[Title page]

Clinical use of alumina-toughened zirconia abutments for implant-supported restoration: prospective cohort study of success and survival analyses

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[Abstract]

Objectives: The aim of this prospective cohort study was to evaluate the effects of a number of clinical variables on the survival of alumina-toughened zirconia abutments used for implant-supported restorations.

Material and Methods: Two hundred and thirteen patients aged 18 years or older were recruited from May 1998 through to September 2010. All patients were treated with dental implant-supported fixed restorations using alumina-toughened zirconia abutments. During the follow-up, each restoration was coded as a dental event, which included censored teeth, loosening or fracture of screws, and abutment fracture. From the coded data, the effects of the investigated clinical variables (restored area, number of prosthetic units, prosthesis type, implant system, and patient gender) on the survival of the alumina-toughened zirconia abutments were analysed. The five-year success and survival rates of the abutments were assessed.

Results: The number of prosthetic units and the type of prosthesis had a significant association with success rate (P < 0.05). Kaplan-Meier survival analysis estimated that the cumulative five-year success rate of alumina-toughened zirconia abutments used in single restorations was 80.3%. Splinted and fixed partial denture restorations had success rates of 96.1% and 96.2%, respectively. The five-year survival rate of the alumina-toughened zirconia abutments was more than 95%, regardless of the type of prosthesis.

Conclusions: Alumina-toughened zirconia abutments are likely to exhibit excellent longterm survival in clinical use for fixed restorations. Single tooth replacement with an aluminatoughened zirconia abutment at the molar region may require special care and extra attention. Titanium has been established as the material of choice for implant reconstruction due to its well-documented biocompatibility and mechanical properties (Adell et al. 1981). Clinical studies have documented superior survival rates for fixed implant restorations supported by titanium abutments (Andersson 1995). However, in a recent systematic review, certain complications were associated with metal abutments supporting fixed implant restorations (Pjetursson et al. 2007). One of the major issues noted was aesthetic concern. The unnatural bluish appearance causing aesthetic problems stems from the thin soft tissue of the periimplant, which is incapable of screening the reflective light from the metallic abutment surface (Yildirim et al. 2000). As an alternative to titanium, the aluminium oxide abutment was next introduced in 1994. However, the inferior mechanical properties (i.e., low ability to withstand fractures) of alumina were not sufficient to be used alone as an implant abutment. Therefore, high-strength, durable ceramic zirconia was developed and used as an implant abutment abutment later in the 1990s (Belser et al. 2004, Guazzato et al. 2004).

Ceramic abutments including zirconia are well known to be superior to metal abutments in terms of their aesthetics, including the possession of radiopaque properties that prevent the gingival discoloration that is common with metal abutments (Jung et al. 2008). In addition, the results of a recently published study showed that significantly fewer bacterial colonies were found on zirconia surfaces compared with titanium surfaces (Rimondini et al. 2002, Scarano et al. 2004). Moreover, the favourable soft and hard tissue reaction to zirconia was comparable to the reaction to titanium (Kohal et al. 2004). Clinically, a previous four-year prospective study indicated that the success rate of zirconia abutments in the anterior dental region was 100% (Glauser et al. 2004). However, clinical studies on zirconia abutments, especially in posterior restorations and implant-supported fixed partial dentures, are still

scarce (Bae et al. 2008).

This prospective cohort study investigated the applicability of alumina-toughened zirconia abutments for implant-supported restorations using survival analysis, which is advantageous for a longevity study of restorations in prosthetic dentistry. The most important feature of survival analysis is that some subjects in the study have not experienced implant failure at the time of analysis, given the impractical nature of a researcher waiting for all failures in all subjects. Second, some subjects are lost to follow-up, drop out of the study, or experience failure because of an unrelated cause, e.g., facial injury leading to implant loss. Third, the exact time of failure usually cannot be determined; instead, the failure is noted only at time of the patient's visit to the dental hospital during follow-up. Survival analysis overcomes these issues and identifies risk factors, irrespective of the original distribution of data (Lee et al. 2010).

