal implant position in clinical practice. Implant angulations were more divergent, so they appeared higher impact on retention and

could pose more complications.[46] Accordingly, we should consider vertical force is axial force for identifying maximum retentive value of Locator and Locator R-Tx.

A universal testing machine and its software were the most important tool to figure out retentive force of implant attachments. There were a lot of machines from small and delicate measurement (micro-loading) to large scale measurement. Standard measurement was recorded either gram (g) or newton (N). Instron universal testing machine was regarded as a gold standard to evaluate maximum tensile strength in vertical and horizontal directions, and it was measured in many studies of the attachments. Software of Instron universal testing machine was compatible to minimal force scale of implant attachments.[34, 35, 37, 44, 47] Moreover, the software could measure retentive force as well as run fatigue at same position of samples that it improved accuracy of the test. Thus, this study used Instron universal testing machine for evaluating retention of Locator and Locator R-Tx.

In order to set crosshead speed of the machine, slow and fast speed test was determined. The slow speed (0.2 cm/min) was represented lateral movement of denture, whereas the fast speed (5 cm/min) was represented denture away from the edentulous ridge during mastication. Vertical retentive force of magnetic attachments (140 - 370 g) was extremely lower than stud attachments (500-1,000 g) in both speeds. In the fast speed, retention of the magnets was the lowest (<20 g) that it was not enough to retain overdentures. Conversely, retention of the studs in the fast speed was higher than in the low speed.[44] In addition, the fast speed was the most common speed with vertical retentive test of stud attachments that it represented functional use of implant-supported overdenture.[38-40] Therefore, this study set up fast speed test (5 cm/min) for testing of Locator and Locator R-Tx.

Many clinical studies showed that retention loss of stud attachments was common in short-term and long-term follow-ups. Fatigue tests were simulated to understand change of the attachments. Fatigue tests were mainly divided into chemical and mechanical fatigue tests.[48, 49]

Disinfectants or cleansing dentures in daily products were normally used for chemical fatigue test. Comparing with water, retention of nylon insert of Locator was changed by type of chemical soaking. All of color-coded Locators were not affected to their retention by sodium bicarbonate-sodium perborate agent. Retention of blue Locator decreased significantly with sodium bicarbonate and sodium hypochlorite agents. Sodium bicarbonate agent only reduced retention of white Locator. However, retention of pink Locator was not changed by any chemical agents.[49] So, pink Locator was generally resistant to chemical degradation.

Mechanical fatigue test was simulated wearing overdenture in situations like chewing and denture insertion and removals. The mechanical fatigue created wear in implant attachments. The attachments were soaked with distilled water or artificial saliva in water bath called “wet condition”, whereas they were placed in normal air room called “dry condition”. There was a study that showed initial retention and SEM visual examination after soaking nylon inserts of Locator in different conditions, and the inserts from different conditions were evaluated on fatigue test and retention loss. The authors found that both initial and final retentions in dry condition (20 ˚C air room) were not significantly different comparing in normally wet condition (20 ˚C and 37 ˚C distilled water). The conditions were similar to retention loss pattern after fatigue. In addition, visual surface inspection under SEM among dry condition and normal wet condition were not significantly different changing. Conversely, nylon insert of Locator in extremely wet condition (60 ˚C distilled water) had significantly less retention than other groups. Retention loss of extremely wet condition was significantly greater than previous conditions. Besides, the nylon insert in extremely wet condition exhibited markable changes in surface characteristics with extensive area of cracking and crazing randomly propagated throughout the central core and outer wall of the insert.[50] Regarding pH of saliva, acidic pH (pH ≤ 4) affected retention of bar and clip attachments both initial force and forces after fatigue through 5,400 cycles.[51] Therefor, we could conclude that both dry and wet conditions in room temperature are a proper retentive test of Locator and Locator R-Tx, and this study was set up the test under air room condition.

For mechanical fatigue test, push and pull test (insertion and removal test) was an ordinary test of implant attachments. The number of cycles was determined to degree of mechanical fatigue. As initial retention of attachments tended to vary, it was recommended to place and remove attachments around 15 times before overdenture insertion. This could allow an adequate appraisal of retention of implant-supported overdentures that it could be exhibited after a short time of patient service.[52] It could also be advantageous to make retention of the overdentures during the first denture placement initially at the minimum, and then gradually, but continually, increase it to desired level. This could facilitate patients in learning how to handle their overdentures without exerting an excessive degree of force of effort.[53] The number of cycles determining run-in period in laboratory test was used arbitrarily by selected cut-off point. Generally, patients inserted and removed dentures for 3 – 5 times a day, so average of 1,080 – 1,800 cycles were compared to 1-year functional life. One of studies used 4 cut-off points for dividing all retention values. They determined fatigue test of a cap attachment in running all 5,500 cycles. They found that incidence of statistically significant differences was minimal starting from 900 cycles. There were exactly relationship of functional time and cycle number in implant attachments.[48] In summary, this study was regulated 1,800 cycles compared to 1-year functional life, and the mechanical fatigue test was total 5,400 cycles compared to 3-year functional life.

The types of implant attachments had different pros and cons. Attachment retention was an important factor for retaining overdentures. Many studies compared attachment retention.

Magnetic attachments were the lowest profile type of attachment and had small dimensions. It had been described as an easy concept “retention without reciprocation”. A laboratory test found that magnetic attachments had significantly lower retention and energy compared to a Locator. This means that less energy was required to dislodge the attachment parts, yet fewer loads were transferred to abutments. It could be hypothesised that magnetic attachments could be the preferred attachment when abutments offered limited support and there was not a favourable prognosis. A

significant decrease in retention of magnetic attachments was detected and the absolute reduction was very small - only 0.1 N. As magnetic attachments had highly constant retentive properties, statistically significant differences were detected due to very small standard deviations. Additionally, the seating of corresponding parts of overdenture magnetic attachments had no contact, thus preventing abutments from overloading. Decreased manual dexterity and multiple abutments could be an indication for using magnetic devices. Wear and subsequent corrosion had been reported with magnetic attachments. However, the micro-laser welding technique and application of ferromagnetic stainless steel had been claimed to solve these problems. As all new generations of magnetic attachments were so-called closed-field systems, their retention was strongly dependent on close contact between the magnetic assembly and keeper. Special techniques were used to preserve their smoothness during the fabrication process. It could be hypothesised that surface wear and scratching of the contact between the magnetic assembly and keeper were imprecise, which decreased the efficiency of the magnetic system.[38]

Bar and clip attachments were a high-profile attachment. Some studies evaluated bar and clip retention. A previous study of 5,500 fatigues measured retention of a metal bar with metal and plastic clips in different dimensions. The dimensions and materials were important factors related to retention. Larger dimensions commonly had greater retention. Plastic clips had more initial and final retention compared to metal clips. These bar and clip attachments surprisingly increased the retentive values after 5,500 fatigues, but it was noticed to apply low crosshead speed (0.1 cm/min) in the test.[54] The number of clips can improve retention of overdentures. Hader bar and clip with two clips (28.32 N) found greater retention than one clip (10.68 N).(55) Furthermore, a study evaluate the assembly of implant attachments, finding that a Hader bar with two clips and two ERA attachments (cap attachment) had the most retention compared to only a bar with four clips or only four cap attachments.[56]

