The Influence of Implant Angulation on the Locator Attachment Retention and Wear.

1. Specific Aims: To test, respectively, the retention and wear of Locator attachment nylon patrices and abutments over extended use when attachments are placed parallel or at 10 and 20 degrees angle to each other. The null hypotheses of this study are that the Locator attachment system will:

1. Show no differences in retentive values, over time, between zero degree and angulated groups (10 and 20 degrees).
2. Exhibit no differences in retention values between different colors of Locator patrices.
3. Demonstrate no differences in wear pattern of the Locator abutments titanium nitride coating as-received and after extended use.
4. Show no difference in wear pattern of the Locator abutments titanium nitride coating between zero degree and angulated groups (10 and 20 degrees).

2. Background: Due to the expected increase in completely edentulous patients that could potentially benefit from implant-retained overdentures, this type of prosthesis has become one of the suggested available treatment modalities for the rehabilitation of the completely edentulous patient(Douglass, et al. 2002). Indeed, the McGill consensus statement first suggested that implant overdenture should become the first choice of treatment for edentulous mandible(Feine, et al. 2002) while lately the York statement of the British Society for the study of Prosthetic Dentistry defined the implant overdenture as the minimum standard of care that should be used for completely edentulous patients (Thomason, et al. 2012).

In this regard, there is strong evidence that oral-health-related quality of life and patient satisfaction of complete denture wearers can be significantly improved with mandibular two-implant overdentures; indeed, these patients perceive a substantial improvement in social and sexual activity(Heydecke, et al. 2005), speech, esthetic(Awad, et al. 2003), satisfaction with chewing(Raghoebar, et al. 2003), indirect food selection(Roumanas, et al. 2002), and comfort and stability of their prostheses (Thomason, et al. 2003). For instance, Raghoebar et al., in a 10-year prospective, randomized clinical trial, evaluated patients' satisfaction and chewing ability for 3 treatment modalities in maladaptive denture wearers(Raghoebar, et al. 2003). He found greater satisfaction rate with mandibular implant supported overdentures in comparison with conventional complete dentures and conventional complete dentures fabricated after preprosthetic surgery (Raghoebar, et al. 2003). From a nutritional standpoint, even though the NHANES III report showed no significant difference between nutrient intake of edentulous patients who received new conventional complete dentures compared to those with new implant supported overdentures, there is evidence that a slight increase in fresh fruit and crisp bread consumption occurs for patients with implant overdentures (Sebring, et al. 1995) (Sandstrom & Lindquist 1987).

Since implant-supported overdentures are generally retained by individual attachments, it is important to select an attachment system that is ideally economic, predictable, simple to install and maintain and has limited dimension and proven longevity of service. Among dental attachment systems, the Locator attachment system (Zest Anchors Inc, Escondido, CA, USA) is considered one of the most popular attachments in dental practice. The manufacturer suggests that this attachment system possesses desirable characteristics such as pivoting, self-aligning, resiliency, durability and low vertical height. Moreover, Cakater et al. showed that the Locator attachment system has superior clinical performance in terms of complications when compared to ball and bar attachments (Cakarer, et al. 2011). For overdentures retained by 2 or more individual stud attachments, placing implants parallel to each other is highly desirable since one could suspect that attachment angulations off the long axis of the implants could potentially impede effective attachment engagement and affect retention for a number of attachment designs. However, due to anatomic and, at times, operator-dependent factors, it is a common finding that implant overdenture attachments might not be

