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The Normalized Failure Index: A Method for Summarizing the Results of Studies on Restoration Longevity?

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Clinical Relevance

A reliable means of combining the results from a number of clinical studies on longevity of restorations could be helpful to clinicians when they are planning treatment.

SUMMARY

Satisfactory restoration longevity is central to operative dentistry and is the subject of a wide variety of publications. However, combining the results of a number of studies to provide an overview, for example, for a meta-analysis may be problematic because of the heterogeneity of the data, and a high proportion of studies may therefore not be included. It is the purpose of this study to present a means whereby the data from cohort studies may be combined to present a representation of restoration longevity, termed the "Normalized Failure Index."

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INTRODUCTION

Clinicians are beholden to provide safe and effective restorations with optimal longevity, even more today than in the past, given that patients are living longer and retaining more of their natural teeth. Dental restorations, however, have a limited clinical durability,[1] with the replacement of failed restorations accounting for >60% of all operative dental procedures.[2] When restorations need replacement, tooth structure is lost, with the patient entering into an accelerating repetitive restorative cycle involving larger restorations, weakening of remaining tooth tissues and structures, and more complex treatments. The ability to predict longevity of restorations of different materials and types is therefore central to longitudinal patient care, let alone patient understanding of treatment provision. To date, however, there is no generally accepted simple but meaningful means of aggregating data on restora-

tion longevity. It is the aim of this paper to propose a means whereby this goal may be achieved.

Materials for Direct Load-Bearing Restorations

The clinical decision as to which restorative material to select for specific applications is complex, involving many factors, including the type and status of the tooth, the patient, the clinician, and the properties of the materials. Different restorative materials perform best in different clinical circumstances, and it is not generally possible to simply substitute one material for another and expect optimum long-term success.

Materials available for use in the provision of direct restorations include dental amalgam, resin composites, compomers, and glass-ionomers. Of these, amalgam and resin composites are most commonly selected for restorations in load-bearing situations in posterior teeth in the UK[3] and elsewhere in the world, but the use of amalgam is diminishing internationally.[4] Nevertheless, amalgam continues to be considered by some to offer a number of advantages over other restorative materials in the restoration of posterior teeth. These advantages are considered to include low cost (albeit that the cost of restorative material is a very small proportion of the cost of the provision of a restoration), ease of use for those familiar with handling dental amalgam, apparent success when used in less-than-ideal circumstances (eg, in the presence of poor moisture control), and its apparent relative insensitivity to the consequences of variation in operative technique. The disadvantages of using amalgam as a restorative material include the requirement for preparation of the tooth being restored, including the sacrifice of sound tooth tissue, in order to create a retentive cavity form unless an amalgam bonding technique is utilized; its poor esthetics (this being of relevance in the current climate of increasing patient demand for good esthetics of both posterior and anterior teeth); and concerns of some patients, let alone environmental issues, regarding the use of a mercury-containing material.

In contrast, the use of resin composites in the restoration of posterior teeth facilitates the application of minimally invasive techniques, provides the opportunity to use adhesive technologies to protect and preserve remaining tooth tissues, and results in tooth-colored restorations, with the capacity to meet the ever-increasing esthetic expectations of patients. However, for those who tend to achieve less-than-satisfactory outcomes in the application of resin composites or who work under circumstances that encourage the placement of low-budget invasive restorations (eg, some third-party fee-per-item remuneration arrangements), the use of composite resins can be considered to be technique sensitive and thereby challenging, especially given that satisfactory clinical outcomes take longer to achieve with esthetically pleasing composite resins.[5]

Methods of Clinical Evaluation

Studies on restoration longevity may be prospective or retrospective. Regarding prospective studies, randomized controlled trials (RCTs) are considered to be the gold standard but tend to investigate the potential and patterns of deterioration of restorative materials in clinical service in selected patients rather than efficacy. Meta-analysis is a statistical technique whereby the data from two or more RCTs are combined, most frequently to provide an overview of clinical attributes of specific interventions. Systematic review methodology is central to meta-analyses so that all relevant studies are included. Meta-analysis has been defined as a technique that combines results from several independent clinical trials that are considered by the analyst to be "combinable."[6] It has been considered, however, that pitfalls abound in the execution of meta-analyses, the value of which are determined by the number and quality of the underlying studies.[7] Notwithstanding the variability of RCT methodologies in assessments of restorative materials, the results of such studies tend to be at variance with the findings of restoration outcomes studies in primary care settings, notably in respect of failure rates[8]—the highly controlled arrangements necessary for a robust RCT being different to the more pragmatic arrangements necessary to successfully complete studies in the demanding primary care setting. As a result, very few clinically relevant RCTs are reported on the longevity of restorations in clinical practice, and, as a result, meta-analyses on the clinical longevity of restorative materials are sparse and of dubious relevance to the general provision of care by practitioners.