A study presented peak load dislodgment (maximum tensile strength in elastic phase) and break load dislodgment (rupture strength in plastic phase) for calculating

release period. Bar and clip attachments remarkably showed more dislodgement than solitary stud attachments and magnetic attachments. Prototypes of solitary stud attachments (Zest anchor and Sterngold ERA attachments) gave half value of break load dislodgement of the bar and clip. Though the magnets were the lowest dislodgement, they were the highest release period to reseat themselves when slow force was applied. The solitary studs and bar and clips were not significantly different in release period.[57]

An original style cap attachment, ERA attachments with four different color-coded nylon inserts (white, orange, blue, and orange) were evaluated their retentions. Initial retention and retention after 5,500 cycles were recorded and calculated. 5,500 cycles simulated three years based on average of five insertions and removals per day. Instron universal testing machine (TTBML model, USA) for maximum tensile load was used with a crosshead speed of 5 cm/min. Fatigue test was set up a cycling frequency rate of 0.2 Hz with 10 mm in cycle motion. The test was simulated lubricant saliva effect under bath with demineralized water maintained at mouth temperature 37 °C. After 500 cycles, all of color-coded nylon inserts had rapidly loss of retention (0.62 – 1.18 kg). After 1,500 cycles, all of them constantly lost retention. They were expected the result of wear. At the end of fatigue test, retention of all color-coded nylon inserts was not significantly different (0.25 – 0.35 kg).[48]

In next generation of cap attachment, Locator attachments with three different color-coded nylon inserts (blue, pink, and white) were evaluated by Instron universal testing machine (3369 model, England). They were measured ten times of each sample with 5 cm/min crosshead speed and 10 seconds interval. Three Locator attachments were explained three significantly different retentions, subsequently by the color-coded manufacturer's recommendation. However, the retentive values: blue (3.83 N), pink (9.4 N) and white (12.39 N) were revealed less than the manufacturer's instruction: blue (6.66 N), pink (10.15 N) and white (22.2 N).[47] Moreover, the studs were concerned about 10 seconds recovering resilient period of nylon inserts when cyclic fatigue test was done.[38]

Locator attachments with all of color-coded nylon inserts were evaluated their retention comparing ERA attachments. Shimazu micromaterial testing machine (MMT-w50NB-10 model, Japan) and software package PDC-30A (Kyowa Electronic Instrument Co., Japan) reproduced fatigue test within 15,000 cycles. The machine was set up with 5 cm/min speed and 2.5 mm dislodgement range (0.17 Hz) under 37 °C demineralized water in the circulating bath. They simultaneously recorded retention of each cycle. Initial retention of Locator attachment (16.10±6.17 N) exhibited higher retention than ERA attachment (12.87±2.35 N). Their initial retentions were not related to manufacturer's instruction. After 800 cycles, they revealed relatively constant retention, and their retentions were not significantly different. At the end of the test, Locator attachments widely exhibited loss of retention (21% - 62%), in contrast, ERA attachments remarkably performed loss of retention (87% - 88%). Pink nylon insert of Locator attachment was preserved the most retention at the end of the test (6 N), but it also showed the leader of wear protection approximately 30 % of reduction and remained the best value after fatigue test.[38-40] Aside from previous studies, some authors determined very short vertical movement 0.2 mm on the stylized RPD at a distance of 12 mm from the central axis of the patrix to simulate chewing forces. The stress tests were conducted in water at room temperature (20 ± 2°C). During 50,000 loading cycles at a frequency of 0.5 Hz, retentive forces were registered consecutively. The variable initial retention of pink nylon Locator was found in 13.25±6.6 N. After 200 cycles, the retention slightly increased to 18.45 N. Subsequently, the retention decreased up to 2 N at the end, which was significantly lower than initial retention.[58] Therefore, pink nylon of Locator could represent medium retention and provide good preservation of retention within 15,000 cycles and frequency 0.14 – 0.2 Hz.

Some authors studied gingival heights (GH) of attachment related to overdenture retention. They found that 0-,2- and 4-mm GH over the gum line were not statistically significant difference except 6 mm GH could exhibit higher retention. However, correcting of GH in clinical practice was corresponded to gingival form and

interocclusal space and not much over the gum line. Moderate GH (2-3 mm) was chosen in many experiments because that it was the most common clinical situation.[59]

In clinical practice, implant angulation was placed to compromised with less remaining bone or less dentist's experience. Some authors investigated retention of nylon insert of single Locator (blue, pink, white, green and red). Three specimens of each angulation (0°, 10°, 20°) were circulated with artificial saliva at pH 7 and 37°C with CS Dental Testing Machine® (Idearum®, Spain). The test was run at 6.36 cm/min cross head speed and 5,400 insertion - removal cycles. The stereomicroscope with 90x magnifier (Olympus SZ61, Japan) detected and measured the surfaces of the nylon insert. Retention of all color-coded nylon inserts of Locators were not similar to manufacturer's instruction. The varieties of retention loss were not concluded in the same patterns. However, most of all color-coded nylon inserts of Locators showed poor retention when they were angulated path of insertions. The deformation of the nylon inserts was clearly detected wear especially nylon core in angulated abutments.[33] In addition, retention of two divergent Locator (20°) were lower than retention of two parallel Locators. But, their retention were not statistically significantly different after 500 cycles of fatigue test.[41] We could conclude that the angulation of implant attachment reduced retention.

Some authors compared the novel cap attachments: Equator and Locator. Equator attachments (Rhein 83, Bologna, IT) was launched in the market with smaller attachment. Ten samples in each type was programmed 14,600 cycles with 2 mm axial movement and 5 cm/min cross head speed by Instron universal testing machine (8870 model, USA). Both attachments with medium retention were not corelated to the manufacturer's instruction. Initial retention of Equator attachments (16.38 N) were closely equal to Locator attachments (17.02 N). After fatigue test, Equators (69.74%) showed extremely loss of retention than Locators (50.24%) from the initial retention. The geometry and design of the attachments were affected to each system after wear, especially Equators were smaller than Locators in width and height.[35]

To summarise, the types of implant attachments individually had characteristics of retentive forces. Magnetic and small implant attachments showed less retention, but could be used where there was limited restorative space and in certain specific areas. Bar and clip attachments tended to high levels of retention, but they required more space and complex fabrication. Cap attachments—especially Locators—were claimed to have sufficient retention and stability for overdentures, and they were easier to fabrication and maintain.

To find out enough overdenture retention to satisfy patients, Burns et al. (1995) demonstrated how much retention was enough in two implant-supported overdentures in vivo. Seventeen patients who had worn successfully the conventional complete denture changed to overdentures with ball or magnet attachments. The subjective and objective retentions and stabilities were followed up and recorded by the questionnaire and the force gauge. As a result, the means of objective retentions were preferred to overdenture with ball attachments (925.10±134.18 g), magnet attachments (479.12±129.08 g) and conventional complete denture (190.55±116.30 g), subsequently. Score of objective retentions corelated with subjective retentive scores in each group (the best score was 3) were 2.98±0.08 N in ball attachments, 2.49±0.49 in magnet attachments and 1.33±0.65 in conventional complete denture. Therefore, the most satisfied retention of overdentures for patients was ball attachments (925.10±134.18 g).[60] In addition, Setz et al. (1998) examined retention of many attachment systems and tested mechanical fatigue test. They compared their investigations and literature reviews, and they assumed that approximately 20 N was an acceptable retention for overdenture.[61] Although there was rare studies of satisfying retention, we could conclude that 10-20 N showed appropriate retention for overdenture patient.[60, 61]

However, no evidence showed retentive value of Locator R-Tx both from articles and manufacturer. Locator R-Tx has size, geometry, and surface coating different from Locator. They could affect to retention of the attachment. Locator R-Tx would replace Locator in nearly future. The authors would like to study these

attachments in vitro. The result could provide information to clinical practice especially in their maintenance period.

