Peer-reviewed paper; submitted August 2020; accepted March 2021

A novel tooth-coloured crown system to treat dental caries in children – Development and validation

Choi JJE, Plaksina P, Foster Page L, Waddell JN, Duncan WJ

Abstract

Background and objectives: Traditional dental caries treatment in children involves surgical removal of the infected dental tissues and subsequent restorations using a filling material. The Hall Technique is known as a ‘no drill, no pain’ restorative procedure using metal preformed crowns. Although clinically effective, this technique has a major aesthetic limitation, the crown is silver rather than tooth-coloured. The objectives of the current study were to develop a novel tooth-coloured crown system for treatment of dental caries in children, and to evaluate the proof of concept, using benchtop testing to examine cementation strength, surface hardness and wear resistance, an *ex vivo* model for heat penetration, and an *in simulo* trial for acceptability to clinicians and marginal adaptation.

Methods: A variation of novel thermoplastic resin preformed systems (PFC) were developed. For mechanical testing, metal PFCs were used as controls. The novel thermoplastic resin crown materials were tested for heat transfer into the dental pulp, cementation bond strength, surface hardness and wear resistance. To validate the new crown systems, six clinicians evaluated five different crown designs and the clinical protocol and gave feedback via a post-trial questionnaire; responses were statistically analysed. The marginal seal of the different PFCs were analysed under an optical microscope and micro-CT scanner.

Results: The tooth-coloured thermoplastic crown materials did not show clinically significant heat transfer to the pulp space and bonded better with resin than a glass ionomer (GIC) cement. Initially, metal PFCs had significantly better surface hardness and wear properties; however, after modifying the thermoplastic resins, they showed comparable wear properties up to 12 months. The response of clinicians to the new treatment method was overall positive or neutral (average score on 5-step Likert scale of 3.57±0.24). Clinicians significantly favoured the aesthetics of the tooth-coloured crowns over metal PFCs (3.67±0.28, p=0.002). All six participants commented that the new treatment would be “more acceptable to the child and the parent”. Recommendations were made to improve the clinical utility of the novel tooth-coloured crowns.

Conclusion: The novel thermoplastic PFCs were found to have acceptable marginal seal, cementation bond strength and the heat generated from thermoplastic crown materials did not affect the pulp. The novel tooth-coloured crowns were significantly better aesthetically than the metal PFCs and were acceptable in a clinical simulation trial. The dental practitioners reported that they were more likely to use these as an alternative to the metal PFC. There is a need for a further *in simulo* trial, incorporating the improved functional characteristics of the prototype crowns, prior to conducting a clinical trial.

Introduction

Dental caries is the most common chronic childhood disease affecting children in New Zealand (NZ) (Ministry of Health, 2010). Māori or Pacific Island children and those of low socio-economic status have more caries than other ethnic groups (Ministry of Health 2010). Traditional treatment of caries has been to remove the infected dental tissues with a dental drill, followed by restoration with a suitable restorative material. This is invasive, often involving the destruction of sound tooth structure, particularly on interproximal surfaces where adjacent teeth meet (Foster Page *et al.* 2014). Treatment often involves local anaesthetic injections, which can lead to dental anxiety in children. Moreover, conventional restorations have a limited lifetime, leading to a cycle of repeated restoration, an inefficient use of oral health resources, more dental pulp disease and early loss of teeth (Elderton 1993; Foster Page *et al.* 2014).

The Hall Technique is a minimally invasive restorative procedure using cemented stainless-steel preformed crowns (PFC). Often this technique can be performed without requiring local anaesthesia, caries removal or tooth preparation; the metal PFC is placed over the tooth, sealing off and arresting tooth decay (Innes *et al.* 2007). Metal PFCs are supplied in different sizes that are adjusted to fit the patient before being cemented (Innes *et al.* 2007; Innes *et al.* 2011; Foster Page *et al.* 2014). Despite numerous advantages, the Hall Technique has a major aesthetic drawback: parents and children express dissatisfaction with the metallic appearance of the crowns, especially when multiple teeth are treated (Guelmann *et al.* 2011). Moreover, metal PFCs can be difficult for some dental practitioners to fit onto the tooth and are relatively more expensive than appropriate primary tooth restorative materials and had limited practitioner uptake of this treatment technique in the past (Moskowitz *et al.* 2005). Hence there is a need for a new crown system which is tooth-coloured, easy to place and inexpensive. Attempts have been made to produce tooth-coloured crowns from composites or metal crowns with white facings (Innes *et al.* 2017). However, these materials were unsuitable as they lacked the plasticity and ductility required for the Hall Technique (Innes *et al.* 2017). Adequate surface hardness and wear properties are an important requirement for Hall crowns since the molars stay in the mouth from 7.9 to 10.5 years. Not all of this time is spent in occlusion with an antagonist, however, a crown still needs to last until the primary tooth exfoliates (ADA, 2012). There are currently no aesthetic (white) crowns that have shown equal longevity and mechanical properties comparable to stainless steel metal PFCs. It would be desirable to have a tooth-coloured PFC that is aesthetically pleasing and easier to place than stainless steel crowns. The aims of this project were:

1) To develop a novel tooth-coloured crown system for dental caries treatment using the Hall Technique.
2) To characterise and test proof of concept of the novel crown using benchtop testing to examine cementation strength, surface hardness and wear resistance, and using an *ex-vivo* model for heat penetration.
3) To validate the newly developed crown system via an *in simulo* trial by dental practitioners, reproducing clinical conditions.

To serve the aims, we had specific objectives;

1) To determine the surface hardness of various thermoplastic materials.
2) To assess the shear bond strength of the thermoplastic materials with GIC and resin cement.
3) To construct various anatomical versions of novel white shell crowns for use in the *in simulo* Hall Technique.
4) Assess the performance of the various thermoplastic novel white shell crowns in the in simulo investigation.

Materials and methods

Background to the development of experimental crown material

The proprietary thermoplastic resin crown system was developed as a collaboration between the University of Otago and commercial partners, using heat injection moulding to manufacture the prototype crowns. The novel crown system employs a thermoplastic resin which is activated by heat when softened in hot water (~70°C) for a few seconds. This confers sufficient ductility that the crown can be expanded to fit over the widest bucco-lingual and mesio-distal dimension of the tooth. Once the thermoplastic crown cools, it becomes sufficiently rigid to be removed and then cemented back onto the tooth, similar to the Hall Technique protocol for metal PFCs. To validate the system, mechanical testing was conducted as follows, using metal PFCs as controls (Table 1). Firstly, the temperature profile was measured to investigate the risk of heat generation which can be damaging to the pulp. Secondly, the surface hardness and wear properties of each material was evaluated, followed by the shear bond strength test to evaluate the bond between the cement and novel thermoplastic resin materials. Lastly, the *in simulo* study was conducted to assess the acceptability of the novel crown system by dental practitioners.

Temperature profile analysis

The protocol for the thermoplastic tooth-coloured crowns involves heating in water at 70°C before placing the crown onto a vital tooth. There is a potential risk of damage to the pulp or surrounding tissues (Dias *et al.* 2019). Therefore, we established this *ex vivo* benchtop model which investigated heat penetration into the teeth after placing the heated thermoplastic crowns.