An alternative means of investigating the performance of restorative materials in clinical service is the longitudinal cohort study. Such studies investigate the performance of dental restorations in a cohort of patients over a period of time. These studies lack the randomization and, more often than not, the restrictive control element of RCTs. These studies, however, provide useful data, but, as with

RCTs, there tends to be lack of standardization of investigative methodology between studies, resulting in lack of direct comparability. In contrast to RCTs of restorative materials, longitudinal cohort studies in operative dentistry, which tend to have greater clinical relevance, let alone being less costly to run than RCTs, offer the means to develop a much-needed evidence-based approach to the restoration of teeth using, in particular, novel restorative materials that tend to have a commercial life expectance of three to five years.

Retrospective cross-sectional studies are also carried out in restorative dentistry.[9] Such studies are much simpler to perform than RCTs and longitudinal cohort studies, examining the performance of restorations that are failing or failed and the reasons for failure. These studies, however, have been considered to suffer important weaknesses,[10] in particular, if the results are expressed in terms of mean age of failed restorations rather than Kaplan-Meier statistics, the later being a method for analyzing incomplete survival data with individual dates of "life" and "death," developed by Kaplan and Meier in 1958 (described in Collett[11] and also in Opdam and others[10]). In this method, the lifetime of restorations that have failed, as well as those that remain in service, is taken into account. Furthermore, defining what constitutes restoration failure is a critical issue in studies of restoration longevity, in particular, when possible interventions include repair or replacement.

It is considered that reliance on data from any one type of study is incapable of giving an overall picture of the performance of a restorative material in clinical service; however, data and findings from different types of study are difficult to compare and contrast. Those looking for an overall picture of the performance of different restorative materials in clinical service are therefore left with a dilemma. Setting aside considerations of the nature of the deterioration of restorations in clinical service, it is suggested that the critical parameters are the rate and nature of failure. Regarding rate of failure, relevant data may be derived from RCTs and longitudinal cohort studies. To bring such data together to give a measure of the success of restorations of different types and materials, a novel index is proposed: the Normalized Failure Index.

The aims of the project were the following:

- To review all prospective clinical trials over the last 30 years to obtain data on the failure rate of amalgam and composite restorations in posterior teeth
- To calculate the value of the proposed Normalized Failure Index as a measure of the performance of restorations of different materials in clinical service

MATERIALS AND METHODS

Data Collection

Using Medline and Embase, a literature search was conducted to identify publications reporting controlled clinical trials of amalgam and resin composite restorations in posterior teeth. The reference lists of the retrieved publications were also searched for studies not included in the databases. Where a study was reported in a series of papers, data were taken from the paper reporting the longest-term data available only, thereby including data for all studies identified on no more than one occasion.

Inclusion Criteria

To determine which papers should be included in the review, the following criteria were used:

- Studies of at least three years duration.
- Studies containing >30 restorations at baseline.
- Studies published in English or with an English translation.
- Studies from the past 30 years.
- Studies reporting on occlusal and occlusoproximal restorations in adult (>18 years of age) patients.
- Studies including "open sandwich" technique restorations, preventive resin (sealant) restorations, and tunnel restorations were excluded.

From the selected studies, the following information was extracted: name of the first author and the year of publication of the study, the length of the study in years, the number of restorations examined at the end of the study, the number of failed restorations, and the mean annual failure rate, determined by dividing the number of failures at the end of the study by the number of restorations remaining in the study divided by the number of years of observation and expressing as a percentage.

To calculate the Normalized Failure Index, the number of restorations examined in each study was multiplied by the annual failure rate to give the failure index (Figure 1). The failure indices from all the included studies were then added together, and this figure was divided by the total number of failed restorations to give the Normalized Failure Index (Figure 2). To demonstrate the use of the Normalized

$$\frac{\text{Restorations failed}}{\text{Restorations evaluated} \times \text{No of years' duration}}$$

Figure 1. *Calculation of the failure index*

Failure Index, publications for composite and amalgam restorations that fulfilled the inclusion criteria were used.

