

# Survival rate of primary molar restorations is not influenced by hand mixed or encapsulated GIC: 24 months RCT

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## Research Article

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# Abstract

**Background:** Glass ionomer cements (GIC) have been considered the top option to restore primary teeth by dentists. The most common supply forms are hand-mixed and encapsulated GIC. There is a lack of information about the impact of different GIC supply forms on restoration survival. This randomized clinical trial compared the survival rate of occlusal and occlusoproximal restorations in primary molars using two of glass ionomer cements versions: hand-mixed (H/M) and encapsulated (ENC) after 24 months. Children aged 3-10 years who presented dentin caries lesions in primary molars were selected at School of Dentistry, University of São Paulo, Brazil. They were randomly assigned to groups: H /M (Fuji IX<sup>®</sup>, GC Europe) or ENC (Equia Fill<sup>®</sup>, GC Europe). The occurrence of restoration failure was evaluated by two blinded and calibrated examiners. The analyses were performed in Stata 13 (StataCorp, USA). To evaluate the primary outcome (restoration survival), we performed an intention to treat (ITT) analysis at 24 months of follow-up. Kaplan-Meier survival analysis was used to verify the survival of the restorations while Cox Regression with shared frailty was performed to assess association between restoration failure and independent variables ( $\alpha=5\%$ ).

**Results:** A total of 324 restorations were performed in 145 children. The survival for H/M group was 58.2% and 60.1% for ENC, with no difference ( $p=0.738$ ). Occlusoproximal restorations had lower survival rate when compared to occlusal ones ( $HR=3.83$ ;  $p<0.001$ ).

**Conclusions:** The survival rate in primary molar is not influenced by the different supply forms of GIC

This randomized clinical trial was registered on ClinicalTrials.Gov on 10/15/2014 under protocol (NCT 02274142).

## Background

Glass ionomer cements (GIC) have been considered the top option to restore primary teeth by dentists<sup>1</sup>. Their properties as chemical bonding to enamel and dentin, fluoride release and uptake, thermal expansion coefficient similar to the tooth, and lower sensitivity to humidity than the composite resin (CR)<sup>2-4</sup> favor their choice. Several studies<sup>2</sup> show that GIC restorations have good clinical results both in primary and permanent dentition mainly focused on Atraumatic Restorative Treatment (ART)<sup>5-7</sup>. Therefore, it is essential to achieve the clinical benefit that GIC can provide by understanding the advantages and difficulties offered by the material.

The most common presentation is the hand-mixed GICs (H/M)<sup>5,7-10</sup>, which require correct dispensing and mixing as specified by the manufacturer. Nevertheless, this GIC allow changing the powder-liquid ratio, making it more or less fluid, according to the professional's preference. However, it is not recommended as this could impair the cement's mechanical properties<sup>11</sup> and jeopardize restoration longevity<sup>12-14</sup>. Moreover, incorrect hand-mixing of a GIC could lead to air incorporation into the material matrix and also have an impact on the material properties<sup>14,15</sup>.

With the aim to reduce these potential problems, the use of encapsulated version (ENC) has been proposed. As the manufacturer pre-dose the powder and liquid inside a capsule, the powder-liquid ratio is standardized, and the mechanical mixing, provides a more homogeneous material<sup>14,15</sup>. There is a lack of information about the impact of different GIC supply forms on restoration survival. To the best of our knowledge, only one clinical trial compared different GIC presentations on occlusal restorations in permanent molars, with promising results for the encapsulated version<sup>16</sup>.

Therefore, the aim of the present randomized clinical trial (RCT) is to compare the survival rate of primary molars restorations performed with hand-mixed and encapsulated versions of GIC after 24 months of follow-up.

## Methods

This article was reported according to CONSORT (Consolidated Standards of Reporting Trial)<sup>17</sup> guidelines, and the checklist is available as a supplementary file.

