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Approach for valuating the significance of laboratory simulation

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ABSTRACT

Objective: The aim of this investigation was to compare the clinical survival rate of all-ceramic FPDs with failures during in vitro simulation.

Methods: 40 anterior FPDs were manufactured from lithiumdisilicate ceramic and alumina-oxide ceramic. The FPDs were adhesively bonded to human teeth and artificially aged to investigate the survival rate during thermal cycling and mechanical loading ($TCML_1$; 3.6 Mio*50N ML). Survival rates were compared to available clinical data, and the TCML parameter 'mastication force' was adapted accordingly for a second TCML run ($TCML_2$; 3.6Mio*25N/35N ML). The fracture resistance of the FPDs that survived TCML was determined. Data were statistically analysed by means of Mann–Whitney *U*-test, and survival rates were determined by curve fitting/regression analysis.

Results: TCML decreased survival rates by 30–50%, depending on the type of material used. Failures during TCML included cracking, chipping or fracture. Increased masticatory loading during TCML caused a higher decrease in the fracture resistance of FPDs. Fracture results were 403N (278/453) and 426N (317/538) for Empress 2 and 325N (164/584) and 405N (344/558N) for Inceram.

Conclusions: Despite the limitations of this study, the results indicate that TCML with 1,200,000*25/35N provide a sufficient prognosis of probable clinical failures. Longer TCML-time with higher mastication forces may help to exclude catastrophic clinical failures.

1. Introduction

Clinical investigations were performed to estimate the effect of medical treatments or the usability of new materials. The results of such investigations are often restricted by high investments and expenditures, sometimes combined with low outcome because of the small number of subjects or the high deviations of the results.[1] Unfortunately, studies, which had been planned over a long-term 5-year observation period, were cancelled without recognizable reason.[2] Computer-controlled Finite Element Analysis (FEA)[3] or time-lapsed laboratory simulations were used for pre-clinical material testing that aimed at predicting clinical behaviour or at least catastrophic failures.[4] Different devices for simulating the oral environment have been described (for instance by DeLong and Douglas,[5,6] Krejci et al.[7] and others[8–11]), but only some devices 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. Particularly chewing force has a significant influence on the fracture resistance of all-ceramic restorations.[12] Nevertheless, it is difficult to determine an optimal chewing force

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because of the variation of in-vivo mean mastication forces between 12N and 70N.[13,14] Despite the large amount of data on laboratory simulations available (Pubmed provides about 200 notations on 'chewing simulator or simulation'), the validity of laboratory tests or simulations is restricted and data correlating in vitro results and in vivo experience are rare.[4,15] To estimate the correlation between clinical data and laboratory results, a comparison of events such as chipping, fracture, or loss of retention during service time is essential. A higher failure rate makes comparison easier, whereas, in the absence of failures, no events can be compared. Calculations of possible correlations may be limited by low failure rates, for example as found for conventionally fixed partial dentures (FPD) with rates up to 11% in a mean observation time of 8 years.[16] Admittedly, the literature includes reports about higher failure rates for all-ceramic restorations, which were partly used in extended, not released indications. These Empress 2 and Inceram restorations showed failure rates of up to 50% and 70% (see Table 1) and were therefore investigated in this study.

The expression of survival rates by means of a mathematical model is difficult; therefore, we adapted a simple equation expressing the survival rate of medical surgery by an exponential dependency from the period of application.[17–19] The equation expresses that clinical failures occur predominantly in the first years after insertion. Although this aim is difficult to achieve because parameters for clinical studies and in vitro studies may differ in the type of restoration, geometry, environment and occlusal forces as well as for other reasons, a basic idea how to evaluate results after chewing simulation would be helpful. If the calculation is applied to the correlation between in vitro and in vivo data, this mathematical model may help to predict failure rates. Therefore, this investigation was a first approach for correlating clinical data with laboratory test results. The aim was to compare the clinical survival rate of all-ceramic FPDs and their failure rates during thermal cycling and mechanical loading (TCML). The simulation parameter 'mastication force' was modified on the basis of an exponential mathematical model to estimate the influence on the simulation and calculation of correlation parameters. The fracture resistance of the FPDs after TCML was determined to investigate the influence of the simulation.