RESULTS

The data collected in respect of amalgam and composite restorations are presented in Tables 1[12-22] and 2[12,17,18,20,23-42], respectively, together with the values obtained for the failure index. When the data for all the included studies were combined (indicated by the figures in the bottom line of Tables 1 and 2), the Normalized Failure Index for amalgam was calculated (2616 ÷ 2542) to be 1.0, with the corresponding value for composite (5988 ÷ 1979) being 3.0.

DISCUSSION

This study introduced the concept of the Normalized Failure Index and used it to examine the survival rates of amalgam and resin composite restorations placed in load-bearing situations in posterior teeth—with the data having been obtained from a review of controlled clinical studies dating back 30 years to the time that composites began to be used in load-bearing situations in posterior teeth. The papers included in the investigation were those that a group of dentists deemed "best available" studies, namely, studies of at least three years' duration and involving >30 restorations placed at the commencement of the study. Of the studies available, there were more addressing resin composites than amalgam. The composite studies, however, tended to include smaller numbers of restorations, and, overall, fewer composite restorations were included, although this was still substantial (n=1979). The reason for this difference may be considered to be multifactorial, ranging from arrangements to undertake clinical assessments of the many composite restorative systems introduced in the last 30 years to the cost differential between clinical studies of amalgams and composite systems. Furthermore, the amalgam studies tended to be older and longer given that amalgams, unlike composite systems, were not subject to such change and, as a consequence, the subject of extended investigations.

The large numbers of restorations included in the present investigation, together with the calculation of the Normalized Failure Index, may be considered to provide an overview of the performance of amalgams and composite systems in controlled clinical studies. In considering the overall Normalized Failure Index values, these indicated that composite systems, when assessed by this approach, performed less well than amalgams when used in similar, controlled situations. The results, however, do not concur with those published in 2004 in a review of the literature by Manhart and others[43] in which the mean values for failure of restorations of differing types were calculated, with the mean annual failure rate for amalgam restorations being 3.0% and 2.2% for direct composite restorations, both placed in stress-bearing situations. Such calculations, which did not take into account the numbers of restorations in each study (as the Normalized Failure Index does), indicated that resin composite restorations in posterior teeth performed better than amalgam restorations, contrary to the findings of the present work. In this respect, it is to be remembered that failure rates for occlusal and occlusoproximal restorations in controlled clinical studies tend to be much lower than in practice-based studies in which materials are applied under circumstances that prevail in the general practice setting.[8]

The results of the study by Manhart and others[43] indicated that composite systems had a higher mean annual failure rate than amalgams when overall mean values were calculated. It could be argued, however, that this simple calculation does not provide a valid perspective, as the different size of the studies (ie, the number of restorations included in each evaluation) is not taken into account. A novel approach was therefore adopted. The product of multiplying the annual failure rate by the number of restorations included for examination at the end of the study was termed the failure index. The failure index for all the papers was totaled and divided by the total number of restorations, to provide an index: the Normalized Failure Index. In this way, studies including larger numbers of restorations have a greater impact on the proposed comparative measure of success in clinical service. This approach of applying the Normalized Failure Index may be considered also to produce a more valid measure of performance than a simple mean age of failure, as used in many

$$\frac{\text{Failure Index total}}{\text{Number of failed restorations}}$$

Figure 2. *Calculation of the Normalized Failure Index*

Table 1: *Amalgam Studies*

Study: First Author's Name	Study Duration (y)	Number of Restorations Evaluated in the Study	Number of Restorations Reported as Having Failed	Mean Annual % Failure Rate	Failure Index (B) (No. of Restorations × Mean Annual Failure Rate)
Collins (1998)[12]	8	52	3	0.7	36
Doglia (1986)[13]	5	96	7	1.5	144
Johnson (1992)[14]	5	175	0	0	0
Kreulen (1998)[15]	15	1171	199	1.1	1288
Osborne (1991)[16]	14	367	47	0.9	330
Mair (1998)[17]	10	35	2	0.6	21
Mjör (1993)[18]	5	88	4	1	88
Plasmans (1998)[19]	8.	291	23	1	291
Roberts (1992)[20]	3	55	2	1.2	66
Summit (2001)[21]	5	40	9	4.5	180
Wilson (1996)[22]	5	172	9	1	172
Total		2542			2616

studies, given that the impact of different sizes of clinical investigations may be minimized through the normalization process. It could be argued that Kaplan-Meier statistics offer similar advantages. It is, however, suggested that the findings of such statistics and the Normalized Failure Index, may be viewed as complementary to give an informed overview of performance.