The aim of this study was to compute the long-term clinical success and survival rates of alumina-toughened zirconia abutments used for implant-supported restorations and to evaluate the effects of a number of clinical variables on these rates.

Material and Methods

Subjects

This study was performed at the Department of Prosthodontics at Seoul National University Dental Hospital in Seoul, South Korea, from May 1998 through to September 2010. Eligible participants were adults aged 18 years or older with successfully osseointegrated implant fixtures. Exclusion criteria were pregnancy and radiation therapy involving the head and neck area. Two hundred and thirteen fixed prosthodontic patients were recruited. The mean age of the patients was 57 years (range, 20 to 86 years). All patients were treated with single implant-supported splinted (without pontics) restorations or fixed partial denture (FPD) restorations (with pontics) at Seoul National University Dental Hospital. The institutional review board for the protection of human subjects reviewed and approved the research protocol (IRB054/06-10).

The following clinical variables were investigated: restored area, number of prosthodontic units, type of prosthesis, implant system, and patient gender (Table 1).

Alumina-toughened zirconia abutments

The alumina-toughened zirconia abutments (ZirAce[®], Acucera, Pocheon, Korea) used for this prospective clinical study were composed of a composite of alumina and zirconia (Al₂O₃/Y(Nb)-TZP). This composite is known to be free of low temperature degradation during the aging process (Kim et al. 2000). Abutments prepared from this composite possess high fracture strength and low hardness compared with abutments prepared from the conventional zirconia 3Y-TZP, which facilitates procedures in the mouth and the laboratory using high speed diamond burs and low speed diamond wheels, respectively. Aluminatoughened zirconia abutments are light yellow in colour, similar to the natural colour of teeth, adding to their desirability.

Clinical Procedures

An impression was taken at the implant fixture level and master casts were produced. Appropriate abutments were selected according to the fixture diameter, soft tissue height, position and shape of adjacent teeth, and inter arch distance. Adjustment of the prefabricated abutment into the final contour was then performed. Next, the superstructure was fabricated with gold alloys or zirconia depending on the clinical situation. In some cases involving single tooth prostheses that were retained by screws, the alumina-toughened zirconia abutment was directly overlaid with a veneer porcelain for zirconia. The alumina-toughened zirconia abutments were screw-tightened to the implant fixtures with a torque of 30 to 35 Ncm after a healing period. The definitive prostheses were permanently cemented or screwed onto the abutments.

Success and survival rating

Survival and success time were coded by the month after placement of the prosthesis. Implant abutment failure was coded as event data. Success was defined as abutments that were free from screw loosening, screw fracture, or abutment fracture. Survival was classified as an abutment that functioned in the mouth regardless of clinical complications. Therefore, only a fractured abutment was excluded from survival data. Removal of the alumina-toughened zirconia abutment because of its fracture was designated as a failure. For subjects whose follow-up times ended without a failure event, the end status was recorded as 'censored' because the actual duration of time to the failure event was unknown. Intact aluminatoughened zirconia abutments that were functioning properly during this investigation period were, therefore, coded as censored.

Statistical analysis

Significance and odds ratio statistics were evaluated for all clinical variables using the Fisher Exact test. Kaplan-Meier survival curves were plotted, and the log rank test was used to identify the variables associated with the alumina-toughened zirconia abutment failure. Prognostic variables were identified with the Cox proportional hazard model by using the language R. A P-value of less than 0.05 was considered statistically significant.

Results

A total of 611 abutments were utilized for implant restorations, and a total of 328 restorations in 213 patients, consisting of 133 implant-supported single, 165 splinted, and 30 fixed partial denture (FPD) restorations, were investigated (Table 1). The average follow-up period was 3.6 years (range, 1 month to 12.8 years). The age distributions for male (mean 58 years) and female (mean 55 years) patients did not significantly differ. Six restorations were fractured and therefore classified as failures. Twenty-three restorations experienced abutment screw loosening, and two restorations underwent abutment screw fracture. The number of success restorations was 297, and the number of survival restorations was 322 (Table 2).

