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The differences between three performance measures on dental restorations, clinical success, survival and failure: A matter of perspective

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ABSTRACT

Objectives. The aim of this retrospective methodology study was to investigate the influence of using different definitions for restoration failure and inclusion criteria on restoration longevity expressed in AFR.

Methods. EPF from fifteen general dental practices were used for collecting the data for this study. From the EPF, 321,749 composite restorations placed in 52,245 patients by forty-seven GDPs between January 2000 and December 2011 were included. Kaplan–Meier statistics were applied and mean AFRs over 2, 5 and 10 years were calculated. The effect on the AFR of using different levels of failure: based on Claims data (CD), Success (SUC), Survival (SUR) and different inclusion criteria of tooth/restoration variables were reported.

Results. Highest AFRs were found for level CD, in which every intervention was considered as failure, and the lowest AFRs for level SUR in which repairs and an endodontic treatments were not considered as a failure. AFRs increased when the observation period prolonged especially for SUR, followed by SUC and CD. An overview of long-term survival studies showed a wide variation in study design, performed clinical examination (USPHS criteria or GDP), number of restorations included, description of restoration failure and found AFRs for CD, SUC and SUR.

Significance. Using failure criteria, Success and Survival, in future clinical studies would enable a better comparison of studies as well as demonstrate the impact of more conservative restorative intervention protocols on patient care.

1. Introduction

Many clinical studies have been published on the performance of dental restorations in which longevity is established and considered as an indicator for the quality of care delivered. For appropriate survival analysis of a population of restorations, it is necessary that for every restoration the date of placement is available. Moreover, as an endpoint of restoration survival, it is either needed to have the date of failure, or the end of the observation period (for not failed restorations). As an outcome measure, preferably annual failure rate (AFR) is used, as it can be calculated for all observation times. Whereas the alternative, median survival, can only be calculated after at least 50% of the restorations are failed [1].

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However, the definition of restoration failure may vary, depending on the perspectives and interests of different stakeholders involved in patient care. A patient will probably consider a restoration as failed when function and aesthetic appearance is not acceptable anymore, resulting in a visit to the dentist asking for an intervention. For the dentist aesthetic problems may not always count as failures, since they do not compromise the health of the tooth. However, the dentist may also consider as failures smaller defects, which the patient did not notice, when they may pose a risk for a more catastrophic failure, such as secondary caries in restorations with marginal gaps. Financial considerations may reduce the patient's tendency, but increase the dentist's tendency to indicate failures. A dental researcher performing a clinical trial on a newly developed material will be interested to distinguish small details between materials within a short observation period. From the point of view of institutions involved in the financing of dental health care, such as government and insurers, a failure may be defined as the moment a similar or increasingly complicated treatment in the same tooth has to be paid for. These differences have a profound effect on the reported outcomes of different types of restoration performance studies.

Studies aiming to evaluate clinical performance of new materials and techniques, are often performed under controlled circumstances within university clinics and using detailed criteria [2]. When examined by independent observers these restorations can be considered as failed, based on criteria such as 'discoloration of margins' or 'exposed dentin surface'. However, these restorations are still functioning well for the patient and may do so for several years to come. Studies evaluating restorations placed by general practitioners, often consider a new (restorative) intervention as failure of the previous restoration [3–5] which is biased by the clinical judgement of either the same dentist who placed the restoration, or a new operator and will vary among dentists [6,7]. For studies based on insurance data, a new intervention on the same tooth will be the definition for failure [8,9]. However, a new restoration, is not necessarily related to the previously placed one. It is unknown to what extent these differences in 'endpoints' for a longevity analysis influence outcome.

Currently repair instead of replacement is considered a preferable treatment option for a defective restoration [10]. Repair has been shown to be able to increase restoration survival [11,12], when the repair restorative intervention is not considered as a failure in the analysis. The same is the case for endodontic treatment which from one perspective can either be considered as a failure related to the restoration or not. Anusavice described this conflicting phenomenon for indirect restorations, where especially different terminology of chipping and performed endodontic treatments complicated the classification of success and failure of crown and bridge restorations [13]. He recommended, for indirect restorations, to define success (no intervention on the placed restoration), survival (restoration still in place and functioning, but repaired, recemented or endodontically treated) and failure (restoration replaced or tooth extracted). For direct restorations these criteria for success, survival and failure are not commonly used, which complicates comparison of survival rates for direct and indirect restorations.