Primary teeth were obtained for testing from children receiving treatment at the paediatric dental clinic at the University of Otago. Ethical approval with Māori consultation (Reference H18/095) was obtained from the Human Ethics Committee of the University of Otago. Inclusion criteria included teeth without any visual evidence of carious lesions or cracks. After obtaining informed consent from the donors, a total of five primary molar teeth were collected at the time of extraction, and fixed in 10% formalin solution. Next, custom box-shaped jigs with lids were 3D-printed (Form 2, Formlabs, Massachusetts, USA). The teeth were secured to the 3D-printed lids in a vertical position, using pattern resin (Pattern Resin, GC, Japan). The root portion was sectioned 2-3 mm below the cemento-enamel junction (CEJ), perpendicular to the long axis of the tooth, using a diamond disk under constant water cooling. The pulp chamber was cleaned of residual pulp tissue with endodontic K-files (ReadySteel, Maillefer Instruments, Ballaigues, Switzerland) and a rose-head tungsten carbide bur was used to widen the access. A thermocouple (K- type thermocouple; Omega, USA) was placed inside the pulp chamber to measure temperature changes in real-time, using temperature data

Table 1. Materials used in the surface hardness testing.

	Materials used in the study	Composition	Brand/Manufacturer
Control	Metal PFC (Size 4s)	Stainless Steel	3M ESPE
Thermoplastic resin Type 1	Resin PFC	Proprietary thermoplastic resin	Hitem and EPD Korea in collaboration with University of Otago
Thermoplastic resin Type 2	Resin PFC 1 + UHMWPE	Ultra High Molecular Weight Polyethelene, UHMWPE-XM330, Mitsui 30 %	Hitem and EPD Korea in collaboration with University of Otago, Mitsui Chemicals
Thermoplastic resin Type 3	Resin PFC 2 + UHMWPE	Ultra High Molecular Weight Polyethelene, UHMWPE-XM221U, Mitsui 30 %	Hitem and EPD Korea in collaboration with University of Otago, Mitsui Chemicals

loggers (EL-USB-TC and LE-GFX-TC, Lascar Electronics, USA), as per our previously-published protocol (Dias *et al.* 2019). Each thermocouple recorded temperature changes at different sites: the pulp chamber (P), the tooth surface (T) and the occlusal surface of the crown materials (C); temperature changes at the three different sites were recorded as a function of time starting at a room temperature of 22^{o}C (Figure 1).

Surface hardness and wear testing

To evaluate the surface hardness of each material, nanoindentation was performed at room temperature (22°C±2) in a UMIS nanoindentation system (UMIS, Fischer-Cripps Laboratories, Australia) at a static load of 60 mN with n=50 indents per specimen across the surface. For surface hardness testing, two additional crown materials were developed and tested. The thermoplastic resin was modified by 1) the addition of 30 % Ultra High Molecular Weight Polyethylene, (UHMWPE-XM330, Mitsui) and 2) the addition of smaller particle size polyethylene, again 30% (UHMWPE-XM221U, Mitsui 30%).

Indentations were made with the load frame for the nanoindentation unit set at 0.2 nm/mN. Post-data analyses of surface hardness were performed using IBIS 2 software (Fischer Cripps Laboratories). The values obtained were statistically analysed with one-way ANOVA.

The prototype crown materials were tested using two-body wear (ball-on-disc) simulation in a universal wear testing machine (UFW200, NeoPlus, South Korea) according to ISO 14569-2. The load during the two-body wear simulation was fixed at 50 N. The frequency of the antagonist (stainless steel) movement was 10 Hz at 60 RPM for 125,000 and 250,000 cycles to simulate wear for 6 months and 12 months *in vivo*. The wear coefficient obtained were measured and statistically analysed using one-way ANOVA and post-hoc test (significance level $p<0.05$).

Evaluation of cement bond strength

Cementation of the PFC is a critical part of the Hall Technique. Since carious tissue is not excavated, it is essential that the lesion be sealed off from the oral cavity, to prevent the progression of decay. Effective cementation is a function of the bond strength between the cement and tooth enamel, and between the cement and the full coverage restorative material. Since the bonding of GIC and resin cements to enamel have already been well established (Alves *et al.* 2013), we focussed on testing the bond between the prototype PFC crown materials and either GIC or resin cements to establish which produced optimal bonding.

A notched-edge shear bond strength (SBS) test as per ISO-29022 was carried out to measure the adhesive bond strength of glass ionomer cement (GIC) and resin cement (Hitem, Korea) to the prototype crown material. The walls of the stainless steel crown material (control) and the three different thermoplastic crown materials, Types 1 – 3 (Table 2) were sectioned to produce planar

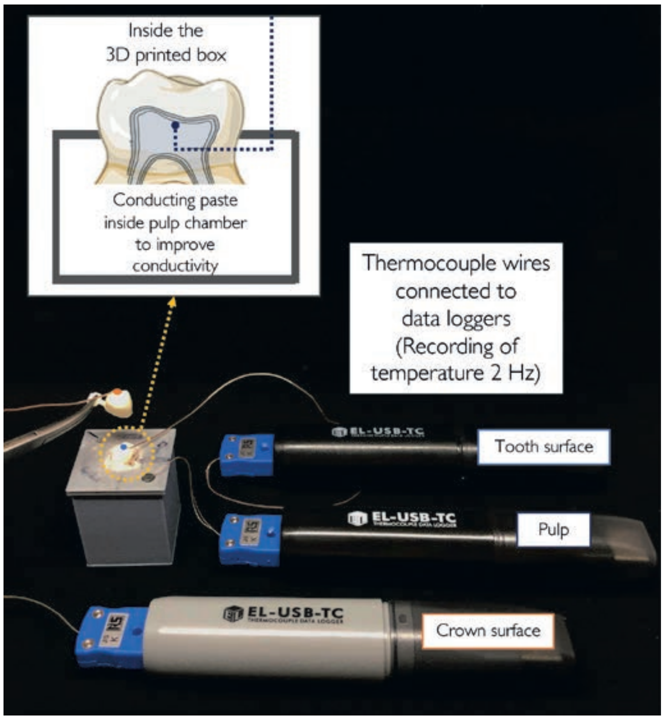

Figure 1. Schematic diagram showing the *ex vivo* model to investigate heat penetration into the teeth after placing the heated thermoplastic crowns. Temperature changes at three sites (tooth surface, crown surface and inside the pulp) were measured and recorded by three data loggers every two seconds.

test specimens measuring 7 mm x 5 mm, and then embedded in self-curing epoxy resin (EpoFix Resin and EpoFix Hardener, Struers, Australia). A laboratory cast trimmer (Handler Model Trimmer; Handler MFG Intl) was used for initial grinding of the epoxy resin to allow exposure of the flat surfaces of the materials. All specimens (n=10/group) were further polished using 1000 grit, 2400 grit and 4000 grit waterproof silicon carbide paper on a polishing machine under constant water irrigation (TegraPol-21, Struers). GIC (Fuji 9, GC, Japan) and resin cement (Hi-gel, Hitem Korea) were applied and bonded to the surface of a plastic rod (2.5mm diameter) and self-cured and light-cured respectively. A universal testing machine (Instron 3369, Instron, USA) was used to test the shear bond strength of all specimens (Figure 2). Testing was conducted using a 100N load cell and a crosshead speed of 1 mm/min. The maximum load for each specimen was recorded using the formula below.

$$\text{Bond strength } (\sigma) = F/A$$

σ = is stress, expressed in MPa
F = is force, expressed in N
A = is bonding area, expressed in mm^2

Data collected were analysed statistically with two-pair repeated measures ANOVA.

