CHAPTER 06

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The general aim of the research described in this PhD thesis was to assess the merits of a selection of restorative innovations in the dental office, more specifically those related to some restorative aspects of oral implantology. According to Prithviraj and colleagues, restorative dentistry will be revolutionized by digital dentistry and digital manufacturing. Among other technological innovations, digital planning, production, and evaluation tools will improve patient care. They urge dental professionals to eagerly embrace new technologies. Most of the findings in this thesis do support their enthusiasm, but not all.

With the exception of chapter 2a, all data were retrieved from a randomized clinical trial on zirconia implant abutments when replacing premolars. The original focus was on the biomechanical and biological aspects of zirconia abutments of different geometries. However, during the course of the trial complications arose related to the restorative composite material that had originally been chosen. As a result, this facet has become an integral part of this thesis. It reflects the relevant point of how best to deal with innovations, especially those regarding the practical clinical risks that may be associated with early adoption of new methods and materials in clinical practice.

The use of zirconia as a ground material for dental implant abutments and metal-free implants seems to be promising. With respect to the former, the results from our human histological case report suggest that a clinically functioning maxillary zirconia implant (ZV3, Wolfratshausen, Germany) can present with ample bone to implant contact (BIC) after two years of clinical service. This is in line with a recent study reporting on 3 maxillary zirconia implants that were retrieved after (on average) 4.5 years. As their assessment was performed on the apical part of implants that were unsuccessfully treated for marginal peri-implantitis and therefore needed to be retrieved, the external validity of this particular study should be considered questionable. Our case report supports the assumption that BIC is apically not affected by marginal peri-implantitis. A threshold of > 50% histological BIC for successfully osseointegrated mandibular and maxillary implants has been suggested, even though BIC in maxillary implants is generally lower than in mandibular implants. However, a correlation between clinical success and BIC is still unknown. It would be interesting for the practitioner to have more prospective follow-up data on the clinical success of a larger number of zirconia implants than presently available in the literature.

From a material-scientific point of view, it was established that zirconia, as an implant abutment substrate, can be resistant to tetragonal-monoclinic transformation (t-m transformation). Low temperature degeneration (LTD) was assessed on the surface and in the bulk material of functionally loaded, retrieved zirconia abutments after one year of clinical service. The fact that most information on the degradation of zirconia in the literature, be it regarding abutments, restorations, or
experimental samples, is obtained from studies using artificially aged specimens and makes the present \textit{ex vivo} clinical setup stand out from other studies. No substantial amount of monoclinic zirconia could be detected, even though the fracture strength after one year was somewhat compromised, in particular for stock zirconia implant abutments. Whether or not this accrues so as to constitute clinical relevance is hard to say on the basis of this study. Of the 50 implant abutments that functioned clinically for a year, not a single one had failed mechanically.

Although raw materials for the production of the CAD/CAM and stock abutments used in our study were similar, the manufacturing process may have influenced physical properties. Advanced ceramic materials such as zirconia have different material properties depending on the manufacturing process. This is in line with the literature analyzing catastrophic historical failure of zirconia hip-ball prosthesis that occurred at the beginning of this century. Those events were caused by t-m transformation, but were “clearly identified to be process controlled.”

Other unexpected adverse events (AE) were encountered within our clinical medical device trial. Lava Ultimate (LU), a new and promising restorative material representing technological innovation, was launched on the dental market in 2011 (3M ESPE), and we chose to restore our premolar implants with it, in conjunction with zirconia abutments. No clinical data on this material was available at the onset of the trial. The restorations were extra-orally bonded to the zirconia abutments according to the manufacturer’s instructions and later screw-retained to the implant. Soon after, a large number of clinical debonding events occurred. AEs were immediately communicated to the manufacturer and might have contributed to the worldwide product recall by the manufacturer (3M ESPE) for crown indications. We published a warning to restorative dentists and their dental technicians, with the aim of reporting the problem as soon as possible. At that time, we were not able to indicate a cause for the failure; in fact, the reason for failure might have been just about anything in the whole production process.

In order to investigate potential reasons for the failure, a second, additional clinical trial was started within the same population. In a within-subject comparison, all variables were kept constant while the restoration material was changed to Lithium Disilicate (LDS). After the same observational time (one year), not a single debonding event had occurred in the LDS group, compared to 80% debondings in the LU group, which strongly suggests a causal relationship between the restoration material and the debonding event.