Chapter 3
Materials and Methods

3.1 Study design

This study was a laboratory experimental study with controlled contributing factors to determine retentive forces of two implant attachment systems.

Table 1 Characteristics of implant attachment systems evaluated in this study

	Locator	Locator R-Tx
N	10	10
Manufacturer	Zest Anchors, USA	Zest Anchors, USA
Nylon insert	Pink medium retention with core and ring (10.15 N)	Pink medium retention with dual step (not available retentive value)
Housing	Stainless steel	Stainless steel
Coating	TiNi	TiCNi (Duratec)

3.2 Sample size

Considering a 95% confidence level, sample size was calculated based on retentive forces of both systems that they were analyzed after fatigue test 5,400 cycles. The parameters used to perform the sample size calculation was obtained from the pilot study (n = 3) with α = 0.05, power = 0.95 with G*Power (Version 3.1.9.2, Germany), resulting in a final sample size of six in each group. However, in recent study, the authors showed that ten samples were recommendation for single implant attachment.[35] Then, the authors proposed ten samples for better evaluation and comparison to others.

In this study, there were two attachment systems in the test; Locator and Locator R-Tx (Gingival height = 3 mm, Zest anchors, USA) (Fig 1, 2). Ten samples of each system were measured maximum retentive force and compared between initial values and after fatigue test. The pink nylon represented medium retention of both systems (Table 1).

Figure 1 Illustration of attachments (Left) Locator (Right) Locator R-Tx

Figure 2 Components of attachments (Left) Locator (Right) Locator R-Tx

3.3 Sample fabrication

Each sample was composed of two parts: the lower part (Implant replica and metal attachment attached in implant replica) and the upper part (Metal housing and nylon in metal housing). Ten samples for Locator and ten samples for Locator R-Tx were made.

Forty of 22 mm diameter cylindrical plastic pipes with 25 mm in height were made. Twenty pipes were used for lower part fabrication contained twenty implant replicas (Regular Platform, NobelReplace Conical Connection, Nobel Biocare, Switzerland). Twenty pipes were used for upper part fabrication (Ten pipes for Locator and ten pipes for Locator R-Tx)

For the lower part fabrication, implant replica was held on the surveyor and axially embedded into self-cured acrylic resin (Unifast TRAD, pink, GC, Japan) in the pipe. Resin excess was removed and polished by stone and rubber burs. Then, Locator and Locator R-Tx were mounted in each implant replica by its driver and torque wrench with 20 Ncm following the manufacturer's instruction. After that, the lower part was inserted and centered to the metal base of the surveyor. The metal housing with black processing insert and block-out spacer were inserted to the attachments.

For the upper part fabrication, the pipe was filled up with self-cured acrylic resin. The center of the resin was marked and removed by the 8-mm round carbide bur. The pipe was held to the metal jig of the surveyor. The pipe's hole was fulfilled with self-cured acrylic resin. During the working time, the pipe was snapped on the metal housing of the lower part and held it on. Resin excess was removed and polished by stone and rubber burs. The pink nylon of each system was changed from the black into the housing by removal and insertion tools following the manufacturer's instruction. (Fig 3)

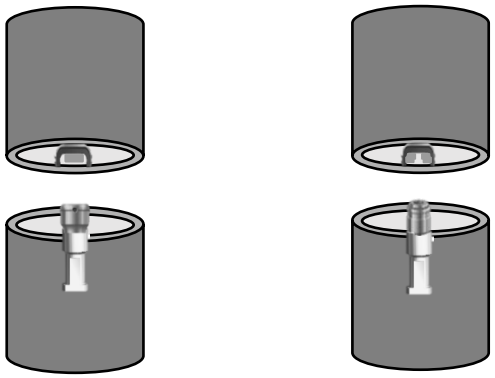

Figure 3 Diagram of assembly used to test (Left) Locator (Right) Locator R-Tx

3.4 Design and Data Collection

Twenty samples, ten of each system, were evaluated. Initial retention and the subsequence after 900 cycles, 1,800 cycles, 3,600 cycles, and up to 5,400 cycles were recorded. It was claimed that 5,400 insertion and removal cycles simulated three years of in wearing dentures based on an average of five insertions and removals per day.[48] The number of cycles could simulate wear of the retentive inserts and exactly change retention of the attachment.

After fabrication, the samples were placed in the Instron universal testing machine (e1000, INSTRON Instruments, England) for maximum retentive load testing using a crosshead speed of 5 cm per minute and 3 mm vertical range (0.14 Hz) in air room condition (Fig 4). The speed was set approximately an in vivo snap removal and the majority of previous studies.[35, 40, 43, 44] Each sample was tested three times and averaged, allowing the calculation of a mean and a standard deviation, to record initial baseline retentive values, which were reported on the graph and table with loads in newton (N) with the software (Instron Bluehill® Universal Software). (Fig 5)

For fatigue test, the samples were cycled up and down in same machine and conditions with the fatigue software (Cyclic Wavefrom Generator, Instron WaveMatrix™). (Fig 6) 900 cycles, 1,800 cycles, 3,600 cycles, and 5,400 cycles, the software was changed to record three times and averaged at those cycles as correcting position of the samples.

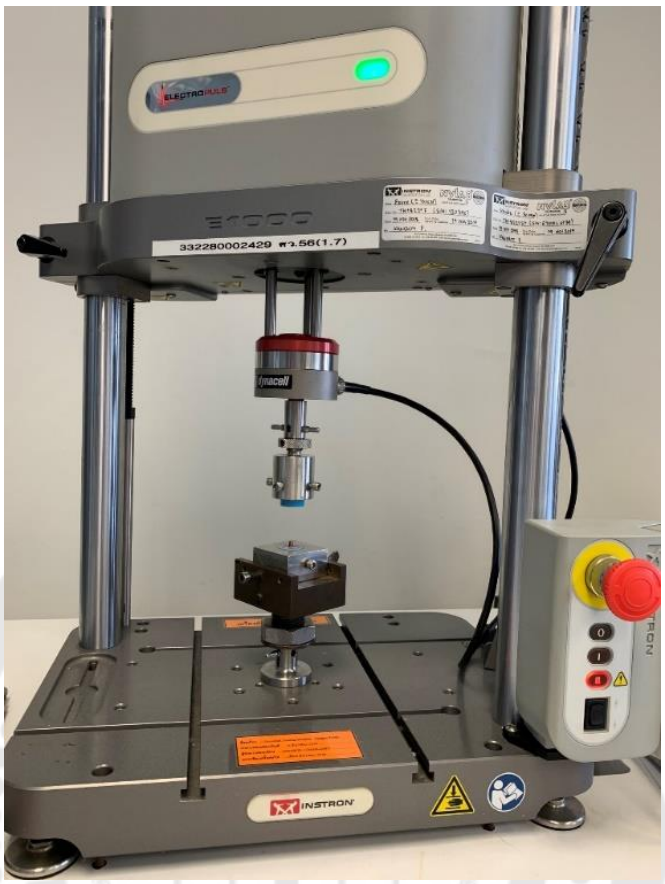

Figure 4 Samples and Instron Universal Testing Machine (e1000, England)

