

## MANDIBULAR IMPLANT OVERDENTURE PERI-IMPLANT TISSUE CHANGES RETAINED WITH NYLON AND RETENTION.SIL600 INSERT: A SPLIT MOUTH STUDY

Mohamed Denewar\*  and Ahmed Khalifa\*\* 

### ABSTRACT

**Purpose:** This split-mouth study aimed to study peri-implant tissue health changes between conventional nylon inserts and Retention.Sil600 (RS600) as a polyvinylsiloxane inserts for mandibular implant overdentures.

**Materials and methods:** Eighteen edentulous patients received two intra-foraminal mandibular implants. Locator abutments were attached with nylon inserts on one side and RS600 on the other. Modified plaque index (mPI), gingival index (GI), and modified bleeding index (mBI) were assessed at 6 months (T1) and 12 months (T2) post-loading.

**Results:** Both insert types showed statistically significant increases in mPI, GI, and mBI from T1 to T2 ( $p < 0.01$ ). For nylon inserts, mPI increased from  $1.04 \pm 0.45$  to  $1.83 \pm 0.45$ , GI from  $1.02 \pm 0.42$  to  $1.06 \pm 0.38$ , and mBI from  $0.79 \pm 0.34$  to  $0.94 \pm 0.35$ . For RS600 inserts, mPI increased from  $0.83 \pm 0.3$  to  $1.61 \pm 0.36$ , GI from  $1.81 \pm 0.37$  to  $1.92 \pm 0.36$ , and mBI from  $1.2 \pm 0.44$  to  $1.7 \pm 0.45$ . No significant differences were observed between nylon and RS600 inserts at either time point for any of the measured indices.

**Conclusion:** Over a one-year period, both nylon and RS600 inserts exhibited similar peri-implant tissue health changes. RS600 may be considered a viable alternative to conventional nylon inserts for mandibular implant overdentures.

**KEYWORD:** Dental implantation, Overdenture, polyvinyl, Attachments, Retention.sil

\* Assistant Professor, Department of Removable Prosthodontics, Faculty of Oral and Dental Medicine, Delta University For Science and Technology, Dakahlia, Egypt

\*\* Assistant Professor, Department of Prosthodontics, Faculty of Dentistry, Mansoura University, Mansoura, Egypt.

## INTRODUCTION

The use of mandibular implant overdentures (MIOD) supported by two intra-foraminal implants is increasingly becoming the preferred treatment option for patients with an edentulous patients. This preference has driven the development of various overdenture retaining systems designed to satisfy the needs of both patients and clinicians. When prosthetic available space is limited and optimal stress distribution is necessary to minimize damage to osseointegrated implants, low-profile attachments such as the Locator® may offer a more advantageous alternative.<sup>(1)</sup>

The durability of implants primarily relies on the integration between the implant and bone. The initial deterioration of this integration typically starts at the marginal alveolar bone. This process is influenced by a variety of factors, ranging from systemic to biomechanical.<sup>(2)</sup> Throughout treatment and follow-up, monitoring changes in the marginal bone level around the implant neck is feasible. These changes in the marginal bone are indicative of the health of the peri-implant tissue (PITH). Several clinical indices for PITH provide a comprehensive understanding of implant-tissue integration.<sup>(3-5)</sup>

The conventional interlocking of male and female parts in Locator® is carried out by nylon insets. This insert is color coded according to the retention desired. The nylon insert is replaceable after a period due to its tear and deterioration. Recently, a new attachment material for female matrices, known as Retention.sil® (RS) (R.S, Bredent Medical, Germany), has been introduced. This material, made from polyvinylsiloxane (PVS), serves as a silicon matrix attachment for implant overdentures, replacing the attachment system component in the denture base.<sup>(6)</sup> RS is resilient and possesses high tensile strength, which ensures the prosthesis remains securely in place through mechanical interlocking and frictional contact. Additionally, it has excellent shock-absorbing

properties, is easy to repair, and is cost-effective. It is available in three versions, providing detachment forces of 200, 400, and 600 g/f.