Table 2. Summary showing the metal PFC and five different designs of resin PFCs used in the *in simulo* trial.

Tested crown type	Details and images showing the prototype crowns	Key features
Metal PFC (Control)		Conventional stainless-steel metal PFC Thin walls and margins
Prototype 1		Anatomical crown made out of thermoplastic Type 1 Wall and margin thickness (X mm). Tag placed lingually.
Prototype 2		Anatomical crown made out of thermoplastic Type 2 Whiter shade due to inclusion of UHMWPE powders Shape, wall and margin thickness, tag position are the same as Prototype 1
Prototype 3		Flat anatomy crown made out of thermoplastic Type 1 Thicker margin than Prototype 1 with grooves to create better sealing around margins. Tag placed lingually.
Prototype 4		Anatomical crown made out of occlusal surface (thermoplastic Type 1) and margin area out of a malleable version of thermoplastic Type 1 to enhance marginal adaptation while maintaining surface hardness. Tag placed buccally.
Prototype 5		Anatomical crown made out of thermoplastic Type 1 Wall and margin thickness (x mm), thicker than Prototype 1-4 to test the possibility of crown being used for prepped teeth

Table 3. Summary of surface hardness values

	SS	Thermoplastic Type 1	Thermoplastic Type 2	Thermoplastic Type 3
Surface Hardness (GPa)	3.52 ±0.02	0.12 ±0.04	0.17 ±0.01	0.28 ±0.02

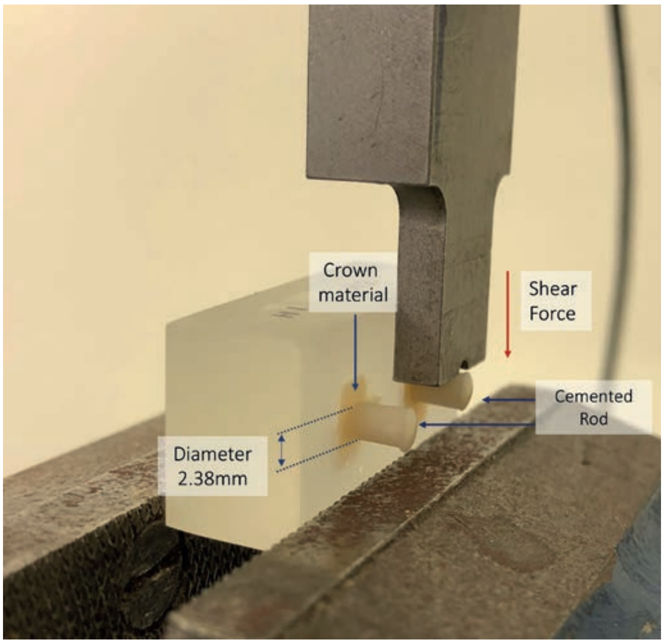

Figure 2. Image showing the shear bond test set up; cement resin rods (diameter 2.38 mm) bonded to crown materials embedded in epoxy block were subjected to vertical shear force until bonding failure.

In simulo trial to evaluate the acceptability and utility of the new crown system

Based on the previous mechanical testing results, the original proprietary crown materials (Type 1) and a strengthened version (Thermoplastic resin Type 2) were used to manufacture five different designs of the prototype crowns (Table 2). The Type 3 prototype material was not used due to difficulty with injection moulding during manufacturing. A trial was then conducted under simulated clinical conditions.

Although metal PFC crowns can be purchased in various sizes and non-curved or pre-curved, the five different prototype designs of the tooth-coloured crowns were limited in one size, as these crowns are still in the developmental stage. All resin PFC prototype crowns were designed and manufactured based on an older version of a primary dentition simulation model (AK-62, Frasaco, Germany) and its typodont teeth. The clinic in which we conducted our *in simulo* trial has switched to a new Nissin primary dentition model (PDI2001-UL-SP-HM, Nissin, Japan), which has larger typodont teeth. Therefore, to fit the new primary dentition simulation model and the pre-made PFC prototype crowns, the typodont teeth were 3D-printed rather than using the standard typodont teeth. To standardise tooth shape and size used in the trial and to facilitate tooth retrieval after cementation in order to investigate the marginal adaptation, all the Nissin typodont teeth (anterior and posterior) were scanned (Ceramill Map 400), scaled down to 88% of original size and duplicated in Peopoly Model Resin via 3D-printing (Meshmixer software; Autodesk, Inc and Formlab). Both anterior and posterior teeth were used for the resin PFCs, and only posterior teeth for metal PFCs, since these are only available for posterior teeth. The 3D-printed teeth were randomly assigned into the simulation dental models for each participant (14 teeth per participant) using a split-mouth method (total crowns in trial n=84).

A step-by-step clinical protocol was developed, based on existing user manuals already produced for metal PFCs (Evans and Innes 2010; Innes *et al.* 2017). Each step was illustrated with appropriate photographs. Several dental practitioners were consulted regarding the clarity and simplicity of the protocol and changes were made prior to the trial.

Based on the previous studies on the Hall Technique (Innes *et al.* 2007; Bell *et al.* 2010; Gilchrist *et al.* 2012), a post-trial questionnaire was developed for the clinicians to reflect their opinions on the aesthetics, effectiveness and acceptability of the new treatment method in comparison to the conventional metal PFC technique. The questionnaire had a 5-point Likert scale and included illustrations of each crown system, with 12 questions organised under three thematic categories: handling of the crown; aesthetics and crown design; effectiveness and acceptability. Open-ended questions were also included to solicit comments from the participants.

Six oral health therapists (OHT)/dental therapists (DT) from the Faculty of Dentistry, University of Otago who had varying levels of experience with the Hall Technique participated in the 3-hour trial, which took place in the Simulation Clinic of the Faculty of Dentistry, University of Otago. The simulation trial included a short introduction and practical demonstration of the novel technique. Participants then placed PFCs onto the 14 teeth sequentially using the 5 different prototype crowns and completed the post-trial questionnaire. Responses from the trial were statistically analysed using SPSS Version 25 (IBM Corp., USA) at a significance level of 5%. Open-ended comments were qualitatively analysed.

After cementation of the PFCs all the specimens were unscrewed from the typodont models and inspected under an optical microscope (Nikon, Japan; magnification 2x to 10x) to determine the marginal adaptation and seal around the tooth circumference (mesial, distal, lingual/palatal, buccal; presence of any defects or bubbles or areas where cements were not evident). One representative specimen from each group was also examined under a Micro CT scanner (Model 1172, Skyscan, Aartselaar, Belgium) to further analyse the seal underneath the crowns, using the settings described in Pimenta *et al.* (2015).

