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Yomna Morad

Assistant Lecturer of Pedodontics and Oral Health, Faculty of Dental Medicine for Girls, Al-Azhar University, Cairo, Egypt, yomnaosama86@hotmail.com

Mohamed El Maaty

Professor of Pedodontics and Oral Health, Faculty of Dental medicine for Boys, Al-Azhar University Cairo, Egypt, dr.abualmaaty@hotmail.com

Mohammed Mostafa

Associate Professor of Pedodontics and Oral Health, Faculty of Dental medicine for Girls, Al-Azhar University Cairo, Egypt, dr.farouz00@gmail.com

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Clinical Evaluation of Carie-Care as Chemo-Mechanical Caries Removal Agent in Disabled Egyptian Children

Yomna O. Morad^{1*}, Mohamed A. El Maaty², Mohammed H. Mostafa³

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azhardentj@azhar.edu.eg

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ABSTRACT

Purpose: compare the chemo-mechanical method of caries removal (CMCR) using Carie-Care™ and conventional technique (Drilling) in normal and disabled Egyptian children. **Materials and Method:** A total of 40 children were divided into two equal groups .Group A: 20 healthy and normal children. Group B: 20 children with different types of disabilities, either intellectual disability, hearing impairment or visual impairment. Their age ranged from 5-8 years .Two primary carious teeth were chosen in each child according to inclusion criteria (total 80 teeth). The eighty primary teeth from forty children were further subdivided equally into two subgroups (40 teeth in each subgroup) according to caries removal technique. Subgroup I: caries was removed with CMCR using the Carie-Care system. Subgroup II: caries was removed with the conventional drilling technique. Then all teeth were restored with Activa kids bioactive restorative material and followed up at baseline, one month, three months and six months intervals. **Results:** Results of this study showed that there was no significant difference between patients' groups regarding complete caries removal, total time taken for complete caries removal, pain and patient comfort, but there was a statistically significant difference between both techniques regarding complete caries removal in disabled children group (Group B), and a significant difference was also found in the time taken for complete caries removal , pain and patient comfort in both patients' groups. Also, there was no statistically significant difference between patients' groups regarding the longevity of Activa kids bio-active restorative material at base line, one month, three months and six months follow up periods. **Conclusion:** Carie-Care™ gel was an efficacious alternative method to treat carious lesions in both normal and children with different disabilities since it allies atraumatic characteristics. Activa kids bioactive restorative material had an excellent performance as a permanent restorative material in vital primary teeth in both normal and disabled children in a period of 6 months.

KEYWORDS

Carie-Care™ ,
Disabled children ,
Conventional drilling,
Activa kids.

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1. Assistant Lecturer of Pedodontics and Oral Health, Faculty of Dental Medicine for Girls, Al-Azhar University, Cairo, Egypt
2. Professor of Pedodontics and Oral Health, Faculty of Dental medicine for Boys, Al-Azhar University Cairo, Egypt
3. Associate Professor of Pedodontics and Oral Health, Faculty of Dental medicine for Girls, Al-Azhar University Cairo, Egypt

* Corresponding author email: yomnaosama86@hotmail.com

INTRODUCTION

Dental caries is one of the most serious dental diseases which results in localized dissolution and destruction of the calcified dental tissues, neglecting treatment could affect the dental pulp ⁽¹⁾. However, the treatment procedures are usually associated with poor patients' sensation. Several approaches for removing and treating dental caries have been used for more comfort. Caries removal in decayed teeth has commonly been done using the mechanical cutting systems. However, these methods have some major disadvantages. First, mechanical preparation often promotes ache, and local anesthesia is thus required. Second, it is often hard to establish how much dental tissues should be removed, which often leads to overextended cavities ⁽²⁾. So possible alternative approaches have been developed as CMCR systems. CMCR includes chemical softening of carious dentin, then its removal with gentle excavation. It involves selective removal of degraded collagen fibrils in carious dentin, while leaving the affected demineralized dentin layer ⁽²⁾.