Most of the studies about the RS are in-vitro studies with little in-vivo studies to investigate the direct biological and mechanical action of the material on the dental implant and the surrounding PITH. RS presented acceptable retention capacities after 540 cycles of loading.<sup>(7)</sup> Other clinical investigation recommended RS as retentive insert for MIOD.<sup>(8)</sup> El-beheiry et al.,<sup>(9)</sup> revealed improvement of maximum bite force with RS. Abouwarda et al.,<sup>(10)</sup> investigate the microstrain with labially inclined implanted anchored with RS. An in vitro study revealed that nylon and PEEK showed a superior rate of retention loss comparing to PVS.<sup>(6)</sup> While Khan et al.,<sup>(11)</sup> revealed that the conventional retentive sleeve material maintains their retentive capacity longer than the RS600. Thus, Schweyen et al.,<sup>(12)</sup> recommended RS as a retentive insert for geriatrics and angulated implants. In another in-vitro study, Schweyen et al., recommend that PVS attachments exhibit better stability of the retention force.<sup>(13)</sup>

During clinical trials, achieving case standardization is challenging due to inherent variations among cases. Additional challenges include the number of patients in each comparison group, which affects the research costs and follow-up duration. In a split-mouth study design, one side serves as the control group for the other side. This approach eliminates biases related to randomization, inclusion and exclusion criteria and provides a clear result without confounding factors belongs to patients' conditions.<sup>(14)</sup>

The objective of this split mouth study is to study the PITH changes beneath the conventional nylon insert and RS600 as PVS material for MIOD.

## MATERIALS AND METHODS

Eighteen edentulous patients were selected. According to the dental and medical history, the

included patients were free from any condition that could adversely affect the rate of bone osteointegration with implant, tissue health and the ability of patient to continue the planned follow up period. Patients with recorded previous history of clenching, bruxism, TMJ disorders or smoking were excluded from study. All patients had an adequate inter-arch restorative space to accommodate the planned MIOD, and an Angel's classification Class I maxillomandibular relationship confirmed through preliminary jaw relationship. The time since the last tooth extraction was a minimum of six months. Cone beam CT (CBCT) scans confirmed that all patients had adequate bone quality and quantity in the mandibular intra-foraminal region to place the necessary implant without requiring bone augmentation.

The procedures of research work, surgical intervention and follow up were explained for patients for approval according to regulations of ethical-committee number (DU-2023-00112), Delta University, Egypt. For each patient, the following of pre-surgical, surgical, pick-up for female-housing, follow-up and evaluation procedures were done.

### **Pre-surgical procedures**

#### ***a. Conventional denture construction***

Following the making maxillomandibular impressions and the transfer of jaw relations to a semi-adjustable articulator using face-bow and protrusive records, the acrylic artificial teeth (Acrostone, Egypt) were arranged according to the lingualized occlusion scheme.<sup>(15)</sup> After a clinical trial, the denture was processed, finished, and polished using traditional methods. The patient received the denture and was monitored for a month to ensure proper adaptation.

#### ***b. Fabrication of implant-placement guide template***

The mandibular denture was replicated.<sup>(16)</sup> The duplicate denture was employed in a double CBCT

scan, with the intaglio surface modified by the addition of gutta-percha opposite the two canine regions.<sup>(17)</sup> The images were then imported into 3D image-planning software (In2guide software by (Cybermed) for virtually design the positions and angles of the implants<sup>(18)</sup> A mucosa-supported stereolithographic surgical guide featuring two metal sleeves and three anchor pins was printed based on the proposed implant locations.

### **Surgical procedures**

An antibiotic dose (Flumox, EPICO, 10th of Ramadan City, Egypt) was given prophylactically an hour before implantation. Local anesthesia (4% lignocaine, Alexandria Co., Egypt) was administered, and a universal surgical-kit (In2Guide Universal Kit, Cybermed Inc.) was utilized for full sequence drilling through the anchored guide sleeves. Each patient received two implants (3.7x11.5 mm; Neo Biotech, Seoul, South Korea). The intaglio of the denture was recessed and filled with a soft liner (Promedica, Germany). Patients were instructed to follow a soft diet and maintain home-care with frequent recall and follow-up visits. After three months, healing abutments were placed for two weeks, with necessary modifications made to the intaglio of the mandibular denture.