absolutely parallel to each other. To this end, one of the main advantages claimed by the Locator attachment manufacturer is retention and angulation versatility. Indeed, 2 options for this system exist on the market: The first one is the Locator Male which is supposed, according to the manufacturer, to allow accommodation of up to 20 degrees of implant divergence; the second type is the Extended Range Male which is instead claimed to accommodate up to 40 degrees of implant divergence. This angulation versatility is, of course, a desirable feature for any attachment system, but should not negatively affect the retention characteristics of the system. For example, Jabbour et al who showed that a minimal interimplant angulation of 3.5 degree in the sagittal plane significantly affected the Locator system retentive properties (Jabbour, et al. 2014). However, these data conflict with that recently published by Stephens et al. who demonstrated that retention of the blue Locator was not negatively affected by implant divergence up to 20 degrees after 5500 cycles. In this study, a significant relationship retention-divergence was only identified at the initial stages of the test. Moreover, Stephens et al identified a significant increase in retentive values at 10 degrees divergence which is counterintuitive and difficult to explain (Stephens, et al. 2014). These results, however, cannot be generalized since only the blue Locator patrices were tested. Moreover, while the manufacturer of the Locator attachment system does not provide guidelines on the frequency with which each attachment should be replaced, Al-Ghafli et al suggested the replacement of Locator matrices of 20-degree mesially tilted implants in 1.8 years. According to their results 0- and 5-degree tilted implant will cause wear of Locator matrices in 5-6 years (Al-Ghafli, et al. 2009).

Therefore, while the Locator manufacturer data suggests ample angulation versatility of this attachment system, independent research in this area is scarce and controversial at best. In absence of definitive, independent published data, clinicians currently base their selection of an overdenture attachment system on the manufacturer-advertised retentive qualities which is less than ideal for evidence-based patient care.

Therefore, the aim of this study was to determine changes in retentive values of Locator overdenture attachments placed at different angulations in a simulated, in-vitro overdenture model. Moreover, the wear characteristics of the titanium nitride coating will also be assessed and compared among the experimental groups as outlined above.

3. Significance: The clinical use of the Locator attachment system has dramatically increased in the marketplace due to the suggested angulation versatility and simplicity of use, yet further independent research is necessary to investigate if this attachment system retention is affected by the attachment potential lack of parallelism. The results of a preliminary in-vitro study suggested that it is likely that patients will notice a significant drop in retention of their overdenture and require more frequent replacement of their attachment patrices when implants are placed at relative increasing angles. These frequent replacements of Locator nylon patrices will lead to increased health care costs for our patients and clinicians. Taking into consideration the cost of nylon replacement parts, office overhead costs of a dental practice, and the widespread use of implant overdentures, the use of Locator attachments could potentially have additional significant cost to the patient and practitioner. In addition, the abutment of the Locator attachment system is coated with titanium nitride which is generally intended to act as a surface hardener. It has been shown, for a different application of this material, such as coating of implant drills, that the longevity of this coating is severely affected by wear(Ercoli, et al. 2004). It is therefore possible that the integrity this coating might be also affected by use of the attachment and more critically in areas/situations where the attachments are non-parallel to each other.

4. Preliminary Research: The aim of our preliminary study was to determine changes in retentive values of Locator overdenture attachments placed at different angulations in a simulated, manually-powered, in-vitro overdenture model, after 400 insertion/removal cycles. Implant angulations of 0, 10, 20 degrees and all

respective Locator patrices (different colors/retention) were tested (N=3)**.** Within the limitations of that preliminary study, the following conclusions were drawn:

1. Implant angulation decreases retentive values of the Locator attachment system.
2. Increasing implant angulation from 10 to 20 degrees decreases the retention values by 50%. (Fig. 1 and 2).
3. Different Locator attachment color patrices provide significantly different retention at specific time points.

Figure 1: 10-degree divergence (In vertical legend: Color of nylon patrice)

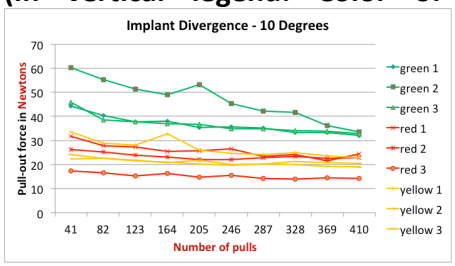
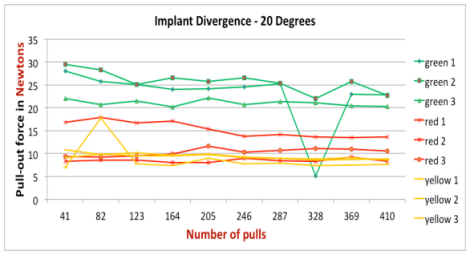


Figure 2: 20-degree divergence (In vertical legend: Color of nylon patrice)



Based on this preliminary data, power calculations and an adequate sample size (assuming type I error = 0.05 and power =0.80) were calculated for the proposed study. For 0- and 10-degree angulations a minimum sample size of 8 was calculated. For 20-degree angulation, a minimum sample size of 13 was assessed. Therefore, in order to have more than an adequate N in each group, a sample size of 15 will be anticipated.

