CHAPTER 3

Approach for valuating the influence of laboratory simulation.

Keywords: chewing simulation, thermal cycling and mechanical loading, zirconia, veneering, CAD/CAM
3.1 Abstract

Objective. The aim of this investigation was to compare the clinical survival rate of all-ceramic FPDs during an in-vitro simulation. This study is only a first approach for valuating the influence of a laboratory simulation.

Materials and Methods. Thirty-two FPDs were fabricated from a zirconia ceramic and a corresponding ceramic veneering. The FPDs were adhesively bonded on human molars, and artificial aging was performed for investigating the survival rate during thermal cycling and mechanical loading (TCML1; $3.6 \times 10^6 \times 50$ N ML). Survival rates were compared to available clinical data, and the TCML parameter “mastication force” was adapted accordingly for a second TCML run (TCML2; $3.6 \times 10^6 \times 100$ N ML). The fracture resistance of the FPDs that survived TCML was determined. FPDs were examined without TCML (control) or after TCML according to the literature ($1.2 \times 10^6 \times 50$ N ML). Data were statistically analyzed (Mann-Whitney-U test), and curve fitting/regression analysis of the survival rates was performed.

Results. TCML reduced survival rates down to 63% of the control group. Failures during TCML were chipping of the veneering ceramic, but no zirconia framework was found. The fracture resistance was significantly reduced from 1058 N (control) to values between 320 N and 533 N after TCML.

Conclusions. The results indicate that TCML with $1.2 \times 10^6$ mechanical loadings à 50 N provides a sufficient explanatory power. TCML with prolonged simulation time may allow for the definition of a mathematical model for estimating future survival rates.
3.2 Introduction

A clinical trial is the first choice for evaluating the effect of medical treatment or usability of new materials. The results of significant clinical investigations are often restricted by high investments and expenditure, sometimes combined with low outcome due to small number of subjects or high deviations of the results [1]. Therefore, *in-vitro* simulations are becoming more and more important for advanced time-lapsed testing of new materials. In times of the ephemerality of dental materials, computer-controlled (Finite Element Analysis FEA) [2] or laboratory simulations were used for pre-clinical investigations of materials or restorations, trying to predict at least catastrophic failures [3]. Various systems for simulating the oral environment were introduced for example by DeLong and Douglas [4,5], Krejci *et al.* [6] and others [7-10]. Some devices even are commercially available (EGO, G; EnduraTEC, USA; Willytech, G; SDE, USA). The variation of simulation parameters such as chewing frequency, thermal loading, moisture, lateral jaw motion, type of abutment, periodontium or antagonistic denture may cause different outcomes [11], but chewing force, especially, had a significant influence on the fracture resistance of all-ceramic restorations. Measurable *in-vivo* mean mastication forces vary between 12 N and 70 N [12, 13]. Data of correlations between *in-vitro* results and *in-vivo* experiences are rare [3, 14], underlining the limited validity of laboratory tests. A comparison between clinical data and *in-vitro* results may be tied up with events during the application, but this may assume remarkable failure rates e.g. up to 10-20 % in five years. An overview comparing *in-vitro* tests of conventional fixed partial dentures (FPD) listed material related failures (loss of retention, fracture) up to 11% in a mean observation time of eight years [15]. Higher failure rates are found only for experimentally enlarged indications or newly introduced materials like zirconia with, in the beginning particularly, insufficient veneering ceramics. Clinical investigations showed cracking of the veneering glass-ceramic culminating in failure rates up to 10% after 48 months [16-19].

It is known that the survival rate of medical surgery is given by an exponential dependency from the period of application \( y = a \times e^{x} \) [20-22], which means that clinical failures predominantly occur in the first years after insertion. The knowledge of *in-vitro / in-vivo* correlation may therefore allow a mathematical failure prospect to be formulated.