### **Pick-up procedure**

Two Locator<sup>®</sup> abutments (Kerator system, New York, USA) were attached to the internal-hex of the left and right implants using their respective mounting keys (Fig 1). A translucent ring with white spacer ring was placed on the head of each Locator<sup>®</sup>. Metal caps with pink nylon inserts were fitted onto the abutments, and the denture was adjusted to accommodate the abutments and caps without causing any instability. The pick-up procedure involved adding cold-cured acrylic resin (Acrostone, Egypt) to the modified intaglio of the denture while the patient was biting. After the resin fully polymerized, any excess material



Fig. (1) Two implants with Locator abutments

was removed from pre-prepared lingual vents (Fig 2a). Each right-side metal cap was expunged from the nylon insert (Fig 2b). RS600 (R.S, Bredent Medical, Germany) base and catalyst was mixed automatically by attached mixing tip. (Fig 2c). The empty metal cap was filled with RS600 and was set under the maximum intercuspation of the patient. After setting, the excess was trimmed with sharp scalpel (Fig 2d).

### Follow up and evaluation

Measurements of modified plaque index (mPI) <sup>(19)</sup>, modified bleeding index (mBI) <sup>(20)</sup>, and gingival index <sup>(21)</sup> for both implants were evaluated at two follow-up periods: after six months of implant loading (T1) and twelve months after loading (T2).

### Statistical Analysis

The data were organized and subjected to statistical analysis using the Statistical Package for Social Sciences (SPSS), version 24 (SPSS IBM Incorporation, England). Quantitative data were presented as mean and standard deviation (SD) following a normality assessment with the Shapiro-Wilk test. All tests were conducted as two-tailed. The Student's t-test was employed to compare two independent variables related to implants, while the repeated t-test was used to compare parametric variables at different time points within the same implant group. The *P* value of  $\leq 0.05$  was considered indicative of statistical significance.

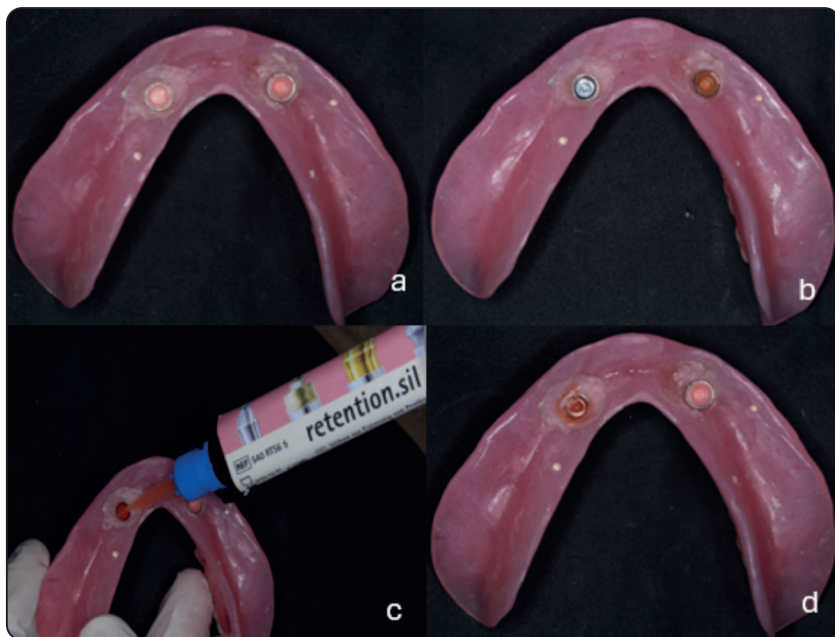


Fig (2) The intaglio of the mandibular denture with Locator female housing with two nylon inserts (a), removing of the patient's right-side nylon insert (b), injection of RS600 at the empty metal cap (c), intaglio of the mandibular denture with RS600 at right side after setting and nylon insert at left side (d).

**RESULT**

The following three tables provide an assessment of changed Plaque Index (mPI), Gingival Index (GI), and changed Bleeding Index (mBI), between nylon and RS600 inserts at T1 and T2.

**Modified Plaque Index (mPI)**

At T1, the mean and SD for mPI for the nylon insert were 1.04±0.45; and 1.83 ±0.45 at T2. For the RS600 group, the imply mPI turned into 0.83 ± 0.3 at T1 and increased to 1.61±0.36 at T2. Both groups confirmed statistically increase in mPI from T1 to T2 (p < 0.01). However, the evaluation among the two inserts did not display a significant difference in mPI at either T1 (p = 0.28) and T2 (p = 0.46).