Several materials have been used in CMCR technique as Caridex®, Carisolv®, Papacarie®, and Carie-Care™ for removal of carious dentin⁽³⁾. One of the recent development in CMCR is Carie-Care™. It is a gel based formulation containing a purified enzyme, derived from the plant *Carica papaya* (Papaya) which exhibits anti- bacterial and anti-inflammatory properties. In addition, it contains clove oil, which is anti-inflammatory and analgesic essential oil with mild anesthetic effect which reduces the pain perception during the operative procedure, chloramines that are used to chemically soften the carious dentin and dye ⁽⁴⁾. It also contains specific gelling agent in accurate percentage to give proper consistency to the gel so there is no spilling over when it's applied⁽⁴⁾.

Children with special health care needs (CSHCN) have limited motor and sensory coordination, most of them do not have the ability and awareness to care for themselves and must rely on their parents

or caregivers for general care. The oral health of CSHCN has always been found poor when compared to otherwise healthy children in respect to the status of their dentition, periodontium and dentofacial anomalies⁽⁵⁾. So early introduction to the dental service is necessary for children with special needs. Currently, research in dentistry has concentrated its efforts on the quality of treatment given to CSHCN. Therefore, CMCR technique for removing caries is an efficient option when supplying oral care for these patients⁽⁶⁾.

Bioactive restorative materials have been introduced for numerous purposes in dentistry ⁽⁷⁻⁹⁾, among these are medicaments that induce healing and/ or create new tooth structures as (mineral trioxide aggregate; BioAggregate), and restoratives that release and recharge fluorides and calcium as (Activa) ^(10,11).

Activa bio-active restorative materials are ionic composite resins which combine the biocompatibility, chemical bond and the ability to release fluoride of glass ionomer cement (GIC) with the mechanical properties, aesthetic and durability of resin based composite (RBC). In addition, it is declared that those materials have bioactive properties as the US Food & Drug Administration has stated that Activa bio-active products contain a bioactive matrix and bioactive fillers which make them different from other tooth colored restorative materials ^(12,13). Therefore, the aim of this study was to compare chemo-mechanical method of caries removal using Carie-Care™ and conventional technique (Drilling) in normal and disabled Egyptian children.

MATERIAL AND METHODS

The design of the current study was a split-mouth trial⁽¹⁴⁾. Research Ethics Committee approval was obtained from Faculty of Dental medicine, Al-Azhar University. Full detailed treatment plan was explained to the children's parents or caregivers and informed written consents for treatment were obtained prior to treatment. A total of 40 children were divided into two equal groups:

Group A: 20 healthy and normal children.

Group B: 20 children with different disabilities.

Normal children were selected from those who were attending at outpatient clinic of Pedodontics and Oral Dental Health department, Faculty of Dental medicine for Girls, Al-Azhar University. And disabled children were selected either from the outpatient clinic of Pedodontics and Oral Dental Health department, Faculty of Dental medicine for Girls, Al-Azhar University, Resala Charity Organization or Al Firdwos orphanage for disabled children.

Children age ranged from 5-8 years, with at least two carious lesions in primary dentition⁽¹⁵⁾. Two primary carious teeth were chosen in each child (total 80 teeth).

Teeth inclusion criteria:

- Primary carious teeth with dentin involvement.
- Carious cavity was large enough so that a hand instrument can be operated⁽¹⁵⁾.
- Teeth were asymptomatic with no clinical evidence of pulp pathosis⁽¹⁵⁾.

Variables of the study

The eighty primary teeth from forty children were subdivided equally into two subgroups (40 teeth in each subgroup) according to caries removal technique⁽¹⁵⁾.

Subgroup I: caries was removed with Carie-Care system.

Subgroup II: caries was removed with the conventional low speed drilling technique.

Caries removal procedure:

Treatment was carried out according to the following steps:

- No local anesthesia was given, unless required.
- Partial isolation was done using cotton rolls, air spray and saliva ejector.

Subgroup I:

Carie-Care™ gel (Uni-Biotech, Pharmaceuticals, India) was applied to the cavitated carious lesion and allowed to work for 60 seconds according to the manufacturer's instruction. When the gel became cloudy, the gel and softened carious dentine were removed gently by scraping with sharp spoon excavator without applying pressure. Second application of the gel was performed when necessary. The gel was then removed and the cavity was wiped with a moistened cotton pellet and rinsed with water⁽¹⁴⁾.