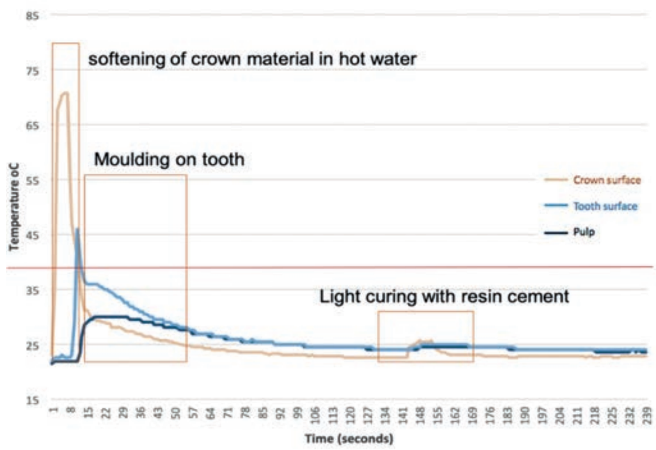

Figure 3. The mean temperature profiles for thermoplastic resin PFC following moulding and cementation. Orange line (C), blue line is the tooth surface (T), dark blue line is the pulp temperature (P). The red line indicates the body temperature 37°C."

Results

Temperature profile analysis

The outer surface of the thermoplastic crowns reached a temperature of 70°C after being submerged into hot water (Figure 3). This lasted about 4 seconds, dropping rapidly after removal. After placing the crown onto the test teeth, the tooth surface temperature increased to 45°C, which lasted for about 3-4 seconds before dropping rapidly. The temperature in the pulp space during the capping procedure increased to 29 ± 0.7 °C. Once the hardened crown was removed, filled with cement and replaced, the temperature from the three different locations kept dropping until the resin cement was cured by the light curing machine (Demi™ Ultra, Kerr) for 20 seconds (from all around the tooth; occlusal and sides) to reach a total curing time of 100 seconds. The crown surface temperature showed an increase for about 20 seconds and the temperature from all locations dropped and merged.

Surface hardness and wear

The metal PFCs showed significantly higher surface hardness (3.52 GPa ±0.02) and wear coefficient (0.8 ± 0.03) compared to the thermoplastic resin PFC materials (Tables 3 and 4). With the inclusion of the finer strengthening powders, there was an increase in surface hardness for prototypes 2 and 3, 0.17 GPa ± 0.01 and 0.28 GPa ± 0.02, respectively (Figure 4a). For wear coefficient, which is a property that can show the materials' durability and service life, the thermoplastic resin Type 1 material showed a decrease after simulated wear from 6 months to 12 months 0.37 ± 0.05 to 0.25 ± 0.09, with no statistical significance (p=0.169) compared to that of Type 2 and 3. However, Type 2 and Type 3 resins which contain UHMWPE powders showed an increase in wear coefficient after 6 months and 12 months simulated wear as shown in Figure 4b. Statistical

Table 4. Summary of wear coefficient values

	SS	Thermoplastic Type 1		Thermoplastic Type 2		Thermoplastic Type 3	
		6 month	12 month	6 month	12 month	6 month	12 month
Wear coefficient	0.8 ±0.03	0.37 ±0.05	0.25 ±0.09	0.23 ±0.09	0.29 ±0.13	0.44 ±0.01	0.57 ±0.08

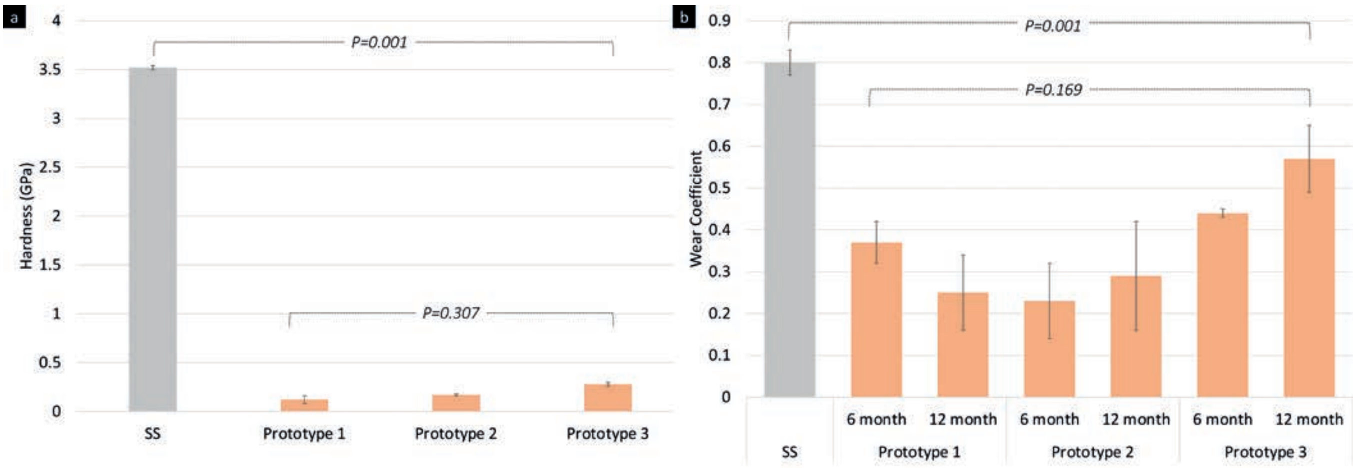

Figure 4. Graphs showing (a) the surface hardness and (b) wear coefficient of the materials studied.

Table 5. Summary of bond strength (MPa) ± Standard deviation.

With resin cement				With GIC cement			
Stainless Steel	Thermoplastic Type 1	Thermoplastic Type 2	Thermoplastic Type 3	Stainless Steel	Thermoplastic Type 1	Thermoplastic Type 2	Thermoplastic Type 3
3.34 ±1.72	1.47 ±0.52	2.2 ±0.64	2.4 ±0.37	1.17 ±0.17	0.75 ±0.24	0.87 ±0.37	0.89 ±0.28

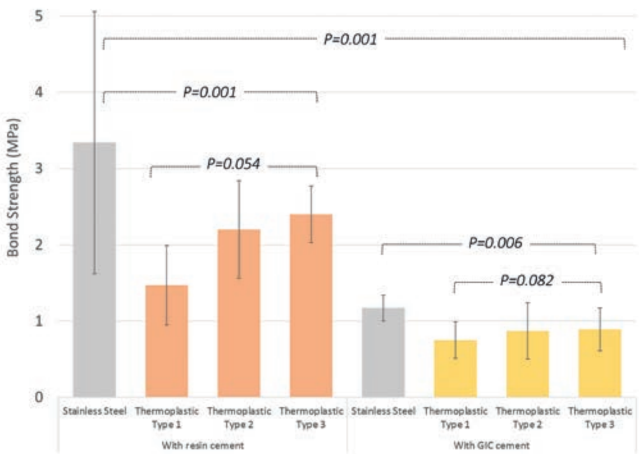

Figure 5. Graph showing the bond strength (MPa) of different thermoplastic crown materials and stainless steel bonded with resin and GIC cement.

significance was found between the wear coefficient between the metal PFC and thermoplastic resin crown materials (p=0.001).

