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Randomised controlled trial of post-operative sensitivity with warm and room temperature composite

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Abstract:	Background. Physical properties of composite improve when it is pre-heated prior to polymerization. However, post-operative sensitivity may be considered a potential complication. A review of the literature revealed no reported RCTs of postoperative sensitivity when using pre-heated composite resin. Objective. To determine if preheating composite leads to changes in postoperative sensitivity in a parallel RCT. Method. 120 eligible, consenting adults were recruited in private dental practice and randomised into two groups of 60 patients. One group had room temperature composite restorations placed and the second had composite pre-heated to 39oC. The primary outcome was sensitivity after 24hours by Visual Analogue Scale, recorded blind by patients. Secondary outcomes were VAS-scores recorded over a month. Blind statistical analysis used Mann-Whitney U test to compare the 24hour Vas-score between groups, and repeated measure ANOVA to assess the change over time. Potential confounders were tested using regression models. Results. 115 patients completed the trial; 57 in the heated composite group and 58 in the room temperature group. Analysis of 24 hours VAS-scores found no statistically significant difference in between the two groups (p=0.162). Examining the potential confounders confirmed the non-significant difference between heated and room temperature groups on the 24hours VAS-score, after controlling tooth type and pre-op pulp test (effect size=0.173, p-value=0.317). Analysis of the secondary outcomes found significant changes (within subject effect) in VAS-scores over the review period (F statistic 4.7, p=0.002), but not a significant (between subject effect) difference between heated and room temperature groups over time (effect size=0.102, p=0.197). There was a significant correlation between pre-operative VAS-score and post-operative Vas-score (p<0.001). Conclusions. For the restorations in this study there was no detectable difference in postoperative VAS-score between pre-heated and room temperature composite. Post-operative sensitivity decreased throughout

	the first month. Post-operative sensitivity was correlated to pre-operative sensitivity.

Randomised controlled trial of post-operative sensitivity with warm and room temperature composite

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The results of this study can be used by clinicians when considering the advantages and disadvantages of pre-heated composite. The study found no evidence of any change in post-operative sensitivity when using pre-heated composite. Since pre-heated composite has superior physical properties, its use for routine care can be considered good practice.

ABSTRACT

Background. Physical properties of composite improve when it is pre-heated prior to polymerization. However, post-operative sensitivity may be considered a potential complication. A review of the literature revealed no reported RCTs of postoperative sensitivity when using pre-heated composite resin.

Objective. To determine if preheating composite leads to changes in postoperative sensitivity in a parallel RCT.

Method. 120 eligible, consenting adults were recruited in private dental practice and randomised into two groups of 60 patients. One group had room temperature composite restorations placed and the second had composite pre-heated to 39^{o}C. The primary outcome was sensitivity after 24hours by Visual Analogue Scale, recorded blind by patients. Secondary outcomes were VAS-scores recorded over a month. Blind statistical analysis used Mann-Whitney U test to compare the 24hour Vas-score between groups, and repeated measure ANOVA to assess the change over time. Potential confounders were tested using regression models.

Results. 115 patients completed the trial; 57 in the heated composite group and 58 in the room temperature group. Analysis of 24 hours VAS-scores found no statistically significant difference in between the two groups (p=0.162). Examining the potential confounders confirmed the non-significant difference between heated and room temperature groups on the 24hours VAS-score, after controlling tooth type and pre-op pulp test (effect size=0.173, p-value=0.317). Analysis of the secondary outcomes found significant changes (within

subject effect) in VAS-scores over the review period (F statistic 4.7, p=0.002), but not a significant (between subject effect) difference between heated and room temperature groups over time (effect size=0.102, p=0.197). There was a significant correlation between pre-operative VAS-score and post-operative Vas-score (p<0.001).

Conclusions. For the restorations in this study there was no detectable difference in postoperative VAS-score between pre-heated and room temperature composite. Post-operative sensitivity decreased throughout the first month. Post-operative sensitivity was correlated to pre-operative sensitivity.

ISRCTN 76727312.

Trial registration number: ISRCTN 76727312. This trial formed part of a Masters program.

