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Clinical longevity of extensive direct resin composite restorations after amalgam replacement with a mean follow-up of 15 years

Jelte W. Hofsteenge [a,*], Johannes D. Scholtanus [b], Mutlu Özcan [c], Ilja M. Nolte [d], Marco S. Cune [a,e], Marco M.M. Gresnigt [a,f]

[a] *Center for Dentistry and Oral Hygiene, Department of Restorative Dentistry and Biomaterials, University Medical Center Groningen, University of Groningen, Antonius Deusinglaan 1, AV, Groningen 9713, the Netherlands*
[b] *Private practice, Leeuwarden, the Netherlands*
[c] *Division of Dental Biomaterials, Center for Dental Medicine, Clinic for Reconstructive Dentistry, Zurich, Switzerland*
[d] *Department of Epidemiology, University Medical Center Groningen, University of Groningen, Groningen, the Netherlands*
[e] *Department of Oral Maxillofacial Surgery, Prosthodontics and Special Dental Care, St. Antonius Hospital, Nieuwegein, the Netherlands*
[f] *Department of Special Dental Care, Martini Hospital, Groningen, the Netherlands*

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ABSTRACT

Objectives: The aim of this retrospective clinical study was to determine the survival of extensive direct resin composite restorations after amalgam replacement on vital molars and premolars after a mean observation period of 15 years.

Methods: Between January 2007 and September 2013, a total of 117 extensive cusp replacing direct resin composite restorations were placed in 88 patients in a general dental practice. These were indicated for replacement of existing amalgam restorations. Tooth vitality, the absence of at least one cusp in premolars, and at least two cusps in molars were considered for inclusion. The long-term follow-up of the restorations, re-evaluated after up to 17 years using the original evaluation criteria is reported.

Results: 81 of 88 patients (92.1%) and 106 of 117 restorations (90.6%) were available for follow-up. The cumulative success rate was 62.0% (95% CI: 47.3–76.2, AFR 2.79%) after a mean observation time of 163.4 months, the cumulative survival rate was 74.7% (95% CI: 59.8–89.6%, AFR: 1.70%) after a mean observation time of 179.1 months. The number of cusps replaced in premolars had a statistically significant influence on the success and survival rate of the restorations (HR of respectively, 2.974 and 3.175, $p = <0.0005$). Premolars with two cusps replaced had 297% more chance of failure than premolars with one cusp replaced.

Conclusions: Extensive direct resin composite restorations placed after amalgam replacement showed good survival after a mean observation period of 15 years. The number of cusps involved had a statistically significant influence on the longevity of the restorations in premolars.

Clinical Significance: With good survival and low annual failure rates, direct resin composite restorations are a suitable treatment for repairing extensive defects in posterior teeth involving multiple cusps and surfaces, provided that they are placed by a dentist who has long experience and is skilled in the placement of direct composite materials.

1. Introduction

Up to 40–45% of dental operative procedures consist of the replacement of old restorations, mostly made from amalgam (59–63%) [1,2]. Amalgam restorations rely on macro mechanical retention which often requires considerable sacrifice of sound tooth structure. The divergent preparation for amalgam restorations undermines the cusps and weakens the tooth. Secondary caries lesions, bulk fracture and fracture of the cusps are common reasons for amalgam replacement [2]. Because of their invasive character, inferior aesthetics, and low acceptance of the public, amalgam restorations are hardly used in modern dentistry [2,3]. When replacement of an amalgam restoration is indicated, this is often accompanied by further extension of the preparation. Extensive cavities have buccolingual width and/or missing cusps as

* Corresponding author.
E-mail address: j.w.hofsteenge@umcg.nl (J.W. Hofsteenge).

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clinical characteristics.

Different restorative treatment options are available for extensive cavities. Both indirect (ceramic or resin composite) or direct (resin composite) restorations may be indicated [4]. Partial indirect restorations (inlays, onlays and overlays) are aesthetically superior, more suitable for restoring the original morphology and have a low shrinkage factor [5,6]. However, the procedure is time consuming, the materials are brittle and expensive when compared to direct resin composite restorations [4,7]. The restoration of extensive cavities with direct resin composite requires advanced operator skills in order to restore morphology and function and maintain marginal seal [4]. Recent systematic reviews and meta-analyses on clinical performance have shown good long-term results for both direct and indirect resin composite restorations, presenting with similar risk ratios for failure [8,9]. In a randomised controlled trial, evaluating both indirect and direct composite restorations that replaced one cusp in premolars, survival rates after 5 years were respectively 83.2% and 89.9% ($p > 0.05$) [5].