Evaluation of cement bond strength

All crown materials (stainless steel and thermoplastic resin Type 1 to 3 materials) showed a higher bond shear strength using resin cement, compared to using GIC cement (p=0.001) (Figure 5). When bonded with resin cement, the strength was the highest when bonded to stainless steel. For thermoplastic resin materials, the bond strength ranged from 1.47 ±0.52 MPa to 2.4 ±0.37 MPa, with resin Type 3 material showing the highest bond strength and the Type 1 material having the lowest (Table 5). There was no statistical difference between the types of thermoplastic resins (p=0.054). Bonding with GIC showed a similar pattern, stainless steel showed statistically higher bond strength compared to the thermoplastic resin materials (p=0.006). The two UHMP polyethylene-fibre reinforced materials showed enhanced bond strengths but with no statistical difference (p=0.082).

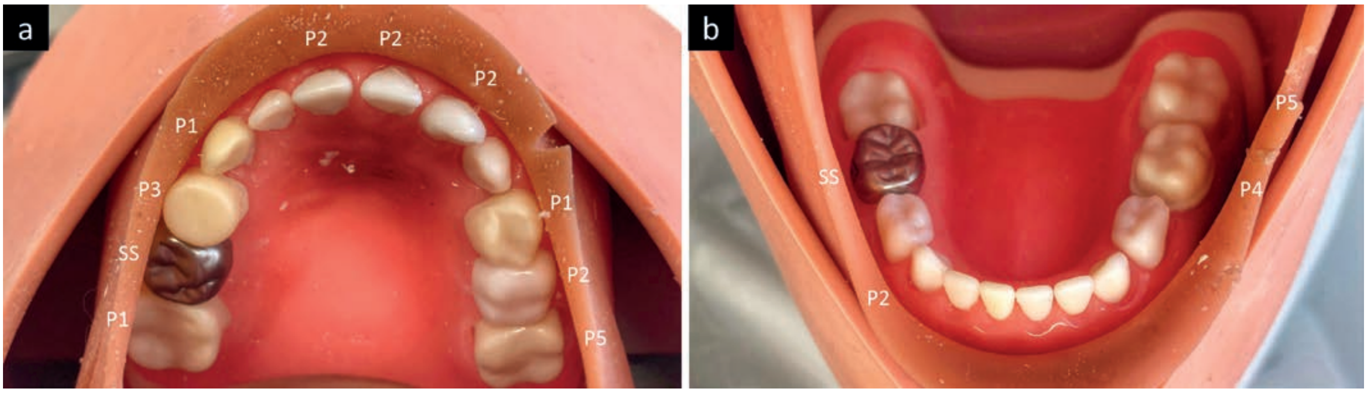

Figure 6. Images showing the PFC crowns placed by Participant # 4. A total of 14 randomly assigned metal PFCs and 5 different prototype crowns were placed onto maxillary (a) and mandibular teeth (b) during the *in simulo* trial. SS: Stainless Steel Metal PFC; P1-P5: Prototype Crown Type 1-5.

Trial to evaluate the acceptability and utility of the new crown system

All participants had previous experience with the Hall Technique except for Participant 1 who had only used a metal PFC after a pulpotomy. The clinical experience of participants ranged from 6 years to 35 years (mean 18.8 years). All participants followed the user guide for the new thermoplastic and most participants were successful in placing all 14 crowns within a given time (maximum 3 hours) (Figure 6).

For the questionnaire, the combined mean numerical response to the questions was 3.57 ± 0.24 on a scale of 1 to 5, which indicated that the participants were neutral or positive towards the new treatment method. In terms of handling the crown (softening, initial fitting, cementing, working time), participants found some designs (P1-3) easier to work with than the others (P4 and P5): Comparing thermoplastic to metal PFC , the comments in response to the open-ended questions were also positive: "*Manipulating the plastic crowns was far easier than metal PFC*", "*These plastic crowns were a lot faster to work with than metal crowns, but if the metal crown did not need crimping, I would say their working time was around the same*".

The average response about working time (Figure 7a) was 3.06 ± 0.08, which indicates that all participants found it to be time-efficient. When responses were compared between metal PFC and prototype crowns, there was no statistically significant difference (p=0.513).

In regards to aesthetics and crown design (aesthetic result, occlusal anatomy, thickness, shape of the margin, tags, expected child/caregiver reaction, any suggested changes), the participants found the tooth-coloured shell more aesthetically acceptable. Comments included "*Metal PFC colour is not good*", "*We don't have options now*", "*They are a lot more aesthetically pleasing than metal crowns*". Responses for aesthetics (Figure 7b) were positive or neutral towards the white crowns (mean 3.67 ± 0.28). Comparing metal PFC and prototype crowns, overall there was a statistically significant difference (p=0.002). In terms of design the comments were generally positive for specific prototypes: "*I think the design is pretty good*" but participants also commented on the specific design features of the new crowns and suggested future improvements.

In terms of effectiveness and acceptability, for the question "Do you feel comfortable giving this treatment to your patient?" the average response from the clinicians was 3.75 ± 0.40, which indicates that all participants would feel comfortable/neutral using this treatment (Figure 7c). When responses were compared between metal PFC and prototype crowns, overall there was no statistically significant difference (p=0.598), except for prototype 4 (p=0.007); participants indicated that they felt significantly less comfortable using prototype 4 crown for the Hall crown treatment compared to the metal PFC and other tooth-coloured prototype PFCs.

The average response about marginal adaptation of the crown was 3.67 ± 0.17, which indicates that all participants found it good/neutral. For the question "Would you use the tooth-coloured shell crowns for your patient if crown design is optimized and finalized?" all six participants replied "*yes*" and suggested that the new treatment would be "*more acceptable to the child and the parent*". When asked: "Would you use the tooth-coloured shell crowns for a conventional caries treatment (e.g. with drilling/caries removal/tooth reduction), not just with the Hall Technique?" almost all participants replied positively and commented "*it would depend on age of a child and when the tooth is about to exfoliate*". For a question "Would you use the tooth-coloured shell crown for anterior caries treatment using the Hall Technique", most participants gave positive answers; "*Definitely for bottle caries in young children, because we won't use drill and use local anaesthetic. This would be more acceptable to the child and the parent*". All participants answered that they would use this type of white PFC with a conventional caries treatment, however the preference was to use them with the Hall Technique.

