

Comparing Stainless Steel Crowns With Prefabricated Resin Crowns in Primary Molar Teeth

Status: RECRUITING

Eligibility Criteria

Sex: ALL

Age: 2 years to 5 years old

Healthy Volunteers: This study is also accepting healthy volunteers

Inclusion Criteria:

- CCHMC pediatric dental patients between the ages of 2 years to 5 years and 11 months, at the time of recruitment, who present to any CCHMC dental clinic location and then are found to need full mouth dental rehabilitation.
- Patients who speak the most common languages at CCHMC will be able to be recruited for the study.

o English, Spanish, Arabic, Uzbek, Nepali, Chinese Mandarin, Russian, French.

* These patients must qualify for treatment at the CCHMC dental in-office general anesthesia (IOGA) area or the Procedure Center (PC). IOGA and the PC will be selected as a venue of treatment to control behavioral factors. This is not specific to the study and would occur due to their treatment needs.

* Participants will have at least one pair of contralateral primary molars with the need for a full coverage restoration in the same arch.

- For example, tooth A & J, B & I, S & L, or T & K
- For each participant, a minimum of one SSC or one PRC will be randomly assigned via a split mouth design to be placed as part of the study.
 - Need for Full coverage and high caries risk will be defined by AAPD Best Practice Guidelines 2,16

o Teeth With

1. Extensive caries
2. Cervical decalcification
3. Developmental defects (e.g., hypoplasia, hypocalcification)
4. When failure of other available restorative materials is likely (e.g., interproximal caries extending beyond line angles, patients with bruxism)
5. Following pulpotomy or pulpectomy
6. For definitive restorative treatment for high caries-risk children as defined by the AAPD
7. For patients who exhibit high caries risk and whose treatment is performed under sedation or general anesthesia. This would be normal and not specific to the study.

* Participants who consent to the study, and who can be available for follow-up recall appointments.

* All participants will be ASA I or ASA II as defined by the American Society of Anesthesiologists.15

Exclusion Criteria:

- Participants who do not meet inclusion criteria will be excluded.
 - Participants whose teeth do not meet the inclusion criteria.
 - Participants who do not wish to participate in the study.
 - Patients who do not wish to or cannot reliably return for follow-up visits.
 - Red dye allergy as patient will not be able to be plaque disclosed during follow-up visits.
 - Participants who do not speak English, Spanish, Arabic, Uzbek, Nepali, Chinese Mandarin, Russian, French.

Conditions & Interventions

Interventions:

DEVICE: BioFLX crown, DEVICE: 3M Stainless Steel Crown

Conditions:

Dental Caries

Keywords:

Pediatric dentistry

More Information

Description:

The main reason for this research study is to learn more about a new flexible white dental crown (BioFLX) by comparing it to an existing flexible metal crown (Stainless Steel Crown). It is of interest to see if this new white crown is clinically equivalent to the existing silver crown that is mainly used in pediatric dentistry. A potential participant for this study would have cavities that require a crown, a type of filling that covers the entire tooth, and recommended dental work be done under general anesthesia.

Contact(s): Patrick T Ruck - patrick.ruck@cchmc.org

Principal Investigator:

Principal Investigator ID:

Phase: NA

IRB Number:

System ID: NCT06713330

Thank you for choosing StudyFinder. Please visit <http://studyfinder.cchmc.org> to find a Study which is right for you and contact clinicalstudies@cchmc.org if you have questions or need assistance.