Subgroup II:

In this subgroup, caries was removed using a low-speed hand piece under water spray with carbide bur without giving local anesthesia.

Restoration of the cavities:

All teeth in both subgroups I and II were restored with Activa kids bioactive restorative material (PULPDENT Corporation, Watertown, USA), according to manufacturer's instruction⁽¹³⁾.

Evaluation of the treatment:

Evaluation of caries removal:

Complete caries removal was evaluated using visual inspection and tactile sensation criteria given by Ericson⁽¹⁶⁾ with the help of mouth mirror and explorer. These criteria are:

- 0 Complete caries removal
- 1 Caries present in the base of the cavity
- 2 Caries present in the base and/or one wall of the cavity
- 3 Caries present in the base and/or two walls of the cavity
- 4 Caries present in the base and/or more than two walls of the cavity
- 5 Caries present in the bases, walls and margins of the cavity

Evaluation of caries removal time:

The total time taken for complete caries removal using both techniques was recorded in minutes using a stopwatch⁽¹⁴⁾.

Evaluation of pain and patient comfort:

For assessment of pain reaction in each patient during caries removal using both methods, a sound (S), eye (E), and motor (M) scale⁽¹⁷⁾ was employed. The type of response obtained for each observation was given a numerical value (score) like Score 1 (comfort), Score 2 (mild discomfort), Score 3 (moderately painful), and Score 4 (painful).

Evaluation of the restoration:

After placement of Activa-kids, the restoration was first evaluated at baseline using United States Public Health Service (USPHS) Criteria⁽¹⁸⁾ (table 1), then patients were recalled after an interval of 1 month, 3 months and 6 months for evaluation of restorations using the same criteria.

Table (1): Modified USPHS criteria

| Criteria | Alpha(A) | Bravo(B) | Charlie(C) |
|---------------------------------|--------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------|
| Marginal Adaptation (MA) | Continuity at the margin (no ledge or ditch) | Slight discontinuity detectable with explorer but not requiring replacement. | Marginal ledge or crevice requiring replacement. |
| Anatomic Form (AF) | Continuous restoration with existing anatomical form | Restoration is not in continuity with existing anatomical form, but the discontinuity is insufficient to expose dentin | Sufficient loss of restoration has occurred to expose dentin |
| Marginal Staining (MS) | There is no discoloration between the restorations and tooth | There is discoloration on less than half of the circumferential margin | There is discoloration on more than half of the circumferential margin |
| Secondary Caries (SC) | There is no clinical diagnosis of caries | | There is clinical diagnosis of caries |
| Retention | Presence of restoration | Mobilization of restoration but still present | Loss of restoration |

Statistical Analysis

Statistical analysis was then performed using a commercially available software program (SPSS 19; SPSS, Chicago, IL, USA).

Qualitative data (evaluation of restoration, caries removal, pain) were expressed as number and percentage and were compared using chi-square test. Independent t test was used to compare parametric quantitative data (time of caries removal).

RESULTS

I- Evaluation of caries removal (Ericsson Scale)

Evaluation of caries removal was presented in figure(1)

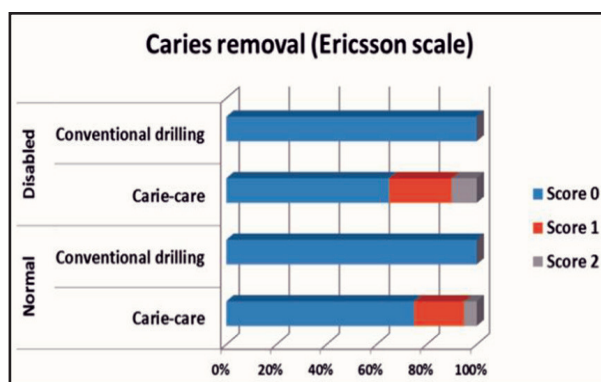


Figure (1) Bar chart showing caries removal scores in different groups

I-a- Comparison of different caries removal techniques:

In normal children, there was no significant difference between both techniques ($p=0.06$), while in disabled children there was a statistically significant difference between both techniques ($p=0.014$).

