

Marginal and Internal Adaptation of Hybrid Abutment Assemblies After Central and Local Manufacturing, Respectively

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Purpose: Central manufacturing of two-piece computer-aided design/computer-aided manufacture (CAD/CAM) zirconia abutments may provide a higher accuracy of internal and external adaptation at the expense of delayed restoration delivery. The aim of this study was to compare the fit of two-part zirconia abutments that were either fabricated centrally with the DEDICAM system or at a local laboratory. The field of interest was the marginal, external, and internal luting gap between the titanium insert and CAD/CAM zirconia coping.

Materials and Methods: Two groups of nine two-piece CAD/CAM zirconia hybrid abutments were subjected to scanning electron microscopy (SEM) to evaluate the precision of fit and thickness of the adhesive joint. Control specimens were fabricated with the CAMLOG DEDICAM system at the manufacturer's site; the test specimens were produced in a local laboratory. After embedding all samples ($n = 18$) in resin, they were sectioned, and the external, marginal, and internal luting gaps between the titanium base and zirconia coping were measured with SEM. Welch's t test was used for statistical analysis of the obtained data.

Results: The overall range of measured gaps between the components of two-piece CAD/CAM zirconia abutments was 0 to 115.5 μm ; the mean overall gap size and standard deviation was $45.61 \pm 5.88 \mu\text{m}$ and showed no appreciable difference between the test and control groups. The mean sizes of the marginal/external and internal gaps showed only negligible differences. The internal gap size was generally larger and showed a higher variability than the marginal/external gaps, albeit on a very low level. None of the reported differences between the test and control specimens were statistically significant. **Conclusion:** Luting-gap sizes of CAMLOG DEDICAM- and locally fabricated CAD/CAM zirconia hybrid abutments showed no appreciable difference. Both configurations of two-piece abutments provided a highly precise fit of hybrid components, overmatching the high-quality standards in CAD/CAM implant-based prosthetic dentistry. INT J ORAL MAXILLOFAC IMPLANTS 2018;33:808–814. doi: 10.11607/jomi.6131

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The use of dental implants and their respective suprastructures to replace single or multiple missing teeth has become a common practice in dentistry with well-documented functional and esthetic results.¹

Two main types of abutments are available for restoring implants: stock abutments, traditionally supplied by dental implant manufacturers to match their respective implant system; and computer-aided design (CAD)/computer-aided manufacture (CAM) abutments. CAD/CAM abutments can be custom designed to re-create the desired emergence profile and supporting crown orientation, facilitating the formation of anatomical mucosal topography and coronal contours for prosthetic replacement. The use of zirconia as a material for CAD/CAM implant abutments has become increasingly widespread because of its pleasing soft tissue esthetics and avoidance of peri-implant soft tissue discoloration.^{2,3}

The technical and biologic equivalence of CAD/CAM zirconia and titanium abutments is commonly accepted today.^{4–6} Two-piece CAD/CAM ceramic abutments (hybrid abutments) have demonstrated

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a higher fracture resistance than one-piece zirconia constructions,⁷ making them preferable from a technical point of view. However, the two-piece design comes at the expense of additional external and internal luting gaps that may comprise a weak point in terms of accuracy, mechanical stability, and longevity of the restoration.⁸

In addition, biologic properties of the interface between the abutment and surrounding junctional epithelium and connective tissue are of critical importance for successful soft tissue integration. Abutment material⁹ as well as macro- and microdesign¹⁰ determine the attachment between the mucosa and abutment surface, and a biologically relevant luting joint of a two-piece abutment may compromise soft tissue adaptation. Although a clinical disadvantage of two-piece abutments could not be demonstrated,¹¹ a minimal luting gap without the potential of plaque accumulation or loss of restoration accuracy is certainly desirable.