### Trial Design and Ethical Aspects

This is a two-sided equity, parallel arms, one-to-one allocation ratio, single-blinded (examiner), controlled randomized clinical trial. This RCT is nested to a caries diagnostic RCT intitled CARies DEtection in Children 1 (CARDEC 1)<sup>18</sup>.

It was conducted in dental office setting with children who sought dental care at the School of Dentistry, University of São Paulo, Brazil. This study was approved by the local research ethics committee (protocol #864.396) and registered on 15/10/2014 on the ClinicalTrials.gov platform (NCT02274142). All parents or legal guardians signed the informed consent form.

Initially children from three to six years of age would be included, however, to cover the largest number of children included in CARDEC 1, we increased this age group to three to ten years old. In addition, we have performed an Intention to Treat (ITT) and subgroup analysis that were not declared on trial registry.

### Sample Size

The sample size estimation was performed on the Power and Sample Size website (<http://powerandsamplesize.com/>). A two-tailed hypothesis was considered. We considered parameters from a systematic review<sup>19</sup>, which reported an average survival rate of 78% after two years of follow-up (mean for occlusoproximal and occlusal restorations after 2 years of follow-up). A clinically important difference of 15% on survival rate between ENC and H/M groups was considered. We added 20% for possible losses to follow up, and 20% for the cluster effect, as the same child could have more than one tooth included in the study. Thus, 116 teeth were needed per group, reaching a minimal sample size of 232 teeth. A significance level of 5% and a power of 80% were used for calculation.

### Eligibility Criteria

Healthy children aged 3 to 10 years, who had sought dental treatment in the University of São Paulo and participating in CARDEC 01 study<sup>18</sup> were assessed. Only children presenting dentin caries lesion in primary molars detected clinically as a cavitation or radiographically as a dentine radiolucency in the bitewing radiograph in occlusal and/or occlusoproximal surfaces were eligible to participate<sup>20</sup>. However, when any signs or symptoms of irreversible pulp inflammation or pulp necrosis were detected clinically (nocturnal pain, fistula, abscess, pulp exposure, pathological mobility) or radiographically (radiolucency into the pulp, furcal bone radiolucency or pathological root resorption) the tooth was excluded.

Children with severe behavioral problems and those whose parents or guardians refused to sign the informed consent form were excluded.

### **Randomization, Allocation concealment, and implementation**

A sequence of random numbers, stratified according to caries experience and in blocks of four, was generated using a Random Allocation Software 2.0<sup>21</sup>, and these numbers were packed in opaque sealed envelopes by an external member of the research team who did not participate in the operative stages of the study to guarantee the allocation concealment.

Children with low experience were considered those who presented dmfs less than or equal to 3, and children with high experience those whose dmfs were higher than 3<sup>20</sup>.

The randomization implementation was made by two team members who did not participate in the research's operative phase, as they were responsible for the treatment plan design. Thus, the operators received the treatment plan to be performed, avoiding selection bias.

The randomization unit was the tooth, so each child could be able to contribute with more than one tooth to the study, and therefore could have received different restorative material in different teeth.

### **Blinding**

The restorations were performed with GIC in hand-mixed (H/M) and encapsulated (ENC) versions. Thus, there was no possibility of blinding participants and operators. Only the outcome assessors were blinded regarding groups.

### **Interventions**

All treatments were performed by trained general dentists and graduate students in Pediatric Dentistry. After clinical and radiographic evaluation and being accepted for the participation in the study, children were randomized the following treatments groups:

- Hand-mixed Group: restorations performed with GIC Fuji IX Gold Label® (GC Europe NV, Leuven, Belgium), in the hand-mixed version with manual dosage and handling.
- Encapsulated Group: restorations performed using GIC Equia Fill® (Easy/Quick/Unique/Intelligent/Aesthetic) – GC Europe NV, Leuven, Belgium, in the pre-dosed encapsulated version and mechanical manipulation.

## **Restorative Procedures**

The procedures were performed without the use of local anesthesia. High speed rotary burs were used for enamel removal to gain access in case of non-cavitated dentin lesions detected radiographically.