The aim of this investigation was to compare the clinical survival rate of all-ceramic FPDs with failures during standard simulation procedures. The simulation parameter “mastication force” was modified for estimating the influence on the simulation and calculation of correlation parameters. The fracture resistance of the FPDs was determined to investigate the influence of the simulation.
3.3 Materials and Methods

The roots of human molars were coated with a 1 mm thick layer of polyether material (Impregum, 3M Espe, G) for simulating the human periodontium, and inserted into PMMA resin (Palapress Vario, Heraeus-Kulzer, G). Molars (n=64) were arranged to form a lower jaw posterior situation (teeth 5/7) with an oral gap of 10 mm. Human teeth with comparable size and root dimensions were used. Beyond this, teeth ensure a clinically relevant modulus of elasticity of the abutments and guarantee a relevant interface between fixed partial dentures (FPDs) and teeth. Varying dimensions of the teeth were, therefore, tolerated. All teeth were prepared according to the directives for ceramic restoration techniques, using a 1mm deep circular shoulder crown preparation.

Thirty-two posterior FPDs of the yttria-stabilized zirconia (Cercon base, DeguDent, G) were fabricated according to the manufacturer’s instructions. The zirconia frameworks were veneered with an experimental glass-ceramic (Cercon Ceram, DeguDent, G) that had, in contrast to the actual released veneering ceramic Cercon Ceram Kiss, a reduced thermal expansion (8.7 [μm/mK] 25-500°C) and firing temperature (750 [°C]). The connector had a height of 3.6±0.4 mm and a width of 3.7±0.5 mm (connector area: 13.4±2.8 mm²). The veneering thickness was 1.4 ±0.5 mm.

The abutments were sandblasted (2 HPa, 50 μm) and the FPDs were conventionally cemented with glass-ionomer cement (Ketac Cem; 3M Espe, G). Type of restoration and cementation were chosen for meeting the available clinical data.

Human molars were adjusted as antagonists in the centre of the FPD pontic using a dental articulator (Girrbach, G) and both tooth and FPD were transferred to the simulator. The antagonist-tooth relation was controlled with an occlusal foil. Thermal cycling and mechanical loading (TCML, Chewing Simulator, EGO, G) was performed for simulating the aging of the FPDs. The loading parameters were based on data from the literature (1,200,000 mechanical loadings [ML] of 50N and 6,000 thermal cycles [TC], 2 min each cycle with distilled water between 5°C and 55°C [6]), which are suggested to simulate five years of oral service. The simulation time was prolonged in a second and third run up to 3,600,000 loadings. The parameter “ML” was adapted for a third run by comparing in-vivo and in-vitro failure rates as described below. Ten specimens of each group were investigated:

0) without TCML (control)
1) after 1 200,000 mechanical loads of 50N/6,000 TC (≈5 years according to Krejci)
2) after 3 600,000 mechanical loads of 50N/18,000 TC
3) after 3 600,000 mechanical loads of 100N/18,000 TC.
During TCML all specimens were controlled for failure detection after 100,000 cycles each. Percent failure rates during TCML were compared to pooled in-vivo data available from Medline [16-19] (Table 3.1).

**Table 3.1:** Clinical data of zirconia 3-5 unit FPDs.

<table>
<thead>
<tr>
<th>Author</th>
<th>Number of FPDs</th>
<th>Number of veneer chipping</th>
<th>Cementation</th>
<th>Total Observation time [months]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bornemann [18]</td>
<td>46</td>
<td>2 (after 6months)</td>
<td>ZnPh</td>
<td>18</td>
</tr>
<tr>
<td>von Steyern [16]</td>
<td>20</td>
<td>3</td>
<td>ZnPh</td>
<td>24</td>
</tr>
<tr>
<td>Pospiech [17]</td>
<td>38</td>
<td>1</td>
<td>GIC</td>
<td>24</td>
</tr>
<tr>
<td>Sailer [19]</td>
<td>44</td>
<td>7</td>
<td>Conventional</td>
<td>36</td>
</tr>
</tbody>
</table>

Both, simulation and in-vivo data showed an exponential decrease of survival rate (SR= ae^{bx}), which agrees with the literature [20-22]. a and b are constants and x gives the loading time in months (in-vivo) or the number of loading cycles (in-vitro). Correlation and curve fitting was calculated with SPSS providing a mathematical model with a and b for in-vitro and in-vivo data. Arranging equations SR_{in-vivo} = SR_{in-vitro} gives

\[
x_{in-vivo} = \frac{(\ln a_{in-vitro} - \ln a_{in-vivo} + b_{in-vitro} \times x_{in-vitro})}{b_{in-vivo}}
\]

This equation expresses the correlation between \(x_{in-vitro}\) [number of thermal cycles] and \(x_{in-vivo}\) [months] and provides a relation factor (f) between in-vitro and in-vivo. This factor was used to adapt the mastication force of the modified simulation.