INTRODUCTION

Although dental amalgam is still used by many clinicians to restore carious lesions in posterior teeth (Brunton et al 2012), there has been a significant increase in the use of resin-based composites and this trend is expected to continue (Roeters et al 2005). Patient reported sensitivity of the restored tooth following treatment (post-operative sensitivity) can be a complication for clinicians placing any restoration. When using composites MacKenzie stated that a transient post-operative sensitivity is so common that patients should be warned in advance (Mackenzie et al 2009). Although the symptoms of post-operative sensitivity commonly subside, Hayashi and Wilson found the occurrence of early post-operative sensitivity was a significant, negative prognostic indicator (Hayashi and Wilson 2003).

Laboratory research suggests pre-heating a composite prior to placement can have significant clinical advantages (Daronch et al 2005) including:

- Improved rheological properties and reduced film thickness (Choudhary et al 2011) (Froe-Salgado et al 2010) (Walter et al 2009) (Blalock et al 2006).
- Better adaption/reduced microleakage (Dos Santos et al 2011) (Lucey et al 2010).
- Increased hardness (Lucey et al 2010) (Nada and El-Mowafy 2011).
- Greater monomer conversion during polymerisation (Daronach et al 2005) (Mundim et al 2011) (Franca et al 2011) (Daronch et al 2006a).
- Reduced curing time (Daronch et al 2005).
- Flowable enough to lute porcelain laminate veneers (Rickman et al 2011).

Despite these improved properties there has not been a wide uptake of the technique of pre-heating composite. One possible reason for the reluctance of dentists to use pre-heated composite is the lack of clinical evidence on post-operative sensitivity when using the technique. A review of the literature revealed there had not been a clinical trial that

examined post-operative sensitivity in vivo after preheating a composite restorative material. However there have been many in vitro studies demonstrating improved properties when a dental composite is preheated prior to polymerization (Daronch et al 2005) (Nada and El-Mowafy 2011) (Munoz et al 2008) (Wagner et al 2009) (Freeman and Krejci 2004 (Trujillo et al 2004). These improved rheological properties, improved adaption, increased hardness and reduced microleakage may or may not reduce post-operative sensitivity.

The primary aim of the study was to determine if pre-heating a composite resin restorative material leads to a change in 24 hour postoperative tooth sensitivity recorded using a patient-centred assessment on a Visual Analogue Scale (VAS). Visual Analogue Scales (VAS) have been validated for use in clinical trials (Price 1983). They are widely used in the dental and medical literature. They assess the pain reported directly by the patients. The VAS uses a continuous scale, 100mm long, on which the patients' to mark their experience of pain (range 0-100; Zero representing "no pain", 100 representing "the worse pain imaginable"). Secondary objectives of the study were to assess the effect of heating composite on patient recorded VAS scores at 1 week, 2weeks and 1month post treatment. The null hypothesis tested was that there is no difference in post-operative sensitivity between composite warmed to 39^{o}C at placement and room temperature composite. The alternative hypothesis being that there is a difference in post-operative sensitivity between the room temperature and the warmed composite.

MATERIALS AND METHODS

This study was a single centre, parallel sided randomised controlled trial (RCT) of post-operative sensitivity recorded on a patient assessed Visual Analogue Scale (VAS). The trial was conducted in the private primary care dental practice of the first author from 2012 to 2014 and formed part of his Masters dissertation. The pre-determined trial protocol received ethical approval from the Dental Research Ethics Committee (reference number

110412/IC/81). There were no protocol deviations during the trial. The trial was registered on the ISRCTN database; registration number ISRCTN 76727312. Prior to commencement of the trial the staff involved in the research completed formal training in research 'Good Clinical Practice' (GCP).

A sample size calculation was performed based on an expected 2 sample t-test of the primary outcome. Previous published papers were used to estimate VAS score standard deviation and the minimally important clinically significant differences in VAS score. For the power calculation the power was set at 0.85, alpha at 0.05, significant difference of means at 1 and a standard deviation of 1.7. This indicated a sample size of 53 in each group, allowing for a 10% drop out rate it was decided to recruit 2 groups of 60 patients. Written informed patient consent was obtained from all participants.