Selective caries removal was performed in occlusal and occlusoproximal lesions for both groups. The caries dentin was removed using hand instruments appropriate for the cavity size. Cavity conditioner (polyacrylic acid – GC cavity conditioner) was applied for 15 seconds using a wet cotton pellet. Rinsing was performed using a sequence of three wet cotton pellets followed by three dry cotton pellets. The GIC was mixed and applied according to the following groups:

### **H/M:**

The GIC hand-mixed was handled in a paper block with a plastic spatula (GC Corporation, Japan) by two trained operators following the manufacturer's recommendations. The GIC was inserted into the cavity with #1 spatula. Press finger was performed with a gloved finger coated with petroleum jelly for 10 seconds. After the initial material setting (from 3 to 5 minutes), the occlusion was checked with carbon paper and adjusted when necessary. Finally, restoration protection was performed with petroleum jelly.

### **ENC:**

The GIC (Equia Fill - GC Corporation, Japan) was activated, following the manufacturer's recommendations, and taken to the mixer by a team member, other than the operator of the restorative procedure. The encapsulated material was inserted directly from the capsule using a capsule applicator (Riva Applicator – SDI Limited®, Australia). Press finger was performed with a gloved finger coated with petroleum jelly for 10 seconds. After the initial material setting (from 3 to 5 minutes), the occlusion was checked with carbon paper and adjusted when necessary. Restoration protection was performed with petroleum jelly.

For all occlusoproximal cavities, metal matrixes and wooden wedges were used. All subjects were instructed not to eat for one hour and received instructions on sugar consumption and oral hygiene for caries control.

## **Outcome Evaluation**

The restorations were assessed clinically continuously, with a minimum of 4 months and a maximum of 8 months between evaluations, up to 24 months by two trained, calibrated, and blinded examiners (D.P.R. and L.B.C), following the Frencken and Holmgren (2001) criteria for occlusal restorations and Roeleveld et al. (2006) criteria for occlusoproximal restorations and the additional files 1 and 2, respectively, shows this in more detail. Kappa test was performed to evaluate the level of inter-examiner agreement.

We considered as success for occlusal restorations the scores 0, 1 e 7, and for occlusoproximal, 00 and 10, which indicate the presence of good restoration, or only minor defect, with no repair needed. If other minor or major restoration failure was noted, the repair of the restoration was performed. In case of bulk fracture, the tooth received a new restoration.

For survival analysis, the reintervention was not considered. If the tooth presented a failure during the evaluation period, it was considered as a restoration failure for survival analysis.

All participants received full dental treatment, except orthodontic appliances. Parents could bring the child if any treatment need was detected between the pre-determined assessments.

## **Outcomes**

This study's primary outcome was restorations' survival performed with hand-mixed and encapsulated GIC in occlusal and occlusoproximal cavities in primary molars after 24 months of follow-up. The occlusal restorations were evaluated according to the criteria proposed by Frencken and Holmgren (2001). For these restorations we considered successful those restorations that did not present an operative need, i.e., scores 0, 1 and 7. For occlusoproximal restorations the criteria used was the one proposed by Roeleveld et al. (2006), where the criteria considered successful were 00 and 10. Minor or major failures, according to the mentioned criteria, were considered as failure for the survival analysis. As a secondary outcome, we aimed to evaluate the cost-effectiveness of both GIC, considering the longevity of restorations. The secondary outcome will be published separately elsewhere.

## **Statistical Analysis**

The analyses were performed in Stata 13 (StataCorp, USA). Kaplan-Meier's analysis shows the survival of the restorations over the 24 months of follow-up. Participants evaluated at least once during the study were included in the analysis.

To evaluate the primary outcome (restoration survival), we performed an intention to treat (ITT) analysis, considering the success and failures at 24 months of follow-up.