5. Materials and methods:

Role of investigator: Dr. Baranovsky will be responsible for the protocol, project implementation, testing procedure and data gathering.

Strategy: 1. Fabrication of aluminum blocks incorporating Locator abutments and patrices mimicking a mandibular overdenture set up, which will be subjected to cycling load (10,000 cycles of insertion/removal) in a computer-controlled testing apparatus. All color range of Locator patrices will be tested.

2. Measurement of initial, residual (3,000, 7,500 cycles) and final retention (10,000 cycles) will be done with a universal testing machine.

3. SEM images of each abutment (occlusal and lateral orthogonal views) will be obtained, before, during (3,000, 7,500 cycles) and after cyclic loading in order to explore qualitative wear patterns.

4. Quantitative energy dispersive x-ray spectroscopy (DX-EDAX) will be used to quantitatively assess the surface composition (presence or absence of titanium nitride coating) for the same views as point 3 above.

Fabrication of testing apparatus: Six aluminum blocks (25 mm x 30 mm x 45 mm) will be machined. 3 of them will incorporate 2 dental implants (4,1mm diameter 10mm length, Bone Level, Straumann, Institute Straumann, Basel, Switzerland) which will be placed a 0, 10, and 20 degrees relative angulation, respectively. 3 other metal blocks will be designed to simulate a two-implant overdenture and incorporate 2 Locator overdenture attachments as described below. Two dental implants will be screwed into each of 3 aluminum blocks (0°, 10° and 20°) 23 mm apart and immobilized in these positions by applying self-polymerizing acrylic resin to the threads during placement. Locator abutments (Locator abutments, 4mm height, Straumann, Institute Straumann, Basel, Switzerland) will then be torqued to the implants according to manufacturer recommendations. The relative angulation between the implants will be checked with a surveyor.

Attachment patrices will be then incorporated with self-polymerizing acrylic resin into the 3 other aluminum blocks simulating the overdenture using a pick up technique. This will be accomplished in the testing

apparatus with a custom-designed computer software application in order to then provide consistent and proper alignment of the patrices and matrices during testing.

Testing groups: 0-degree angulated group, 10-degree divergent angulated group, 20-degree divergent angulated group. For 0-degree angulated implants pink, blue and clear patrices will be tested. For the 10- and 20-degree angulated implants, green, red and yellow patrices will be utilized. Adequate sample size for each patrice color was calculated based on the results of the preliminary study. The custom-designed testing apparatus is designed with 3 independent testing stations each consisting of one simulated arch (aluminum block incorporating the implant and locator abutments) and one simulated overdenture base (aluminum block housing the attachment patrices). Each of the testing stations is powered by a stepper motor and a sliding apparatus that allow automated insertion and removal of the simulated overdenture. The entire system is controlled by a custom-built computer software (LabVIEW v7.1 Virtual Instrument) that controls and monitors the back and forth (insertion/removal) motion of each testing station. The software also controls the characteristics of the motion applied to the testing stations (number and speed of each removal cycle) (Please, see the flowchart).

Retention Measurement in UTM: The initial retention (second removal/dislodgement which is defined in the study as baseline as first removal is generally an outlier with retention forces greater than 30% above values obtained at the second dislodgement), residual (3,000, 7,500 cycles) and final retention force measured after 10,000 insertion/removal cycles will be measured with a Universal Testing Machine (MTS Alliance RT 45) (crosshead speed of 2mm/sec).

Cyclic Load procedure: Specimens will be subjected to cycling load (insertion/removal cycles).

SEM images: SEM (S/240, Leo microscopy, Thornwood, NY) images of each abutment (occlusal and orthogonal views as mentioned above), before, during (3,000, 7,500 cycles) and at the end of cyclic loading will be obtained, in secondary electron emission mode in order to explore wear patterns.