The patients were allocated by computer generated block randomisation into two groups of 60 patients. The randomisation was concealed in sealed sequential envelopes ensuring operator and assistants were unaware of the allocation sequence before they were opened. One group of patients had composite restorations placed at room temperature while the other had the composite heated to 39^{o}C before placement. The randomisation envelopes were not opened until after the cavity preparation to prevent any possibility of bias during tooth preparation. Although the operator was not told which composite (pre-heated or room temperature) was being passed to him, it was not possible to guarantee the blinding of the operator during the placement of the restoration because of the differences in the viscosity of the composite between the 2 techniques. However, the patient remained blind to the allocation at all times and the patient recorded the outcome of their treatment on Visual Analogue Scales, at home alone, while they remained blind to their allocation.

The inclusion criteria for the study were:

- Patient is over 18 and under 70.
- Patient is capable of informed consent.
- The tooth gives positive response to testing with an electric pulp tester.

- The cavity to be restored is a one or two surface cavity.

Exclusion criteria were:

- The patient is unable to return the VAS assessment sheets at the appropriate time.
- The tooth to be filled is periodontally involved (grade 2 or grade 3 mobile).
- The tooth to be filled is an abutment tooth for a removable prosthesis.
- The tooth to be filled has undergone orthodontic treatment within the last 3 months.
- The tooth to be filled has had periodontal surgery within the last 3 months.
- The tooth is not able to be restored as laid out in the study protocol.

Primary Outcome:

The primary outcome of the trial was the assessment of post-operative sensitivity at 24 hours by a patient-assessed Visual Analogue Scale (VAS) score.

Secondary Outcomes:

1. The assessment of post-operative sensitivity at baseline, 1 week, 2 weeks and 1 month by VAS scores.
2. Assessment of the influence of the potential confounding variables by regression modelling.
3. Assessment of time related changes in overall post-operative sensitivity over the duration of the study.

There are a number of clinical and patient related factors which have the potential to influence post-operative sensitivity. Each known potentially confounding variable was recorded for each participant to enable the assessment of these potential confounders and their ability to influence the overall results. The primary and secondary outcomes and the potential confounding variables were pre-defined and pre-specified measures, including how and when they were to be assessed. No changes to the selection of the outcome measures occurred during the trial.

The composite used in the study was HFO Enamel Plus shade UD3, which is a microhybrid composite with 75% filler by weight, manufactured by GDF GmbH, Rosbach, Germany. HFO composite and the ENA HEAT composite heater carry CE marks showing conformity to MHRA regulations for medical devices. Other materials used during the trial are listed below in Table 1. The materials and heater used throughout this trial were used according to the manufacturer's instructions.

The protocol mandated an independent dentist (associate partner) to review the collected data (including the VAS scores) on a weekly basis looking for signs of excessive sensitivity or other adverse reaction. If any untoward event occurred, a stop committee was to be convened to determine the continuing safety of the study. There was no untoward event and no recourse to a formal stop committee during the trial.

Statistical Analysis

The SPSS (version 20; SPSS, Chicago, Ill) software package and RStudio were used for data analysis and statistical significance was set at the 5% level. Descriptive statistics were performed to demonstrate the properties of heated and room temperature groups including sample sizes, means, and standard deviations. Patients' features at baseline were also statistically described in the initial analysis. The non-parametric Mann-Whitney U test was used to compare the 24 hour VAS score difference between heated and room temperature groups. Regression model was used to examine the potential confounders of the VAS score outcome. A change of more than 10% of the coefficients in the regression model by introducing one more variable would make the additional variable a potential confounder. Repeated measure ANOVA was also performed to assess the time effect over the changes of VAS score at baseline, 24 hours, 2 weeks and 1 month. Wilks' Lambda test was used to test the VAS score over the four time points, and post-hoc pairwise analysis with Bonferroni corrections was performed to examine the difference between each two pair-wised time points

RESULTS

The patient flow through the trial is shown in the CONSORT flow diagram (Figure 1). 149 patients attending for routine dental care were approached to take part in the study. 120 patients consented and recruited between September 2013 and February 2015. 115 patients completed the trial; 57 in the heated composite group and 58 in the room temperature composite group. There were no Serious Adverse Events (SAEs) or Related Adverse Events (RAEs) reported during the trial. All analyses were performed on the original assigned groups. The primary outcome was explored and descriptive statistics are displayed in Table 2. Focusing on 24 hour VAS score, the heated group has a mean of 4.23 (SD=9.24) versus room temperature group with a mean of 3.03(SD = 8.49). At the baseline, various factors had been examined, including patients' demographic features such as gender and age, tooth information such as tooth type, number of tooth surfaces, etc, and other clinical relevant test results. Heated group and room temperature group shows similar descriptive statistics within each categories, showing good stratification.

