Clinical Evaluation

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ABSTRACT

This retrospective clinical study assessed private dental practice patients to determine the safety and efficacy of Valplast flexible partial dentures as compared to the safety and efficacy of conventional rigid partial dentures.

The subject population consisted of four men and seven women. Five of them wore conventional partial dentures and six wore Valplast flexible partial dentures. The average age of the subjects was sixty years old. Most of the subjects had worn their partial dentures for approximately 3 ½ years, although one had worn a Valplast partial denture since 1991.

These subjects had average periodontal health and habits for their age, education and income. Most had lost several teeth and expected to lose more as they aged. Most had declined recommended periodontal therapy, but came in every year or two for an examination and prophylaxis.

Clinically, subjects from both groups presented with similar levels of oral health. They reported few sore spots and had little hard or soft tissue abrasion. The probing depths and recession were normal for their age and periodontal status. Two subjects, one from each group, presented with extremely reddened palates that were probably due to the continuous wear of the partial dentures.

Radio-graphically, the groups had a similar distribution of abutment teeth with good, horizontal bone support and abutment teeth with advancing periodontal disease. An exit survey that asked questions about comfort, function and esthetic reported both groups were satisfied with their partial dentures, with over 90% of the responses being ***Good*** or ***Very Good***.

In this retrospective clinical review of private practice patients who wore either Valplast or conventional partial dentures for approximately three and a half years, there was no different in the safety and efficacy of the removable partial dentures.

Title: **Valplast Flexible Denture Clinical Evaluation**

Null Hypothesis: Valplast flexible partials dentures and conventional rigid partial dentures differ in their safety, efficacy and patient acceptance.

Introduction

In the past ten years, there has been renewed dentist and patient interest in flexible partial dentures. These partial dentures have no metal clasps, which appeals to those who are concerned about esthetics. They also believed to be less traumatic to periodontally compromised abutment teeth. Most large dental laboratories currently offer two to five brands of partial dentures that are totally or partly flexible. The leading brand is Valplast, a flexible nylon. En 1998, approximately 365,000 Valplast flexible partial dentures were delivered in the U.S. and the 1999 projections are more than 500,000.

This retrospective single-blinded clinical study was conducted to evaluate one of the flexible materials, Valplast, and demonstrate its safety and efficacy. Valplast was first marketed in the US almost fifty years ago and is in use throughout the world. This performance history distinguishes it from the other flexible materials, which are relatively new. *In vitro* testing at Indiana University that compared Valplast to three other flexible brands determined that only Valplast had the mechanical properties essential for a long lasting dental prosthesis. The testing included 3-pt. load deflection for elastic memory, high deflection to mimic clasp moving over teeth repeatedly, and high-cycle low-load masticatory deflection. (Attachment B) Aside from its flexibility, Valplast has met or exceeded all Spec. 12 and ISO 1567 requirements.

Valplast partial dentures (VPD), because of their flexible nature, function differently from conventional partial dentures (CPD). The clasp is a thin nylon arm that extends over the attached mucosa to clasp just under the buccal eminence of the tooth. The framework usually does not have occlusal rests and the partial is entirely tissue- borne. When a bolus of food is pressed onto the prosthetic teeth, the flanges flex lightly away from the gingival margins. Mastication on one side of a distal free-end partial, eg. the left side does not cause an equivalent amount of displacement on the right side due to the flexibility of the major connector. Because the nylon can be processed thinner than acrylic, it is very comfortable to wear. The clasp arms are translucent, which helps the partial to blend into the patient's gingival pigmentation.

Tissue-borne acrylic partial dentures have been used in dentistry for many years, but not as long-term appliances. They are called "flippers" or "treatment partials" and usually provide interim tooth replacement. If these are to be worn for an extended period of time, their retention would be unacceptable. Additionally, the teeth adjacent to the edentulous space could experience adverse orthodontic and periodontal effects.
Dental professionals have been taught to understand the advantages and disadvantages of CPDs. They are aware that rigid partial denture frameworks need to have occlusal rests for tooth-borne support. They understand the torquing forces that arise upon unilateral mastication

and try to compensate by using well-placed indirect retention. They also know that the tissue-borne portions need to be relined as the osseous support resorbs and to look for evidence of antero-posterior rotation in the framework.