In countries with dental service that is covered by insurance reimbursement, large datasets of claims data from dentists may be available and can be used for longevity calculations [14,9]. Furthermore, Electronic Patient Files (EPFs) are implemented in many countries in general dental practices, and big data on restoration properties, patient related variables and dates of placement, replacement and censoring, can be collected and analysed [5,3,15]. To improve quality of survival studies and to be able to compare outcomes of longevity studies, it is important to understand what the influence of different definitions of restoration failure on the calculated longevity is. The aim of the present study was to investigate the influence of using different endpoint definitions and inclusion criteria in restoration longevity analysis, on the outcome expressed in Annual Failure Rate (AFR).

2. Materials and methods

2.1. *Inclusion and data collection*

An earlier described database was mainly used [15] with data on direct composite restorations, placed between January 2000 and December 2011 in permanent teeth. The data were digitally extracted from the EPF, transformed into an Excel data file and sent to the research group using an application designed by Exquise®, Kwadijk, NL. Data were anonymous and coded, only the practitioners held the code list for their own patients. Practitioners with less than 500 restorations and restorations with missing data on restorative material, were excluded. Design and protocol were approved by the local ethics committee, METC (CMO Arnhem-Nijmegen file nr. 2013/483).

2.2. *Outcome parameters and independent variables*

Date of restoration placement, date of last check-up visit of the patient and date and type of re-intervention were recorded. When no intervention on a restoration was performed, the restoration was considered successful and censored at the last check up date. Different levels of failure were defined:

Level Claims Data (CD). This level was defined as follows:

- Each restorative intervention on the same tooth is considered as failure, with the exception of intervention on t = 0.

Level Success (SUC). According to Anusavice [13] success is defined as a restoration on which no intervention has taken place. This level was defined as follows:

- A restoration placed in the same tooth including *one or more* surfaces of the previous restoration was considered as a failure.
- Extraction or endodontic treatment were considered as failure.

Level Survival (SUR). According to Anusavice [13] survival is defined as a restoration that is still functioning and (partially) in place. This level was defined as follows:

Table 1 – AFR_2, AFR_5 and AFR_{10} by 3 different levels of failure and inclusion of different tooth/restoration related variables.

Included variables	N (%)	Failure criteria[a]	AFR (%) 2 years	AFR (%) 5 years	AFR (%) 10 years
All restorations	321,749 (100)	CD	4.9	5.1	5.4
		SUC	4.2	4.7	5.0
		SUR	2.4	3.1	3.6
Anterior restorations	100,224 (31.1)	CD	4.9	5.1	5.2
		SUC	4.2	4.8	5.1
		SUR	3.1	3.7	4.0
Posterior restorations	221,525 (689)	CD	5.0	5.1	5.4
		SUC	4.1	4.6	5.0
		SUR	2.1	2.8	3.4
1 surface restorations	135,000 (42.0)	CD	4.5	4.8	4.9
		SUC	4.0	4.6	4.8
		SUR	3.4	4.2	4.5
≥2 surface restorations	186,749 (58.0)	CD	5.3	5.4	5.7
		SUC	4.3	4.7	5.2
		SUR	1.7	2.3	2.9
Posterior & ≥2-surface restorations (Class II)	155,056 (48.2)	CD	5.2	5.3	5.6
		SUC	4.1	4.5	5.0
		SUR	1.5	2.2	2.9
Anterior & ≥2-surface restorations (Class III & IV)	31,693 (9.9)	CD	5.9	5.9	6.0
		SUC	5.1	5.5	5.9
		SUR	2.3	2.7	3.0

[a] CD = Based on claims data, SUR = based on survival, SUC = based on success [13].

- Only restorations placed in the same tooth including *all* surfaces of the previous restoration were considered as a failure. As a result, repairs on restorations are not considered as a failure.
- Extraction was considered as failure.
- Endodontic treatment was considered as censoring.