The optical analysis revealed even sealing from all four sides (mesial, distal, lingual and buccal) of the PFC-fitted plastic typodont teeth. There was excess cement around the margin and the mean marginal gap was

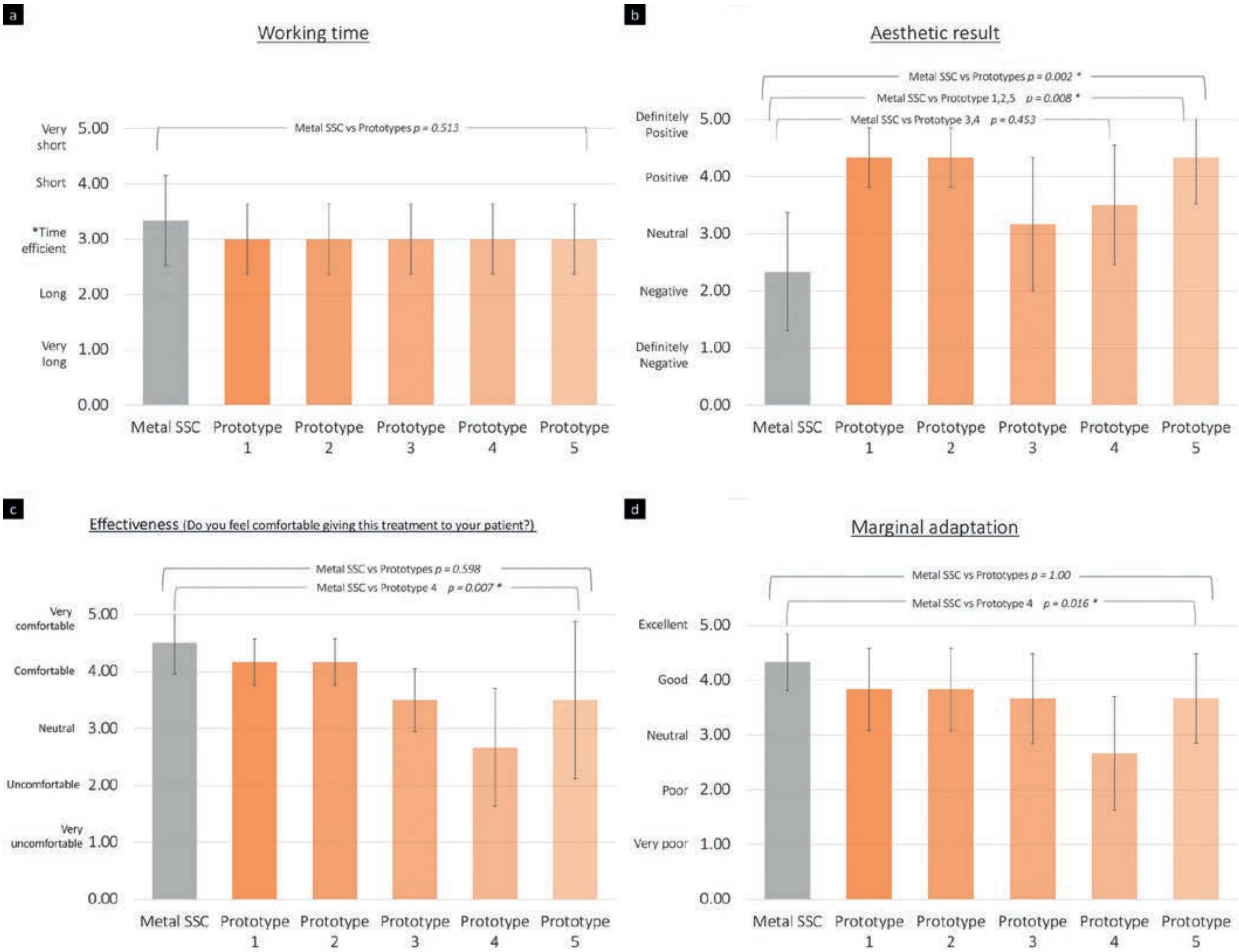

Figure 7. Working time (a), aesthetic result (b), effectiveness (c) questionnaire responses

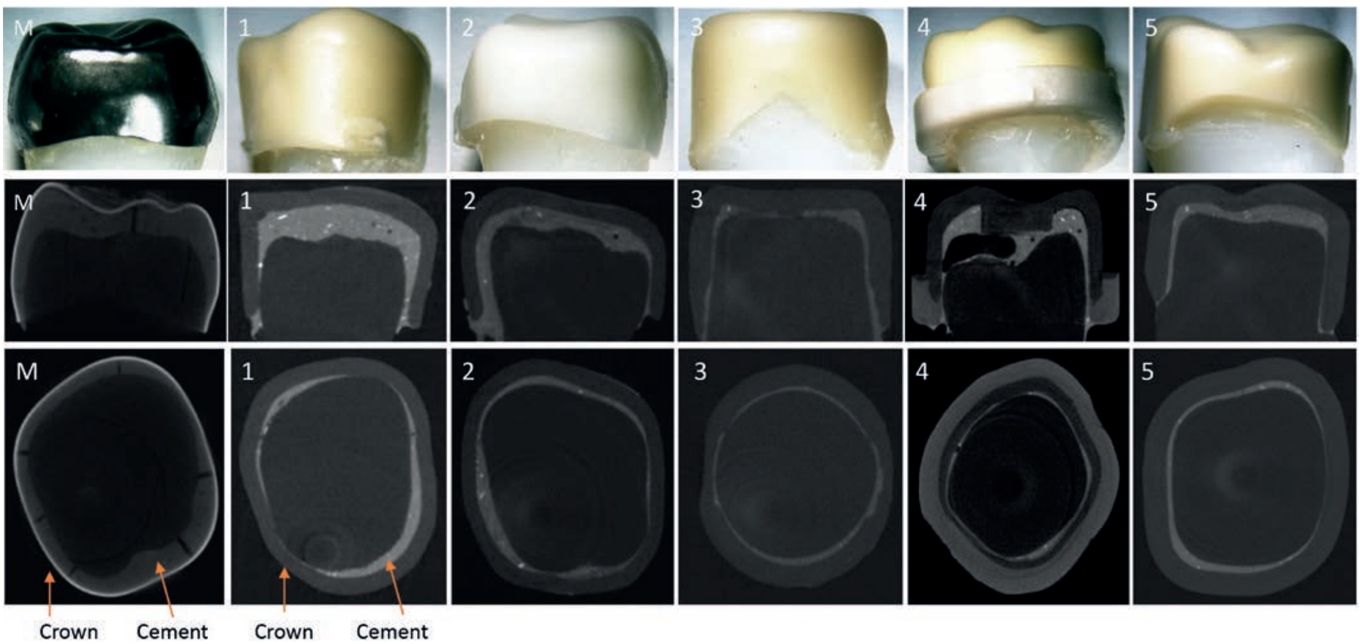

Figure 8. Light microscope images of representative crowns from each group (first row); MicroCT images from the side view (2nd row) and the occlusal view (3rd row). M = Metal PFC, 1-5 = Prototype crown 1-5. Note the crown and cement labelled for metal and thermoplastic crowns. Prototype 4 CT images show the thicker crown walls due to the thick margin design.

0.14 ± 0.05 mm. Several specimens presented with air bubbles located primarily on the interproximal sides of the specimens (mesial or distal). Micro CT images showed a good marginal seal for all crown designs (Figure 8).

Discussion

In this study we developed a range of novel, thermoplastically-modifiable, tooth-coloured pre-formed crowns (PFCs) for treatment of dental caries in children using the Hall Technique. Biomechanical testing and simulated clinical application by experienced operators provided validation and proof of concept for these prototype devices.

The first phase of the study evaluated the mechanical properties (potential heat damage to the pulp, cementation, wear and surface hardness) of the novel thermoplastic crown. The malleable phase of the novel thermoplastic resin material is designed to be activated in 70°C hot water after immersion for 3-4 seconds. Potentially, heat transfer from the activated crowns could damage the pulp. Our results suggest that the thermoplastic PFCs will not be detrimental to the dental hard tissues and pulp, since the crown temperature drops down rapidly during the moulding phase. However, a weakness of our study is that we carried out the trial with the tooth structure and pulp chamber at 22°C room temperature. This requires further research, starting with the tooth structure and pulp chamber at 37°C human body temperature and establish if the temperature of the new thermoplastic crown material causes an increase above 5°C which potentially could be deleterious to the tooth (Zach and Cohen 1965).