This study was conducted to address the question of flexibility as an acceptable clinical feature. It could be presumed that VPDs are acceptable if they perform in a similar fashion as CPDs in a private practice patient population. CPDs aren't perfect, but they have a performance record that is acceptable to the professional dental community.

Therefore the oral health status of the subjects at the time of their examinations was important. If, after 3 ½ years of wearing their partial dentures, the subjects from both the VPD and CPD groups presented with "average oral health ", then it could be concluded that both styles of partial dentures were safe and efficacious restorative choices.

It was expected that "average oral health" in this particular population could include some bone loss, periodontal inflammation and mobility. As some of these patients chose inconsistent dental care, some carious teeth were also possible. It was decided that if a particular group presented with signs of an aggressive and rapid deterioration since the delivery of their prostheses, then it could be concluded that their partial dentures might not be safe and/or efficacious.

Subjects

Dr. Lingen, a part time Prosthodontics professor at Northwestern University, has delivered VPDs in his private practice for many years. He agreed to provide a randomly selected group of patients with either VPDs or CPDs for Dr. Foley's blinded evaluation.

The eleven subjects aged 44-71 (ave. 60 years old), had worn their partial denture for at least 2 ½ years, with the average duration being 3 ½ years. One subject had worn VPDs since 1991.

Four of the subjects were male and seven were female. Most had a high school education and were from a middle class suburb (Oak Lawn, IL). Several were retired. They had an average dental awareness, periodontal health and habits for their age, education and limited incomes. Most had lost several teeth and expected to lose more as they aged. Most had declined recommended periodontal therapy, but came in every year or two for an examination and prophylaxis.

Dr. Lingen's Staff contacted thirty-nine of their VPD patients who were named on a list provided by Master Touch Laboratories, Valplast's main laboratory in New York.

All of the patients had been given VPDs between October 1995 and May 1998. These patient names were not screened for having particular types of VPDs. Of the 39 possible subjects, only six could be scheduled into the clinical study appointments. Again, none of the names were reviewed for success or problems with their VPDs or selected for oral hygiene skills. In fact,

one patient had transferred to another practice that participated in her HMO program, but came back to Dr. Lingen's office for the study.

The staff recruited CPD patients by compiling a list of patients who had removable partial dentures delivered from 1995-1998. They called these patients until they had all of the clinic slots scheduled. Again, none of the names were reviewed for success or problems with their CPDs or selected for oral hygiene skills. Dr. Lingen did not see the list of patients prior to scheduling and had no influence in their selection.

Methods

At the time of scheduling, the study was explained to the subjects. They were told that they would receive their routine radiographs and examination, a dental prophylaxis and a $50 incentive payment. They would also receive an additional, more detailed periodontal examination by Dr. Foley and have clinical photographs taken of their teeth and partial dentures. This information was re-explained to them at the time of the appointment before they read and signed an Informed Consent.

While the subjects had their teeth cleaned and radiographed, Dr. Lingen polished their partial dentures. The hygienist asked them to complete a written satisfaction survey and recorded their use of coffee, tobacco and the number of hours they wore their partial denture each day. Dr Lingen then completed their oral cancer examinations, dental examinations, and treatment plans.

The subjects were next moved to a separated treatment room and were cautioned not to discuss their partial denture with Dr. Foley. Dr. Foley then proceeded to conduct a thorough soft tissue, hard tissue and periodontal examination. After all clinical indices were recorded, the subjects' partial dentures were returned to them and clinical photographs were completed.