Table 2: *Composite Studies*

Study: First Author's Name	Study Duration (y)	Number of Restorations Evaluated in the Study	Number of Restorations Reported as Having Failed	Mean Annual % Failure Rate	Number of Restorations × Mean Annual Failure Rate (B)
Busato (2001)[23]	6	90	13	2.4	216
Collins (1998)[12]	8	161	22	1.7	274
de Rosa Rodolpho (2006)[24]	17	282	98	2	564
Ernst (2001)[25]	3	165	35	7.1	1164
Freilich (1992)[26]	3	105	1	0.3	315
Gaengler (2001)[27]	10	62	16	2.5	161
Gordan (2005)[28]	4	39	1	0.6	23
Kohler (2000)[29]	5	51	16	6.3	321
Lundin (1999)[30]	10	117	25	2.1	246
Mair (1998)[17]	10	56	4	0.7	39
Mjör (1993)[18]	5	91	9	3.3	300
Nordbo (1998)[31]	7	51	16	4.5	230
Raskin (1998)[32]	10	37	32	8.6	318
Roberts (1992)[20]	3	53	5	3.1	164
Sturdevant (1998)[33]	5	97	14	2.9	281
Turkun (2003)[34]	7	70	4	0.8	56
Turkun (2005)[35]	3	47	3	2.1	99
van Dijken (2000)[36]	11	33	9	2.5	83
van Dijken (2002)[37]	3	65	17	8.7	566
van Dijken (2003)[38]	6	82	3	0.6	49
Wassell (2000)[39]	5	65	5	1.5	98
Wendt (1994)[40]	3	35	3	29.	102
Wilder (1999)[41]	17	85	20	1.4	119
Wucher (2002)[42]	3	40	6	5	200
Total		1979			5988

In the present work, if the average of the data presented as the failure index is calculated, the result is 1.22% for amalgam, while the Normalized Failure Index is 1.03. For composite, the average of the calculated failure index is 3.07%, while the Normalized Failure Index is 3.03. There are therefore marked similarities in the outcome of the two approaches. In this respect, it is important to recognize that normalizing data is a form of averaging, but with a provision to limit the effect of "outlying" data. In the absence of outlying data in a data set, normalized values will inevitably be very similar to average values. When outlying data are present, the average value will be somewhat misleading relative to typical values, while normalized values should be more representative. This is what we are attempting to achieve with the Normalized Failure Index: an approach that may often give values very similar to average values but a more representative value than the average when there may be outlying data in the data set or the data set is heterogeneous.

One difficulty in the calculation of the Normalized Failure Index arises if one paper is included that has a much greater number of restorations than other studies. In the first draft of the present work, the paper by Martin and Bader[44] was included, as it presented the results of 3764 large amalgam restorations. These restorations were placed by a large number of dentists (n=74) who were operating under routine clinical conditions as part of an insurance scheme (Kaiser Permanente, Portland, OR), so it may be considered to represent a wealth of data from a large database with a broad spectrum of patients, and this should not be ignored. However, it differs from the other papers insofar that it used Kaplan-Meier statistical methodology, with success of the individual restorations included being defined as an absence of replacement of the restoration, whereas in the majority of the other studies included in the present work, US Public Health Service (USPHS)–type criteria were utilized. It may therefore be considered that the Normalized Failure Index should be applied only to studies in which the understanding of failure is the same. In this regard, the Normalized Failure Index brings together data from studies that are of similar type/methodology but that may incorporate internal heterogeneity (ie, heterogeneity within the specific designs of the included papers). In the Martin and Bader paper, criteria for success are fundamentally different from USPHS criteria. In this respect, an interesting development from the present study would be to carry a calculation of the Normalised Failure Index on studies using data from large third-party databases, such as the work by Martin and Bader[44] and Lucarotti et al.[1]