There is no fixed threshold for the marginal gap of two-piece abutments that guarantees successful epithelial attachment, but there is abundant evidence that luting gap sizes below 120 μm —as originally suggested by McLean and von Fraunhofer¹² for cement films in general—are safe in terms of providing an attachment-friendly micro-environment around the marginal luting zone of implant and abutment constructions.^{13–15}

Central manufacturing of two-piece CAD/CAM zirconia mesostructures offers theoretical advantages in terms of construction accuracy and ultimately restoration longevity; however, pertinent data have not been published so far. The present study compares local and central manufacturing in terms of *in vitro* marginal, external, and internal luting gap sizes of CAD/CAM-manufactured two-piece zirconia abutments.

MATERIALS AND METHODS

Abutment Manufacturing

A total of 18 prefabricated titanium inserts (CAMLOG) were processed in a local dental laboratory (Sirius Ceramics). Based on CAD data derived from a clinical case (maxillary left central incisor) (Fig 1), the virtual design of a zirconia mesostructure was digitally transmitted to CAMLOG (manufacturer of the CAMLOG/DEDICAM system). Nine zirconia copings were computer-milled at the CAMLOG premises (control group), and nine zirconia copings were milled in the local laboratory (test group), respectively. All insert-coping pairs (test and control) were assembled in the laboratory under strict adherence to the processing manual of the utilized resin cement (Multilink hybrid abutment, Ivoclar Vivadent).

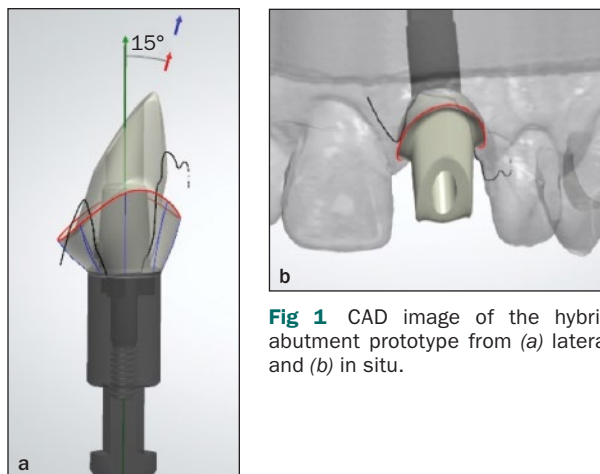


Fig 1 CAD image of the hybrid abutment prototype from (a) lateral and (b) in situ.

Abutments were finished with air abrasion of the bonding surfaces of the titanium inserts with 50- μm aluminum oxide particles at 2.0 bars pressure for 20 seconds at a distance of 10 mm. The inner part of the zirconia copings was treated with 100- μm aluminum oxide particles at 1.0 bars pressure for 20 seconds at a distance of 10 mm. Afterward, all titanium inserts and zirconia copings were ultrasonically cleaned in 96% ethylalcohol. The luting surfaces were conditioned with Monobond Plus (Ivoclar Vivadent). All specimens were cemented by the same operator (C.F.). Excess resin was removed from the bonding margins before it became fully set and polished.

The resulting internal and external luting gaps are shown in Fig 2.

Specimen Fabrication

After nondestructive assessment with computed tomography (CT) proved to not be feasible in preliminary testing, all specimens were prepared for scanning electron microscopy (SEM) examination of polished micrograph sections. Specimens were embedded in a polyurethane-based model resin (Sherapolan 2:1, Shera Werkstofftechnologie) in a standardized fashion using UNICLIP specimen holders (Wirtz/Buehler). Horizontal alignment and precutting to the required specimen sizes were performed automatically with the precision grinding and cutting machine Accutom-50 (Struers). After setting adjustment with the required parameters (accuracy: $\pm 5 \mu\text{m}$, cutting disc width: 0.6 mm) according to abutment dimensions, polished thin sections were fabricated under water cooling and continuous scrutiny for macro- and microscopic integrity (10 \times magnification, Photomakroskop, Wild). After final control, specimens were sputtered with Au-Pd for SEM assessment.