The clinical longevity of direct resin composite restorations has been investigated in both practice- and university-based studies [10–14]. Whilst university-based studies reveal the performance of restorations and materials under controlled conditions, practice-based studies are more influenced by factors on multiple levels (patient, operator, etc.) [11]. Practice-based studies reported mean annual failure rates (AFR's) between 1.5% and 4.9% after follow-up ranging from 4.6 to 22 years [10–12]. The authors concluded that direct composite restorations with more surfaces involved had an increased risk of failure. In some practice-based studies, a lower survival rate for larger restorations was reported [10,11,15], however, evidence exists that survival rates do not differ based on the size of the restoration [16]. A university-based study of direct resin composite class II restorations reported an AFR of 1.1% after as long as 30 years or 1.6% after 27 years [13,14]. Krämer et al. observed an AFR of under 1% after 10 years for direct composite mesio-occlusal (MO) / disto-occlusal (DO) or mesio-occlusal-distal (MOD) restorations [17]. However, the extension of most restorations in these studies was small to moderate [13,14,17].

As direct resin composite restorations are used frequently with good results reported in the literature, the range of indication is extended. This leads to the application of direct resin composite restorations in more extensive cavities [18,19]. In addition, *in vitro* studies indicate promising results for direct resin composite restorations in these extensive cavities [20–22]. However, there are only few *in vivo* studies of extensive direct composite restorations, most with a relatively short evaluation period, up to 3.5 years; [23–25] therefore, clinical studies of the survival of extensive direct composite restorations with long observation periods are needed [26]. The general aim of this retrospective study was to determine the survival of extensive direct resin composite restorations after amalgam replacement on vital molars and premolars made in a prospective study after a mean period of 15 years and to identify any mitigating factors.

2. Materials and methods

2.1. Study design

The present retrospective study is a prolongation of a prospective clinical study [24]. The operative procedures were part of routine dental care. Hence no ethical committee approval was required at that time. For evaluations of the prolongation of the prospective clinical trial, this retrospective study was not considered clinical research with test subjects as defined in the Medical Research Involving Human Subjects Act (WMO) (METc communication 2020/181) and registered in the national trial register (research register number: NL9100).

2.2. Inclusion and exclusion criteria

Between January 2007 and September 2013, a total of 117 extensive cusp replacing direct resin composite restorations in posterior teeth were placed by a single dentist in 88 patients in a general practice. Direct resin composite restorations were indicated for replacement of existing amalgam restorations where dentine substrates were stained by amalgam metal ions [27]. Information was given to each patient regarding alternative treatment options and informed consent was obtained. Extensive restorations were placed due to complete or incomplete fracture of tooth structure, weakened cusps after cavity preparation, and/or secondary caries lesions.

Table 1
Protocol for conditioning the cavity and application of resin composite.

1. Application of etching gel (37% phosphoric etching gel, Ultra-Etch, Ultradent) for 20 s
2. Rinsing with water spray (5 s)
3. Changing cotton rolls and control of dry field
4. Gentle drying with compressed air
5. Application of primer (Quadrant Unibond Primer, Cavex Holland) for 20 s
6. Evaporation of solvent (2 s) by compressed air
7. Application of adhesive resin (Quadrant Unibond Sealer, Cavex Holland)
8. Gently blowing excess adhesive resin
9. Photo-polymerization (20 s)
10. Application of composite (Clearfill Photoposterior, Kuraray) in a layer of ≤2 mm
11. Photo-polymerization (20 s)
12. Repeating step 10 and 11 until slight overfill
13. Finishing and polishing

Table 2
Distribution of restored teeth, numbers of restored cusps in the maxilla and mandible.

	Premolars (n)		Molars (n)			Total (N)
	1 cusp	2 cusps	2 cusps	3 cusps	4 cusps	
Maxilla	9	11	11	7	7	45
Mandible	2	13	21	11	25	72
Total (N)	11	24	32	18	32	
	35		82			117

The inclusion criteria were:

1 Need of three surface restorations with coverage of at least two adjacent cusps in molars.
2 Need of three surface restorations with coverage of at least one cusp in premolars.
3 Presence of existing amalgam restorations on at least the occlusal surface.
4 Presence of extensive black stained dentine upon removal of existing amalgam.
5 Lack of macromechanical retention necessary for non-adhesive restorations.
6 Absence of pain and endodontic complications.
7 Functional occlusal contacts with an antagonist tooth.
8 At least one proximal contact.