The investigated clinical variables (restored area, number of prosthetic units, type of prosthesis, implant system, and gender) had no significant effect (P > 0.05) on survival of the alumina-toughened zirconia abutments. Furthermore, statistical comparison among the survival curves demonstrated no significant difference (P > 0.05) for the cumulative five-year survival rates of zirconia abutments in single, splinted, and FPD restorations. The survival rates were found to be 98.3%, 99.2%, and 96.1%, respectively, for single, splinted, and FPD restorations.

Table 3 shows the results of Fisher Exact tests for the effects of the clinical variables on the success of the alumina-toughened zirconia abutments. The number of prosthodontic units and type of prosthesis had a significant association with success rate. The success rate of an alumina-toughened zirconia abutment was the lowest in single restoration. The log rank test also indicated that the single restoration significantly decreased the success rate of the abutments (P < 0.001). Kaplan-Meier survival curves showed that the cumulative five-year

success rate of alumina-toughened zirconia abutments in single restoration was 80.3%, while the success rates for splinted restoration and FPD restoration were 96.1% and 96.2%, respectively (Fig. 1). The Cox proportional hazard model showed that the number of prosthodontic units and the type of prosthesis were decisive factors for the success of the alumina-toughened zirconia abutments.

Conditional inference trees with the survival function, estimated by Kaplan-Meier curves, are shown for every subgroup of patients identified (Fig. 2). The applied tree-structured model is helpful for relating the risk of abutment failure to certain subgroups of patients. The type of prosthesis (single, splinted, or FPD restoration) and the region of the dental restoration were the most important variables for abutment survival. Subjects treated with a single crown in the posterior region appeared to have the worst prognosis (Fig. 2).

Discussion

The present study demonstrated successful use of alumina-toughened zirconia implant abutments for single and multiple restorations with high survival rates (more than 95%) during the follow-up period. The promising clinical use of zirconia implant abutments for the support of single crowns was shown in a previous study, where two-thirds of the restorations replaced incisors and canines, and the remaining one-third of the restorations replaced premolars. However, there were no molar restorations in this study (Glauser et al. 2004). The present study, in contrast, evaluated the outcome of alumina-toughened zirconia abutments when they were used in the posterior (molar) area as well as the anterior area. The results indicated that the abutments can be successfully employed in both regions. These clinically important results are supported by additional studies that evaluated zirconia frameworks in high-loaded areas and also showed promising outcomes (Molin & Karlsson 2008, Raigrodski et al. 2006, Sailer et al. 2007). Similarly, a meta-analysis found that the cumulative five-year survival rate was 99.1% for single ceramic abutments, and that the cumulative five-year rate with no complications was about 93% for both anterior and posterior restorations (Jung et al. 2008).

Evaluation of the success rate in the current study, however, demonstrated that care must be taken in the use of an alumina-toughened zirconia abutment for a single molar restoration. Screw loosening appeared to be the major complication for an implant-supported single crown. Screw loosening was found in 7.0% of the restorations (23 restorations) during the follow-up period, while abutment fracture was found in only 1.8% of the restorations (6 restorations). Several studies documented clinical possibilities for incidences of screw loosening and found that loosening generally occurs when the functional loading of the restoration causes a slight rotational freedom between the implant head and the abutment (Jemt & Lekholm 1993, Jemt & Pettersson 1993, Johansson & Ekfeldt 2003). The results of the current study indicated that screw loosening occurred primarily in the posterior region, reflecting the high functional loading in this region. Moreover, a previous study reported that abutment screw loosening was the most frequent technical complication with single crown restorations, occurring at an estimated cumulative incidence of 5.1% (95% confidence interval: 3.3–7.7%) after five years (Jung et al. 2008). This finding is in line with the results of the present investigation. In contrast, neither abutment screw loosening nor abutment screw fracture occurred during one to three-year follow-up periods in two additional recent studies (Nothdurft & Pospiech 2010, Zembic et al. 2009). Further investigation is required to compare the interface and screw mechanics of zirconia abutments with titanium implants, although the high strength and durability of zirconia and alumina-toughened zirconia compensate at least in part for their brittleness.

