Diseno experimental In-Vitro

The Effect of Two Elastomeric Impression Materials on the Fit of an Implant Bar

Luis A. Alicea Sotomayor, DMD
Otton Fernandez, DDS, MSD
Thesis Committee

– Santos Lebrón, DMD, MS
  Program Director
– Kathleen Crespo, MS, EdD
– Augusto R. Elías, DMD, MSD
– José Morales, DMD
– Walter Psoter, DDS, PHD
Background

Osseointegrated dental implants have long term clinical stability in whole arch restorations.

- 96-99% success in mandible
- 80-90% success in maxilla

Osseointegration

Anchorage of the alloplastic material to bone, once the osseointegration process reaches its mature state, with no intervention of connective tissue.

Osseointegration

- Rigidity of implants requires precise fitting of the superstructure to assure stability of the screws under functional stress.

- If uncontrolled loads (magnitude and direction) are transmitted to implants and surrounding tissues, adverse biological reactions can occur.

10) Sellers, Grady: J.P.D. 1989

SCREWED, IMPLANT SUPPORTED AND RETAINED FIXED-DETACHABLE PROSTHESIS

Advantages

- Evidence of long term success shown.

- Fixed for the patient, but removable by the dentist.

- Appropriate for patients with inadequate bone height on posterior mandible.

Disadvantages

- Difficulty to obtain passive fit. 1,2) Brånemark, P.I. et al.

- Cantilever to distal extension. 3) Spierkermann, Hubertus
Passivity

A passive fit is characterized by a complete absence of vertical and horizontal misfitting gaps without fixing screws.

Passivity is achieved when the screwed metal superstructure fits with all the abutments.

White, G.E. : Osseointegrated Dental Technology 1993
Jemt, T : JPD 1996
Lack of Passivity

- Leads to:
  - Patient discomfort.
  - Biological adverse reactions.
  - Prosthetic mechanical failure (over loading).
  - Increased chair and laboratory time.

Impression Materials

The first step to achieve passive fit in a screwed system is to transfer the exact position of the implant from the mouth to the working model via an impression material.
Polyether

- Most frequently used and recommended elastomeric impression material for implant impression techniques \(^{35,36}\).

- Advantages over other elastomeric impression materials are dimensional stability, rigidity and tear resistance \(^{15,29,30,33-38,68}\).

- Disadvantages of this material are:
  - High permanent deformation \(^{49,68}\).
  - Unpleasant smell and taste.
  - High storage contraction after polymerization.
  - Increased distortion after disinfection by immersion \(^{46,47}\).
Polyether References

33) Johnson, G. et al. : J.P.D. 1985
34) Johnson, G. et al. : J.P.D. 1986
35) Bränemark, P.I. et al. : Chicago, Quintessence, 1985
37) Iturregui, J. et al. : J.P.D. 1993
47) Langenwalter, E. M. et al. : J.P.D.
Addition Silicones

- Addition silicones are alternative elastomeric materials to polyethers also used for implant impression making \(^{(35,36)}\).

- Unlike earlier forms of addition silicones, hydrophilic addition silicones have improved rigidity and surface characteristics that approach polyethers \(^{(44,54,55,61)}\).

- Suitable odor and taste.

- Are less costly than polyethers \(^{(62)}\).
Addition Silicones References

35) Brånemark, P.I. et al. : Chicago, Quintessence, 1985
55) Vassilakos, N. et al. : J. Dent. 1999
56) Valderhaug, J. et al. : J.P.D. 1984
Silicones vs. Polyethers

1) Silicones have less permanent deformation and dimensional changes \( (44,46-49,68) \).

2) Equal detail reproduction \( (50,52,53-55) \).

3) Castability \( (44,54,55) \).

4) Wettability \( (54) \).
Silicones vs. Polyethers

References

52) Tjan, A. H. et al. : J.P.D. 1986
55) Vassilakos, N. et al. : J.Dent. 1993
56) Valderhaug, J. et al. : J.P.D. 1984
Significance

- Addition silicones have demonstrated an equivalent dimensional stability to polyether in experimental studies \((44,46-49,68)\).

- However, implant manufacturers continue to recommend polyether for implant impressions \((35,36)\).

- Two previous implant studies, conducted at UPRSD, suggest that silicone impression materials demonstrate similar or greater dimensional stability than polyether \((44,45)\).


Significance

- Sectioning of the Implant Bar

- Findings by Bravo, et. al. suggest casting the metal superstructure and taking an intraoral soldering index whenever the distances between divergent implants surpass the approximate 17 mm limit. (45)

Significance

The importance of this study is to determine whether the results of the two previous in-vitro implant studies regarding equivalent or better dimensional stability of silicones over polyether is clinically replicable.
Aim

To compare the fit of a clinically acceptable implant bar prepared from a master model to the fit on ten working casts, each independently constructed from one of two elastomeric impression materials and measured at four bar lengths.
Preliminary Study

- **Purpose**
  - Explore operational feasibility of this study.