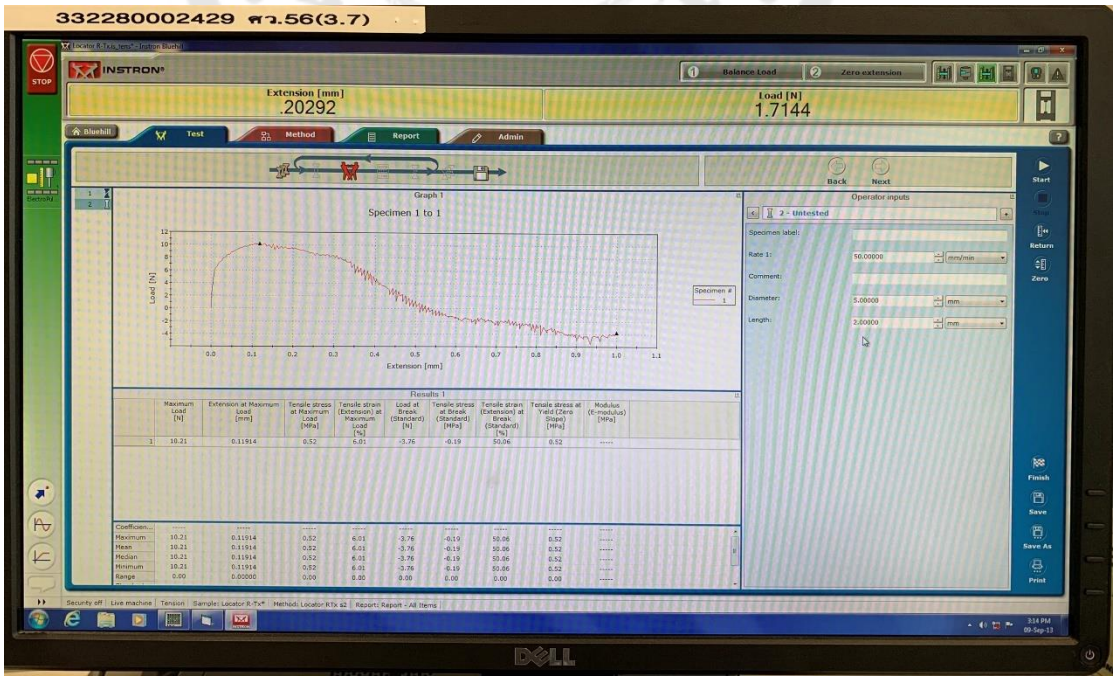

Figure 5 Setting on computer screen of Instron Bluehill® Universal Software

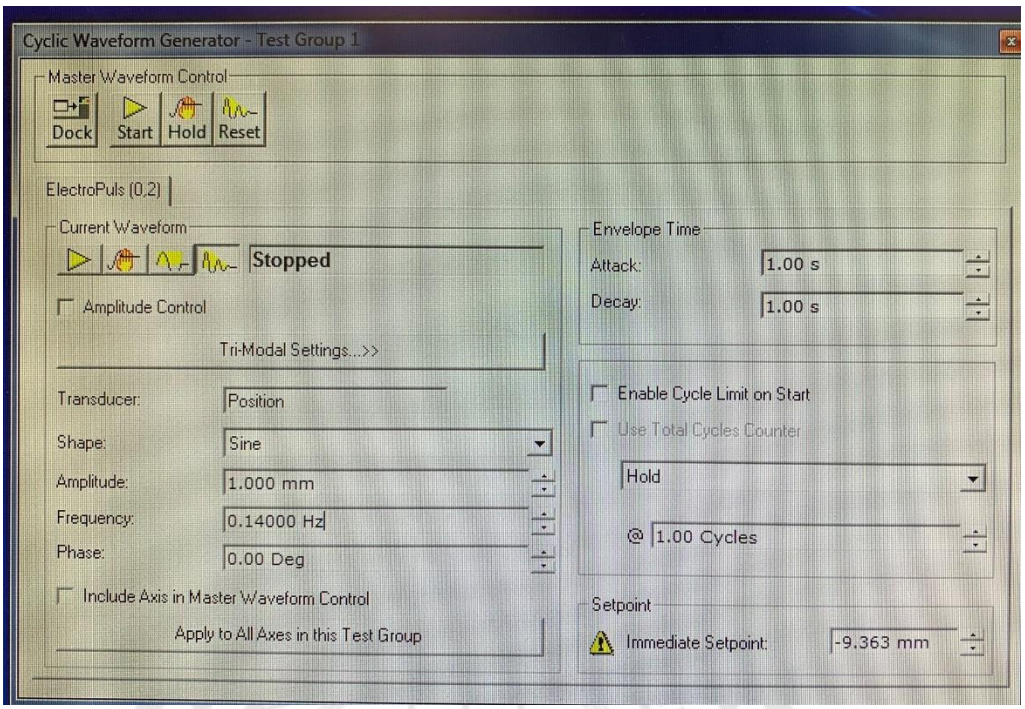

Figure 6 Setting on computer screen of Cyclic Wavefrom Generator, WaveMatrix™

3.5 Statistical analysis

Descriptive statistic was determined means and standard deviations for maximum retentive loads. The retentive loads were showed in tables and graphs. Maximum retentive forces of each system were compared at base line, 900 cycles, 1,800 cycles, 3,600 cycles, and 5,400 cycles by independent t-test. Within implant attachment system was compared change of retentive forces at base line, 900 cycles, 1,800 cycles, 3,600 cycles, and 5,400 cycles by one-way ANOVA. The level of statistical significance was set at $p < 0.05$ with the statistic software (SPSS Statistic 17.0).

3.6 Venue of the study

1.Dental Material Science Research Center, Faculty of Dentistry, Chulalongkorn University, Thailand

2. Development Research Unit, Faculty of Dentistry, Srinakharinwirot University, Thailand

Chapter 4
Results

The descriptive statistics of changing retentive forces between Locator and Locator R-Tx over cycle sequences were described as means and standard deviations in Table 2. Both systems underwent the overall continuous decrease in retentive forces during the fatigue test. With Locator system, the mean retention fell from 19.95 ± 0.78 N at the baseline to 11.65 ± 0.94 N at 5,400 cycles (representing 3 years of functional life). With Locator R-Tx system, the retention fell from 19.24 ± 1.12 N to 10.70 ± 1.75 N. Although each cycle was found that the retentive forces of Locator were higher than Locator R-Tx throughout the whole fatigue test, both systems were not statistically significantly different ($P<0.05$) in each cycle. The box plot showed the distribution of retention forces obtained by two systems (Fig 7). Additionally, the data distribution of Locator R-Tx was noticed more than Locator throughout the whole fatigue test.

Within Locator system, the retentive forces were found to be statistically significant different between cycle sequences across the whole fatigue test except for between 1,800 and 3,600 cycles ($P>0.05$). On the contrary, within Locator R-Tx system, no statistically significant differences were found between the retentive forces between cycle sequences across the whole fatigue test except for between 900 and 1,800 cycles ($P<0.05$).

Although each system increased in percentage reduction of retentive forces across the whole fatigue test, both systems were compared and found to have no statistically significant differences within same cycle throughout the whole fatigue test ($P<0.05$). The percentage reduction of both systems was found markedly about 30 % of the beginning force between 900 and 1,800 cycles (representing ½ - 1 year functional life). After 5,400 cycles, both systems dropped to about 50 % of the beginning force. The box plot showed the distribution of the percentage reduction obtained by both systems (Fig 8).

Table 2 The descriptive statistics showed mean, standard deviation and percentage reduction of Locator and Locator R-Tx all fatigue cycles.