Fracture testing: All FPDs were loaded until failure using a testing machine (Zwick, Ulm, G, v=1mm/min). The force was applied using a steel ball (d=12 mm) while a 1 mm thick tin foil between pontic and antagonist was used to prevent force peaks. The FPDs were optically examined before and after fracture testing. Failure mode was divided into fracture of the veneering or the core. Medians and 25/75 percentiles of the fracture resistance [N] were calculated. Statistical analysis was performed using regression/curve fitting models and Mann Whitney-U test for comparing pair wise differences between the results (\(\alpha=0.05\)).
### 3.4 Results

TCML:
All groups showed failures of the veneering during TCML. The survival rate was 70% after TCML 1) and 30% after TCML 2) and 3). All failures during aging were chipping of the veneering ceramic. No fracture of the core material could be determined. Fig. 3.1 gives a comparison of the percent survival rate of *in-vivo* and *in-vitro* data. *In-vitro* data were converted from number of mechanical loading to a monthly chart as described above. As a result of the calculation of the relation factor, the mastication force of the third simulation was doubled \((f=2; \ 100\ N)\).

**Fig. 3.1:** Survival rate *in-vivo* [months] and *in-vitro* [mechanical loadings]

![Graphs showing survival rate](image)

The mathematical calculation of SR resulted in a very good fitting with a correlation \(R^2\) of 0.892 (in-vivo data), 0.969 (simulation #2) and 0.983 (simulation #3). Parameters a and b are shown in Table 3.2.
Table 3.2: Simulation, type of failure and calculated curve-fitting parameters.

<table>
<thead>
<tr>
<th>Simulation #</th>
<th>In-vitro</th>
<th>In-vivo</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>without TCML (control)</td>
<td>1,200,000 ML of 50N/6,000 TC</td>
</tr>
<tr>
<td>Failure during TCML</td>
<td>--</td>
<td>3 veneering</td>
</tr>
<tr>
<td>Failure during fracture testing</td>
<td>all veneering</td>
<td>all veneering</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Parameter a</th>
<th>Parameter b</th>
</tr>
</thead>
<tbody>
<tr>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>--</td>
<td>--</td>
</tr>
</tbody>
</table>

Fig. 3.2 gives an impression of the veneering fracture during TCML. The calculated correlation between the 5-years in-vivo survival rate and TCML was about 750,000 ML for the 50N simulation and 590,000 ML for the 100 N simulation.

Fig. 3.2: Zirconia FPD after TCML (1,200,000 ML of 50N/6 000 TC).
Fracture test:
The median fracture resistance (25%/75%) without TCML (#0) was 1058 N (841/1505), which was significantly higher compared to the values after aging. After the first simulation fracture results of 533 N (424/1169) were found. The median fracture resistance after simulation #2 was 517 N (single results were 392 N, 517 N and 540 N), and after TCML (#3) a median of 320 N was found (320 N, 270 N and 441 N). Significant differences could be determined between the groups #1 and #3. After fracture testing one fracture of the core was found for each group (Fig. 3.3).

**Fig. 3.3:** Fracture Force [N] (without TCML and after TCML with 50N/100N and 1.2 x 10^6 or 3.6 x 10^6 ML); identical letters indicate non significant differences (median, 25%/75%).

3.5 Discussion
The influence of TCML on the tested FPDs was obvious: on the one hand increasing the failure rate up to 70% and on the other hand significantly reducing the fracture resistance after 1.2 x 10^6 ML to 50% and after 3.6 x 10^6 ML to only 70% of the initial values without TCML. **Fig. 3.1** showed that the 100 N simulation led to a faster decrease of the survival rate compared to the *in-vivo* situation and, therefore, may underestimate the tested materials. The survival rate after the 50 N simulation showed a sufficient approximation after 30 and 60 months.