To evaluate the association between restoration survival and independent variables such as surface (occlusal or occlusoproximal), caries experience ( $dmfs \leq 3$  or  $> 3$ ), type of molar (first or second molar), sex (male or female), age and arch (upper or lower), Cox Regression with shared frailty was used. Initially, the analysis was performed in a univariate model. Independent variables reaching a  $p$ -value  $< 0.20$  (cavities and tooth type) fitted in the adjusted model. The final model only included variables showing  $p \leq 0.05$ . As only the independent variable surface reached this  $p$ -value, we have conducted a subgroup analysis, considering the survival of occlusal and occlusoproximal restorations. Hazard ratios (HR) and relative risk (RR) were calculated with 95% confidence interval (CI). The significance level was set at 5%.

## **Results**

From 470 teeth in 147 children eligible to participate in the study, 305 were included. The reasons for exclusion of 165 teeth are described in Fig. 1.

From 305 teeth of 147 children included, 161 cavities were randomized for hand-mixed group and 162 cavities were allocated to the encapsulated group (Fig. 1). Considering all children, 67 (46.2%) were girls and 78 were (53.8%) boys. Moreover, 58 children (40.0%) were 3 to 4 years old and 87 (60.0%) were 5 to

10 years old, and 40 (27.6%) presented dmfs values from 0 to 3, and 105 (72.4%) presented dmfs of 4 or higher. The baseline characteristics are described in Table 1.

Table 1  
Baseline characteristics of the participants, distribution according to the groups, and chi-square test.

<b>Variables</b>	<b>Hand-Mixed</b>	<b>Encapsulated</b>
	<b>n %</b>	<b>n %</b>
<b>Sex</b>		
<i>Female</i>	65 (40.4)	82 (50.6)
<i>Male</i>	96 (59.6)	80 (49.4)
<b>Age</b>		
<i>3 to 4 yrs-old</i>	57 (35.4)	81 (50.0)
<i>5 to 10 yrs-old</i>	104 (64.6)	81 (50.0)
<b>dmfs</b>		
<i>0 to 3</i>	35 (21.7)	38 (23.5)
<i>4 or more</i>	126 (78.3)	124 (76.5)
<b>Dental Arch</b>		
<i>Upper</i>	83 (51.6)	83 (51.2)
<i>Lower</i>	78 (48.4)	79 (48.8)
<b>Type of Molar</b>		
<i>First molar</i>	63 (39.1)	69 (42.6)
<i>Second molar</i>	98 (60.9)	93 (57.4)
<b>Surface</b>		
<i>Occlusal</i>	113 (70.2)	95 (58.6)
<i>Occlusoproximal</i>	48 (29.8)	67 (41.4)

Moreover, 258 included teeth (positive follow-up rate of 79.9%) were followed-up up to 24 months, in 113 children (77.9%). The interexaminer Kappa value was 0.99. The drop-out for the hand-mixed group was 29 teeth (18.0%) and for the encapsulated group was 36 (22.2%), with a p value of 0.457 (by chi-square test adjusted by the cluster). Considering the 323 restorations included, only 7 (2.2%) samples were not assessed in any follow-up period.

The Kaplan Meier curves show the estimated survival for the restorations according to restored surface after 24 months of follow-up (Fig. 2). Figure 3 shows the most prevalent reasons of failure over the 24 months, according to Frencken and Holmgren (2001) and Roeleveld et al. (2006) criteria.

Tables 2, 3 and 4 shows the ITT results, Cox Regression with shared frailty and subgroup analysis, respectively, and no statistically significant differences were found.