A Shapiro-Wilk test confirmed the non-normal distribution of the data from the 24hour VAS score for both the heated group (Shapiro–Wilks 0.520, $p<0.001$) and the room temperature group (Shapiro-Wilks 0.407, $p < 0.001$). Therefore, the appropriate test for the primary outcome is the non-parametric Mann Whitney test. The output of the non-parametric analysis revealed no significant difference in post-operative sensitivity between heated and room temperature composite after 24 hours ($p =0.162$).

The data from the VAS scores recorded at baseline, 1 week, 2 weeks and 1 month were explored and tested for normality for room temperature group and pre-heated group. The data was not normally distributed (p-values< 0.001 for both heated and room temperature groups); therefore Mann Whitney tests were used to compare the two groups at each time point. There was no statistically significant difference between pre-heated and room temperature composite in the recorded VAS scores (baseline VAS p=0.431, 1 week VAS

p=0.401, 2 week VAS p=0.536, 1 month VAS p=0.646). In each case the Null Hypothesis that pre-heating the composite does not affect the VAS score was retained.

The data sets of the potential confounders that are listed in Table 2 were examined. In table 2, model 0 uses regression model with 24 hour VAS score as the outcome variable, and the only predictor used in the model is the group variable (heated or room temperature). The estimated coefficient beta is 0.132 with non-significant p-value = 0.436. Models 1-10 are regression models using 24 hours VAS score as the outcome variable and two independent variables including temperature group as one predictor and one of the potential confounders as an additional predictor. There are 10 potential confounders, and after introducing them into the regression model one by one, we identified 'tooth type' and 'pre-op pulp test score' as the confounders because the coefficient of original predictor 'heated.roomtemp' changed over 10% from the original regression model (LeMorte 2015). Finally, model 11 included both confounders, 'tooth type' and 'pre-op pulp test score', in the regression.

From Table 3 we can see 'teeth type' is a confounder, however even if we are controlling the teeth type, there is still no significant difference of 24h VAS score between heated and room temperature groups (p = 0.212) with effect size 0.216, Similarly, when controlling the 'pre-operative pulp vitality test score', there is still no significant difference between the two groups (effect size 0.100, p-value = 0.568). We can control both confounders at the same time (model 11) and there is still no significance difference between the two groups (p = 0.317) with the effect size of 0.173

Finally we were interested in how overall post-operative sensitivity changed over time (figure 2). The groups were combined and the changes in the overall VAS score over time were explored. A repeated measures ANOVA test was used to see if the combined VAS results changed over time. A significant result was detected using a Wilks' Lambda test (p<0.001) and this indicates that the data supports the alternative hypothesis that the VAS scores change

through time. Pairwise analysis (with Bonferroni correction for multiple testing) was performed to identify where the differences in occurred. The analysis detected a significant difference between baseline and 1 month (effect size= 0.18, p = 0.008), the 24 hour VAS score versus 1 week (effect size= 0.178, p = 0.012), 2 weeks (effect size= 0.286, p = 0.001), and 1 month VAS score (effect size= 0.336, p < 0.001), There is also a significant change in VAS score at 1 week versus 1 months ((effect size= 0.158, p = 0.027).

DISCUSSION

The results of the study show no detectable difference between the 2 sides of the trial. Therefore we retain the null hypothesis that there is no evidence of a difference in post-operative sensitivity between composites placed at room temperature and the composites preheated to 39^{o}C. A comprehensive literature review showed this is the first trial to measure post-operative sensitivity in vivo using heated composite therefore a direct comparison with other studies on this issue is not possible.