The cement bond strengths of the stainless steel PFCs were significantly higher than the thermoplastic prototype crown materials for both the GIC and resin bonding systems (Figure 5). The weakest link in the long term success of any crown system is the efficacy of the bonding system, due to it having the lowest strength and modulus of elasticity of the tooth material/cement/crown configuration (Jongsma *et al,* 2012). This is especially the case when the material of the new resin PFC crown system has a lower modulus of elasticity than the conventional stainless steel crown material, which could result in a failure at the interface between the crown and the cement. Our study found that the bond strength of the GIC to the stainless steel crown material was lower than the bond strength of the resin bonding system to the new resin PFC crown materials. This finding will need to be closely monitored in any future clinical trial of the new resin PFC crowns, especially when using GICs. Future research should also evaluate the bond strength of resin modified GIC to the new thermoplastic prototype crown materials as an alternative to GICs.

The surface hardness and wear properties of stainless steel PFCs were also significantly higher than the thermoplastic prototype crown materials. This was expected since the two materials have distinctively different chemical structure. With the inclusion of UHMWPE particles, the wear resistance of the thermoplastic crown material showed a marked improvement, to a value (0.57), 71% of the values achieved for stainless steel (0.8), while the surface hardness was still significantly lower for all three types of thermoplastics. Ultra-high molecular weight polyethylene (UHMWPE) has been used as a strengthening material in medical prostheses such as joint replacements, due to its biocompatibility (Bladen *et al.* 2012) and contribution to increased wear resistance when mixed with other thermoplastics. Wear resistance is an important mechanical property since it is linked to the longevity and the success rate of the Hall system when treating dental caries in children. Innes *et al.* (2017) reported that the success rate for stainless steel Hall crowns was 98% after two years and 97% after five years, which was higher than that of glass ionomer restorations and comparable to composite restorations. Yilmaz *et al.* (2011) and Roberts *et al.* (2005) reported that the mean age of the harvested SSCs in their studies were 19.6 months to 2.4 years, which gives an indication of how long these SSCs survived in function.

How long would the novel thermoplastic crowns need to survive? The upper and lower limits for eruption and shedding of 1st and 2nd maxillary and mandibular primary molars can be subtracted from each other (ADA, 2012). These teeth stay in the mouth from 7.9 to 10.5 years. Not all of this time is spent in occlusion, so one would expect that the PFC needs to last in function for up to 8 years on average. These results indicate that further strengthening is required for thermoplastic PFCs, since all three types lacked the surface hardness and wear resistance required to function for this length of time. However, the simplicity and aesthetics of the tooth-coloured thermoplastic PFCS compared with SSCs should be taken into consideration. Being thermoplastic resin, a repair of the occlusal surface would be easier than SSC, which may be an area for future studies.

For the second part of the study, we examined user experience and outcomes after simulated clinical use. Unsurprisingly, the new white resin PFCs had significantly better aesthetics than metal PFCs and were considered more clinically acceptable. Evaluation of the marginal seals beneath the PFCs used in this simulation trial were evaluated under light microscope and CT scanning, which showed comparable seal between metal and resin PFCs.

The simulation trial had several limitations which highlighted areas for improvement in future trials. Firstly, the current study employed 3D-printed resin teeth inserted into a conventional Nissin model. This was due to the prototype crowns being made for a Frasaco model, whereas the trials were conducted in the simulation clinic which has new Nissin models with larger primary teeth. The typodont teeth for the new Nissin models were scanned and decreased in size to make 3D-printed teeth which could still fit the new models and be suitable for the pre-made resin thermoplastic PFCs. Placing the crowns over the reduced size teeth made it easier to place all the crowns during the trial, however, participants reported that the 3D-printed teeth needed to be closer to each other, as tighter contact areas and less mobility would be more realistic and clinically relevant. This can be improved by manufacturing the crowns based on the correct primary tooth simulation models.

Secondly, the prototype crowns had different shades, depending on which resin material was used for manufacturing. For example, Prototype 2 crowns were a whiter shade compared to the other prototype crowns. The whiter shade comes from the inclusion of UHMWPE powder (its intrinsic colour; so the more particles added, the whiter it becomes) which may have influenced the participants' responses to aesthetics. In fact, two participants gave more positive responses to Prototype 2 crowns and commented that future prototype crowns would be preferred by clinicians when made whiter in shade, whatever the composition is. For future manufacturing, controlling the shade will be beneficial to minimise such bias.

Attempts have been made previously to produce tooth-coloured crowns from composites or metal crowns with white facings, however, these materials were unsuitable as they lacked the plasticity and ductility required for the Hall Technique (Innes *et al.* 2017). To the authors' knowledge, our resin PFC system is the first to pose a serious challenge to metal PFCs. Our thermoplastic resin PFC system is not only more aesthetic than the metal PFCs but also has other novel features and further clinical applications. Since the novel thermoplastic crown material can be softened in hot water, it will be easier for the clinician to manipulate the material to custom-fit to deciduous teeth, compared to the metal PFCs. Reduced cost is another advantage of resin PFCs, since cost-benefit is a significant consideration for a publicly-funded service and is a barrier to uptake of this technique by some District Health Boards in NZ. Being non-metal, cheaper thermoplastic resin PFCs may also reduce treatment times for the procedure, resulting in reduced costs for health providers and increased patient acceptance.

Based on the findings of this research, several prototype designs can be discarded following feedback from practitioners (e.g. Prototypes 3 and 4). Future development should focus on one particular prototype with a larger variety of sizes to choose from. The shape of the current prototype crowns is based on typodont teeth which are not the most accurate representation of children's teeth. Not only are the current prototype and the conventional metal PFCs limited in size and design, there are currently no PFCs that are made to fit Māori and Pasifika children's teeth. In NZ, Māori and Pasifika children are high dental caries risk groups and more often receive Hall Technique treatment (Ministry of Health, 2010). Their teeth are reported to be bigger than those of non-Māori and non-Pacific decent. It is desirable that we make tooth-coloured PFCs that can fit teeth of children from different ethnicities.

Product development is an iterative process requiring input from commercial partners, biomaterials scientists, translational researchers and clinicians. We expect to further develop the prototypes and to employ the testing regime that we have now established, before moving on to clinical trials. There is evidence for the clinical effectiveness of the Hall Technique in NZ and more children are receiving this treatment (Boyd *et al.* 2020). Novel tooth-coloured PFCs with further optimisation could further increase uptake of the Hall Technique in NZ, enabling children to have an improved dental experience with less anxiety and better health outcomes by reducing social stigma in children who could otherwise receive disfiguring metal crowns for treatment of dental decay.

Conclusion

Within the limitation of this study and simulation trial, a novel thermoplastic crown system has been successfully developed and validated. The new tooth-coloured PFCs were found to be clinically acceptable. They had acceptable marginal seal, cementation bond strength and did not affect the pulp. Dental practitioners may be more likely to use the system than conventional metal PFCs, due to improved aesthetics and ease of placement. There is a need for further product development and then further simulation trials before proceeding to clinical testing.