The authors of the present work acknowledge that long-term randomized clinical trials (RCTs) and subsequent meta-analyses are required to fully assess the value of restorative materials for posterior teeth. Such studies are, however, very resource intensive and often begin to yield meaningful results only when test materials, such as resin composite and adhesive systems, have been superseded by new generations of materials. As a consequence, there is an increasing tendency to view such studies as having limited value as an assessment of efficacy, in particular, when conducted in environments other than general practice. Furthermore, it is the opinion of the authors that it is unlikely that there will be RCTs in sufficient numbers to appropriately investigate the many varied new materials and restorative systems anticipated in future years, in particular, RCTs in the real-world setting of general dental practice, the environment in which materials find their principal application. As a consequence, the Normalized Failure Index may be considered to be a useful means to bring together data on restoration longevity from cohort studies, which are more common and in many ways more realistic and manageable in the settings in which the test materials will eventually be used. As with any index, let alone the normalizing of data, it is accepted that there are certain limitations and loss of detailed data, as included in reports of individual studies. In this regard, the Normalized Failure Index is proposed as a readily calculable new tool for summarizing the results of a number of studies that use similar methodologies. A limitation may be that values for mean failure rates, as used in the calculation of the Normalized Failure Index, do not reveal different patterns of failure, such as a number of early failures followed by a limited tendency to failure, as compared to good early performance with subsequent increasing tendency to fail (N. Opdam, personal communication). In addition, potentially substantial studies should now be commissioned to investigate its statistical validity since there is no precedent for its calculation.

An alternative method of assimilating data from a number of studies is the meta-analysis. It would be helpful to be able to compare the Normalized Failure Index with a meta-analysis for purposes of validation. The authors are not, however, aware of

such an analysis having been carried out on the longevity of amalgam compared to composite systems. In addition, meta-analyses can suffer from a shortage of homogeneous comparable data from a variety of studies, with many candidate studies having to be excluded through the application of various inclusion and exclusion criteria. As such, meta-analyses are therefore generally restricted, by the nature of the analysis and the need for homogeneity of the data, to only a small number of studies. This approach has the benefit of strict criteria but invariably leads to the exclusion of large amounts of valuable data of clinical relevance. The concept of the Normalized Failure Index is to allow inclusion of a much larger number of studies that may be more heterogeneous.

Finally, the finding, according to the Normalized Failure Index, that composite resins performed less well than dental amalgam in occlusal and occluso-proximal preparations is considered to be of particular note. With the increasing application of resin composites in minimally invasive preparations, it will be of considerable interest and importance to monitor the ways in which resin composite materials may begin to be found to realize their potential in the restoration of posterior teeth and to further modify the teaching and practice of operative dentistry accordingly.

CONCLUSION

A novel method of assimilating results from a number of studies on restoration longevity, the Normalized Failure Index, has been described. According to the Normalized Failure Index, when applied to a selection of studies conducted over the last 30 years, resin composites were found to perform less well than dental amalgam in the restoration of posterior teeth.

Conflict of Interest

The authors of this manuscript certify that they have no proprietary, financial or other personal interest of any nature or kind in any product, service and/or company that is presented in this article.

Addendum

Subsequent to this paper having been accepted for publication, new evidence has emerged on the clinical performance of posterior composites. Amongst the new information now available in the literature, the data presented in papers by Opdam et al.[45] and Pallesen et al. [46] are considered to be of particular importance, with both papers reporting favourable durability of large numbers of posterior composites over extended periods -twelve and eight years respectively, with the restorations. These studies provide new evidence from the "real world" of primary dental care of the ways in which resin composite materials are being found to realise their potential in the restoration of posterior teeth. The Normalized Failure Index, if adopted, will require frequent updating to provide a contemporaneous measure of the performance of materials such as resin composites in clinical service.

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Erratum

Figures one and two were unclear in, FJT Burke, V Singh, and NHF Wilson (*2013*) The Normalized Failure Index: A Method for Summarizing the Results of Studies on Restoration Longevity?. Operative Dentistry: September/October 2013, Vol. 38, No. 5, pp. 488–496. They have been recreated below. You have our apologies for any confusion they might have caused.

$$\frac{\text{Restorations failed}}{\text{Restorations evaluated x No of years' duration}}$$

Figure 1.

$$\frac{\text{Failure Index total}}{\text{Number of failed restorations}}$$

Figure 2.