SEM Assessment

Internal and external luting gaps were measured by means of SEM (scanning electron microscope LEO

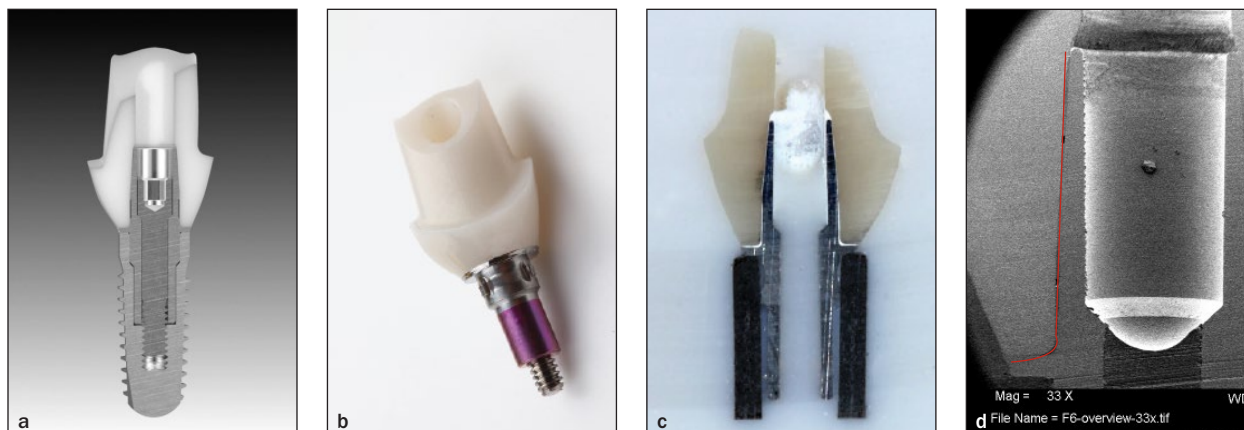


Fig 2 (a) Construction and actual test specimen of two-piece hybrid abutment (b) before and (c) after sectioning and (d) SEM with internal and external luting gaps.

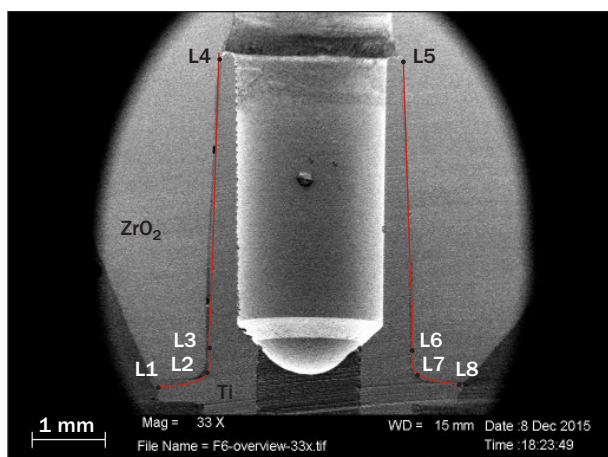


Fig 3 Landmarks for the measurement of external (L1, L8) and internal gaps (L2 to L7) in the SEM images. Red line represents the luting gap between zirconia coping and titanium insert.

1430, Zeiss). Specimens from the control and test groups, respectively, were assessed in random groups of three according to the SEM's capacity. The distance between the zirconia and titanium surfaces was determined at eight prespecified landmarks (L1 to L8) according to distinctive construction properties of the titanium insert (Fig 3).

The landmarks L1 and L8 would form part of the mucosal attachment surface in the clinical situation and were grouped as "external gaps" with potential contact to the peri-implant soft tissues; the remaining landmarks comprised the horizontal abutment shoulder (L2, L7) and the vertical tube of the titanium insert (L3 to L6) and were subsumed as "internal gaps" for statistical analysis. Whereas the external gaps determine the long-term performance in terms of biologic inertia, the internal gaps represent the actual bonding sites

and are responsible for the mechanical and dimensional properties of the restoration.