Table 2

Intention to treat analysis considering the primary outcome (survival of restorations) and frequency of restorations with success and failures at 24 months of follow-up

<b>Intention-to-treat survival analysis (primary outcome)</b>				
<b>Trial groups</b>	<b>Survival proportion</b> %	<b>SE</b>	<b>HR (95%CI)</b>	<b>p</b>
<i>Hand-mixed group</i>	60.9	0.04	1.00	0.626 *
<i>Encapsulated group</i>	59.3	0.05	0.91 (0.61 to 1.35)	
<b>Success at 24 months (intention to treat analysis)</b>				
<b>Trial groups</b>	<b>Success</b> N (%)	<b>Failure</b> N (%)	<b>RR (95%CI)</b>	<b>p</b>
<i>Hand-mixed group</i>	100 (62.1)	61 (61.1)	1.00	0.498 *
<i>Encapsulated group</i>	99 (37.9)	63 (38.9)	0.88 (0.62 to 1.26)	
SE = Standard Error; HR = Hazard ratio; 95%CI = 95% confidence interval; RR = relative risk				
* p value calculated by Cox regression with shared frailty adjusted by type of restoration (Occlusal or Occlusoproximal)				

Table 3

Cox Regression with shared frailty in univariate and adjusted models -analysis between failures in restorations and associated factors

	Unadjusted HR (95%CI)	p	Adjusted HR (95%CI)	p
<b>Group (ref.: hand-mixed)</b>				
Encapsulated	0.99 (0.66 to 1.48)	0.967	0.90 (0.60 to 1.35)	0.617
<b>Sex (ref.: female)</b>				
Male	0.86 (0.56 to 1.34)	0.516	*	
<b>Age (ref.: 3 to 4 yrs-old)</b>				
5 to 6 yrs-old	1.27 (0.81 to 1.98)	0.294	*	
<b>dmfs (ref.: 0 to 3)</b>				
4 or more	0.84 (0.51 to 1.39)	0.500	*	
<b>Dental arch (ref.: upper)</b>				
Lower	0.97 (0.65 to 1.45)	0.894	*	
<b>Molar type (ref.: 1st molar)</b>				
2nd molar	0.55 (0.37 to 0.82)	0.003	0.89 (0.59 to 1.34)	0.572
<b>Surface (ref.: Occlusal)</b>				
Occlusoproximal	3.97 (2.68 to 5.87)	< 0.001	3.83 (2.44 to 6.00)	< 0.001
HR = hazard ratio; 95% CI = 95% confidence interval				
* variable did not include in the adjusted model				

Table 4

Subgroup analysis considering occlusal and occlusoproximal restorations considering the survival of restorations performed with hand-mixed or encapsulated glass ionomer cement

Trial groups	Survival proportion %	SE	HR (95%CI)	p
<i>Occlusal restorations</i>				
<i>Hand-mixed group</i>	71.4	0.05	1.00	0.281
<i>Encapsulated group</i>	77.6	0.05	0.70 (0.36 to 1.35)	
<i>Occlusoproximal restorations</i>				
<i>Hand-mixed group</i>	34.3	0.08	1.00	0.717
<i>Encapsulated group</i>	30.2	0.07	1.10 (0.66 to 1.81)	
SE = Standard Error; HR = Hazard ratio; 95%CI = 95% confidence interval				
* p value calculated by Cox regression with shared frailty adjusted by type of restoration (Occlusal or Occlusoproximal)				

### Harms:

No damage or harms has been found.

## Discussion

This RCT was performed in a controlled clinical environment (dental office setting) and demonstrated that both hand-mixed and encapsulated versions did not influence the restorations' survival. It is possible to observe a trend to better results for encapsulated material, especially for occlusal surfaces.

The GICs showed an excellent survival rate for occlusal cavities, corroborating with previous studies<sup>19,22</sup>. This result was predictable because occlusal cavities usually present a more robust dental structure to support the restorative materials<sup>23</sup>, favoring their longevity. For this reason, the occlusal cavities were considered in this study so that we could observe if there would be any difference in the clinical results obtained for the encapsulated material.

Table 1 shows an imbalance between the cavity type in the two groups, with more occlusal cavities in both groups. This fact led us to perform other analyses, which were not foreseen in the study design and registry, such as intention to treat (ITT) and subgroup analysis. These analyses, to our knowledge, make

the results clearer, showing that despite the imbalance found in the baseline, there was no statistically significant difference in either group.