The subjects then signed for their payments and were dismissed. A few subjects were recalled on a subsequent day due to camera difficulties. All or some of their photos were then retaken.

Indices

1. Subjective Gingival Abrasion Index

Q: Do you have any sore spots in your mouth? If yes, identify and score as

- S1 – Slight discomfort, but not affecting wearing of partial
- S2 – Discomfort causing intermittent wearing of partial
- S3 – Discomfort sufficient for patient to totally discontinue wear of partial and seek professional care

2. Objective Hard Tissue Abrasion Index

- 1 - Hard tissue wear on teeth in contact with partial denture
- 0 - No hard tissue wear noted

3. Objective Gingival Abrasion Index

- 1A- Slight abrasion
- 1L- Slight laceration
- 1U- Slight ulceration
- 2A- Moderate abrasion
- 2L- Moderate laceration
- 2U- Moderate ulceration
- 3A- Severe abrasion
- 3L- Severe laceration
- 3U- Severe ulceration

4. Tooth Mobility

- 1M- Less than 1 mm in bucco-lingual direction
- 2M- More than BL, no intrusion possible
- 3M- can be moved BL and occlusoapically

5. Furca Probing

- 1F- Probe enters curve of furca, but no more than 2 mm
- 2F- Prove enters cul-de-sac more than 2 mm, not through & through
- 3F- Through and trough involvement

6. Purulence and Suppuration

- 1 - Purulence noted
- 0 - No purulence noted

7. Periodontal Probing

Depth of pocket recorded in millimeters at 6 sites per tooth

8. Bleeding on Probing

Recorded after periodontal probing at 6 sites per tooth

1- Bleeding within 3 and 30 seconds
2- Bleeding within 2 seconds
3- Bleeding immediately upon probe placement

9. Clinical Attachment Level

Distance from height of gingiva to cementoenamel junction noted in mm at 6 sites per tooth.

- Positive value if height of gingiva is above CEJ, denoting swelling
- Negative value if height of gingiva is below CEJ, denoting recession

Clinical Photographs

Photographs were taken of the partial dentures laying on a piece of paper, from both the occlusal and the underside. Using retractors or mirrors, intraoral shots were taken with the partial dentures in and out. The following views were taken if they included the partial denture area:

Anterior
Right Side
Left Side
Maxillary Arch
Mandibular Arch

Results

The six patients in the Valplast Partial Denture (VPD) Group had 31 teeth that were in contact with their flexible partial dentures. The Conventional Partial Denture (CPD) group had 29 teeth that were in contact with their rigid partial dentures. Each group had two smokers and all subjects but one drank coffee regularly. All subjects wore their partials continuously, including at night, except for two in the VPD group. During the soft tissue exam, it was discovered that VPD subject had asymptomatic mucoceoles in his right mandibular vestibule, but they did not contact his VPD and has been there for an unknown duration. The results are summarized in Chart 1.

Subjective Hard and Soft Tissue Abrasion index

At the examination, one VPD patient had a sore spot on his edentulous ridge and CPD patient reported soreness in the retro molar pad area. At a photo session two weeks after her initial examination, another CPD patient had a painful new ulceration at the edge of the buccal flange. All three partial dentures were adjusted.

Objective Soft Tissue Abrasion Index – Ulcerations, abrasions, and Lacerations

The six VPD patients cumulatively had 2 abrasion, 1 ulceration, and 1 extremely reddened palate. The five CPD patients cumulative had 3 abrasions, 1 ulceration, 1 laceration, 1 inflamed cleft, and 1 extremely reddened palate.

Objective Hard Tissue Abrasion Index

The VPD and CPD groups each cumulatively had two hard tissue abrasion sites.

Mobility

The VPD Group cumulatively had 12 mobile teeth, with an average score of 1.2.
The CPD group cumulatively had 18 mobile teeth, with an average score of 1.5.

Furcations

The VPD group cumulative had 6 sites with an average score of 1.5.
The CPD group cumulatively had 8 sites with an average score of 1.3.