The exclusion criteria were the presence of cement base material underneath the amalgam or incomplete vertical fractures in the dentine.

2.3. Clinical procedures and restoration fabrication

Details of the clinical procedures are specified in the original article [24]. In short, cavity preparation and restoration were performed in a general dental practice. One operator (JS), who had extensive experience in restorative adhesive dentistry, placed all the restorations. In most cases a dry working field was created with suction and cotton rolls. Rubber dam was applied in some cases. Cavities were conditioned using a three-step total-etch technique (37% phosphoric acid, Quadrant Unibond Primer and Sealer, Cavex, Holland). A midifil hybrid resin

Table 3
Life table of the specified details on failures.

Tooth (FDI)	Surfaces	Cusps	Follow-up (Months)	Intervention	Indication
47	5	4	11	Endodontic treatment	Endodontic complications
47	5	2	11	Endodontic treatment	Endodontic complications
46	5	4	17	Endodontic treatment	Endodontic complications
47	5	4	21	Total replacement	Caries
45	5	2	28	Endodontic treatment	Endodontic complications
46	5	4	34	Partial replacement	Faulty contact
35	5	2	38	Partial replacement	Caries
47	5	4	42	Partial replacement	Restoration fractured
44	5	2	46	Total replacement	Restoration missing / mobile
46	5	4	46	Partial replacement	Caries
36	5	4	48	Partial replacement	Dentin exposed
46	4	2	56	Partial replacement	Faulty contact
26	5	4	61	Partial replacement	Faulty contact
36	5	4	69	Partial replacement	Dentin exposed
37	4	2	72	Partial replacement	Faulty contact
27	5	3	80	Total replacement	Restoration missing / mobile
37	4	2	86	Total replacement	Tooth fractured
15	5	2	86	Extraction	Prosthetic purposes
25	5	2	88	Partial replacement	Caries
47	4	2	89	Total replacement	Restoration missing / mobile
26	5	4	96	Extraction	Pain
36	4	2	108	RepairPartial replacement	Caries
26	5	3	115	Extraction	Prosthetic purposes
16	5	2	119	Partial replacement	Restoration fractured
35	5	2	121	Endodontic treatment	Endodontic complications
26	5	2	130	Total replacement	Restoration caused pain
36	5	4	145	Endodontic treatment	Endodontic complications
15	5	2	153	Extraction	Prosthetic purposes
36	5	4	156	Partial replacement	Faulty contact
36	5	4	161	Partial replacement	Caries

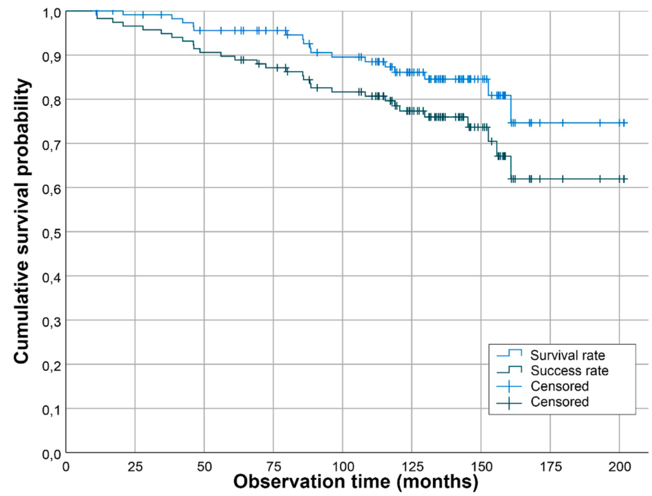

Fig. 1. Kaplan-Meier cumulative survival & success curve ($n = 117$).

Table 4
Cox regression analysis on the influence of the variables on the success rate. HR = hazard ratio.