- **Methods**
  - Bar constructed in same manner as this study.
  - Evaluators: three prosthodontic residents.
  - Evaluation: visual, 10x stereomicroscope, fit checker and digital movement.
  - Sectioning site detection.
Preliminary Study

Results:

- Master Model: 92% agreement (fit).
- Working Models: 80% agreed (unfit).
- Inter-examiner Kappa Statistic, 0.62
- Sectioning site, 31% agreement.
Preliminary Study
Conclusion & Recommendations

- Use expert evaluators.

- Eliminate fit checker test.

- Eliminate sectioning site-evaluation.

- Construct different bar lengths (4).
Methods and Materials
The master model used in this study was constructed with heat curable polymethylmethacrylate, simulating a clinical case of an edentulous mandible, for the elaboration of a fixed-detachable type prosthesis described by Brånemark.

1,2) Brånemark, P.I. et al.  
The ten working models were constructed in type IV dental stone from the transfer of the Paragon® implant system with two elastomeric materials, Impregum® and Aquasil® (29-31,44,45).

Two impression materials:
- Polyether (Impregum®)
- Addition Silicone (Aquasil®)

Controlled temperature, humidity, time of day, quantity of dispensed material, tray and impression making technique.

Dispensing Form
- Polyether – Hand mixing
- Additional Silicone – Gun auto mixing
Implant Bar Preparation

- The implant system component used was Paragon® SCS.

- An implant bar was constructed using consensus from White’s criteria.

- A single operator (LAA) constructed the implant bar for the master model.

Paragon® SCS, Paragon Implant Company, Encino, CA
Preparation of the Implant Bar

- To achieve the passive fit, the bar was sectioned.

- A soldering index was made using a GC pattern resin.

- The bars were seated under Hi-Heat Soldering Investment, and soldered using the torch method.
Implant Bar Evaluation

Passive fit on the master model was evaluated according to the consensus described in the literature by Goll, Klineberg, White and others.
Implant Bar Evaluation

Master Model

Four UPRSD Board Certified Prosthodontics Faculty members (experts), evaluated the implant bar fit to the master model.
IMPLANT BAR EVALUATION

Working Model

- Four experts assessed the fit.

- Each model was assigned a random number; the evaluator was blind to the elastomeric materials the model was fabricated from.

- All evaluations were conducted with consistent lighting and a true color 20 watt lamps.
Each examiner evaluated the models independently.

The three evaluation methods were performed on different days for each of the four bar lengths.

The order of the evaluation method was at random for each examiner.
# Implant Bar Evaluation

<table>
<thead>
<tr>
<th>Methods</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Visual</strong></td>
<td></td>
</tr>
<tr>
<td>Direct</td>
<td>Yes - Accepted</td>
</tr>
<tr>
<td>Stereo microscope</td>
<td>No - Rejected</td>
</tr>
<tr>
<td><strong>Digital Movement</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes - Accepted</td>
</tr>
<tr>
<td></td>
<td>No – Rejected</td>
</tr>
</tbody>
</table>
The Four Implant Bar Lengths

- The bar was sectioned between implants five and four, four and three and three and two.
Experimental Design
Hypothesis A – Fit by Material

- The null hypothesis $H_0$: The fit of an implant bar evaluated on casts poured with silicone impression material are equal to the fit from casts obtained from polyether.

- The alternate hypothesis $H_A$: The fit of an implant bar evaluated on casts poured with silicone impression material are superior to the fit from casts obtained from polyether.
Hypothesis B – Fit by Bar Length

- The null hypothesis $H_0$: There is no difference upon evaluation of the passive fit of the implant bar at different bar lengths; 2 to 5 implants.

- The alternate hypothesis $H_A$: There is a difference upon evaluation of the passive fit of the implant bar at different bar lengths; 2 to 5 implants.
Data Analysis

A) The dependent variable is:
   1) Passive fit by measurement technique.
      yes, accepted
      no, rejected

B) The independent variables are:
   1) Impression materials (Impregum® and Aquasil®)
   2) Bar Length
Statistic Tests

- A Chi Square Analysis was performed for the overall percentages of acceptance for both impression materials.

- Kappa Statistics were calculated to determine the reliability of the evaluation methods employed.

- Logistic regression was employed to calculate the odd ratios for failure by bar lengths.
Results
Results

- **Master Model Evaluation**
  - The bars were evaluated by visual (direct, stereomicroscope) and digital movement.
  - The four experts accepted the four-implant bar lengths.
Results

- Ten (10) working models, five (5) for each impression material were evaluated.