To our knowledge, there is only one RCT that compares GIC Hand-Mixed and Encapsulated, and the authors classified the used GIC as "medium viscosity" in permanent molar occlusal cavities, with results of one-year follow-up<sup>16</sup>. This study shows a higher success rate of encapsulated GIC, different from our findings. Some factors may have influenced the results such as the restorations performed on permanent molars, whose masticatory force is more potent than that applied to primary teeth, or factors such as type of tooth and location, operator, secondary lesions, individual risk of caries and bruxism which may have exacerbated the difference between the materials<sup>24,25</sup>. Another relevant point may be related to manipulating the material, mainly for the hand-mixed. In the present study, handling was performed by two operators with significant experience in teaching and handling these materials, which may explain the lack of difference between groups. We also hypothesize that as the RCT used medium-viscosity GIC, the material could be more sensitive to changes in dosage and handling.

Our results show that both materials showed similar survival rates in occlusoproximal cavities and had lower survival rates than occlusal restorations. However, this difference is not related to supply form but rather to issues related to the configuration of cavities<sup>22,26</sup>. The reduced performance found for the occlusoproximal cavities might be related to the configuration of the cavities. As previously stated, GIC requires support from the surrounding structures<sup>23</sup>, so variables related to cavity conformation need to be better studied for understanding the behavior of this restorative material in this type of cavity.

Another relevant issue related to occlusoproximal cavities might be humidity control. Lesions at the gingival or subgingival margin level are difficult for controlling the humidity and may negatively influence the restorative materials' clinical success. Such aspects compromise the survival of occlusoproximal restorations<sup>22</sup>.

We believed that the restorations' survival of the ENC group for the different cavity types would be greater than the H/M group. A possible explanation is that there would be less influence of operators for dosage and handling, thus reducing the incorporation of air bubbles or the possible change in the powder-liquid ratio recommended by manufacturers<sup>12-15</sup>. As the dosage and handling in our H/M group were performed exclusively by two trained operators with experience in GIC, it might have an impact on our results and can be considered a potential limitation of this trial. Future studies might consider a pragmatic trial design or a "real-world" design, with less control over variables, to strengthen the scientific evidence on this topic and check if our previous assumptions were correct.

## Conclusion

The survival rate in primary molar is not influenced by the different supply forms of GIC. Also, occlusoproximal cavities present reduced performances when compared to occlusal cavities.

## Declarations

**Ethics approval and consent to participate:** This research was previously approved by the Research Ethics Committee of the School of Dentistry, University of São Paulo, under the protocol #864.396. All legal guardians of the participants were informed about the risks and benefits of the study and signed the consent form.

**Consent for Publication:** Not applicable

**Availability of data and materials:** The datasets generated and/or analysed during the current study are not publicly available because there are a higher number of data that have not yet been evaluated/analyzed by the authors of the paper and that make up the secondary outcomes of this trial but are available from the corresponding author on reasonable request.

**Competing interests:** The authors declare that they not have no competing interests.

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**Authors' contributions:** RCO was responsible for data acquisition, results interpretation, and drafted the manuscript. LBC, TFN, LRAP, TG, TKT, ALP were involved in the trials' phases and data acquisition. ICO performed the statistical analysis and helped in the data interpretation. MMB was part of the study's design. FMM was part of the study's design, performed the statistical analysis and the data interpretation. DPR was the PI, responsible for the study design, and corrected the text. All authors reviewed the manuscript's final version.