Variable		HR	95% confidence interval		p
			Lower	Upper	
Age		1.006	0.961	1.052	0.810
Sex	Female vs Male	0.641	0.307	1.338	0.240
Tooth	Premolar vs Molar	1.176	0.346	3.996	0.790
Jaw	Mandible vs Maxilla	0.936	0.428	2.045	0.870
Surfaces involved	3 vs 4 vs 5	2.048	0.603	2.207	0.210
Cusps involved	Premolar: 1 vs 2	2.974	2.974	2.974	<0.0005[a]
	Molar: 2 vs 3 vs 4	1.228	0.629	2.396	0.550

[a] Statistically significant. All failures in the premolars were in teeth involving two cusps in the restoration. 25 of 35 premolars had 2 cups replaced.

Table 5
Cox regression analysis on the influence of the variables on the survival rate. HR = hazard ratio.

Variable		HR	95% confidence interval		p
			Lower	Upper	
Age		1.005	0,947	1067	0.860
Sex	Female vs Male	0.382	0,141	1037	0.059
Tooth	Premolar vs Molar	1.419	0,329	6115	0.640
Jaw	Mandible vs Maxilla	1.578	0,577	4319	0.370
Surfaces involved	3 vs 4 vs 5	0.836	0,612	11,453	0.190
Cusps involved	Premolar: 1 vs 2	3.175	3175	3175	<0.0005[a]
	Molar: 2 vs 3 vs 4	0.908	0,370	2229	0.830

[a] Statistically significant. All failures in the premolars were in teeth involving two cusps in the restoration. 25 of 35 premolars had 2 cups replaced.

composite (Clearfil Photo Posterior, Kuraray, Tokyo, Japan) was applied in layers of ≤ 2 mm using a syringe technique. Each layer of resin composite was polymerized using an LED polymerization device at ~1000 mW/cm^2. The application protocol is summarized in Table 1. Patients received individual instructions to maintain plaque control.

2.4. Evaluation

During the original study, patients attended the practice on a regular basis for periodic check-ups at 6 month intervals. Failures that only affected the success rate were repairs due to faulty contact points or exposed dentin and endodontic treatments. A faulty contact point was an inadequate or missing contact point that needed repair due to discomfort, such as food impaction. Failure that affected survival rates were secondary caries, extraction, missing restoration, fractured restoration, tooth structure fractured, or pain caused by the restoration. Patients were asked to contact the practice if they perceived any problem with the restored teeth. As this is a continuation of the original study, the

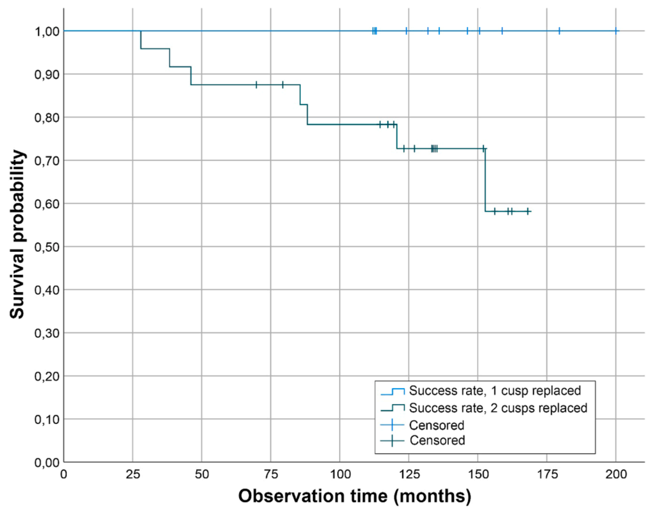

Fig. 2. Kaplan-Meier curves of the success of the restorations on premolars, stratified by the numbers of cusps, with one (n = 11) or two (n = 24) cusps replaced.

restorations were re-evaluated up to 17 years, employing the same evaluation criteria as used in the initial study. The patients visited the practice for periodic check-ups at a 6 monthly interval after finishing the original study. Patient files were checked retrospectively regarding events.

2.5. Statistical analysis

The results were analysed using R version 3.3.3 (R Foundation for Statistical Computing, Vienna, Austria) and IBM SPSS statistics 28.0 (IBM Corp. NY, USA). The overall cumulative success and survival rates over time was calculated using the Kaplan–Meier estimates. The 95% CI (confidence interval) and AFR (annual failure rate) are reported. Cox regression analysis with frailty index was used to analyze the influence of multiple variables (age, sex, type of tooth, jaw, number of surfaces involved and number of cusps restored) on the survival and success rates of the restorations. A frailty index was used to correct for the dependence between restorations as multiple patients received more than one restoration. A p-value < 0.05 was considered to indicate statistical significance.