**Gingival Index (GI)**

Table II shows the GI change comparisons. In the nylon group, GI slightly increased from 1.02 ± 0.42 at T1 to 1.06 ± 0.38 at T2, displaying a statistically exchange (p < 0.01). The RS600 group exhibited a growth in GI from 1.81± 0.37 at T1 to 1.92± 0.36 at T2; with statistically change within group (p < 0.01). Nonetheless, the between-group comparison did not have a significant difference at T1 (p = 0.29) and T2 (p = 0.84).

**Modified Bleeding Index (mBI)**

Table III shows the mBI change comparisons. The nylon inserts revealed mean = 0.79±0.34 at T1, which increased to 0.94± 0.35 at T2, with statistically significant different (p <0.01). The mean of mBI RS600 inset was 1.2±0.44 at T1 to 1.7±0.45 at T2 with significant increase within time (p < 0.01). Between-group assessment did not show significant variations at T1 (p = 0.25) and T2 (p =0.73).

TABLE (I) Between and within group comparison of mPI

	Time		P**
	T1 Mean (SD)	T2 Mean (SD)	
nylon	1.04(0.45)	1.83(0.45)	<0.01
RS600	0.83(0.3)	1.61(0.36)	<0.01
P*	0.28	0.46	
<i>* independent t test</i>		<i>** dependent t test</i>	

TABLE (II) Between and within group comparison of GI

	Time		p**
	T1 Mean(SD)	T2 Mean(SD)	
nylon	1.02(0.42)	1.06(0.38)	<0.01
RS600	1.81(0.37)	1.92(0.36)	<0.01
p*	0.29	0.84	
<i>* independent t test</i>		<i>** dependent t test</i>	

TABLE (III) Between and within group comparison of mBI

	Time		p**
	T1 Mean (SD)	T2 Mean (SD)	
nylon	0.79(0.34)	0.94(0.35)	<0.01
RS600	1.2(0.44)	1.7(0.45)	<0.01
p*	0.25	0.73	
<i>* independent t test</i>		<i>** dependent t test</i>	



## DISCUSSION

In this study, the overdenture was assisted by combined anchorage from two different inserts, nylon and RS600, for Locator<sup>®</sup> suprastructure to anchor MIOD. Locator<sup>®</sup> is a widely used anchor system for MIOD that ensures correct seating and appropriate retention as it offers self-alignment and dual retention and requires a minimal restorative space. The nylon inserts are interchangeable and available in different retention values. Nylon is used for its biocompatibility and elastic properties; however, it tends to undergo deformation and necessitates continuous maintenance.<sup>(22)</sup> Recently, RS has been introduced as an alternative material for nylon insert, but research on this component remains limited. It is made of polyvinylsiloxane (PVS), which adapts resiliently to attachments, ensuring the dentures maintain a secure yet flexible fit. This system is regarded as consistently retentive, easy to remove, and cost-effective.<sup>(13,23)</sup> RS600 revealed retention within the required range which is about 5-7N.<sup>(24)</sup> Therefore, it is in demand due to its suitability for the elderly people.

The duration of the study was one year. This period is sufficient to evaluate the peri implant tissue changes due to change in biological interactions. While, the split mouth study design was achieved previously to study implant behavior and peri-implant tissue health by mounting different system in each quadrant.<sup>(1)</sup> Split mouth study is useful at small sample size studies to avoid the heterogeneity which could affect the outcomes.

The result revealed significant increase in plaque index within time for both inserts. This may be accumulation of micro-flora and their adherence to the matrix due to the surface roughness within time.<sup>(25)</sup> The attachment of micro-organisms to surfaces is governed by both non-specific initial attachment and specific factors which called secondary attachment. The initial attachment is facilitated by hydrophobic interactions, with

greater adherence occurring when the material's surface free energy aligns more closely with the micro-organism's mechanical adhesive properties. Subsequently, the number of micro-organisms increases during the secondary phase of adhesion, which involves specific adhesin-receptor interactions, where the micro-organism binds to surface receptors through its adhesins<sup>(26)</sup>

The roughness of nylon inserts may result from moisture, which accelerates the alteration of polymer properties. Water can attach to polymer chains that have robust polar ketone group (C=O), via hydrogen bonds, acting as a softening agent.<sup>(27)</sup> The ketone group is present in nylon chemical ingredients. This chemical group efficiently interacts with water, spacing out the chains and consequently diminishing the material's mechanical properties. The accumulation of bacteria could be attributed to the diffusion of water throughout the polymer matrix. Water infiltrated the polymer chains to become loosened and compromising its intactness and integrity.<sup>(28)</sup>