I-b-Comparison of both children groups using the same technique:

There was no significant difference between patients' groups ($p=0.75$) using both techniques.

II- Time of caries removal (min)

Results of time of caries removal were presented in figure (2).

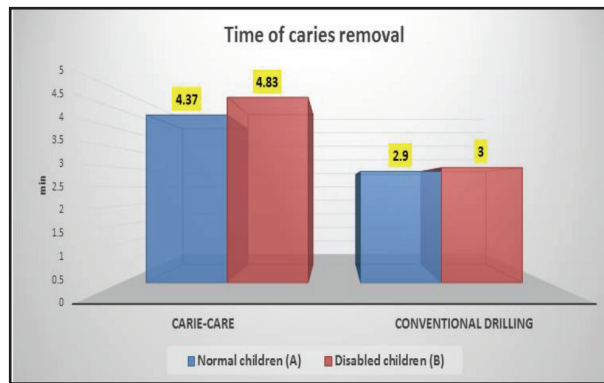


Figure (2) Bar chart showint mean time of caries removal in different groups

II-a- Comparison between children groups:

There was no significant difference between both groups ($P=0.1003$) using both techniques.

II-b- Comparison between caries removal techniques:

There was a statistically significant difference between both groups using both techniques ($P<0.0001$).

III-Evaluation of pain and discomfort

Evaluation of pain and patient discomfort was presented in figure (3)

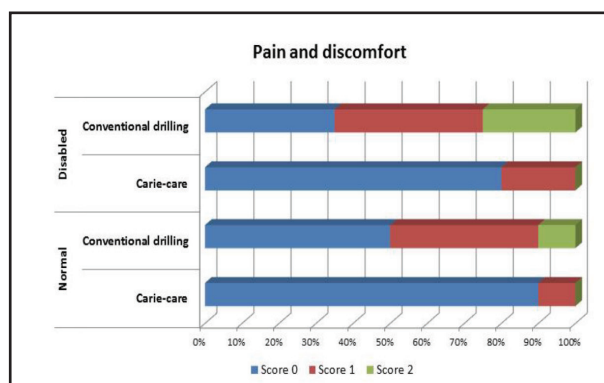


Figure (3) Bar chart showint pain and patient discomfort scores in different groups

III-a- Comparison of different caries removal techniques:

There was a statistically significant difference between both techniques ($p=0.019$) in both patients' groups.

III-b-Comparison of both children groups using the same technique:

There was no significant difference between patients' groups ($p=0.38$) using both techniques.

IV- Evaluation of restoration

Comparison of different caries removal techniques

Normal children

There was no significant difference between different caries removal techniques at the whole follow up periods regarding the 5 criteria used for evaluation of restoration. (table 2)

Disabled children

There was no significant difference between different caries removal techniques at follow up periods regarding the 5 criteria used for evaluation of restoration.

Comparison of both children groups using the same technique

Caries removal by Carie-care:

The difference was not statistically significant between different patient groups, at baseline, 1 month, 3 months and 6 months follow up periods.

Caries removal by conventional drilling

The difference was not statistically significant between different patient groups, at baseline, 1 month, 3 months and 6 months follow up periods.