- Four (4) experts employed three (3) evaluation methods at four (4) different bar lengths.
## Results

Table 1: Number, Percent Acceptance and Rejection of Working Models by Implant Bar Lengths.

| Impression Material | Number Implants/Bar Length | Direct Vision | | | Microscope | | | Digital Movement | | |
|---------------------|-----------------------------|---------------|---|---|-----------------------------|---|---|-----------------------------|---|
|                     |                             | Accept n (%)  | Reject n (%) | Accept n (%) | Reject n (%) | Accept n (%) | Reject n (%) | Accept n (%) | Reject n (%) |
| Polyether           | 5                           | 0 (0%)        | 20 (100%)    | 0 (0%)       | 20 (100%)    | 1 (5%)       | 19 (95%)    |                |              |
| Silicone            | 5                           | 11 (55%)      | 9 (45%)      | 10 (50%)     | 10 (50%)     | 16 (80%)     | 4 (20%)      |                |              |
| Polyether           | 4                           | 0 (0%)        | 20 (100%)    | 0 (0%)       | 20 (100%)    | 0 (0%)       | 20 (100%)    |                |              |
| Silicone            | 4                           | 14 (70%)      | 6 (30%)      | 12 (60%)     | 8 (40%)      | 16 (80%)     | 4 (20%)      |                |              |
| Polyether           | 3                           | 0 (0%)        | 20 (100%)    | 0 (0%)       | 20 (100%)    | 0 (0%)       | 20 (100%)    |                |              |
| Silicone            | 3                           | 16 (80%)      | 4 (20%)      | 16 (80%)     | 4 (20%)      | 18 (90%)     | 2 (10%)      |                |              |
| Polyether           | 2                           | 0 (0%)        | 20 (100%)    | 0 (0%)       | 20 (100%)    | 0 (0%)       | 20 (100%)    |                |              |
| Silicone            | 2                           | 19 (95%)      | 1 (5%)       | 19 (95%)     | 1 (5%)       | 19 (95%)     | 1 (5%)       |                |              |
Results

- The silicone working casts showed a higher overall percent acceptance than polyethers’ (p = 0.009).

- Only one working cast prepared from polyether impression material, using digital movement evaluation, was accepted.

- For the data analysis the working models obtained from polyether were not included.
Results

- Table 2: Addition Silicones Models Evaluation Technique.

- 20 models for each bar lengths 1 to 4.
## Results

Table 3. Kappa Statistic and Percent Agreement for the three evaluation methods.

<table>
<thead>
<tr>
<th></th>
<th>Direct Vision</th>
<th>Stereo Microscope</th>
<th>Digital Movement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct Vision</td>
<td>-</td>
<td>0.96 (98%)</td>
<td>0.85 (93%)</td>
</tr>
<tr>
<td>Stereo Microscope</td>
<td>-</td>
<td>-</td>
<td>0.81 (91%)</td>
</tr>
<tr>
<td>Digital Movement</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>
Results & Discussion

The regression analysis was performed using the values obtained from the silicone working models.

This decision was based on the percentage of acceptance (Direct Vision) of silicone material (75 %) over polyether (0%).
## Results

**Table. 4 Difference in Failure by Implant Bar Lengths (Silicones).**

<table>
<thead>
<tr>
<th>Bar Lengths</th>
<th>OR</th>
<th>95% C.I.</th>
<th>Statistically Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Upper</td>
<td>Lower</td>
</tr>
<tr>
<td>Length 2 **</td>
<td>4.74</td>
<td>0.48</td>
<td>46.8</td>
</tr>
<tr>
<td>Length 3 **</td>
<td>8.13</td>
<td>0.88</td>
<td>75.3</td>
</tr>
<tr>
<td>Length 4 **</td>
<td>15.52</td>
<td>1.7</td>
<td>139.3</td>
</tr>
</tbody>
</table>

* Overall Models Significance = 0.0018
** Reference Category = Length (2 implants)
Conclusions

- The results of the present study demonstrate a difference in favor of the models obtained from hydrophilic addition silicone materials over polyether impression materials.

- The implant bar with a length of 25 mm or longer had a higher probability to be rejected when compared to the referent length.

- An expert can reliably employ direct visual examination to evaluate implant bar seating.
Recommendation

- Further studies employing mechanical mixing (Penta Mix®) are necessary to standardize the dispensing mode of the impression materials in order to reduce the dispensing and mixing variables.

- Evaluations of the fit on the working models by apprentices (dental students) and knowledgeable dentists, in addition to experts, will provide external validity to the findings of the present study.