Another critical factor for successful implant restoration is the quality of the attachment that forms between the mucosa and the abutment surface (Abrahamsson et al. 1998). The zirconia abutment has more favourable effects on the peri-implant soft tissue than does the titanium abutment. Our previous one-year clinical report on the biological stability of aluminatoughened zirconia abutments also demonstrated that the hard and soft tissue responses around the abutments were stable (Bae et al. 2008). Moreover, no remarkable inflammatory or otherwise disadvantageous tissue responses were observed around the alumina-toughened zirconia abutments, although no systematic quantitative evaluation was performed. Such a positive influence on the peri-implant soft tissue supports the clinical application of aluminatoughened zirconia abutments for both anterior and posterior implant-supported restorations. Minor gingival recessions were observed, especially at the buccal gingival areas; however, no significant bone loss was observed in the periapical radiographs.

The present study showed the superior success and survival rates of alumina-toughened zirconia abutments in splinted and FPD restorations with only a few incidences of screw loosening, screw fracture, and abutment fracture. The results were similar to those of previous studies that evaluated metal abutments (Jemt & Lekholm 1993, Johansson & Ekfeldt 2003). Multiple connected restorations appeared to be protected from complications by 'tripodization', even in the high functional loading areas (e.g., molar regions) (Jemt & Lekholm 1993, Jemt et al. 1992). The results of the current investigation also indicate that alumina-toughened zirconia abutments can be adequately used for splinted and FPD restorations regardless of the restored area.

In terms of the type of prosthesis, this study found that a single crown was highly susceptible to technical complications (i.e., screw loosening) compared with the other fixed-type restorations. Two-stage, external hexagon systems were previously reported to cause complications concerning the implant–abutment connection complex (Goodacre, et al. 1999). In particular, a higher incidence of screw loosening and screw fracture was described to be associated with this type of implant–abutment connection (Walton & MacEntee 1997). Importantly, all of the investigated implant systems in the current study had external hexagon connections. Single-tooth applications with the external hexagon screw connection are exposed to more rigorous loading, providing an explanation for the frequent screw loosening observed for single implant-supported restorations (Rangert et al. 1997). However, no complications were reported for single zirconia abutments in the canine and posterior regions during the follow-up period of three years for two-stage, external hexagon systems in another study (Zembic et al. 2009). Further studies will be required to clarify the survival rates and complications associated with implant–abutment connection systems, including internally connected complexes.

In conclusion, prefabricated alumina-toughened zirconia abutments exhibit an excellent clinical profile for the long-term survival of fixed restorations. These abutments appear to offer sufficient stability to support implant restorations at both anterior and posterior areas. However, considering the complications, including screw loosening and screw fracture as well as the abutment fracture, single tooth replacement with a zirconia abutment at the molar region may require special care and attention.

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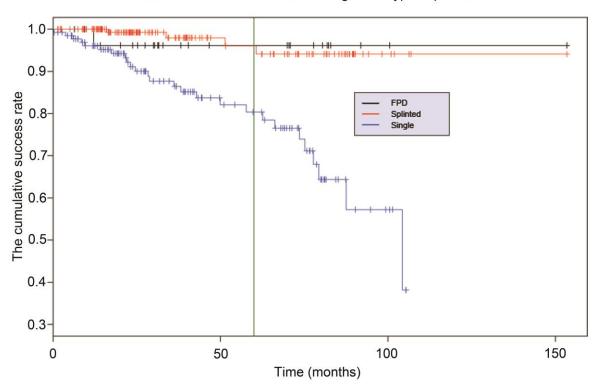
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Zirconia abutment success according to the type of prosthesis

Fig. 1. Survival curves were tested for statistical difference (P < 0.001). For splinted and FPD restorations, the median survival time is undefined since less than half of the subjects have experienced the event. On the other hand, the median survival time for the single crown cases were 104.3 months. The green vertical line represents 60 months (5 years).