Distance measurements were performed blindly by two different investigators (T.S., S.S.) and re-assessed at a later time. Inter- and intra-rater agreements were high (Cohen's $\kappa \geq 0.75$), and arithmetic means of the four assessments were employed for further statistical analysis.

Statistical Analysis

To determine the required sample size, a post hoc power analysis was performed according to Faul et al¹⁶ (Program: G*Power 3.1.6, University Düsseldorf). The power calculation revealed that an analysis of nine abutments in each group (total of 18) with a statistical power of 80% and a .05 level of significance would yield significant results in two-sided *t* tests from an effect size of 1.4 (Cohen's *d*) onward.

The results were analyzed using the OriginLab 2011 statistical package (OriginLab Corporation). The level of significance was set at 5% ($P < .05$) for all applied statistical tests. Normality of data distribution was visually assessed with quantile-quantile (QQ) plots and statistically verified with Kolmogorov-Smirnov and Shapiro-Wilk tests in both groups for all measurements. Therefore, parametric descriptive (mean, standard deviation) and inference statistics (Welch's *t* test) were employed. Correlation between internal and external gap sizes was tested with linear regression and Spearman's rank correlation coefficient R^2 .

RESULTS

Size of Marginal and Internal Gaps

The measured gap sizes in the control and test specimens are shown in Table 1. With regard to the external/

Table 1 Results of SEM Gap Measurements (μm , mean \pm SD)

Parameter	All specimens (n = 18)	Control group (n = 9)	Test group (n = 9)	Δ (%)	Significance
Distance L1	16.34 \pm 7.19	16.40 \pm 6.34	16.28 \pm 8.50	-0.77	NS
Distance L8	20.13 \pm 6.36	20.28 \pm 5.95	19.98 \pm 7.11	-1.50	NS
External gaps	18.59 \pm 6.95	18.34 \pm 6.29	18.24 \pm 7.78	-0.58	NS
Distance L2	74.43 \pm 16.36	79.76 \pm 14.04	69.09 \pm 17.53	-13.38	NS
Distance L3	60.49 \pm 12.70	64.54 \pm 6.95	56.45 \pm 16.05	-12.53	NS
Distance L4	43.01 \pm 25.31	42.96 \pm 14.46	43.07 \pm 33.95	0.25	NS
Distance L5	39.58 \pm 16.74	47.44 \pm 11.37	31.71 \pm 18.09	-33.16	.044*
Distance L6	44.06 \pm 11.48	44.65 \pm 10.12	43.47 \pm 13.29	-2.64	NS
Distance L7	65.64 \pm 11.03	64.70 \pm 12.58	66.58 \pm 9.01	2.91	NS
Internal gaps	54.54 \pm 20.65	57.34 \pm 17.61	51.73 \pm 23.13	-9.79	NS
All gaps	45.61 \pm 05.88	47.59 \pm 23.01	43.62 \pm 25.02	-8.34	NS

*Statistically significant difference ($P < .05$). NS = not significant.

marginal gaps, group differences were virtually nonexistent; the distance at L8 was marginally larger than at L1, and the gaps in the test group were at best slightly smaller in the test as compared with the control specimens (Table 1).

The internal gaps were generally larger than the marginal ones in both groups. Within this group, the apically located landmarks L4 and L5 showed appreciably smaller gaps than the coronal sites (L2/L3 and L7) with the exception of L6 (Table 1, Fig 4). At landmarks L2, L3, and L5, specimens in the test group showed appreciably smaller gaps, with the difference at L5 (31.71 \pm 18.09 vs 47.44 \pm 11.37 μm ; difference of 33.2%) being statistically significantly different ($P < .05$). At all other sites, differences were marginal (Table 1).

Accuracy of Fit Between Zirconia Abutment and Titanium Insert

All in all, the accuracy of the fit between the zirconia abutment and titanium insert was very high. Especially with regard to the external gaps, there was no difference between the control and test specimens, and the mean gap size was well below 20 μm . Internal gaps were on average approximately three times as large, but still below 60 μm on average; here, the test specimens scored slightly better than the controls, but the overall difference of 51.73 \pm 23.13 vs 57.34 \pm 17.61 μm was statistically not significant.