Many of the patients gave scores of zero for the first 24hr score. A possible reason why there were so many zero scores in the dataset was that most of the patients were recruited to the study when they turned up for a routine examination rather than for an emergency appointment to resolve discomfort. Furthermore, the protocol dictated a sectional matrix band (Triodent v-ring system, Triodent, New Zealand) was to be used and their use is limited by the width of the box (Cho et al 2010). Therefore the selection criteria for the study were inhibited by requirement to use the Triodent band and cavity size was always likely to be moderate to ensure the protocol could be followed. In order to assess the size of the cavity, the protocol for our study set out to measure the volume of the cavity by recording if one, two or three compules of composite were used for each cavity. However, having recorded this data, all the cavities were found to be filled with just one compule of composite. Furthermore no cavities within the trial exposed the pulp and no linings were placed in the cavities (other than the standard composite bond). Caution is therefore needed in the

interpretation of these results and it should be noted that these results are from a trial of small to moderate sized cavities. Notwithstanding this consideration, it is interesting to note that most patients did not have post-operative sensitivity and this trial provides data to show the overall incidence of post-operative sensitivity with composite restorations is low.

Flowable composites have some useful properties; they have reduced filler loading, increased particle size and have a low viscosity (Van Noort 2007). When placed in a cavity they have high wettability of cavity walls and therefore are less likely to have voids between the composite and tooth tissue (Hervas-Garcis et al 2006). They are initially attractive for use as restorative materials however, they have high polymerisation shrinkage (3.5 to 6.3%). Furthermore due to low filler content they are mechanically weak and not as durable as conventional composites with higher filler content (Van Noort 2007). Heating a conventional composite has the potential to use the advantages of a flowable composite without the disadvantages. Pre-heating reduces the material's viscosity increasing adaption at room temperature (like flowable composites) but the pre-heated conventional composite doesn't sag or lose its shape in the same way (Daronch et al 2006b) (Rickman et al 2011).

The literature of in vitro studies on warmed composite confirms that the benefit of pre-heating a composite is that the clinician gains some benefits of a flowable composite without changing the advantageous properties of the microhybrid composite. Indeed pre-heating the microhybrid composite improves the physical properties of the composite with lower polymerization shrinkage (1.7 to 3.1%), increased cure rate and monomer conversion (Daronch et al 2006b) providing greater wear resistance and improved marginal adaption Dos Santos et al 2011). From the results of this study, these improvements are achieved with no detectable increase in post-operative sensitivity.

This trial has been able to detect a significant correlation in post-operative sensitivity to pre-operative sensitivity. In addition the trial was able to detect statistically significant differences

in post-operative sensitivity between difference types of restored teeth (molar, premolar, anterior). Furthermore these results monitored post-operative sensitivity over time and quantified the significant decrease in post-operative sensitivity over the review period. These secondary findings validate the sensitivity of the protocol used in this study. In contrast, no differences were found in patient reported VAS scores between pre-heated composite and room temperature composite. We therefore retain the null hypothesis that there is no detectable difference in post-operative sensitivity between pre-heated and room temperature composite restorations.

CONCLUSIONS

From the presented data of this trial, for small and medium sized cavities, the following conclusions are drawn:

1. There is no detectable difference in post-operative sensitivity between pre-heated and room temperature composite restorations for the restorations placed in this trial.
2. When teeth are restored with composite, there is a significant correlation between patient reported pre-operative sensitivity and patient reported post-operative sensitivity.
3. Teeth type and pre-operative vitality test score are confounders (they affect the post-operative sensitivity), however when we control for both confounders there is no significant detectable difference between the preheated and room-temperature groups in terms of the VAS.
4. When teeth are restored with composite, post-operative sensitivity significantly reduces from 24 hours after placement to that recorded 2 weeks later and that recorded 1 month later.

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DECLARATION OF CONFLICTING INTERESTS

The Authors declare that there is no conflict of interest.