	Locator			Locator R-Tx		
	Retentive force (N)		Percentage reduction (%)	Retentive force (N)		Percentage reduction (%)
Cycle	Mean	SD		Mean	SD	
0	19.95	0.78	0.00	19.24	1.12	0.00
900	18.54	0.68	7.08	17.79	1.35	7.56
1,800	14.34	1.08	28.20	13.48	1.63	30.08
3,600	13.60	1.04	31.90	12.58	1.45	34.68
5,400	11.65	0.94	41.70	10.70	1.75	44.62

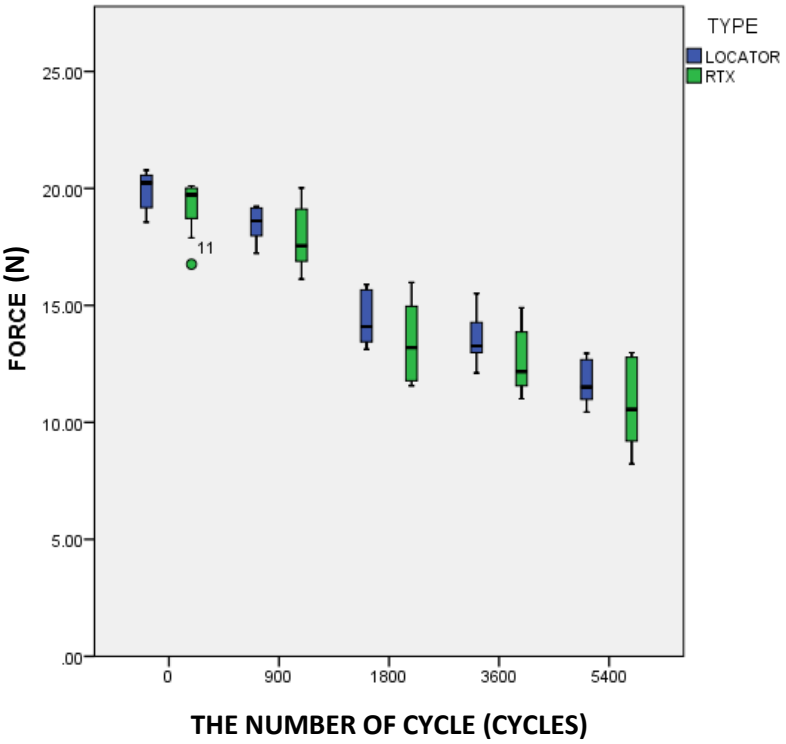

Figure 7 The box plot showed retentive force of Locator and Locator R-Tx all fatigue cycles.

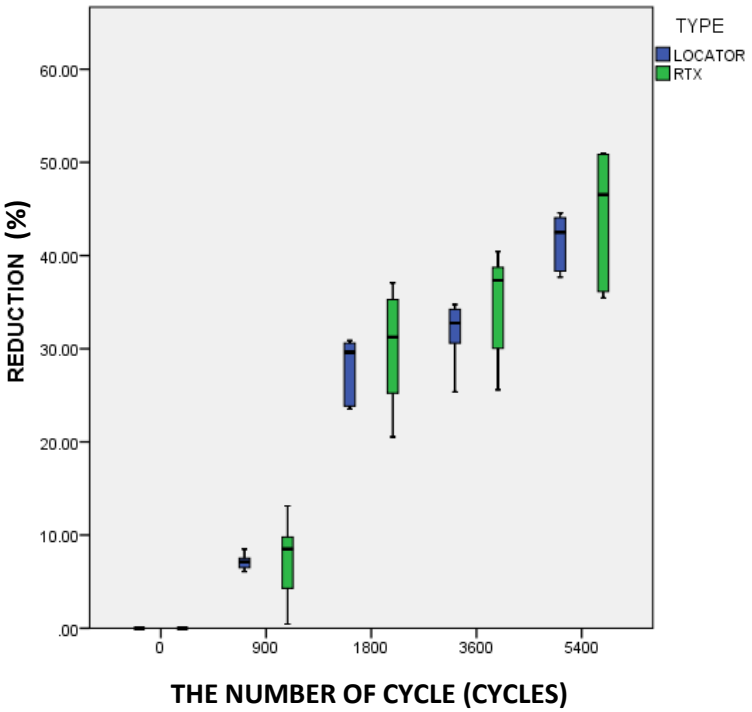

Figure 8 The box plot showed percentage reduction of Locator and Locator R-Tx all fatigue cycles

Chapter 5
Discussion and Conclusion

The null hypothesis of this experiment was acceptable because the retentive forces after simulated wear in three years of two attachment systems were found to be equal. In the same way, prior to the fatigue test, both systems with the pink retentive inserts were closely equal to the retentive forces.

Retention of Locator from the manufacturer evidently revealed the retentive values of all retentive levels: blue (6.66 N), pink (10.15 N) and white (22.20 N). Many studies have sought to explore the retention of different tools and methods. In a previous laboratory study, three retentive levels of a single Locator were investigated and achieved three significantly different retentive values. All colour-coded Locators were consecutively 10 cycles in vertical pull out to evaluate initial retention, and they were determined to have a 10-second interval in each cycle due to the elastic recovery of the nylon inserts. However, each retentive level was reported to be lower than the manufacturer: blue (3.83 N), pink (9.40 N) and white (12.39 N). In addition to the retention of blue Locator being significantly lower than the manufacturer, white Locator was also. Conversely, pink Locator had the closest retentive values to the manufacturer. Nonetheless, different levels of retention matched the manufacturer's recommendation by selecting different retentive levels dependent upon patient needs. Each retentive level was observed with the dimensional misfit between the slightly oversized male part and the smaller diameter inner ring of the female abutment. Therefore, the different retentive levels were observed to be attributed to slight incremental differences in dimensions of the male parts.[47] However, some studies sectioned retentive component to measure nylon size of stud attachments affecting the retention. There was controversy that nylon size was not only main part of retention, but hardness and elasticity of nylon inserts also might be another factor of retention.[40, 48] Additionally, another study evaluated the retention of all colour-coded Locators. The authors put up slightly faster

crosshead speed than other studies (6.4 cm/min), and they set up the test under controlled conditions of 37°C, pH 7, and artificial saliva. They found that the initial retentive values of Locators arranged subsequently by the colour-coded levels: blue (9.03 N), pink (9.42 N) and white (11.33 N). Although the retention of pink Locator was close to the manufacturer, the retention of blue and white Locators was different. The retention of blue Locator was higher than the manufacturer and similar to pink Locator. Meanwhile, white Locator was greatly lower than the manufacturer.[33] In other studies, the authors picked up pink Locator as a reference for Locator system. The initial retention of pink Locator (10.58 N) in 10 cycles in vertical pull out closely resembled the manufacturer. Besides, further studies by same authors revealed the initial retention of all colour-coded Locators. They developed tools and methods to continuously pull out using a spring jig (shock-absorbing spring) under simulated oral conditions. Locator was tested in a controlled 37°C demineralised water. The initial retention of pink Locator was approximately 8.88 – 15.20 N, and it showed standard deviation variations in three studies (SD = 0.1-9.4 N). Although the initial retention of blue Locator (16.50 N) was greatly higher than the manufacturer, white Locator (16.61 N) was greatly lower than the manufacturer. In summary, the initial retention of all colour-coded Locators were not significantly different.[38-40] A further study measured the initial retention of blue Locator. The retention of blue Locator (15.36 N) in 10 cycles of vertical pulls out was higher than the manufacturer.[45] However, another study used a large sample size (n = 10) to evaluate the retention of pink Locator, which was found to be higher than the manufacturer (17.02 N).[35]

From the literature review for the initial retention of a single Locator, there were different numbers of first period for initial retention, ranging from 3 – 15 consecutive cycles. Furthermore, there were different initial retentive values dependent upon different tools and methods, ranging from approximately 3 – 17 N.[33-43, 45, 47] Although most of the initial retentions of all colour-coded Locators were arranged correspondingly to same retentive levels as the manufacturer's level, the initial retentions of each level were not significantly different. Pink Locator showed retentive value close to the

manufacturer, and it was a more reliable retention than the other colours. However, in this study, the initial retention of the pink Locator (19.95 N) was higher than the manufacturer and all previous studies.

