RESEARCH PROTOCOL

- **Title of project:** Evaluation of the Effectiveness of Bioactive Composite in Treating Dental Caries in Primary Teeth: Randomized Clinical Trial
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Aims :

To evaluate the clinical sucsess of ACTIVA™ KIDS BioACTIVE restoration and to compare it with RMGIC (GC FUJI® II 2 LC CAPSULE) and conventional composite (Tetric®n-ceram, Ivoclar vivadent).

Hypothesis of the clinical study:

There is a significant difference between ACTIVA™ KIDS BioACTIVE and RMGIC (GC FUJI® II 2 LC CAPSULE) and the conventional composite (Tetric®n-ceram, Ivoclar vivadent) in clinical success.

Study design :

Experimental prospective double blinded (the patient and the examiner) split-mouth randomized controlled trial. The study will be divided into two groups :

The first study : The cavities will be restored with ACTIVA™ KIDS BioACTIVE, and conventional composite (Tetric®n-ceram, Ivoclar vivadent) as split mouth technique.

The second study : The cavities will be restored with ACTIVA™ KIDS BioACTIVE, and RMGIC (GC FUJI® II 2 LC CAPSULE) as a split mouth technique.

Materials and Methods :

Informed consent :

An informed consent will be signed by the parents after their approval to participate in the study.

Sample size :

The sample size was calculating using G. power. The sample size consist of 40 restorations in 20 patients for group1 and 40 restorations in 20 patients for group 2.

Inclusion criteria :

The selected teeth will be in either side of the jaw, upper or lower jaw, and both primary molars (first and/or second) with occlusal and proximal enamel/dentine caries with a 4/5 score according to ICDAS. All teeth should be vital, restorable and free of these symptoms : spontaneous pain, swelling, fistula, abscess or tenderness on percussion, pathological mobility.

Exclusion criteria :

If one or more of the above mentioned criteria is not obtained, the patient will be excluded from the study.

Randomization technique :

First we use the randomization website (www.randomization.org) to distribut the patients in the two groups of the study for example and not as a limitation patient number (1) in group (1) and patient number (6) in group (2).

Then in the same group the child himself throw the dice1which was numbered from 1 to 6 to select the side of the restoration (right or left) (1,3,5 reffered to the right side of the jaw) and (2,4,6 reffered to the left side of the jaw).

Then the patient throw the second dice 2 to select the restoration (1,3,5 reffered to composite restoration/ 2,4,6 reffered to bioactive) dice 3 (1,3,5 reffered to bioactive/ 2,4,6 reffered to RMGI).

Clinical procedures :

The teeth will be anesthetized by Lidocaine 2% + Epinephrine 1/100000 (Lignospan® standard) and isolated using rubber dam. Caries will be removed using a high speed diamond bur. The proximal box will be prepared taking into consideration the following dimensions :

1- The bucco-lingual dimensions involve the middle third of the intercuspal space of the occlusal surface of the tooth.
2- The buccal and lingual outlines of the box are parallel to the buccal and lingual surfaces of the tooth.
3- The gingival floor should exceed the contact point.
4- The axial wall should be perpendicular to the gingival floor.
5- The cavo-surface margin is not beveled.
6- The unsupported enamel should be removed.

Any residual caries will be removed by low-speed handpiece or excavator.

After caries removal, a metal matrix band (YOUNG ™, USA) and a wedge will be inserted to preserve the gingival interproximal embrasure.

The restorative materials will be chosen according to the randomization and placed in the cavity according to the manufacturer's instructions (table 1). (Randomization should be determined ahead of time.

Evaluation criteria :

All the teeth will be evaluated after 3, 6, 9 months by two blinded and calibrated evaluators using modified United States Public health Service (USPHS) modified Ryge Criteria.

The included criteria were : (Anatomical form, Marginal integrity, Marginal discoloration, Color stability, Recurrent caries, Surface texture)

Manufacturer's Instruction : (Table 1)

Composite	RMGI	Bioactive Composite
-After cavity preparation, apply the rubber dam and the matrix then wash and dry the cavity. -Etching dentine for 15 s and enamel for 30 seconds. -Apply the bonding agent and cure it for 20 s. -Apply Tetric to a maximum of 2mm and cure it for 20 s (≥ 500 mW/cm). -check the occlusion. -finish with superfine diamond bur, silicon point and finishing strip.	-After cavity preparation, apply the rubber dam and the matrix then wash and dry the cavity. -Apply cavity conditioner to remove smear layer. -shake the capsule or tap its side on a hard surface to loosen the powder. -push the plunger until it is flush with main boody. -to activate the capsule we will put it into a capsule GC capsule applier and click the lever once. -we will put the capsule into the amalgamater and mix it for 10 seconds at high speed (=/- 4000RPM). -immediately we will put the mixed capsule into the GC applier then click twice to prime the capsule then syringe. -extrude cement directly into the preparation,	After cavity preparation, apply the rubber dam and the matrix then wash and dry the cavity. -Etching dentine for 15 s and enamel for 30 seconds. -Apply the bonding agent and cure it for 20 s. -Apply the material by put the mix tip in the cavity, make the layer to a maximum of 2mm - Keep the mix tip submerged in the material at all times, and allow the material to flow ahead of the mix tip. Do not withdraw the tip faster than the material fills the space or air bubbles will result. -Keep the tip submerged in the material and avoid pulling the tip in and out of the cavity prep. -the occlusal surface can be shaped during

	form the contour the cure for 20 seconds (470 nm wavelength) - check the occlusion. -finish with superfine diamond bur, silicon point and finishing strip. -apply GC FUJI COAT ant cure for 10 seconds.	self- cure stage which happens within 20 s. -lighe curing for 20 s. -finish with superfine diamond bur, silicon point and finishing strip.