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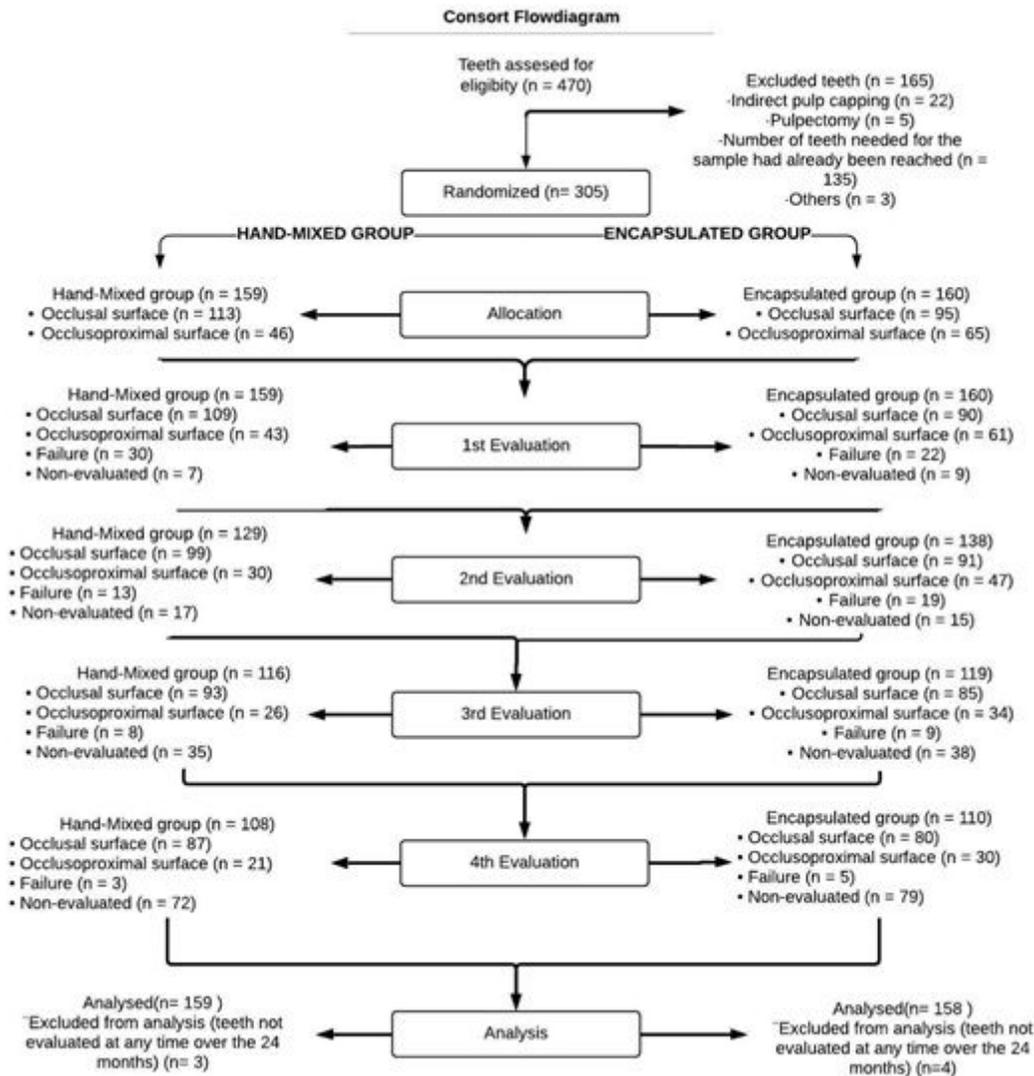
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## Figures