On tooth/restoration level, tooth number (FDI system, Fédération Dentaire Internationale) and number of restored surfaces were recorded. Based on the tooth number, teeth were divided into anterior (incisors and canines) and posterior teeth (premolars and molars).

For the SUR and SUC analyses, data sets were refined based on the following criteria:

- To exclude temporary restorations, restorative interventions in the first month were ignored and the observation was censored.
- When a MO restoration was placed as the first restoration and the intervention treatment was a DO restoration, analysis for the initial restoration was censored as many MO and DO restorations in posterior teeth are likely independent (box type) restorations. Also for MBP and DBP class III/IV restorations in anterior teeth, this exception was made.
- When a crown was placed within 1,5 year after initial direct restoration, this restoration likely served as base for a crown placement and was censored. Crown placement after more than 1,5 year service time of a direct restoration was considered as failure.

2.3. *Statistical analysis*

Statistical analyses were performed with SPSS 25. Longevity of restorations was explored with survival tables and Kaplan Meier graphs. Out of the survival tables, mean Annual Failure Rates over 2, 5 and 10 years (AFR_z) were calculated according to the formula: $AFR_z\ (\%) = 1 - \sqrt[z]{x} * 100$, in which 'x' level of survival and 'z' the years of observation. The effect on the AFR of using different levels of failure and different inclusion criteria of tooth/restoration variables (anterior/posterior restorations and 1 surface /≥2 surface restorations) were calculated.

3. Results

Restorations placed by 47 GDPs working in 15 practices were included in the dataset. Before analysis, restorations were excluded due to missing data on restorative material or treated surfaces (n = 14.313) or being placed by practitioners contributing with less than 500 restorations (n = 1.542). 321,749 direct composite restorations were included in the final dataset placed in 52,245 patients (25,171 male; 27,074 female; age 5–94 years; mean age 37 years). The mean number of included restorations per patient was 6.2 (95%CI, 5.3–7.0). The observation period varied between 0 and 12 years (mean observation time 3.7 years). Most restorations were placed in the posterior region and included ≥2 surfaces. The annual failure rates (AFRs) after 2, 5 and 10 years for the different levels of failure and inclusion criteria, are shown in Table 1.

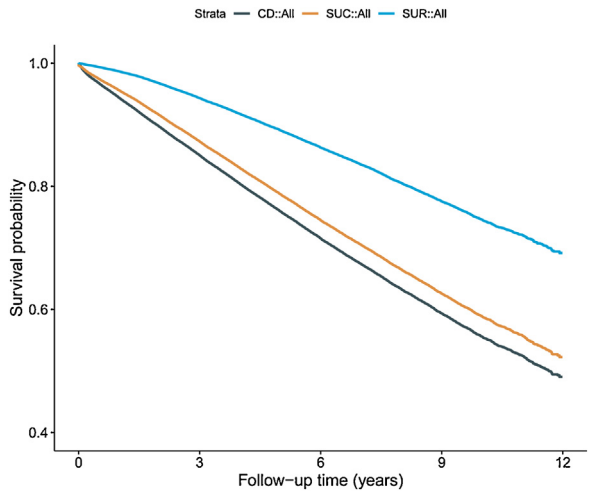

Fig. 1 – Survival graph of restorations for the levels CD, SUC and SUR.

3.1. *Influence of level of failure and excluding tooth/restoration related variables*

Overall, the highest AFRs were found for level CD (Failure based on Claims Data) and the lowest AFRs for level SUR (Survival) in which repairs and an endodontic treatment were not considered as a failure. This result is illustrated in the survival graph in Fig. 1, showing the overall restoration survival for the three different levels of failure. AFRs increased when the observation period was longer especially for SUR, followed by SUC and CD. Comparing posterior and anterior restorations, the AFR for CD was higher for posterior teeth than for anterior teeth, while the AFR for SUC and SUR was lower for posterior teeth. For one surface restorations, differences between CD, SUC and SUR are smaller than for larger restorations (at least two surfaces). AFRs of CD and SUC for one surface restorations were lower than the AFRs of CD and SUC for larger restorations. However, the AFRs of SUR were lower for larger restorations compared to one surface restorations. For class II composite restorations, the 10–year AFRs were 5.6% when based on claims data, 5.0% when based on success and 2.9% when based on survival. For class III & IV composite restorations the 10–year AFRs were higher for all levels of failure, 6.0% when based on claims data, 5.9% when based on success and 3.0% when based on survival.