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MATERIAL/PRODUCT USED	PRODUCT NAME	MANUFACTURER
ACID ETCH	KERR GEL ETCHANT	KERR CORPORATION, ORANGE, CA, USA
BONDING SYSTEM	OPTIBOND FL	KERR CORPORATION, ORANGE, CA, USA
ELECTRIC PULP TESTER	PARKELL PULP VITALITY TESTER	PARKELL INC., EDGEWOOD, NEW YORK, USA
POSTERIOR SECTIONAL MATRIX SYSTEM	TRIODENT V-RING SYSTEM	TRIODENT Ltd, KATIKATI, NEW ZEALAND
ANTERIOR MATRIX STRIP	HAWE STRIPROLL	KERRHAWE SA, BIOGGIO, SWITZERLAND
LIGHT CURE UNIT	VALO LED	ULTRADENT PRODUCTS INC., UTAH, USA.
TIMER	SALTER BIG BUTTON TIMER	SALTER HOUSEWARES, TONBRIDGE, KENT, UK
COMPOSITE HEATER	ENA HEAT, COMPOSITE HEATING CONDITIONER	MICERIUM S.p.A., AVEGNO, ITALY
OCCLUSAL INDICATING PAPER	MADAME BUTTERFLY SILK	ALMORE INTERNATIONAL INC., PORTLAND, OR, USA
FINISHING PRODUCTS	SINGLE USE DIAMOND FG BUR SUPER-SNAP FINISHING AND POLISHING DISK ASTROBRUSH	DE HEALTHCARE PRODUCTS, DENVER, PA, USA SHOFU INC., KYOTO, JAPAN IVOCLAR VIVADENT AG, SCHAAN, LIECHTENSTEIN
THERMOMETER	WETTERLADEN24.DE ROOM CONTROL. THERMOMETER-HYGROMETER-STATION	WETTERLADEN24 GSCHWEND, GERMANY

Table 1: Products and materials used during the study

DESCRIPTIVE STATISTICS						
		N	Minimum	Maximum	Mean	St Dev
24 hour Vas Score	Heated	57	0	55	4.2254	9.23794
	Room temp.	58	0	40	3.0345	8.48934

BASELINE DATA			
VARIABLE		HEATED group (n=57) Number (%)	ROOM TEMP group (n=58) Number (%)
Gender	Female	32 (56.1)	26 (44.8)
	Male	25 (43.9)	32 (55.2)
Tooth type	Premolar	29	39
	Molar	27	16
	Anteriors	1	3
Number of tooth surfaces involved in the restoration	1 surface	28 (49.1)	26 (44.8)
	2 surfaces	29 (50.9)	32 (55.2)
Tooth previously restored	Yes	18 (31.6)	20 (34.5)
	No	38 (68.4)	38 (66.6)
Matrix band used	Yes	25 (43.9)	25 (43.1)
	No	32 (56.1)	33 (56.8)
Tooth in occlusion	Yes	53 (93)	52 (89.7)
	No	4 (7)	6 (10.3)
		Mean (SD)	Mean (SD)
AGE; Years		42.68 (13.79)	42.26 (13.84)
PRE-OP PULP TEST SCORE		1.82 (1.10)	2.20 (1.66)
POST-OP PULP TEST SCORE		1.84 (0.83)	2.16 (1.23)

ROOM TEMPERATURE AT TIME OF COMPOSITE PLACEMENT	20.46C (2.43)	20.17C (2.34)

Table 2: Descriptive statistics and baseline data on primary outcome.

VARIABLE	COEFFICIENT (SE)	P-VALUE
Model 0 Heated.roomtemp[a]	0.132 (0.169)	0.436
Model 1 Heated.roomtemp[a] Gender[b]	0.127 (0.172) -0.196 (0.172)	0.464 0.250
Model 2 Heated.roomtemp[a] Teeth.type 2[c] 3 4	0.216 (changed over 63% from model 0, SE = 0.172) -0.162 (0.997) 0.064 (0.468) 0.506 (0.456)	0.212 0.872 0.892 0.270
Model 3 Heated.roomtemp[a] surface[d]	0.129 (0.170) -0.072 (0.170)	0.440 0.674
Model 4 Heated.roomtemp[a] Previous rest[e]	0.128 (0.170) 0.103 (0.179)	0.455 0.566
Model 5 Heated.roomtemp[a] Matrix[e]	0.144 (0.172) 0.067 (0.173)	0.404 0.701
Model 6 Heated.roomtemp[a] Occlusion[e]	0.125 (0.170) -0.211 (0.299)	0.460 0.48
Model 7 Heated.roomtemp[a] Age	0.136 (0.170) -0.004 (0.006)	0.420 0.515
Model 8 Heated.roomtemp[a] Preop. pulp	0.100 (over 24% change from model 0, SE = 0.174) -0.060 (0.061)	0.568 0.330
Model 9 Heated.roomtemp[a] Post pulp	0.126 (0.175) 0.016 (0.084)	0.47 0.848
Model 10 Heated.roomtemp[a] Room temp	0.132 (0.171) 0.001(0.036)	0.44 0.97
Model 11 Heated.roomtemp[a] Teeth.type 2[c] 3 4 Preop. pulp	0.173 (0.172) -0.068 (0.992) 0.066 (0.465) 0.636(0.458) -0.124 (0.063)	0.317 0.946 0.887 0.167 0.051