Various studies assessed the retention of two-implant overdenture which was commonly a mandibular implant-supported overdenture in daily clinical scenarios. Overdentures were pulled up with metal chain hooks. Most studies utilised four hooks for the retention test, which was able to measure retention in many directions. In a series of studies, the authors evaluated initial retention of all colour-coded Locators, with both two and four-implant supported overdentures representing a clinical situation of mandibular and maxillary implant-supported overdentures. Two-implant overdentures with two Locators were measured for initial retention: blue (19.01 – 20.63 N), pink (19.64 – 40.07 N) and white (49.20 - 65.20 N). Four-implant overdentures with four Locators were measured for initial retention: blue (26.24 - 33.53 N), pink (60.63 - 64.25 N) and white (72.00 - 94.15 N). The initial retention of all Locators was sorted corresponding to the retentive levels of the manufacturer. On the contrary, all initial retentions tended to be greatly higher than two and four times of the manufacturer's values.[62-65] However, one study evaluated the initial retention of Locators with only three hooks. They showed the lower initial retention of two Locators: pink (12.33 N) and white (28.95 N).[66] Similarly, another study evaluated initial retention of Locators with only three hooks, showing the lower initial retention of two Locators: pink (15.56 N).[67] They were even close to the retention of a single Locator. Therefore, the number of metal chain hooks affected the retention measurement of the Locator. Alternatively, there were many tests that simulated two-implant overdenture with a pair of the attachments in a resin block. One such study discussed the initial retention of all colour-coded Locators: blue (77.6 N), pink (72.7 N) and white (83.8 N). Although retention of blue Locator was higher than pink Locator, both Locators were not significantly different. The retention of all Locators was not arranged according to the retentive levels of the manufacturer due to blue and pink Locators. All initial retentions were greatly above twice the values from the manufacturer.[36] Besides, there were plentiful retention tests of two pink Locators. Initial

retention of two pink Locators had a large variation, ranging from 14 - 109 N, although the average of initial retention was approximately 50 N.[34, 41-43] However, some studies showed that the initial retention of two blue Locators range from 22 - 43 N.[68-71] Additionally, some studies showed the initial retention of two white Locators ranging from 47 - 86 N.[37, 72, 73]

In summary, the tools and methods were important to the retentive value results. Different measurement sensors and software were computed from the force pull up on both metal chains and resin blocks, and different retentive values for Locators were found. Some experiments used metal chain hooks which tended to lower the retention more than resin blocks. This could reduce the stability of strain gauge attached to the metal chain hook. Conversely, the resin block model was more rigid than a strain gauge, so it could be precise to the vertical force parallel to the implant attachments. Most initial retentions of all colour-coded Locators with two and four implants were arranged corresponding to the same retentive levels as the manufacture's level. Most of two and four Locators showed higher retentive values than the manufacturer when comparing two and four Locators. Two pink Locators had the greatest initial retention variation.

For Locator R-Tx, the manufacturer did not clearly state the retentive forces. These are only revealed for the retentive levels, for example, a light level in the blue retentive insert and a medium level in the pink retentive insert. It was therefore difficult to compare with the manufacturer's reference. However, in a previous study of pink Locator R-Tx, the authors examined the initial retentive values of two parallel implants with pink Locator R-Tx (20.10 N), and the retentive value was close to the two pink Locators of the manufacturer (20.30 N). Although the retentive value from the previous study was slightly higher than the initial retention in this study (19.24 N), the retentive values of both studies were not significantly different.[43] Therefore, the initial retention could not completely conclude which has better retention between Locator and Locator R-Tx. Yet we could assume that both single and two implants with Locator R-Tx were not

different in initial retention. Locator R-Tx—a novel implant attachment—could positively replace the Locator to satisfy the patients' first impression when wearing overdentures.

Initial retention of implant attachments was important for initial impressions when a patient using implant-supported overdentures, but retention after functional use was also significant. The mechanical fatigue test simulated functional use under oral conditions, especially pull in and out tests which represented insertion and removal of overdentures. After the fatigue test, most studies had discussed both remaining retentive values and percentage reduction. Percentage reduction preferred to compare each attachment since it was calculated individually from initial retention to final retention. In addition, the number of cycles determined the degree of mechanical fatigue test. Many Locator fatigue studies described both short and long cycles, ranging from 540 – 15,000 cycles. These cycles were determined at approximately 1/2 - 10 years of use based on an average of 3 - 5 insertions and removals per day.[33-43] In a previous study, the authors evaluated fatigue test of a single Locator at 5,400 cycles, showing the final retention of all colour-coded Locators: blue (10.11 N), pink (8.82 N) and white (9.30 N). These did not corresponding to retentive levels of the manufacturer. Although pink and white Locators changed normally through wear and were found to have a 6% and 18% of reduction, blue Locator increased to 12% of initial retention. The author claimed abnormal deformation of blue nylon resilience. Pink Locator was reported to have 8.82 N of remaining retention and a 6.4% reduction, which was a lower retention and percentage reduction than this study (11.65 N, 42% of reduction). It was assumed that a faster crosshead speed (6.36 cm/min), electrical fatigue machine, and continuously analysing software affected the results.[33] Another study exhibited retention loss of all colour-coded single Locators after cyclic fatigue test, and the remaining retention after 15,000 cycles was: blue (6.24 N), pink (11.95) and white (10.28 N). They were not relative to the retentive levels of the manufacturer. Although the number of cycles was 3 times the number used in this study, the remaining retention of pink Locator was approximately close to this study (11.65 N). Yet the number of cycles (5,400 cycles) compared that the remaining retention (8.85 N) was lower than this study (11.65 N). This

could be due to the shock-absorbing spring used in the study to absorb impaction of the retentive component. The percentage reduction changed ranging from 21 - 62% at 15,000 cycles. Blue Locator showed the greatest loss at 62% of reduction. Pink Locator was the lowest at 21% of reduction, and it was lower than 42% of reduction found in this study. Meanwhile, when comparing the number of cycles at 5,400 cycles, both studies were approximately close to 42% of reduction.[40] Nevertheless, another study investigated the fatigue of a single pink Locator at 14,600 cycles. They found that the remaining retention was 8.47 N, which was lower than the previous study (11.95 N). Moreover, the percentage reduction reached out to 50% of reduction, which was greatly higher than the previous study. This might be affected by wear in dry conditions. Although when comparing the number of cycles at 5,000 cycles, the remaining retention of the study (11.51 N) was very close to this study at 5,400 cycles (11.65 N), percentage reduction (32% of reduction) was lower than this study at 5,400 cycles (42% of reduction).[35]

To summarise, the tools and methods—especially number of cycles—affected the remaining retention and percentage reduction after the fatigue test. The remaining retention was not in accordance with the retentive manufacturer's levels due to non-pattern of wear. Although it could not definitively determine the remaining retentive value and percentage reduction after a fatigue cycle, most of studies showed that the tendency of retention after fatigue test was a decrease at least 20% of reduction. However, at 5,400 cycles representing three-year function life, we found that the remaining retention of a single pink Locator is about 8 – 12 N, and the percentage reduction was approximately 30 - 40% of reduction.