Table (2): *Evaluation of restoration in normal children*

| Time | Criteria | Carie-care (I) | | | Conventional drilling (II) | | | Chi square test | |
|-----------|---------------------|----------------|--------------|----------------|----------------------------|--------------|----------------|-----------------|--------|
| | | A (Alpha) | B (Bravo) | C (Charlie) | A (Alpha) | B (Bravo) | C (Charlie) | X ² | P |
| Base-line | Marginal Adaptation | 20 (100%) | ----- | ----- | 20 (100%) | ----- | ----- | 0 | 1ns |
| | Anatomic Form | 20 (100%) | ----- | ----- | 20 (100%) | ----- | ----- | 0 | 1ns |
| | Marginal Staining | 20 (100%) | ----- | ----- | 20 (100%) | ----- | ----- | 0 | 1ns |
| | 2ry Caries | 20 (100%) | ----- | ----- | 20 (100%) | ----- | ----- | 0 | 1ns |
| | Retention | 20 (100%) | ----- | ----- | 20 (100%) | ----- | ----- | 0 | 1ns |
| 1M | Marginal Adaptation | 20 (100%) | ----- | ----- | 20 (100%) | ----- | ----- | 0 | 1ns |
| | Anatomic Form | 20 (100%) | ----- | ----- | 20 (100%) | ----- | ----- | 0 | 1ns |
| | Marginal Staining | 20 (100%) | ----- | ----- | 20 (100%) | ----- | ----- | 0 | 1ns |
| | 2ry Caries | 20 (100%) | ----- | ----- | 20 (100%) | ----- | ----- | 0 | 1ns |
| | Retention | 20 (100%) | ----- | ----- | 20 (100%) | ----- | ----- | 0 | 1ns |
| 3M | Marginal Adaptation | 17 (85%) | 3 (15%) | ----- | 17 (85%) | 3 (15%) | ----- | 0 | 1ns |
| | Anatomic Form | 19 (95%) | 1 (5%) | ----- | 19 (95%) | 1 (5%) | ----- | 0 | 1ns |
| | Marginal Staining | 19 (95%) | 1 (5%) | ----- | 20 (100%) | ----- | ----- | 1.03 | 0.31ns |
| | 2ry Caries | 20 (100%) | ----- | ----- | 20 (100%) | ----- | ----- | 0 | 1ns |
| | Retention | 20 (100%) | ----- | ----- | 20 (100%) | ----- | ----- | 0 | 1ns |
| 6 M | Marginal Adaptation | 14 (70%) | 4 (20%) | 2 (10%) | 11 (55%) | 9 (45%) | ----- | 7.06 | 0.29ns |
| | Anatomic Form | 14 (70%) | 4 (20%) | 2 (10%) | 13 (65%) | 7 (35%) | ----- | 2.86 | 0.24ns |
| | Marginal Staining | 15 (75%) | 3 (15%) | 2 (10%) | 11 (55%) | 9 (45%) | ----- | 5.62 | 0.06ns |
| | 2ry Caries | 19 (95%) | ----- | 1 (5%) | 20 (100%) | ----- | ----- | 0 | 1ns |
| | Retention | 19 (95%) | 1 (5%) | ----- | 20 (100%) | ----- | ----- | 0 | 1ns |

DISCUSSION

The development of caries removal techniques in pediatric dentistry is aiming toward a more biological and conservative direction⁽¹⁹⁾. Minimally invasive dentistry is a technique that has evolved a new way for preservation of tooth and treating dental decay. It was developed to decrease the operating time, pain and stress, and minimize patient anxiety⁽²⁰⁾. The use of CMCR agents for removal of dental decay has considerably aided minimal invasive caries removal techniques⁽²¹⁾.

Carie-care was used in this study for treatment of children as it does not contain sodium hypochlorite or any other strong chlorinating agent which exist in most of other CMCR agents⁽⁴⁾, instead has most of the ingredients from natural sources. So there is no chance of irritation even if the gel comes in contact with the adjacent soft tissues⁽¹⁴⁾.

The results of evaluation of caries removal according to Ericsson criteria showed that low speed drilling was more effective than Carie- Care in both groups, this was in agreement with other previous studies^(14,22,23), but disagrees with another study which showed that CMCR was as effective as using bur in removing dental decay⁽¹⁶⁾.

Also the results showed a higher mean time was recorded using Carie-Care gel, in comparison to conventional low speed drilling, these results were in accordance with a previously conducted study which⁽¹⁴⁾ showed that total time taken for completion of caries removal using Carie-Care™ system was longer as compared to conventional method of caries excavation. This may be because hard carious lesions required more than one or two application of gel to decompose the infected dentin. Contradictory to this study, the time taken for caries removal by CMCR method was about the same as that taken by the conventional method in another study⁽²⁴⁾.

Regarding pain and patient comfort, the results demonstrated that using Carie-care gel was associated with less pain and more patient comfort in comparison to conventional drilling technique,

with statistically significant difference between both techniques. These results were in agreement with results of a recent study⁽¹⁴⁾ where the children who treated with Carie-Care™ gel experienced significantly more comfort, and less pain compared to patients in which carious lesions were removed using the dental drill. In disagreement with the present study, there was no significant difference between both techniques in terms of pain⁽²⁵⁾.