Table 3: Regression models of univariate (heated or room temp group) and models including a potential confounder as explanatory variable.
[a] categorized as 'room temperature' (reference category) and 'heated'
[b] categorized as 'female' (reference category) and 'male'
[c] categorized as Teeth type 1 = incisor (reference category), teeth type 2 = canine, teeth type 3 = premolars, teeth type 4 = molars.

[d] categorized as ‘1’ (reference category) and ‘2’.
[e] categorized as ‘yes’ (reference category) and ‘no’.

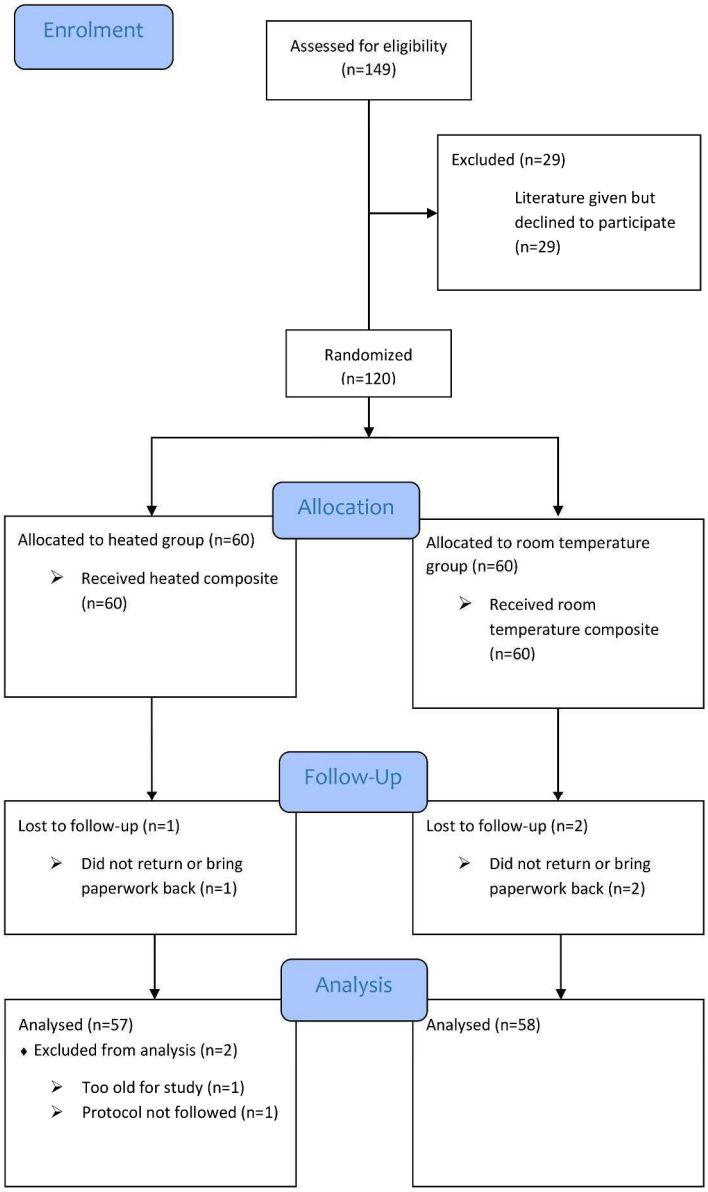

Figure 1: Consort flow diagram
Figure 1
240x397mm (300 x 300 DPI)