Spectroscopy: Quantitative (DX-4; EDAX, Mahwah, NJ) energy dispersive x-ray spectroscopy analyses of each abutment will also be performed at the same intervals as above in order to assess the chemical composition of each abutment surface.

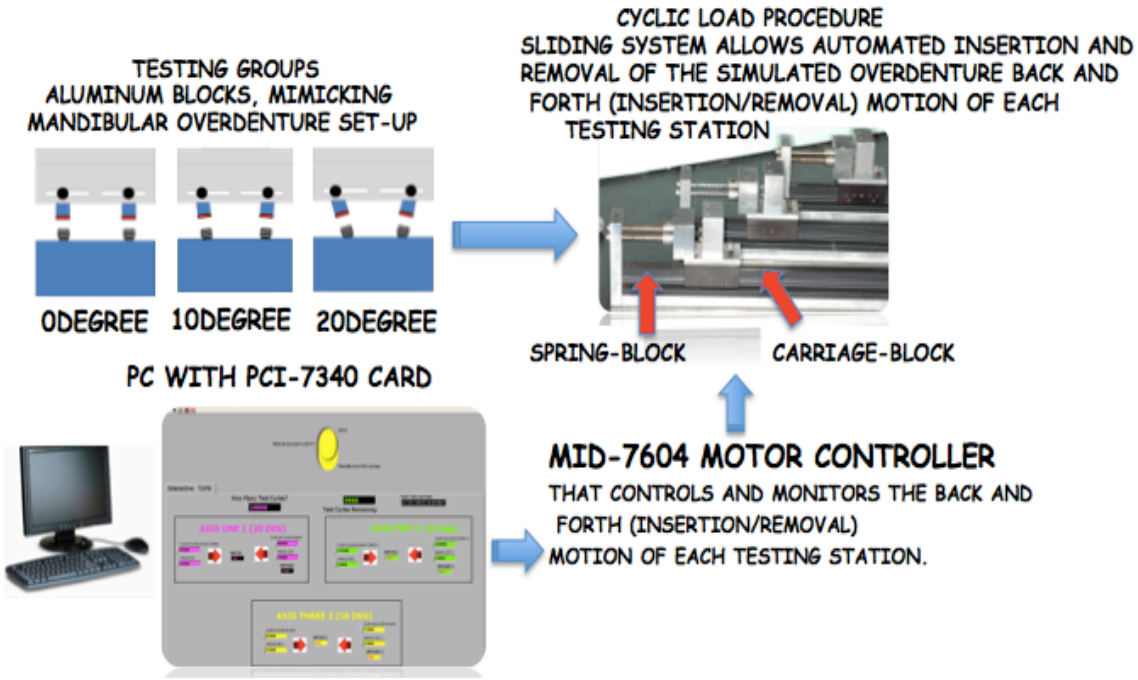
Statistical Analysis: One-way ANOVA will be used to calculate differences among different color patrices retention for the 0-degree group. Two-way ANOVA will instead be used to assess differences in retention between 10- and 20-degree angulation group and among different patrices color.

Qualitative and descriptive analysis will be reported for the SEM and EDAX examinations.

Time frame:

1. Testing: June 2015-January 2016.
2. Data-gathering and analysis: January-March 2016
3. Manuscript submission March-June 2016

Flowchart describing experiment schematically:



References:

Al-Ghafli, S. A., Michalakis, K. X., Hirayama, H. & Kang, K. (2009) The in vitro effect of different implant angulations and cyclic dislodgement on the retentive properties of an overdenture attachment system. *J Prosthet Dent* **102**: 140-147.

Awad, M. A., Lund, J. P., Shapiro, S. H., Locker, D., Klemetti, E., Chehade, A., Savard, A. & Feine, J. S. (2003) Oral health status and treatment satisfaction with mandibular implant overdentures and conventional dentures: A randomized clinical trial in a senior population. *Int J Prosthodont* **16**: 390-396.