3.2. *Comparison outcomes of longevity studies*

In order to put findings in perspective a description of studies, published in the last 10 years, evaluating longevity of composite restorations with a minimum mean follow up of 3 years and at least 100 included restorations, is shown in Table 2. This table shows variation in study design, performed clinical examination, number of restorations included, description of restoration failure and AFRs for CD, SUC and SUR. Overall, highest AFRs are found for studies based on claims data. AFRs defined on SUC are higher compared to AFRs defined on SUR.

4. Discussion

The present study was performed to investigate the influence of using different criteria and including or excluding restorations in a dataset for restoration survival. For this purpose we used a big dataset retrieved from EPFs of several dental practices limited on direct composite resin restorations. As far as we are aware, this is the first methodological study on the comparison of different definitions of failure and inclusion/exclusion criteria for direct composite restorations expressed in AFR. Results from our analysis and the comparison with the results of previous long-term survival studies, shown in Table 2, will be further discussed.

As expected, the highest AFRs were found when any new restorative intervention on a specific tooth is considered as a failure of the previous restoration, as occurs when claims data are used (CD). Previous studies that used claims data where those from Burke and Lucarotti [9,16], based on English NHS insurance data, and Raedel et al. [14,8] based on data from a big German insurance company (Table 2). These studies show higher failure rates varying from 5.0 to 13.6% as compared to studies based on SUC (AFRs varying from 0.9 to 4.7%) or SUR (varying from 0.1 to 3.2%AFR) outcome. The high failure rates in CD studies may be explained from the results of the present study as many relevant inclusion and exclusion criteria that were used to modify the CD dataset into the SUC and SUR dataset were not employed, such as allowing for two independent restorations in the same tooth. Looking at all restorations in the present study, AFRs after 2 years increased from 4.2% (SUC) to 4.9% (CD) which is an increase of 17%. However, for longer observation times this difference decreased, which may be related to short term new claim on restored teeth not being clinical failures but planned treatments, e.g., consecutive treatments in a specific treatment plan. Based on our findings, we would conclude that survival data based on claims data may provide an overestimation of the actual failure rate of restorations, especially when this data is based on a short observation period.

A limitation of our study is that we cannot investigate the influence of dentists claim behaviour, and indirect the Dutch reimbursement system, on the results. As an example, a full composite build up of an anterior tooth can be claimed as two 2-surface restorations or as one 4-surface restoration. For other countries with other claims systems, this may result in different characteristics resulting in other differences between claims data CD and actual SUR and SUC data. Therefore, longevity data based on CD should be interpreted with much care.

Especially for direct restorations it may happen that in clinical research, restorations showing deficiencies are considered failed, nevertheless some of these restorations are further monitored without repair or replacement. For indirect restorations the difference between interventions leading to restoration or tooth loss and minor interventions resulting in a further clinical service of the restoration, is already more common in survival studies following the recommendations by Anusavice [13]. In our present study, we demonstrated that when an intervention resulted in survival (SUR) and not in failure (SUC), annual failure rates decreased considerably. For

Table 2 – Descriptive analysis on studies evaluating longevity of posterior composite restorations for at least 3 year follow up and ≥100 restorations included.