Acknowledgements

The authors would like to thank University of Otago Research Grant and Cure Kids Innovation Seed Funding for their support of the current study. The authors thank our research collaborator Hitem and EPD Korea for manufacturing the prototype crowns for research. The authors also thank the Bachelor of Oral Health staff from the University of Otago for their participation and support for the simulation trial. We also thank Mrs Jacqueline Noble for her help in Simulation Clinic and Dr Carolina Loch Santos da Silva for her assistance with Micro CT scanning.

Author details

Joanne Jung Eun Choi B.DentTech (Hon), PGDipCDTech, PhD. Senior Lecturer
Corresponding author: joanne.choi@otago.ac.nz
Polina Plaksina BDS, B.DentTech. Student
Lyndie Foster Page BSc, BDS, DipClinDent, MConDent, PhD. Honorary Associate Professor
John Neil Waddell HDE, MDipTech, PGDipCDTech, PhD . Professor
Warwick Duncan BDS, MDS, PhD. Professor, Sir John Walsh Research Institute, Faculty of Dentistry, University of Otago

References

Alajmi M and Shalwan. (2015). Correlation between Mechanical Properties with Specific Wear Rate and the Coefficient of Friction of Graphite/Epoxy Composites. *Materials*. 8:4162-4175.

Alves FB, Hesse D, Lenzi TL, Guglielmi Cde A, Reis A, Loguercio AD, Carvalho TS, Raggio DP. (2013) The bonding of glass ionomer cements to caries-affected primary tooth dentin. *Pediatric Dentistry* 35:320-324.

American Dental Association (2012). Tooth eruption, The Journal of the American Dental Association 136:1619.

Bell SJ, Morgan AG, Marshman Z, Rodd HD. (2010) Child and parental acceptance of preformed metal crowns. *European Archives of Paediatric Dentistry*. 11:218-224.

Boyd DH, Thomson WM, Leon de la Barra S, Fuge KN, van den Heever R, Butler BM, Foster Page LA (2020). A Primary Care Randomized Controlled Trial of Hall and Conventional Restorative Techniques. *JDR Clinical & Translational Research*. https://doi.org/10.1177/2380084420933154

Chadwick B, Dummer P, Dunstan F (2002). How long do fillings last? *Evidence-Based Dent.* 3:96-99.

Dean AA, Bark JE, Sherriff A, Macpherson LM, Cairns AM. (2011) Use of the 'Hall technique' for management of carious primary molars among Scottish general dental practitioners. *European Archives of Paediatric Dentistry.* 12:159-162.

Dias M, Choi JJE, Uy CE, Ramani RS, Ganjigatti R, Waddell JN. (2019) Real-time pulp temperature change at different tooth sites during fabrication of temporary resin crowns. *Heliyon*. 5:e02971.

Elderton R. (1993) Overtreatment with restorative dentistry: when to intervene? *International Dental Journal.* 43:17-24.

Evans D and Innes N. (2010) A Hall Technique: A minimal intervention, child centered approach to managing the carious primary molar. A User's Manual. University of Dundee.

Foster Page LA, Boyd DH, Davidson SE, McKay SK, Thomson WM, Innes NP. (2014) Acceptability of the Hall Technique to parents and children. *New Zealand Dental Journal.* 110:12-17.

Gilchrist F, Morgan AG, Farman M, Rodd HD. (2013) Impact of the Hall Technique for preformed metal crown placement on undergraduate paediatric dentistry experience. *European Journal of Dental Education.* 17: e10-e15.

Guelmann M, Shapira J, Silva D, Fuks A. (2011). Esthetic Restorative Options for Pulpotomized Primary Molars: A Review of Literature. *Journal of Clinical Pediatric Dentistry*. 36:123-126.

Hujoel PP, DeRouen TA. (1992) Validity issues in split-mouth trials. *Journal of Clinical Periodontology*. 19: 625-627.

Innes NP, Evans DJP, Stirrups DR (2011). Sealing caries in primary molars: randomized control trial, 5- year results. *Journal of Dental Research*. 90:1405-1410.

Innes NP, Evans DJP, Stirrups DR. (2007) The Hall Technique; a randomised controlled clinical trial of a novel method of managing carious primary molars in general dental practice: acceptability of the technique and outcomes at 23 months. *BMC Oral Health*. 7:18.

Innes NPT, Evans DJP, Bonifacio CC, Geneser M, Hesse D, Heimer. (2017) The Hall Technique 10 years on: Questions and answers. *British Dental Journal*. 222:478-483.

Jongsma LA, Kleverlann CJ, Feilzer AJ (2012). Clinical success and survival of indirect resin composite crowns: results of a 3 year prospective study. *Dental Materials*. 28:952-960.

Lesaffre, E., Philstrom, B., Needleman, I., Worthington, H. (2009) The design and analysis of split-mouth studies: What statisticians and clinicians should know. *Statistics in Medicine*. 28: 3470-3482.

Ministry of Health (2010). Our Oral Health: Key findings of the 2009 New Zealand Oral Health Survey. Wellington: Ministry of Health.

Ministry of Health. Ministry of Health. (2010) Our Oral Health: Key findings of the 2009 New Zealand Oral Health Survey. Wellington: Ministry of Health.

Moskowitz M, Sammara H, Holan G (2005). Success rate of root canal treatment in primary molars. *Journal of Dentistry*. 33:41-47.

Pimenta MA, Frasca LC, Lopes R, Rivaldo E. (2015) Evaluation of marginal and internal fit of ceramic and metallic crown copings using x-ray microtomography (micro-CT) technology. *Journal of Prosthetic Dentistry*.114:223-228.

Public Health Advisory Committee. (2003) Improving child oral health and reducing child oral health inequalities. Report to the Minister of Health from the Public Health Advisory Committee. Wellington.

Roberts J, Attari N, Sherriff M (2005). The survival of resin modified glass ionomer and stainless steel crown restorations in primary molars, placed in specialist paediatric dental practice. *British Dental Journal.* 198: 427–431.

Roshan D, Curzon M, Fairpo C. (2003) Changes in dentists' attitudes and practice and in paediatric dentistry. *European Journal of Paediatric Dentistry*. 4:21-27.

Santamaria RM, Innes NP, Machiulskiene V, Evans DJ, Alkilzy M, Splieth CH. (2015) Acceptability of different caries management methods for primary molars in a RCT. *International Journal of Paediatric Dentistry*. 25:9-17.

TeMoananui R, Kieser JA, Herbison PG, Liversidge H (2008). Estimating Age in Māori, Pacific island European children from New Zealand. *Journal of Forensic Science.* 53:401-404.

Threlfall AG, Pilkington L, Milsom KM, Blinkhorn AS, Tickle M. (2005) General dental practitioners' views on the use of stainless-steel crowns to restore primary molars. *British Dental Journal*. 199:453-455.

Yilmaz Y, Kara NB, Yilmaz A, Sahin H (2011). Wear and repair of stainless-steel crowns. *European Journal of Paediatric Dentistry.* 12:25-30.

Zach L, Cohen G (1965). Pulp response to externally applied heat. *Oral Surgery, Oral Medicine, Oral Pathology.* 19:515-530.