

# A 36-month Prospective Randomized Clinical Pilot Trial Comparing Stainless Steel Crowns With Prefabricated Resin Crowns In Primary Molar Teeth

Chao JH, Ruck PT, Matusak AM, Thikkurissy S, Gosnell ES, Cincinnati Children’s Hospital Medical Center, Cincinnati, OH

## Intro

Preformed stainless steel crowns have long been the gold standard for full-coverage pediatric dentistry restorative options since their inception in the 1950’s. Stainless steel crowns are relatively easy to place, inexpensive, and have a track record of clinical success. The clinical drawbacks of stainless steel crowns include their esthetic appearance with guardian/parental acceptance, can cause significant magnetic resonance imaging artifacts, and may pose a relative risk for potential nickel allergen responses.<sup>1-5</sup> In 2023 a new commercial product BioFlx (NuSmile Ltd., Houston, TX, United States) became available.<sup>6</sup> This material is based on a biocompatible hybrid resin polymer.<sup>6</sup> Per the manufacturer, through in-vitro wear testing, the resin polymer displays a self-adaptive technology that tolerated cyclic loading better than previous resin-based materials.<sup>6</sup> There has been a clinical interest in an esthetic alternative to stainless steel crown that still matches its physical properties, which BioFlx may provide.<sup>7-14</sup> However, due to its novelty, there is no empirical data to support successful long-term clinical outcomes.

## Objective

The objective of this 36-month prospective, randomized controlled, split-mouth pilot study, is to compare a new prefabricated resin crown material against the gold standard stainless steel crown in primary molars that require full coverage restorations. The results of this study can help determine if resin polymer crowns clinically perform like stainless steel crowns, and if they are an acceptable esthetic alternative treatment option for a full coverage restoration of a primary molar.

## Methods

IRB-approved initial study (IRB # 2024-0022) aims to recruit 50 pediatric patients for this pilot study.

Inclusion criteria:

- ASA I or II, high caries risk patients aged 2 to 5 years and 11 months at the time of recruitment, who present to CCHMC dental clinic and require full mouth dental rehabilitation under general anesthesia.
- Minimum of one pair of contralateral primary molars in need of full coverage restorations in the same arch.

Exclusion criteria:

- Patients with multiple grossly carious primary molars needing extractions, where the planned full coverage restoration has no opposing tooth to occlude against.
- Patients who do not wish to or cannot reliably return for follow-up visits.
- Patients with red dye allergy as they will not be able to be plaque disclosed during follow-up visits.

## Results

Enrolled subjects will be Followed-up at a 6 ,12, 18, 24, 30, and 36 months postoperatively to check for the performance of restorative materials using the modified United States Public Health Service (USPHS) criteria. Examiners will grade the stainless steel crowns and BioFlx crowns in four criteria: plaque retention, gingival health, occlusal wear, and crown retention. The USPHS assigns scores to clinical characteristics for a type of restorative materials. A score of ALPHA (A) is clinically ideal, BRAVO (B) is clinically acceptable, where as a score of CHARLIE (C) is clinically unacceptable.

USPHS rating process							
Simplified Oral hygiene Index (OHI-S)							
Alpha	0	No debris or stain present					
Alpha	1	Soft debris covering not more than one third of the tooth surface being examined or the presence of extrinsic stains without debris regardless of surface area covered.					
Bravo	2	Third but not more than two thirds of the exposed tooth surface.					
Charlie	3	Soft debris covering more than two thirds of the exposed tooth surface.					
Gingival Health according to the Modified Gingival Index (MGI)							
	MGI Score	Diagnosis	Modified gingival index criteria	Color	Texture	Volume	Extent
Alpha	0	Healthy	Absence of inflammation	Normal	Normal	Normal	None
Alpha	1	Mild inflammation (partial unit)	Slight change in color, a little change in the texture of any portion of, but not the entire, marginal, or papillary gingival unit	Slightly more reddish or bluish reddish	Slightly glazy	Slight edema of the margin	Part of gingival unit
Bravo	2	Mild inflammation (entire unit)	Criteria as above but involving entire marginal or papillary gingival unit	Slightly more reddish or bluish reddish	Slightly glazy	Slight edema of the margin	Entire gingival unit
Charlie	3	Moderate inflammation	Glazing, redness, edema, and/or hypertrophy of the marginal or papillary gingival unit	Red or reddish blue	Glazy	Edema and/ or hypertrophy of the margin	Entire gingival unit
Charlie	4	Severe inflammation	Marked redness, edema and / or hypertrophy of the marginal or papillary gingival unit, spontaneous bleeding, congestion, or ulceration	Markedly red or reddish blue	Spontaneous bleeding or ulceration	Edema and/or hypertrophy of the entire unit	Entire gingival unit
Occlusal Wear							
Alpha	occlusal surface intact						
Bravo	Wear of occlusal surface without tooth surface exposure						
Charlie	Wear of occlusal surface with tooth surface exposure.						
Crown Retention							
Alpha	Intact crown						
Bravo	Partial loss of Crown Material						
Charlie	Crown Lost						

Clinical photos will be taken with parental consent to aide with scoring and documentation at each follow-up visit.



Intraoral photos 1, 2, and 3 showing plaque retention, gingival health, crown retention, and occlusal wear of stainless steel crowns and BioFlx crowns of a study participant who returned 6 months postoperatively for follow-up.



## Results



Intraoral photos 4 and 5 showing level of plaque retention of stainless steel crowns and BioFlx crowns using a red dye containing disclosing solution applied prior to patient receiving dental prophylaxis.

## Discussion

In the recruitment process, researchers learned that of the patients treated at CCHMC, majority of their parents are not as concerned about the esthetics of stainless steel crowns as initially purported to be. Preparation for BioFlx crowns is more technique sensitive than that of stainless steel crowns, requiring circumferential reduction and a minimum of 2 mm of occlusal reduction for proper seating and cementation. In 6-months postoperative follow-up visits, BioFlx crowns have shown more occlusal wear and more plaque retention compared to that of stainless steel crowns.

## Conclusions/ Future study

Thus far for this pilot study, 17 patients were recruited, with a total of 46 BioFlx crowns and 41 stainless steel crowns placed. Five patients have returned for their first follow-up visit, with the remaining 12 scheduled to return in the coming months. Data will continue to be collected to compare the clinical success of BioFlx crowns to that of stainless steel crowns.

## References

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