Author	Year publication (country)	Study design	Clinical evaluation	Anterior, Posterior or all included	N restorations	AFR_x (%) success (over x years)	AFR_x (%) survival (over x years)	Repair failure success/ survival (Y/N)	Endodontic treatment failure success/ survival (Y/N)	Prosthodontic treatment failure success/ survival (Y/N)	Extraction-failure success/ survival (Y/N)
Present study	*2018 (NL)*	*RS*	*Dentist*	*All*	*254,896/103,437*	$5.0_{10}/5,1_{10}$	$3.4_{10}/4.0_{10}$	*Y/N*	*Y/N*	Y[b]/Y[b]	Y/Y
Reported AFR based on CD											
Lucarotti and Burke [9][a]	2018 (UK)	RS	Dentist	All	3,504225	10.0_5 8.1_{10} $6,9_{15}$	1.3_{10}	Y	Y	Y	Y
Raedel et al. [14]	2017 (GER)	RS	Dentist	Posterior	18,406,756	$5,0_4$ /$6,3_4$[d]	$1,4_4/1,1_4$[d]	Y	N	N	N
Raedel et al. [8]	2017 (GER)	RS	Dentist	All	17,024,344	$9,4_4$ – $13,6_4$[e]	$7,0_4/11,6_4$[e]	Y[h]	N[h]	Y[h]	Y[h]
Reported AFR based on SUC											
Bernardo et al. [31]	2007 (POR)	RCT	Dentist	Posterior	892	$2,2_7$	Na	Y	N	N	N
Collares et al. [32][b]	2017 (NL)	RS	Dentist	Anterior	72,196	$4,7_{10}$	Na	Y	Y	Y	Y
Kubo et al. [33]	2011 (JAP)	RS	USPHS[mod]	All	503	1.9_{10}	Na	Y	Y	N	Y
Laske et al. [3][b]	2016 (NL)	RS	Dentist	All	70,869	4.4_{10}	Na	Y	Y	Y	Y
Laske et al. [7][b]	2016 (NL)	RS	Dentist	Posterior	188,683	4.6_{10}	Na	Y	Y	Y	Y
Lindberg et al. [34]	2007 (SWE)	PS	USPHS[mod]	Posterior	135	1.1_9	Na	Y	Y	N	N
Mahmoud et al. [29]	2014 (EGY)	RCT	USPHS[mod]	Posterior	156	1.5_3	Na	Y	Y	N	N
Mahmoud et al. [30]	2014 (EGY)	RCT	USPHS[mod]	Posterior	160	0.9_3	Na	Y	Y	N	N
Opdam et al. [36]	2007 (NL)	RS	Dentist	Posterior	1,955	1.7_5 1.9_{10}	Na	Y	Y	N	Y
Opdam et al. [35]	2007 (NL)	RS	Dentist	Posterior	376	1.4_9	Na	Y	Y	N	Y
Opdam et al. [4]	2010 (NL)	RS	Dentist	Posterior	747	1.4_{12}	Na	Y	N	N	Y
Palotie et al. [37]	2017 (FIN)	RS	Dentist	Posterior	5,169	4.2_{13}	Na	Y	Y	Y	Y
Suni et al. [38]	2013 (FIN)	RS	Dentist[g]	All	36,537	$4,3_{10}$	Na	Y	?	?	N?
van de Sande et al. [39][a]	2013 (BRA)	RS	FDI	Posterior	306	3.2_5, 2.9_{11} 2.3_{15}	Na	Y	Y	N	N
van Dijken and Pallesen [23]	2014 (SWE)	RCT	USPHS[mod]	Posterior	114	$2,1_{10}$	Na	Y	N	N	N
van Dijken and Pallesen [25]	2015 (SWE)	RCT	USPHS[mod]	Posterior	153	$1,7_8$	Na	Y	N	N	N

van Dijken and Pallesen [26]	2015 (SWE)	RCT	USPHS^{mod}	Posterior	196	$1{,}2_{3}$	Na	Y	N	N	N
van Dijken and Pallesen [27]	2016 (SWE)	RCT	USPHS^{mod}	Posterior	183	$1{,}1_{5}$	Na	Y	N	N	N
van Dijken and Pallesen [28]	2017 (SWE)	RCT	USPHS^{mod}	Posterior	134	$2{,}8_{6}$	Na	Y[h]	N[h]	N[h]	N[h]
Reported AFR based on SUC and SUR											
Baldissera et al. [40]	2013 (BRA)	RS	FDI	All	374/219	$0{,}8_{17}/0{,}7_{17}$	$0{,}1_{17}$[f]	Y/N	Y/Y	N/N	Y/N
Casagrande et al. [12]	2017 (NL)	RS	Dentist	Posterior	59,722	$4{,}1_{10}$	$2{,}9_{10}$	Y/N	Y/Y	Y/Y	Y/Y
Da Rosa Rodolpho et al. [41]	2011 (BRA)	RS	FDI	Posterior	362	1.8_{22}	0.8_{22}	Y/N	Y/N	N/N	Y/Y
Fennis et al. [42][g]	2014 (NL)	PS	Dentist	Posterior	158	3.1_{5}	2.5_{5}	Y/N	Y/Y	Y/Y	Y/Y
Kopperud et al. [43]	2012 (NOR)	PS	Dentist	Posterior	3,276	3.0_{4}	2.4_{4}[i]	Y/N	N/N	N/N	N/N
Pallesen et al. [44]	2013 (DK)	PS	Dentist	Posterior	4,355	2.1_{8}	1.2_{8}[i]	Y/N	N/N	N/N	N/N
Rho et al. [18]	2013(KOR)	RS	USPHS	Posterior	138	$4{,}3_{12{,}5}$	$1{,}7_{12{,}5}$[j]	Y/N	Y/Y	Y/Y	Y/Y
Soncini et al. [45]	2007 (USA)	RCT	Dentist	Posterior	753	$3{,}8_{5}$	$3{,}2_{5}$	Y/N	N/N	N/N	N/N
Wierichs et al. [5][c]	2018 (GER)	PS	Dentist	All	192	1.4_{10}	0.6_{10}	Y/N	Y/N	Y/N	Y/Y