2. Materials and methods

The roots of human teeth were coated with a 1-mm thick layer of polyether material to simulate the human periodontium. Therefore, we dipped roots into hot wax to achieve a wax layer measuring 1 mm in thickness and embedded the covered roots in PMMA resin (Palapress Vario, Heraeaus-Kulzer, G). We fixed a gypsum-key onto the crowns to ensure a later replacement of the teeth in the PMMA socket and separated gypsum-key and tooth from the PMMA socket to leave a mould. The wax was removed from the root and replaced by poylether (Impregum, 3 M Espe, G), and tooth and gypsum-key were replaced, forming a 1-mm polyether layer on the root. Then, we arranged incisors ($n = 40$) and canines ($n = 40$) comparable in size and root dimensions in PMMA resin (Palapress Vario, Heraeaus-Kulzer, G), forming a maxillary situation (teeth 11/13) with an oral gap of 8 mm. Each tooth was prepared according to the directives for Inceram and Empress 2 all-ceramic restoration techniques using a 1-mm deep circular shoulder crown preparation. Because of the uniqueness of human teeth, we conducted individual preparations hand-free to achieve a rounded shoulder with a depth of 1 mm, a preparation angle of 3° and an occlusal reduction of 1.5 mm.

We produced 40 anterior FPDs of leucite-reinforced lithiumdisilicate press-ceramic (Empress 2 layering, Ivoclar-Vivadent, Schaan, Germany) and alumina-oxide sintering glass-infiltrated ceramic (Inceram Alumina, Vita Zahnfabrik, Bad Säckingen, Germany) according to the manufacturers' instructions. The composition in weight % was as follows: Empress 2: 59.2 SiO_2, 20.9 Al_2O_3, 11.8K_2O, 4.8 Na_2O, and additional <1.5 CaO, BaO, B_2O_3, CeO_2, TiO_2, pigments; Inceram: 39–42 La_2O_3, 15–17 Al_2O_3, 15–17 SiO_2,

Table 1 – Published clinical data for Inceram and Empress 2 FPDs

Author	Type of restoration	Number of FPDs	Number and type of failure	Cementation	Total Observation time (months)
Inceram					
Kern et al.[32]	15 Anterior (RBFPD)	15	5 fractures	Resin	60
Pospiech et al.[33]	9 Anterior (RBFPD)	9	4 fractures/5 chippings	Resin	6
Olsson et al.[34]	8 Anterior/7 posterior	15	3 fractures 2 trauma fractures	Resin	60
Sorensen et al.[35]	21 Anterior/19 premolar	40	7 fractures	GIC	36
von Steyern et al.[36]	11 Premolar/9 posterior	20	3 fractures	ZnPh	66
Suarez et al.[37]	Posterior FPD	18	1 tooth fracture	ZnPh	36
Pröbster et al.[38]	11 Anterior/9 posterior	15	2 fractures	Resin	35
Empress 2					
Kinnen[39]	16 Anterior/27 posterior	43	8 fractures/18 chippings	Resin/GIC	47.1
Taskonak[40]	10 Anterior/10 posterior	20	8 fractures/2 chippings	Resin	12
Pospiech[41]	17 Anterior/34 posterior	51	1 fracture/9 chippings	Conventional/resin	12
Sorensen[2]	23 Anterior/37 premolar	60	2 fractures/2 chippings	Resin	15
Zimmer et al.[42]	31 Anterior/premolar	31	3 fractures/1 chippings	Resin	38
Bohlsen[43]	6 Anterior/31 posterior	37	/	Resin/GIC	24
Marquardt[44]	Anterior/premolar	31	6 fracture/1 chipping	Resin	50