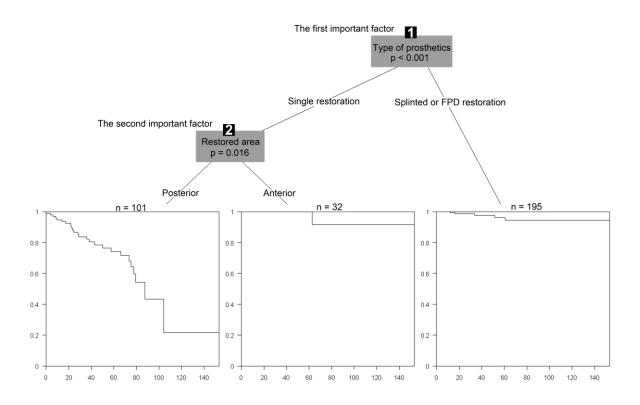


Fig. 2. Conditional inference tree with the survival function. The prosthesis type (single crown vs. multiple fixed restoration) was the most important variable. Subjects treated with single crown in posterior region showed the worst prognosis whereas multiple (splinted or FPD) restorations indicates a good prognosis.

Variables		Number of restorations
Restored area		
	Anterior	60
	Posterior	268
Number of prosthetic units		
	One unit	133
	Two units or over	195
Type of prosthesis		
	Single	133
	Splinted restoration	165
	Fixed partial denture	30
Implant system		
	Osseotite*	15
	USII [†]	42
	TiUnite Mk III [‡]	179
	Hexplant [§]	39
	Restore	53
Gender		
	Female	165
	Male	163

Table 1. The clinical variables investigated in this study

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[§] Warantec, Seoul, Korea

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Coded events	Number of restorations 274		
Censored			
Lost to follow up	18		
Patient's death	2		
Traumatic injury	1		
Implant fixture fracture	1		
Implant fixture disintegration	1		
Abutment screw loosening	23		
Abutment screw fracture	2		
Fracture of the zirconia abutment (failure)	6		
Total	328		
Success*	297		
$Survival^{\dagger}$	322		

Table 2. Demographic data and sample characteristics in this study

* Success = Total – (Abutment screw loosening + Abutment screw fracture + Fracture of the zirconia abutment)

 † Survival = Total – Fracture of the zirconia abutment

	Abutment screw loosening and Success fracture		Failure		Exact test		
Variable	N (%)	N (%)	N (%)	Total	significance	Odds ratio (95% CI)	
Restored area					0.088		
Anterior	58	1	1	60		1	
Posterior	239	24	5	268		3.51	(0.85, 31.21)
Number of					$< 0.001^{\ddagger}$		
prosthetic units							
One unit	107	22	4	133		1	
Over two units	190	3	2	195		0.11	(0.03, 0.30)
Type of prosthesis*					$< 0.001^{\ddagger}$		
Single	107	22	4	133		7.00	(1.05, 298.34)
Splinted	161	3	1	165		0.72	(0.07, 36.69)
FPD	29	0	1	30		1	
Implant system [†]					0.418		
USII	40	2	0	42		0.33	(0.02, 5.01)
TiUnite Mk III	164	12	3	179		0.60	(0.12, 5.94)
Hexplant	33	3	3	39		1.18	(0.18, 13.41)
Restore	47	6	0	53		0.83	(0.13, 9.38)
Osseotite	13	2	0	15		1	
Gender					0.130		
Female	145	16	4	165		1	
Male	152	9	2	163		0.53	(0.22, 1.2)

Table 3. Success rate, exact test significance, and odds ratio statistics for zirconia implant abutments by clinical variables

* The odds ratios were calculated between FPD and one of the other two variables.

[†] The odds ratios were calculated between Osseotite and one of the other four variables.

[‡] Two-sided exact test significance at P < 0.05.