[a] AFRs over different years applicable, not all mentioned here.
[b] When a crown was placed within 1,5 year after initial direct restoration, this restoration likely served as base for a crown placement and was censored. Crown placement after 1,5 year was considered as failure.
[c] Only endodontically treated incisors, canines and premolars were included.
[d] AFR_4 for interproximal / occlusal surfaces.
[e] Range of AFR_4 for different restoration sizes (up to ≥4 surfaces included.
[f] Only overall results concerning repair/replacement present.
[g] Indirect and direct composite restorations included.
[h] Only failure based on claims data reported.
[i] Described as acceptable restoration, defined as ẗminor effects, without need for repair of replacement.̈
[j] AFR survival considering not replaced restorations, but scored with Charlie, as no failure.

all restorations AFRs for 2 and 10 years dropped by 51% and 33%, while for class II restorations this was 71% and 48%, respectively. This effect was greater for larger restorations than for small restorations, which is logical, as for 1-surface restorations only endodontic interventions determine the difference between SUR and SUC as 1-surface restorations could not be identified as repaired from the EPF data. Due to this large difference, we recommend that for both indirect and direct restorations definitions for different level of failures are described (Success and Survival) and reported in all types of clinical trials in order to enable comparison of study results. The fact that repair is considered nowadays as a state-of-art minimally invasive intervention, justifies the separate analysis of these types of treatment.

A further limitation of the study is that we cannot show the differences between failure based on either dentists' judgements or defined criteria (USPHS and FDI) [2,17]. A previous study of Rho et al. [18] has investigated this aspect and showed that a number of clinically functioning restorations, when evaluated according to these criteria were considered as failed and accordingly, AFRs more than doubled from 1.7 to 4.3%. From the oral health care perspective, we would recommend that only restorations that actually received an intervention should be considered as unsuccessful. Especially the Charlie criteria according to USPHS and FDI definitions include items regarding discolorations, dentin exposure at the outline, absence of proximal contact that do not in all cases imply that a restoration is not functioning satisfactorily. Such defects often do not justify a restorative intervention and doing so would lead to overtreatment. For controlled trials evaluating a new restorative material AFRs on actually repaired or replaced restorations would then be reported in the survival analysis, while the USPHS or FDI criteria still can be very useful to identify differences between materials on a more detailed level, such as they have been used in specific trials for material comparison like the studies of van Dijken et al. [19–28] and Mahmoud et al. [29,30]. However, the reported AFRs in these studies are lower and hard to compare with studies based on data from private practice because these studies are often performed in a selected patient group. The studies from Table 2 that used different criteria for survival and success showed the same reduction in AFR as the present study.

The present study showed that Claims Data when employed for survival analysis of restorations, most likely result in an overestimation of failed restorations. Secondly, distinguishing Success and Survival for direct restorations and including different restorations related variables lead to significantly different failure rates. Using failure criteria, Success and Survival, in future clinical studies would enable a better comparison of studies as well as demonstrate the impact of more conservative restorative intervention protocols on patient care.

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