Cakarer, S., Can, T., Yaltirik, M. & Keskin, C. (2011) Complications associated with the ball, bar and locator attachments for implant-supported overdentures. *Med Oral Patol Oral Cir Bucal* **16**: e953-959.

Douglass, C. W., Shih, A. & Ostry, L. (2002) Will there be a need for complete dentures in the united states in 2020? *J Prosthet Dent* **87**: 5-8.

Ercoli, C., Funkenbusch, P. D., Lee, H. J., Moss, M. E. & Graser, G. N. (2004) The influence of drill wear on cutting efficiency and heat production during osteotomy preparation for dental implants: A study of drill durability. *Int J Oral Maxillofac Implants* **19**: 335-349.

Feine, J. S., Carlsson, G. E., Awad, M. A., Chehade, A., Duncan, W. J., Gizani, S., Head, T., Lund, J. P., MacEntee, M., Mericske-Stern, R., Mojon, P., Morais, J., Naert, I., Payne, A. G., Penrod, J., Stoker, G. T., Tawse-Smith, A., Taylor, T. D., Thomason, J. M., Thomson, W. M. & Wismeijer, D. (2002) The mcgill consensus statement on overdentures. Mandibular two-implant overdentures as first choice standard of care for edentulous patients. Montreal, quebec, may 24-25, 2002. *Int J Oral Maxillofac Implants* **17**: 601-602.

Heydecke, G., Thomason, J. M., Lund, J. P. & Feine, J. S. (2005) The impact of conventional and implant supported prostheses on social and sexual activities in edentulous adults results from a randomized trial 2 months after treatment. *J Dent* **33**: 649-657.

Jabbour, Z., Fromentin, O., Lassauzay, C., Abi Nader, S., Correa, J. A., Feine, J. & de Albuquerque Junior, R. F. (2014) Effect of implant angulation on attachment retention in mandibular two-implant overdentures: A clinical study. *Clin Implant Dent Relat Res* **16**: 565-571.

Raghoebar, G. M., Meijer, H. J., van 't Hof, M., Stegenga, B. & Vissink, A. (2003) A randomized prospective clinical trial on the effectiveness of three treatment modalities for patients with lower denture problems. A 10 year follow-up study on patient satisfaction. *Int J Oral Maxillofac Surg* **32**: 498-503.
Roumanas, E. D., Garrett, N. R., Hamada, M. O., Diener, R. M. & Kapur, K. K. (2002) A randomized clinical trial comparing the efficacy of mandibular implant-supported overdentures and conventional dentures in diabetic patients. Part v: Food preference comparisons. *J Prosthet Dent* **87**: 62-73.
Sandstrom, B. & Lindquist, L. W. (1987) The effect of different prosthetic restorations on the dietary selection in edentulous patients. A longitudinal study of patients initially treated with optimal complete dentures and finally with tissue-integrated prostheses. *Acta Odontol Scand* **45**: 423-428.
Sebring, N. G., Guckes, A. D., Li, S. H. & McCarthy, G. R. (1995) Nutritional adequacy of reported intake of edentulous subjects treated with new conventional or implant-supported mandibular dentures. *J Prosthet Dent* **74**: 358-363.
Stephens, G. J., di Vitale, N., O'Sullivan, E. & McDonald, A. (2014) The influence of interimplant divergence on the retention characteristics of locator attachments, a laboratory study. *J Prosthodont* **23**: 467-475.
Thomason, J. M., Heydecke, G., Feine, J. S. & Ellis, J. S. (2007) How do patients perceive the benefit of reconstructive dentistry with regard to oral health-related quality of life and patient satisfaction? A systematic review. *Clin Oral Implants Res* **18 Suppl 3**: 168-188.

Thomason, J. M., Kelly, S. A., Bendkowski, A. & Ellis, J. S. (2012) Two implant retained overdentures--a review of the literature supporting the mcgill and york consensus statements. *J Dent* **40**: 22-34.

Thomason, J. M., Lund, J. P., Chehade, A. & Feine, J. S. (2003) Patient satisfaction with mandibular implant overdentures and conventional dentures 6 months after delivery. *Int J Prosthodont* **16**: 467-473.