Upon critical appraisal, the study design we used was not suitable for proving this causal relationship; randomization between the two treatment modalities would have been preferable. Given the fact that the AEs occurred unexpectedly, however, this is the strongest evidence available. As LU was marketed around the world, the need for an explanation for the failure was urgent. In a lawsuit against 3M, “hundreds of thousands of defective dental crowns” were referred to in the USA alone. While the second trial was still not completed, the fractured failures were fractographically analyzed. It could be shown that the fractures were most likely debonding related.

Even though there are different theories, a key reason for the debonding could have been water

1* Notice: Change in Indication — Lava™ Ultimate Restorative, Effective June 12, 2015.
2* Lawsuit: U.S. District Court for the District of Minnesota Case number 16-CV-01304-DWF-JSM
uptake, which can lead to stress at the cementation layer, especially in full-crown restorations, due to their geometry. It is interesting to note that the published "change in indication" by the manufacturer only affected the full-crown indication. A clinical study on LU indirect restorations without a core build-up prior to impression-taking showed much lower debonding rates after one year of clinical function (5%). Unfortunately, no more clinical data on LU has become available to date, and no new studies on LU full-crown restorations are obviously being planned. However, the phenomenon behind the failure needs to be analyzed in order to develop sufficiently valid methods for pre-clinical testing. That said, a generalized skepticism towards technological innovation does not lead to more clinical data either. More vigorous clinical pre-market testing by the manufacturer could have prevented this unfortunate course of events, and should serve as an expensive lesson learned.

Digital impression-taking is increasingly being performed in the dental office. For instance, we might cite a marketing claim (Cerec Omnicam) for a digital impression technique, which is compared to the conventional method. Dentsply Sirona has also promised to provide more comfort and safety for the patient and offered less operating time for the dentist compared with conventional treatment. Both claims are verifiable and are in line with a recently published review on this topic. In our study, however, accuracy was not the outcome parameter sought, although obviously of major importance. For small areas, digital impression techniques have been shown to have ample accuracy, but given longer span-fixed dental prostheses (FDP), especially quadrant-crossing FDPs, data from the literature are inconclusive regarding their applicability for restorative purposes.

Another technological innovation is represented by CAD/CAM individualized zirconia implant abutments. The use of a stock abutment is a more conventional treatment modality, where the emergence profile is circular; this does not correspond well with the naturally occurring condition. Both types of implant abutments for single premolar tooth replacement were compared clinically and followed for one year. They performed equally well, that is to say, none of the clinical, radiographical, and subjective parameters studied were statistically significantly different between the two abutment types. No catastrophic abutment failures were seen either. Given the absence of observed monoclinical content, this is not surprising. Interestingly, the pink esthetic score improved significantly over time, but patient satisfaction did not. The question may arise why patient and expert opinions did not match. This phenomenon has been described before. Frequently patients are less critical about esthetic aspects than professionals.

Hence, the additional value of CAD/CAM individually designed zirconia abutments could not be demonstrated, and patients were generally very satisfied with the esthetic outcome, regardless of the abutment type.

How should these findings be interpreted then? One reasonable conclusion would be to make use of stock abutments exclusively, with the only question remaining being whether or not the findings are also valid for other implant positions or solely for the premolar region. Alternatively, it could be concluded that the restorative team should not expect too much performance enhancement.
from the individualization of an implant abutment, regardless of the implant position, and should carefully consider whether the additional expense of manufacturing individual abutments is justified or not.

The most frequently encountered esthetic complications in the long term are loss of papilla and recession in buccal tissue height. Immediate implant placement can assist – but not guarantee – preservation of the approximal bone level and therefore improve the chance of maintaining the papilla. A thin tissue biotype, facial malposition, and little facial bone have been identified by others as the main risk indicators for buccal recession. In such cases, individualization and the use of ceramic abutment materials may be highly preferable so as to improve the esthetic appearance. Such determinants, in combination with patient-specific factors such as excessive maxillary gingival display or patient’s expectations, the restorative team should be able to make personalized, patient-specific decisions about which stage of technological innovations should be administered. Based on the (combined) results of the various studies included in this PhD thesis, the following general conclusions can be drawn:

- Zirconia implants can achieve ample bone to implant contact in man.
- No substantial tetragonal-monoclinic crystal transformation could be demonstrated after one year of clinical service of zirconia implant abutments, neither in the bulk material nor on the surface; CAD/CAM zirconia abutments did not deteriorate substantially in fracture strength after one year of clinical service either.
- When using zirconia implant abutments, the choice of restorative material is critical to the functional success of the total restoration: lithium disilicate performed well.
- Digital impression-taking is a swift technique, much appreciated by the patient.
- CAD/CAM customized zirconia implant abutments, when replacing premolars, did not outperform stock alternatives after one year of clinical function.
References