**Figure 1**

CONSORT flowchart of the participants' progress through the trial phases

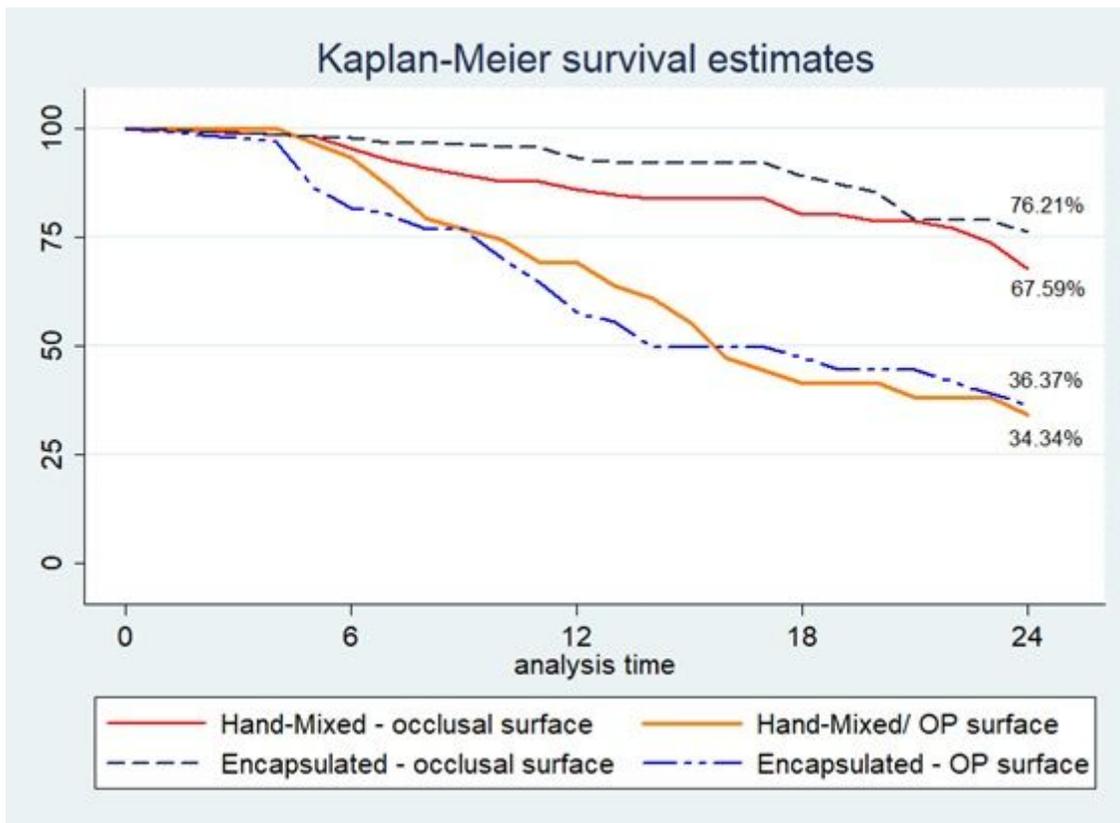


Figure 2

Kaplan- Meier survival estimates after 24 months follow-up

**MOST PREVALENT SCORES OF SUCCESS AND FAILURE OF RESTORATIONS**

	SCORE		SCORE		SCORE		SCORE	
	SCORE	N (%)	SCORE	N (%)	SCORE	N (%)	SCORE	N (%)
Occlusal Restorations – Frencken and Holmgren criteria	0	163 (80.29)	0	140 (80.46)	0	97 (76.99)	0	38 (65.52)
	1	11 (5.42)	1	4 (2.30)	1	1 (0.79)	1	2 (5.42)
	7	9 (4.43)	7	18 (10.34)	7	19 (15.08)	7	14 (4.43)
	TOTAL EVALUATED	203	TOTAL EVALUATED	174	TOTAL EVALUATED	126	TOTAL EVALUATED	58
	1ST EVALUATION		2ND EVALUATION		3RD EVALUATION		4RD EVALUATION	
Occluso-proximal Restorations – Roeleveld et al. criteria	00	57 (54.80)	00	35 (54.69)	00	22 (55)	00	8 (57.14)
	10	14 (13.46)	10	9 (14.06)	10	11 (27.5)	10	2 (14.3)
	30	19 (18.27)	30	11 (17.18)	30	5 (12.5)	30	3 (21.43)
	TOTAL EVALUATED	104	TOTAL EVALUATED	64	TOTAL EVALUATED	40	TOTAL EVALUATED	14

Figure 3

Overall scores of restorations' success and failure.

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