The aging effects on the investigated FPDs were comparable between *in-vitro* simulation and *in-vivo* behaviour. No failures of the zirconia core were found, but cracks and fracture of the veneering ceramic were observed. Especially affected areas were the cusps, where antagonists
caused selective loading or wear, and lateral tooth movement furthermore resulted in shear loading on the veneering. These fracture types may point out the necessity of using (human) antagonists or at least articulated clinical relevant situations with standardized tooth-shaped antagonists. Crack propagation may be supported by irregular veneering thickness [2] or insufficiently adjusted thermal expansion coefficient and firing temperature of zirconia and glass-ceramic veneering [23, 24]. Newer ceramic veneering (Ceram Kiss) for Cercon zirconia clearly showed improved properties as a consequence of changes in both processing parameters. Beyond this, a special framework design that supports the veneering ceramic may further improve survival rates.

The calculation with exponential decay gave a correlation between in-vivo data and in-vitro simulation. Using 50 N, a total of 750 000 ML were necessary for simulating five years of oral service. 590 000 ML were adequate, using a mastication force of 100 N. The calculated survival rates after ten years were about 70% for interpolated in-vivo data and comparable with 50 N simulation (73%). Using 100 N during simulation reduced survival rate obviously stronger to 63%. This data may conform to the assumption of in-vivo chewing forces between 12 N and 70 N [12, 13]. Nevertheless, the results indicate that a reduced simulation force of about 35 N (calculated f= 0.7) may match the long-term in-vivo data negligibly better. That means that weaker materials may be aged with lower loading force for achieving relevant simulations.

Despite the few clinical data available and the small number of in-vitro samples, the correlation between clinical and in-vitro failures led to a good correlation (R=0.983). The assumption of a mathematical model (SR=formula) may allow a restricted estimation of a future behaviour of the tested restorations. With the help of the mathematical model, a failure rate of approximately 70% after ten years of service is estimated for zirconia FPDs with partly insufficient glass-ceramic veneering. By that time, only ongoing clinical investigations may confirm or disprove these results. As suggested by the manufacturer, the newer veneering material shows distinctly improved in-vitro and in-vivo failure behaviour.

Even though the individuality of abutment teeth and FPDs is reflected in a high variation of the fracture results, a clear tendency to a strong TCML-dependent aging of the combination of zirconia – glass-ceramic veneering could be determined. This does conform to other authors describing a strength decrease of ceramic materials after aging [25] or the interface between core and veneering. Even high strength zirconia underlies aging due to phase transformation and crack growth [26]. Assuming maximum bite forces between 70 N and 909 N, depending on the type of measurement, sex, denture, or food and others factors [27], all new FPDs (without TCML) may provide no clinical problems. After aging the median fracture was significantly reduced to 533N or lower, indicating increasing deterioration of the restoration
(veneering or interface between core and veneering). Strength of the FPDs (core and veneering) is reduced to such an extent, that cracking of the veneering during clinical loading may be pre-programmed. The single core failures in fracture testing after simulation may promise a calculated lifetime of the zirconia core of higher than 30 years (3.6 x 10^6 ML with 50 N). However, beyond this, other clinical parameters such as bonding and sealing qualities (secondary caries) contribute to the survival of restorations and should be considered in further studies.

The results show that the explanatory power of simulations with 1.2 x 10^6 times 50 N may provide adequate estimations. The quality of the tested material is rather underestimated and catastrophic failures should be excluded. Enhanced TCML with prolonged simulation time (and increasing number of failures) allows the definition of a mathematical model for estimating future survival rates. Detailed clinical data with gradual failure results would be preferable for improving the valuation. Modified simulation parameters such as an adapted chewing force should allow a distinct view on the properties of dental restorations. However, this study is only a first approach for valuating the influence of a laboratory simulation. Further verification of other simulation parameters and transfer to other dental materials seems necessary.
3.6 References