In order to test if the internal and external gap sizes were a common indicator of manufacturing quality, correlation between the two was tested in the entire sample and in both groups separately. There was virtually no correlation with an R^2 of 0.09 (ie, only 9% of the

variance of internal gap size was explained by external gap size), and this lack of correlation occurred in both subgroups without relevant difference.

DISCUSSION

Hybrid two-piece CAD/CAM zirconia abutments can be fabricated in two different ways:

- The CAD/CAM manufacturing of the zirconia mesostructure is carried out at a central production facility of the manufacturer and is delivered to the laboratory with the corresponding prefabricated titanium insert for subsequent luting.
- The zirconia mesostructure of the two-piece abutment is CAD/CAM manufactured and luted in a local dental laboratory based on the prefabricated titanium insert.

Central manufacturing of two-piece CAD/CAM zirconia mesostructures may in theory provide higher accuracy, and consequently, the potential for a reduction of internal and external luting gaps of two-piece abutments; on the other hand, the process of definitive restoration delivery is prolonged when abutment components are fabricated on the central manufacturer premises. No pertinent data have been published so far to confirm a technical benefit of central manufacturing, and moreover, the potential clinical relevance of a possible luting joint reduction for implant longevity needs to be established by demonstrating meaningful differences in gap size.

The mucosal attachment around dental implants serves as a protective barrier between the oral cavity and peri-implant bone,¹⁷ and hazards such as plaque accumulation, mechanical loading, and prosthetic interference can compromise its integrity.

The present investigation showed no meaningful and/or statistically significant differences of internal and external gap sizes between centrally and locally manufactured zirconia abutments, and both methods provided sufficient degrees of accuracy for implant-abutment connections.

The study results show no correlation between internal and external gap sizes but a significant gap difference at landmark L5 between the control and test groups. The reason for this is unclear, but it has been demonstrated that gap size and marginal fit are significantly dependent on the CAD/CAM system used.¹⁸ A subtractive milling method is utilized to fabricate the mesostructure of hybrid abutments out of an industrially prefabricated solid zirconia block. This manufacturing process has some limitations, as the precision fit of the inside contour of the mesostructure depends on the size of the smallest available milling tool. If the cutting tool is larger in diameter than some parts of the inner contour of the mesostructure, a decrease of internal fit and inferior marginal properties might be the result. As found by some authors, there is a reverse relation between marginal and internal fit of CAD/CAM systems used.¹⁹ A large internal gap width has smaller marginal gap dimensions, while a smaller axial gap could contribute to an underseating of the restoration and a larger occlusal and marginal gap. Most of the cutting tools for zirconia are incapable of cutting sharp internal angles, which results in an internal binding and consequently to inaccuracies in seating.

There is no specific threshold for an acceptable marginal gap size of two-piece hybrid abutments and only sparse published evidence in the narrower sense for comparison. However, the underlying issue of luting gap size as a determinant of soft tissue integration is not inevitably linked to two-piece abutments, but pertains to cement-luted bonds between metal and/or ceramics. For the latter, there is decades-long experience that has failed to decidedly unsettle the original assumption of a threshold of $\leq 120 \mu\text{m}$ for biologically inert luting gaps by McLean and von Fraunhofer,¹² and even more ambitious assumptions have never undercut $50 \mu\text{m}$ ^{20,21}; therefore, the marginal gaps in the present trial (with a maximum of $32 \mu\text{m}$) are comfortably within any reasonable safety zone. The absence of an appreciable difference underscores that both central and local manufacturing and assembly of zirconia abutments on prefabricated titanium inserts are very reliable and accurate in terms of marginal luting gap size.

The study design attempted to emulate day-to-day conditions of abutment manufacturing and assembly as accurately and realistically as possible. In order to isolate a possible influence of central manufacturing of the zirconia coping and assembly on the prefabricated insert, all other steps of the design and manufacturing process were performed in a strictly standardized and identical fashion within the limits of possibility set by inevitable inter-laboratory variations.