Adding to moisture, temperature is another important factor deteriorating the performance of unreinforced polyamide 66.<sup>(29)</sup> Polyamides react to moisture contents in the oral cavity by reversibly releasing or absorption of water particles and molecules diffuse into polyamide chains, forcing them apart and destruct bonds. After a year a significant absorbed amount of water in the polymer may damage the surface which causes grasping of plaque<sup>(30)</sup>

On the other hand, the PVS silicone material appeared to lack strong polar groups capable of binding water within its polymer chains, resulting in consistent retention forces even after one year of artificial aging.<sup>(13)</sup> While the interaction of various factors, including the chemical and physical properties of the attachment material and the composition and type of patients' saliva, affects the surface characteristics of RS600 on the denture's

fitting surface after setting. Dispensing fluid RS600 onto the relieved denture surface can lead to the incorporation of air bubbles and inconsistencies, which diminish the retention and increase roughness of the attachment system.<sup>(12)</sup> Additionally, applying polyvinyl siloxane (PVS) requires the removal of excess material with a sharp scalpel, resulting in a rough surface. It is documented that PVS, when used as a soft liner for removable complete and partial dentures, should be replaced regularly due to bacterial colonization that occurs intraorally within a few months.<sup>(8)</sup>

The incidence of gingivitis increased over time for both types of inserts. This can be attributed to the accumulation of plaque, which harbors microflora that secretes toxins, leading to mucosal inflammation. Additionally, the increased plaque provides a favorable environment for bacterial colonization and growth.<sup>(31)</sup> Another contributing factor to the rise in gingivitis is the decreased awareness and decline in oral hygiene practices associated with advancing patient age<sup>(32,33)</sup> Also, for research purposes, the female housing for both groups were not changed through the study time to investigate the results without bias.

Another factor which increases gingivitis is the mobility of the denture and anterior biting of the patient.<sup>(34)</sup> The up-down movements may be due to the inherited residence of the retention and the anterior alignment of anchor without any posterior anchorage to ensure the favorable diagonal supporting frame form. The resiliency of both attachments, which allow denture movements and accumulation of food particles and plaque under the denture.<sup>(32)</sup> With locator attachments, food residues can accumulate in the central depression of the insert and inhibit the locking of the matrix and create a problem with the hygiene of prosthesis.<sup>(8)</sup>

The results revealed a significant increase for mBI with both inserts by time. This correlates to the increased mPI and GI. Gingival inflammation is dependent on recorded plaque score.<sup>(35)</sup> For that,

plaque accumulation increases irregularities around abutment which accelerates bacterial collection and adhesion for inflammatory bleeding.<sup>(36)</sup> Another reason is the posterior rotational hinge movement of the prostheses beneath the frontal implants. Anterior-implant distribution design deploy the chance for the anterior implants to act as a fulcrum for posterior part of restoration display enhancing trauma to inflamed peri-implant tissue during action.<sup>(31)</sup> Additionally, mucosal trauma may be due to reduction of retention which enhance the range of rotation and, in turn, enhances traumatic action for pre-implant tissue.<sup>(37)</sup> Nevertheless, following a period of dramatically reducing retentive force, the retentive force of the nylon inserts of the Locator<sup>®</sup> increased after a year when compared with at quarter and semi-annual periods.<sup>(6)</sup> Opponent to that, Chiu investigated the effect of water temperatures on Locator<sup>®</sup> attachment structure and retention and discovered that water temperatures at 60°C significantly reduced its retentive value.<sup>(38)</sup> Schweyen evaluated the retentive force of Locator<sup>®</sup> and vinylpolysiloxane attachments after a fatigue test and thermal undulation and discovered that the Locator<sup>®</sup> showed a considerable decline in retention forces, while the PVS groups showed no change in retention forces.<sup>(13)</sup>

The limitation of the study can be summarized in the number of patients and the period of follow up. In future research, another color-coded nylon insert may be compared with RS400 or RS200. Also, the number of implants should be investigated as a cofactor affecting the pre-implant tissue change.

## CONCLUSION

Over a one-year period, both nylon and RS600 inserts exhibited similar peri-implant tissue health changes. RS600 may be considered a viable alternative to conventional nylon inserts for mandibular implant overdentures. However, further long-term studies with larger sample sizes are warranted to confirm these findings and evaluate other clinical parameters.

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