Suppuration

Neither group had suppurative sites.

Probing Depths and Recession

The VPD group had clinical probing depths averaging 2.16 mm. As a group, 15 teeth had 37 mm of cumulative gingival recession, averaging 6.1 mm per patient.

Te CPD group had clinical probing depths averaging 1.99 mm. As a group, 26 teeth had 77 mm of cumulative gingival recession, averaging 15.4 mm per patient.

Bleeding on Probing

The VPD group had a cumulative total of 4 sites that bled upon probing.
The CPD group had a cumulative total of 7 sites that bled upon probing.

Chart 1 **RESULTS**

ASSESSMENT	VALPLAST	CONVENTIONAL
Subjective Abrasion Index		
Number of Incidents	1	2
Cumulative Severity Score	1	3
Objective Soft Tissue Abrasion Index		
Ulcerations	1	1
Abrasions	2	3
Lacerations	0	1
Additional Soft Tissue Observations		
Inflamed Palate	1	1
Inflamed Cleft	2	1
Objective Hard Tissue Abrasion Index	2	2
Mobility Index		
Number of Mobile Teeth	12	18
Average Mobility Score	1.2	1.5
Furcation Index		
Number of Sites	6	8
Average Furcation Score	1.5	1.3
Suppurative Index	0	0
Probing Depths		
Average Depth of Pockets	2.16	1.99
Recessions		
Total Millimeters of Recession	37	77
Average Loss (mm) per Patient	6.1	15.4
Number of Involved Teeth	15	26
Bleeding on Probing		
Total Number of Sites	4	7
Radiographic and Photographic Assessment	See attachment A	

Radiographic Assessment

Several of the subjects had old radiographs, but it was difficult to find meaningful images because of the high volume tooth loss in this population. An effort was made to find films that showed osseous support for key abutment teeth before and after the delivery of the partial dentures. Overall, there appeared to be no difference in the morphology of the osseous support between the two partial denture designs. There was evidence of continued loss of bone height due to progressive periodontal disease, but no signs of vertical bone loss or traumatic occlusive changes in one group versus the other. Additionally, there were examples of strong osseous support with both partial designs. There is a detailed description of the radiographic findings in Attachment A.

Patient Satisfaction Survey

100% of the responses for either partial denture design indicated patient satisfaction for comfort, chewing efficacy, and esthetics. All of the questions were answered with adequate, good, or Very good on the Lickert scale. 91% of the VPD responses and 95 % of the CPD responses were *Good* or *Very Good*.

Discussion

Subjectively, there appeared to be no difference between the VPD and CPD groups. It is normal for partial denture patients to need an occasional adjustment to relieve a sore spot – especially if it has been a while since their last dental appointment. Subjects in booth groups indicated that they could chew adequately and comfortably with their partials.

Two subjects, one from each group, had very red, inflamed palates. The VPD subject smoke and both reported continuous wear. When VPD subject returned two weeks after her initial examination, her palate was greatly improved due to increased brushing and reduced wear duration. Other subjects wore their partials continuously, but may have cleaned their partials better than these two subjects. (See Attachment A – Subject # 1).

The photographs also show that these subjects ad many teeth restored with large amalgam or composite restorations. There were also many crowns, some of these subjects had many teeth restore with large amalgam or composite restorations. There were also many crowns, some of which were over contoured. The periodontal health of these subjects was determined by many restorative and oral hygiene factors and was not solely attributable to the style of their partial dentures.

Radiographically, it was apparent that most of the subjects had periodontitis before receiving their removable partial dentures. Current radiographs showed a balance mix of stable abutment teeth and those with active bone loss. There did not appear to be a difference between groups. (See attachment A).

Objectively, the periodontal indices were not clinically different between the groups. The VPD group had an average probing depth of 2.16 versus the CPD average probing depth of 1.99. both of these probing depth averages were surprisingly shallow, given the periodontal status of the subjects. Fifteen teeth in the VPD had mild recession, as did 26 teeth in the CPD group.