Even though a nondestructive CT analysis would have been technically preferable, the SEM examination of polished micrograph sections is a well-established method in luting gap assessment and comprises one present industry standard in dental material science.

Overall, the applied methods in specimen fabrication and assessment should provide a reasonably realistic reflection of the day-to-day situation in two-piece abutment manufacturing and assembly; the very comfortable distance of the gap sizes measured in the present trial to even the most strict assumptions of safety margins underscores the validity of the aforementioned conclusion that both methods under scrutiny provide biologically and mechanically safe implant abutments.

There is a relative abundance of literature concerning the gap size at the implant-abutment interface and the fit of conventionally cast vs CAD/CAM fabricated abutments^{5-7,22-30}; in contrast, the luting gaps between the titanium insert and zirconia abutment in two-piece hybrid constructions have not been extensively studied so far.

Apicella et al³¹ examined the internal and external fit of Lava hybrid abutments in comparison to one-piece titanium abutments. The study yielded a significant advantage of the one-piece abutments: whereas the marginal gap in the two-piece abutments was $70 \pm 25 \mu\text{m}$, the distance between titanium one-piece abutment and zirconia copings was $37 \pm 30 \mu\text{m}$ ($P < .05$). The internal gap sizes ($55 \pm 40 \mu\text{m}$ at the axial wall) were comparable with those of the present trial; the fact that the marginal gaps were much smaller in the present study sample is probably due to significant progress in CAD/CAM technology in the last decade. Hamilton et al³² described vertical gap sizes in two-piece abutments between 4 and $63 \mu\text{m}$ that were largely comparable to those in the present trial. Therefore, what little published evidence on the topic is available supports the key results of the present trial.

All in all, the results of the present trial appear to be valid despite the small sample size. Local manufacturing of two-piece hybrid abutments meets or exceeds the high standards set by industrial production, and the high consistency of the results makes

reproducibility very likely, provided the local laboratories follow the same high-quality standards.

At best, differences occurred in favor of the locally manufactured abutments; any remotely meaningful difference (ie, internal gaps at L2, L3, and L5) showed this tendency, and differences favoring central manufacturing were few (L4, L7) and quantitatively marginal (< 5%). However, the differences at L2, L3, and L5 and the statistically significant difference at L5 should not be interpreted as a precision advantage of local manufacturing. First and foremost, this has methodologic reasons: in the present evaluation, the number of statistical analyses exceeds the number of specimens under consideration, resulting in a very high likelihood of a statistical Type I error (false positive result). Moreover, the correlation analysis of external and internal gaps provided no indication of a general manufacturing quality issue that should in principle have affected all landmarks more or less simultaneously. In principle, the central manufacturing should provide a more predictable and consistent—if not more accurate—fit between the titanium insert and zirconia abutment and may therefore be preferable; however, the present trial allows the choice between central and local manufacturing to be left to the individual's discretion.

Within the limitations of this investigation, a meaningful difference of internal and external gap sizes between centrally and locally manufactured zirconia abutments could not be demonstrated. Both methods provided degrees of accuracy that lie well within the limits that have been established as a prerequisite for clinical safety of implant-abutment connections.

Therefore, the main result of the present study is the absence of a tangible precision benefit of the central manufacturing of two-piece hybrid constructions with titanium insert and zirconia abutment. Presently, this construction principle seems to provide the best combination of mechanical, esthetic, and biologic properties as the basis for single-tooth replacement, especially in load-bearing areas.

CONCLUSIONS

Both centrally and locally manufactured two-piece hybrid abutments with titanium inserts exceeded the established criteria for internal and external fit. There were no meaningful or statistically significant differences between centrally and locally manufactured two-piece hybrid abutments. The choice between both manufacturing strategies can be left to the individual practitioner's discretion. Central manufacturing may be preferred because of greater predictability and consistency of results.

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