Two and four implant-supported overdentures are available in clinical situations of mandibular and maxillary overdentures. It is necessary to understand how long the functional life of the overdentures is when they are used. The cyclic fatigue test is a mechanical test to simulate oral conditions. A series of studies were undertaken to determine the remaining retention and percentage reduction of two and four implants with all colour-coded Locators. The overdentures were pulled in and out with metal

chain hooks in 540 cycles. In two implants with Locators, they found that the remaining retention was: blue (3.52 – 14.80 N), pink (19.15 - 33.60 N) and white (32.00 – 39.80 N), and the percentage reduction was: blue (25 – 83%), pink (34 – 52%) and white (35 – 39%). In four implants with Locators, they found that the remaining retention was: blue (20.62 – 25.14 N), pink (39.94 – 45.38 N) and white (43.66 – 56.69 N), while the percentage reduction was: blue (4 – 38%), pink (25 - 38%) and white (21 - 54%). Although the remaining retention and the percentage reduction of Locators were not constantly specific values, they showed consequent colour-coded level followed by the manufacturer after the fatigue test. Pink and white Locators were had greater retention after fatigue, while the blue Locator exhibited remarkably more retentive loss.[62-65] However, another study evaluated two implants with all colour-coded Locators. They simulated the fatigue test at 2,160 cycles in resin blocks. All the colour-coded Locators had slightly different remaining retention (25.80 – 32.00 N) and percentage reduction (61 – 67%).[36] In addition, other studies looked at two implants with Locators after a fatigue test. The remaining retention and percentage reduction showed large variation dependent on the tools and methods used, especially the number of cycles ranging from 540 - 14,600 cycles. Remaining retention was revealed in many studies: blue (16 - 30 N); pink (10 - 25 N); and white (28 - 55 N). Percentage reduction was calculated and exhibited as: blue (15 - 27%), pink (26 - 82%) and white (21 - 50%).[37, 41-43, 68, 69, 71, 73, 74]

As described, it was complicated to exactly compare the remaining retentive values and percentage reduction for all colour-coded Locators. However, we could conclude that all Locators tended to have retention loss after the fatigue test simulated at least 540 cycles under oral conditions, representing a 6-month functional life.

Only one study from the literature conducted a fatigue test for Locator R-Tx. Two implants with pink Locator R-Tx were fatigued within 1,440 cycles, representing a 1-year functional life. The remaining retention at 1,440 cycles (14.00 N) was slightly higher than this study (13.48 N) which evaluated only single pink Locator R-Tx at 1,800 cycles representing a 1-year functional life. Conversely, the percentage reduction of both studies was surprisingly similar to 30% of reduction in a 1-year functional life.[43]

However, this study conducted a longer fatigue test at 5,400 cycles, representing a 3-year functional life. We found that the remaining retention at only between 900 – 1,800 cycles rapidly declined, with an approximate 20% reduction. Then, the other periods of fatigue showed a constant retention loss of approximately 10% reduction in each cycle period. Finally, Locator R-Tx gradually decreased to 45% of reduction and remained at 10.70 N of final retention. Meanwhile, Locator in this study had a gradual retentive loss through the fatigue test of approximately 10% of the reduction in each cycle period. At the end of the test, the Locator reached to 42% of reduction and remained within 11.65 N of final retention. Consequently, the retention of both Locator and Locator R-Tx after simulated fatigue test in three years were not significantly different. Both systems were also similar to the characteristic of retentive loss. In addition, We could conclude that Locator and Locator R-Tx were promoted in initial retention, and they were also recommended to have a durable functional life of at least three years (< 50% of reduction).

Although this study was showed higher retentive values of Locator than Locator R-Tx all period of the test, the retention of both systems was not statistically significantly different. Locator had the core retention, which was main part of the retention, but the core was absent in Locator R-Tx. It was reformed to smaller hex drive 0.050 inches to reduce food debris inside the hole and to compatible to the hex driver in standard implant prosthetic kits. However, Locator R-Tx was improved to be longer and narrower in geometry and dual step attachment to replace the core retention. We could assume that new design without core retention replace the core retention of Locator. In addition, Locator R-Tx was developed not only the retention, but the Duratec surface coating was also changed to increase wear resistance. Pink colour of the attachment and the metal housing was more esthetic for gingiva and denture base. More flat grooves on cameo surface of the housing resisted to movements of the housing in denture base. New geometry and design of Locator R-Tx could be useful in real clinical situations.

In addition to the parallel implant attachment, the divergent implant attachment is also found in real clinical situations. A study showed a tendency for implant placement

by less experienced surgeons to exhibit more implant divergence.[52] Locator was claimed to have a compensate implant angulation to total 20 degrees in a normal range, and 40 degrees in an extended range, while Locator R-Tx had a developed geometry and design without core retention to compensate for implant angulation to a total of 60 degree. Many studies compensated for implant angulation. Initial retention of a single blue Locator was evaluated in a study with parallel, 10, 30, and 45 degrees. They found that parallel, 10, and 30 degrees were not significantly different (13 – 15 N), but 45 degrees angulation (6.58 N) had greatly lower initial retention than the previous groups.[45] In addition, two implants with blue Locators at different angulations were measured to for percentage of reduction after 5,500 fatigue cycles. Parallel two implants showed 27% of reduction, but 10 and 20 degree angulation of two implants were found to have over 50% of reduction.[71] A study evaluated all colour-coded Locators with 0 – 20 degrees of angulation. They found over 20 degrees of angulation was higher than initial retention by about 14 – 28 % due to greater friction in the first period, but they showed more percentage reduction in this group after a fatigue test, with an approximate 35 – 65% reduction due to greater wear deterioration.[64] Furthermore, a study compared two pink Locators and two Locators R-Tx with different implant angulations. For initial retention, 30 degrees angulation did not affect either system. 60 degrees of angulation showed greatly higher initial retention of both systems, in particular Locator increased above 50%. 60 degrees angulation had higher initial retention than two parallel implants. For more angulations, greater frictions between retentive components were more retention at only the first period of use. The manufacturer claimed Locator R-Tx with all colour-coded inserts can be assembled with 60 degrees of angulation because it was compensated to implant divergent by design of attachment without core retention. However, the initial forces were considered to be unnecessarily high, making it difficult for the patient to seat and remove the overdenture. Moreover, after a fatigue test of 1,440 cycles, both 30 and 60 degrees of angulation had a higher percentage reduction of (approximately 30 – 57%), especially the Locator in 60 degree (57% of reduction). The parallel group exhibited less percentage reduction

(approximately 26 – 30%). As described, it could be claimed that Locator R-Tx was better compensated than the Locator, and it might increase longevity of the attachment in daily clinical use.[43] In addition, some studies evaluated implant compensation compared to 10, 20, 30, and 60 degrees of angulation. They found that 10, 20, and 30 degrees of angulation were not different in percentage reduction than the parallel group, but 60 degrees of angulation had a distinctly greater percentage reduction of over 50%.[41, 43, 72] In particular, green extended range of Locator was approved in 20 degrees angulation. It did not have a significantly different retention to parallel white Locator.[73]

In summary, it could be concluded that the Locator was moderately compensated to 30 degrees angulation, especially for extended range. Locator R-Tx was highly compensated at more 30 degrees of angulation. However, we did not recommend compensating implant angulation because it had been reported to have more clinical complications and more implant divergence.