3. Results

In total, 117 restorations were placed in 88 patients: 57 women and 31 men; mean age at placement: 51.3 years old (range: 36–69 years). The mean observation time was 163 months (range: 11 to 202 months). Fifteen mandibular premolars, 20 maxillary premolars, 25 maxillary molars, and 57 mandibular molars were treated in this study. The number of replaced cusps in the restored teeth is specified in Table 2. A total of 81 of 88 patients (92.1%) and 106 of 117 restorations (90.6%) were available for follow-up. Seven patients with 11 restorations were lost to follow up: three patients died, two could not be contacted, one moved away, and one refused participation. In total, 30 failures were observed, of which 26 teeth were still in function. Types of failures were endodontic treatment (n = 6), secondary caries lesion (n = 6), faulty contact (n = 5), extraction (n = 4), missing restoration (n = 3), fractured restoration (n = 2), exposed dentin (n = 2), tooth structure fractured (n = 1), or restoration caused pain (n = 1). Three of the four extractions were indicated for prosthetic purposes: full dentures were indicated. Information on the follow-up period, indications and interventions needed is reported in Table 3. The cumulative success rate was 62.0%

a. Pre-operative status of tooth #46, mesiobuccal cusp fractured, multiple crack lines apparent.

b. Preparation after reduction of distobuccal and lingual cusps.

c. Post-operative status, immediately after restoration. Note the voids on the occlusal and buccal surface.

d. Restoration (survival) after follow-up of 143 months (≈12 years). Note the surface staining in the voids. The distal ridge of the 46 is rounded during restoration of the 47.

Fig. 3. a-d. A representative case pre-operative and post-operative.

a. Per-operative status of tooth #16, only the distobuccal cusp is preserved.

b. Post-operative status, immediately after restoration.

c. Restoration (survival) after a follow-up of 134 months (≈11 years), occlusal view. Note the loss of tooth structure on the distobuccal cusp and the slightly rough surface of the restoration in general. Loss of tooth tissue is probably due to attrition, also apparent on teeth #15 and #14. Morphology is less pronounced in comparison to the original restoration.

d. Restoration after a follow-up of 134 months (≈11 years), buccal view. Note the marginal staining, the small overhang on the mesial side, and the slightly deficient contour.

Fig. 4. a-d. A representative case per-operative and post-operative.

(95% CI: 47.3–76.2%) after a mean observation time of 163.4 months with a mean AFR of 2.79%; the cumulative survival rate was 74.7% (95% CI: 59.8–89.6%) with a mean AFR of 1.70% after a mean observation time of 179.1 months (Fig. 1).

A Cox regression analysis on influence of the variables on the success rate (Table 4) revealed that only the number of cusps involved was a significant factor for the success of extensive direct composite restorations in premolars. Premolars with two cusps involved have 297% more chance on an event in comparison to premolars with one cusp involved ($p < 0.0005$). A Cox regression analysis on the influence of the variables on the survival rate reported similar results (Table 5) The Kaplan-Meier curves of the success of the restorations on premolars stratified by the number of cusps are illustrated in Fig. 2. In contrast, the effects of age, sex, tooth type, jaw, the number of surfaces involved, and the number of cusps involved in molars were not statistically significant ($p > 0.05$).

The follow-up of two representative restorations in this study are illustrated in Figs. 3 and 4. As shown, there is some surface and marginal staining, and the restorations became dull when they are not covered with saliva. However, the restorations were functional and had maintained their anatomical form. The strength and tightness of the contact point and the shape of the approximal contour are difficult to optimize in direct resin composite restorations.

4. Discussion

To the best of our knowledge, there are no studies on the long-term survival of extensive direct resin composite restorations after amalgam replacement on vital teeth. The calculated survival rate after a mean observation time of 179 months was 74.7%, with a mean AFR of 1.70%. In comparison, Laegreid (2012) reported a survival rate after 3 years of function of 87.7% (with an AFR of 4.2%) of molars restored with extensive direct resin composite restorations with at least one cusp restored [25]. Fennis et al. (2014) reported a survival rate of repairable failures of 89.9% after 5 years of function (AFR 2.02%) for cusp-replacing composite restorations on premolars [5]. On the other hand, Deliperi and Bardwell (2006) found no failures and excellent clinical behavior of 25 direct resin composite cusp covering restorations in molars after 30 months of function [23].