In the present study, all cases in group A and B revealed Alpha level where complete marginal adaptation and no ditch or crevice were observed at baseline and at 1 month, with no significant difference between different caries removal techniques. Then at 3 months, there was a slight decline from Alpha level. At 6 months, there was more decline from Alpha level and Charlie level was recorded, but this difference was not statistically significant. Shrinkage stress arises from polymerization reaction of resin containing restorative materials was the main cause of clinical problems like poor marginal adaptation, but Aactiva contains ionic resin network and bioactive fillers which can further decrease the polymerization shrinkage⁽²⁶⁾, in a previous study the polymerization shrinkage stress of Aactiva was tested and compared with other materials, it was observed that shrinkage stress of Aactiva was low and no significant differences was found between the tested materials⁽²⁷⁾. But in another study the marginal integrity of Aactiva was evaluated and it was found that the best bond strength outcome for Aactiva bioactive restorative, occurs when the adhesive was used prior to restoration and the self-adhesive property of Aactiva is poor⁽²⁸⁾. This may explain why Charlie level was recorded after 6 months.

Regarding anatomic form criterion all cases revealed Alpha level at baseline and at 1 month, with no significant difference between different caries removal techniques. Then at 3 months, there was a slight decline from Alpha level. And at 6 months, there was a decline from Alpha level and Charlie level was recorded, but this difference was not statistically significant. In agreement with

this study, the wear resistance of Activa bioactive restorative material was compared to that of resin composite, resin modified glass ionomer (RMGI) and glass ionomer (GI) and it was concluded that the wear of Activa bioactive restorative material was equivalent to resin composite but significantly less than RMGI and GI restorative, this is due to the addition of resin monomer to Activa which are claimed to impart resilience to the material to enhance its resistance to wear, fracture and marginal chipping⁽²⁹⁾.

Concerning the marginal staining criterion, all cases in both groups revealed Alpha at baseline and at 1 month. Then at 3 months, there was a slight decline from Alpha level. And at 6 months there was a decline from Alpha level and Charlie level was recorded, but this difference was not statistically significant. Resistance of Activa to marginal staining was evaluated in another previous study and was rated as excellent where there were no observations of marginal staining at one year⁽³⁰⁾. But the results of a previous study revealed that there was greater microleakage at tooth margin-material interface in Activa than in universal hybrid composite resin or resin-modified glass ionomer restorative material which leads to greater marginal staining⁽³¹⁾. This may explain why Activa showed marginal discoloration on more than half of the circumferential margin (Charlie) in groups AI and BII after 6 months of follow up.

Regarding the presence of secondary caries, Activa bioactive restorative material showed no secondary caries in both techniques and in both groups at the end of three months evaluation period. But it showed secondary caries in one case in both groups after 6 months follow up period. The absence of secondary caries may be attributed to active release of calcium, phosphate, and fluoride ions from Activa bioactive restorative materials and their interactions with the dentin and enamel⁽³²⁾. On the other hand secondary caries occurred after 6 months, this may be due to active caries or high caries experience in some patients and higher levels of caries in children with disabilities as a

result of their great limitations in oral hygiene performance due to their manual dexterity, sensory and intellectual disabilities⁽³³⁾.

Concerning retention of the restoration, none of restorations were partially or completely dislodged in both techniques and in both groups at baseline, one month and three months intervals. While at 6 months the restoration was partially dislodged in one case in both groups and both techniques with no significant difference. In agreement with the findings of this study, a previous study evaluated retention of Activa-bioactive restorative material by restoring 158 anterior and posterior teeth, then recalled at two years. It was concluded that retention of restoration was excellent, one restoration out of the 158 partially de-bonded and was replaced⁽³⁰⁾.

CONCLUSION

CMCR technique using Carie-Care™ gel was an efficacious alternative method to treat carious lesions in both normal and children with different types of disability since it allies atraumatic characteristics. Activa kids bioactive restorative material has a high performance as a permanent restorative material in vital primary teeth in both normal and disabled children in a period of 6 months.

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