In addition to the vertical direction of the pull-out test which was simulated to measure retention of implant-supported overdentures, rotational directions are also assessed to determine the stability of overdentures. Previous studies evaluated anterior, posterior, and lateral rotations. Two-implant overdenture with a Locator was tested. They found that retentive forces in liner (10.6 N), anterior (14.8 N), posterior (14.6 N), and lateral (7.7 N) directions. Anterior and posterior directions had higher retentive forces than the linear direction, but the lateral direction had a lower retentive force than the linear direction. The authors discussed that the anterior and posterior directions of the two implants promoted resistant forces. Conversely, the lateral direction had friction on only one side of the two implants, and the friction force of the other side decreased overall retentive force, referred to as a “blocking effect”. Moreover, wear simulation effects at 2,000 cyclic fatigues with different directions. Only the linear direction had a 24% reduction decline, but all rotational directions increased 3 – 8 % of initial retention. The authors claimed that wear was only simulated in a liner direction, with the same position wear pattern of core retention decreasing retentive force. Meanwhile, rotational directions changed the position of wear pattern, and the ring retention of the Locator

could have more friction from deformation in 2,000 cycles fatigue.[39] Therefore, the Locator could improve stability of the overdentures in laboratory test, but the results might change when there are more cycles and mixed directions in real clinical situations.

A variety of tools and methods had been used in previous studies, and they directly influenced the retentive values of the attachments. A universal testing machine and its software were used to determine the measurements. The Instron universal testing machine (macromaterial testing machine) with Bluehill software—a standard machine—was used for testing in this study. In a previous study, the authors showed that retention of the Locator was similar to this study.[35] However, a micromaterial testing machine and a fatigue testing machine were used to measure retention of the Locator. They were showed to have lower retentive forces than the macromaterial testing machine since they might measure forces more delicately in low force tests.[33, 40, 66] In this study, implant overdentures were tested only according to a vertical removal force direction. Although they generally did not have a specific path of insertion and removal in clinical situations, the vertical direction was a standard test for retention. In addition, we observed during the machine processing when the retentive insert pressed down on the attachment. The range of the position could be zero force as a calibration of force or balanced load. This might be inaccuracy of force before the attachment had been calibrated zero force. Therefore, the balance of force and the accuracy of position should be clearly determined for all sample tests.

The crosshead speed used was 5 cm/min in this study and the same in most previous studies of Locator. This speed was to easy compare with other studies. Some studies containing other types of attachments used a faster speed than 5 cm/min, which tended to have a lower attachment retention.[38, 39] In addition, we observed in the pilot test with slow speed test (0.2 cm/min) that we found double peak load dislodgement in the load and extension diagram. Although the double peak exhibited only in the first of fatigue test, it was absent after fatigue test. Therefore, this result could support dual step attachments only in the first functional use and in the mastication (slow speed test).

Moistness, pH and temperature control could be simulate oral conditions of the test. Demineralised water or saliva substitute with different pH was served as a protective layer and lubricant that might decrease fatigue wear. Room temperature or mouth temperature was set up in the tests. In only extreme conditions, chemical degradation of the plastic component affected attachment retention, for example; more acidic pH < 4, high temperature > 60 ˚C.[50, 51] However, it could not be concluded which of these factors clearly affected attachment retention in normal situations. In this study, the test was in dry condition that it might slightly affect to the results.

Some studies ensured a sufficient retentive force for overdenture patients. In the literature review, Caldwell et al. (1962) simulated chewing tools to evaluate food adhesiveness. They showed that approximately 10 N of retaining forces for normal food, and about 15-20 N of sticky food.[75] Burns et al. (1995) claimed that 10 N for ball attachment overdenture resulted in excellent satisfaction among patients and good satisfaction with about 5 N of magnetic attachment overdenture.[60] Naert et al. (1999) assessed retention of implant-supported overdentures with different attachments. They measured subjective and objective retentions by interviewing and dynamometer from patients worn the overdentures. They found that the initial retention of the overdentures with different attachments ranged from 6.42 - 16.43 N. The patients then used the overdentures for five years, and retention of the overdentures were re-evaluated. They found that the remaining retention of the overdentures ranged from 1.08 – 12.52 N, and the percentage reduction of them reached out to 14 – 70 %. Magnetic attachment showed poor retention in all functional periods. Bar and clip attachments maintained the highest retention at all times. Moreover, they found that subjective and objective retention were weakly correlated, but the magnetic attachment tended to have low satisfaction from the patients' interviews.[76] Setz et al. (1998) and Rutkunas et al. (2004) compared their mechanical fatigue experiments and previous clinical studies, concluding that around 20 N was an acceptable retention for overdentures.[39, 61]

Although there were rarely studies to show obviously satisfying retention, it could be concluded that 10-20 N showed appropriate retention for overdenture patients.

Therefore, in this study, retention of a single attachment could be satisfying for overdentures within a 3-year functional life.

Nowadays, there were more clinical studies with acceptable results for single-implant overdentures. A clinical study compared two-implant overdentures and single-implant overdentures by immediate loading with a 1-year follow-up. General satisfaction, social life, chewing ability, comfort, and fit were not significantly different between the two groups. In radiographic examination, marginal bone loss of the single-implant overdenture was indicated in success criteria.[77] Prospective clinical research of midline single-implant overdenture showed low biological complications within a 5-year follow-up. Although the patients had high plaque accumulation around the dental implant and attachment, a low gingival response and marginal bone loss was exhibited.[78] A randomised clinical trial comparing single- and two-implant supported overdentures was assessed for implant survival, patient satisfaction, and prosthetic complications within a 5-year follow-up. Although both groups were not significantly different in effective of the results, denture fracture was predominantly noticed around midline single implants.[79] Relining the denture base was also found to be more frequent in midline single implants.[80] Moreover, a meta-analysis study of three trials regarding overall nylon replacements comparing two-implant overdentures and single-implant overdentures revealed no significant differences as there were statistically significantly more nylon replacements in the two-implant overdentures at the five-year follow-up.[81]

This study attempted to simulate single-implant overdentures in a clinical situation, although it was known that single-implant overdenture could tend to rotate in multiple directions and risk prosthetic complications. We believed that single-implant overdentures could be more acceptable for those who could not afford more implants.

However, a limitation of this study was that the retentive force demonstrated only axially vertical removal of the attachments. The results of the in vitro study were information only pink attachment. The study lacked saliva, temperature, and pH control which could affect the results. There was multifactor for overdenture retention under oral conditions, for example, mastication, multiple direction of overdenture movement, and

chemical degradation. Readers should keep in mind that the results were not concluded all in real situations. More clinical studies could be undertaken to better support decisions to use different attachment systems.

Within the limitations of this laboratory study, we could conclude the following:

1. Retention of Locator and Locator R-Tx were not significantly different for both initial retention and final retention within 5,400 cycle fatigue tests, representing a 3-year functional life.

2. Although all the retentive values in each cycle period of Locator were higher than Locator R-Tx, both systems did not have significantly different retention throughout the whole fatigue test.

3. Overdenture patients were satisfied with 10 – 20 N of retentive force, and the single Locator or Locator R-Tx demonstrated sufficient retention after a 3-year functional life for overdenture patients.

4. Locator R-Tx—a new implant attachment model—would replace Locator. Locator R-Tx was developed with geometry and materials to solve some problems of Locator. This study supported that retention of Locator R-Tx was equal to Locator, which was a well-design attachment and a popular attachment in the world market.

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