The present study shows only a significant effect on the survival of the number of cusps involved in premolars. The number of surfaces involved had no significant influence on the survival of the restorations. A systematic review by Opdam et al. (2016) concluded after meta-analyses of a total of 2816 restorations a significant effect on the number of surfaces in premolars ($p < 0.001$, HR of 1.45 for every extra surface) and molars ($p = 0.002$, HR of 1.24 for every extra surface) [28]. That systematic review included both Black's Class I and Class II restoration, reporting AFR's ranging between 1.6% (low caries risk) and 4.6% (high caries risk) [28]. The minimum number of surfaces involved in the present study was four, which could influence the effect of the number of surfaces involved on the survival. Van de Sande et al. (2013) found a significant influence ($p < 0.001$) of the type of tooth on survival, which was not found in this study, but also could not demonstrate a significant influence of the number of surfaces involved ($p = 0.515$) [16]. Only vital posterior teeth were included in the present study; therefore, the results cannot be extrapolated to endodontically treated posterior teeth. Previously, statistically significant differences ($p < 0.001$, HR of 25.3, 95% CI:9.7–66) were reported in long-term survival between vital and endodontically treated teeth restored with direct resin composite, with

AFR's of 0.08 and 1.78% after an evaluation period from 6 up to 13 years, respectively [29].

The present study focused mainly on the influence of restorative and tooth-specific criteria. However, patient- and operator-related factors might have influenced the survival of resin composite restorations. Caries risk has a significant effect on the survival of direct resin composite restorations, reported in the systematic review by Opdam et al. [28]. In addition, bruxism and other parafunctional habits impact the chance on survival as well, where occlusal stress could lead to a higher failure rate (HR of 2.61, 95% CI: 1.28–5.33) [16]. These factors should be studied in a more detailed manner in future studies.

Few restorations will last for a lifetime, which will result in replacement by a larger restoration which will eventually fail and lead to an even larger restoration, threatening the pulp and then tooth survival. This cycle is described as the restorative cycle by Elderton (1988) and Simonson (1991) [30,31]. Most of the failures in the present study were tooth preserving failures (26 out of 30) in which the tooth could be preserved with repair, (partial) replacement, or other treatment options. Fracture of tooth tissue, a cusp fracture, was only seen in one case. Therefore, restoration of severely biomechanically compromised posterior teeth with direct resin composite led to a prolongation of the restorative cycle of the tooth. Only four teeth were extracted (three for prosthetic purposes) and all other teeth were still in function. Direct resin composite restorations are additive to the tooth structure and therefore less invasive in comparison to indirect restorations. Repair or refurbishing with direct resin composite is also easier than with indirect ceramic restorations, involving fewer steps in the repair procedure [32].

With an survival rate of 74.7% and AFR of 1.70% after 15 years of function, the prognosis of the extensive direct resin composite restorations from the present cohort that replaced large amalgam restorations are be considered acceptable by the authors. Together with the easy repairability, relative low costs and minimal invasiveness, direct resin composite restorations should be considered for restoration of extensive defects involving multiple surfaces and cusps, in posterior vital teeth that are scheduled for re-restoration after amalgam removal.

5. Conclusions

Extensive direct resin composite restorations after amalgam replacement showed good clinical longevity results after a mean of 15 years of clinical service. The number of cusps involved influences the longevity of extensive direct resin composite restorations on premolars with statistically significance.

CRediT authorship contribution statement

Jelte W. Hofsteenge: Conceptualization, Methodology, Formal analysis, Investigation, Visualization, Writing – original draft. **Johannes D. Scholtanus:** Conceptualization, Methodology, Investigation, Writing – review & editing. **Mutlu Özcan:** Conceptualization, Methodology, Writing – review & editing. **Ilja M. Nolte:** Software, Formal analysis, Writing – review & editing. **Marco S. Cune:** Conceptualization, Methodology, Writing – review & editing. **Marco M.M. Gresnigt:** Conceptualization, Methodology, Writing – review & editing, Supervision.

Declaration of Competing Interest

All authors declare that they have no conflicts of interest.

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