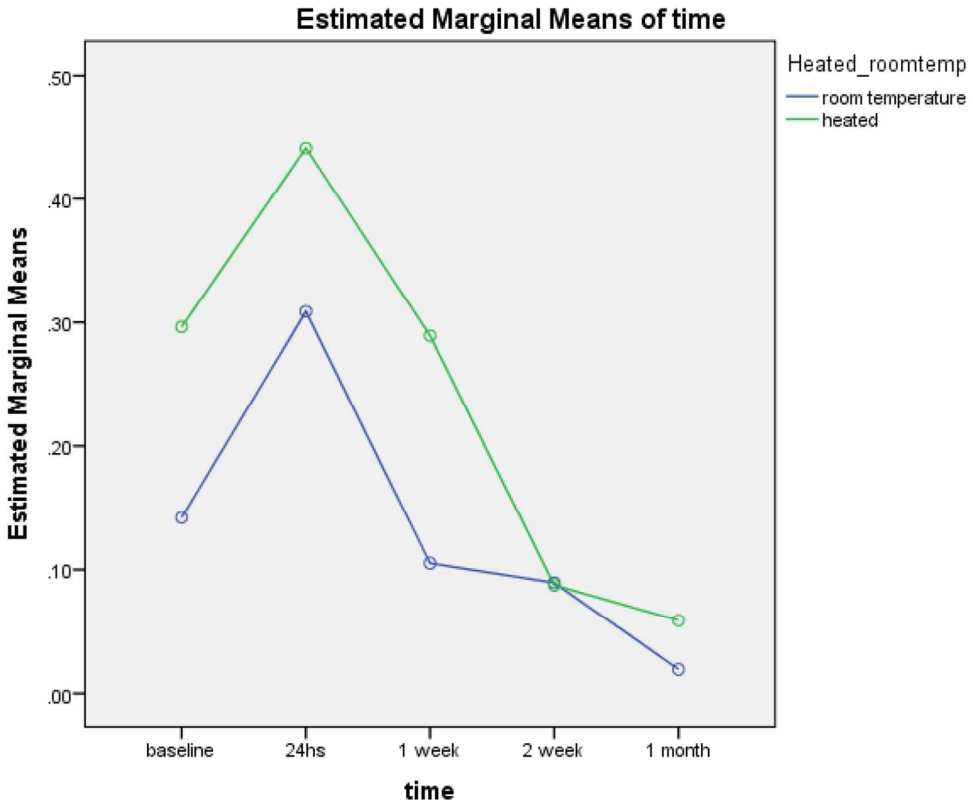

Figure 2: This is the plot for the trend of VAS score for room temp and heated group over time.
Figure 2
127x107mm (300 x 300 DPI)

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
1	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4-5
	2b	Specific objectives or hypotheses	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	5
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6-7
	6b	Any changes to trial outcomes after the trial commenced, with reasons	5 & 7
Sample size	7a	How sample size was determined	5
	7b	When applicable, explanation of any interim analyses and stopping guidelines	7
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	6
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	6
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	6
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	6
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	6

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	8
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	8 & 9
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	8
	14b	Why the trial ended or was stopped	8
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 3
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Figure 1 & page 8
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	8 & 9
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	9
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	7-8
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	10 & 11
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	11
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	11 & 12
Other information			
Registration	23	Registration number and name of trial registry	1
Protocol	24	Where the full trial protocol can be accessed, if available	Master's thesis
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	N/A

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Captions

Table 1: Products and materials used during the study

Table 2: Descriptive statistics and baseline data on primary outcome.

Table 3: Regression models of univariate (heated or room temp group) and models including a potential confounder as explanatory variable.

[a] categorized as 'room temperature' (reference category) and 'heated'

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[c] categorized as Teeth type 1 = incisor (reference category), teeth type 2 = canine, teeth type 3 = premolars, teeth type 4 = molars.

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Figure 1: Consort flow diagram

Figure 2: This is the plot for the trend of VAS score for room temp and heated group over time.