The CPD group had a higher occurrence of soft tissue irritations, mobile teeth, and sites that bled upon probing. Interestingly, the CPD group had both a higher number of mobile teeth and those teeth had a slightly higher average mobility severity score. Yet Dr. Lingen often prescribed VPD to patients with the most fragile, mobile teeth. Because baseline mobility scores were not available on these subjects and this sample size was small, no conclusions can be drawn from this observation.

The subject who had worn a Valplast partial denture for eight years was one of the few subjects to have no mobility or recession. (See Attachment A – Subject # 8).

Both the VPD and CPD groups had equal numbers of hard tissue abrasion – none of which appeared to be related to their partial dentures. Most of the hard tissue abrasion that was noted seemed to be due to abfractions or toothbrush abrasion. Neither group had suppurative sites.

Conclusions

Conventional partial dentures and Valplast partial dentures appear to be similar for safety, efficacy, and satisfaction in patients who have worn them for approximately 3 ½ years.

ATTACHMENT A

This section contains:

-Clinical photographs for ten patients

These photos provide detailed information regarding the design of the partial dentures and the condition of the oral tissue after daily wear for approximately 3 ½ years. One of the patients, who had a maxillary single tooth nesbit, could not return for retaking of her photos. Her clinical data and radiographs were included in the analysis.

-Baseline and recent radiographs for eleven patients

Radiographs that showed osseous levels prior to the date of the study were duplicated for comparison to current films. This radiographic section, although limited, provides valuable diagnosis information.
An effort was made to note radiographic consistencies and changes. The observations were then tallied by VPD and CPD groups.

RADIOGRAPHIC SUMMARY	COMMENT	SUMMARY
SUMMARY TALLY OF COMMENTS	**NEGATIVE**	**POSITIVE**
VALPLAST Partial Dentures	**3**	**8**
CONVENTIONAL Partial Dentures	**4**	**5**
VALPLAST PARTIAL DENTURES	**Negative**	**Positive**
ID# Date of Films and Comments		
1. 1989 and 1999		
Estimate 2+ mm bone loss around abutment	**2 mm**	
Edentulous ridges smooth		**Ridges**
Evidence of active periodontal disease	**Perio**	
2. 1991 and 1999		
Abutment molar still has good, horizontal bone		**Abutmt bone**
4. 1997 and 1999		
Severe perio, many over contoured crowns		
Nesbit replaces bicuspid lost due to perio	**Perio**	
7. 1996 and 1999		
Long span nesbit replaces bridge		
Abutment bone looks good		**Abutmt bone**
Edentulous ridge smooth		**Ridges**
8. 1994 and 1999		
Has worn VPD for 8 years		
Abutment bone looks good		**Abutmt bone**
Horiz. Bone between incisors		**No perio**
No movement of clasped tooth		**Stable abutmt**
11. 1996 and 1999		
Nesbit replaces endodontic failure		
Abutment bone looks goods, esp. with recent ext.		**Abutmt bone**

CONVENTIONAL PARTIAL DENTURES	NEGATIVE	POSITIVE
ID # Date of Films and Comments		
3. 1999 and 1999		
Abutmt bone at clasped teeth good		**Abutmt bone**
5. 1994 and 1999		
Evidence of active periodontal disease	**Perio**	
Super erupted molar clasped since 1996		
6. 1999		
Edentulous areas smooth		**Ridges**
Abutment bone looks good		**Abutmt bone**
Incisors have active periodontal disease	**Perio**	
9. 1992,1993 and 1999		
Edentulous areas smooth		**Ridges**
Little change in abutment bone height		**Abutmt bone**
10. 1985 and 1999		
Patient refused regular cleanings – heavy calculus		
Evidence of active periodontal disease	**Perio**	
Estimated 2+mm bone loss around abutments	**2 mm**	