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Original Article

Post-Operative Pain Following Full Mouth Rehabilitation and Stainless-Steel Crowns Placement in Children with Early Childhood Caries: A Pragmatic Before and After Study

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Abstract:

Aim: This study investigated pain/discomfort& swelling complaints in children with carious primary molars before and after receiving stainless steel crowns (SSCs) as full mouth rehabilitation under general anaesthesia (GA).
Subjects& Method: This before-and-after study was conducted on 90 children. They were 2-6 years old and needed complete oral rehabilitation under general anaesthesia. Before and after anaesthesia during follow-up appointments at 4 weeks, and 6 months, pain/discomfort & swelling were assessed by a questionnaire given to each parent and if reported pain at any recall period further assessment is needed in the following follow-ups. A total of 457 crowns were involved.
Results: In the current study 82(91.1%) children continued the first follow-up (1 month). 4 participants (5.5%) out of 82 complained of pain on both sides post-operatively at the 4-week follow-up and none of them complained of swelling. With 73 participants (81.1%) completed the 2nd follow-up period (6 months). 69 out of the 73 study participants (94.5%) reported no pain, and 71 out of 73 participants (97.3%) reported no swelling. There was a statistically significant difference between preoperative and postoperative pain/discomfort &swelling ($P < 0.0001$).
Conclusion: With 94.5% of participants reporting no pain, the quality of life for the participants significantly improved.

Keywords: Early Childhood Caries, Stainless Steel Crowns, Full Mouth Rehabilitation, General Anaesthesia, Pain, Discomfort& Swelling.

I. INTRODUCTION:

Dental caries is a prevalent chronic disease that influences the standards of life, especially in children, causing pain, chronic infections, and sleep disturbance **(Petersen, 2005)**. Dramatically, many children must accept toothache as a normal part of life **(Innes et al., 2007)**. Dentalgia, or toothache, is a pain in the dental pulp and/or periodontal tissues caused by dental or non-dental diseases **(Raab, 1991)**. Early childhood caries (ECC) is an extreme kind of tooth decay that impacts babies and small children,

unfortunately treating ECC is incredibly challenging. SSCs have been the most successful posterior restorations for primary teeth with severe ECC for over 50 years, with success rates above 95% **(Gumus et al., 2020**). The primary purpose of having an appropriate treatment plan is to achieve an outcome that will not cause a failure in the stomatognathic system and to provide long-term stability, ensuring an excellent quality of life for patients and not obligating them to accept pain as a normal part of life **(Gallagher et al., 2014)**. It is crucial to bear in mind that a dental appointment may necessitate parents to take time off work and miss school days, thereby placing financial strain on the family **(Mathew and Jeevanandan, 2023)**. Most children can receive dental care in a conventional setting, but some patients do not respond well to typical behaviour modification techniques. Therefore, dental rehabilitation under GA provides numerous advantages, guaranteeing safety and comfort for children, saving significant time and effort for dentists, and efficiently completing lengthy procedures that require multiple visits without wasting time or causing distress to the child or parents. Furthermore, it lessens the necessity for recurrent visits for conscious sedation or local anaesthesia in large restorations, providing a more convenient, safer, and economical alternative **(Cantekin et al., 2014)**. Using SSCs in uncooperative patients, for full mouth rehabilitation under GA may be necessary, which could reduce the risk and cost associated with repeated exposure to GA in children and hence improve their quality of life.

As pain is primarily an individual experience, various assessment tools (such as self-report and observational scales) have been used. The Wong-Baker scale, which has also proven to be effective with children, and this adapted form of the VAS, have shown a strong correlation in previous studies. However, the Wong-Baker scale has been linked to overestimation of pain because apprehensive children who are not in pain might not choose a happy face on the scale particularly if they are young and show uncooperative behaviour towards dentists. For that reason, following surgery, pedodontists can use observational scales to assess children's pain levels. Additionally, the distinct characteristics of each patient, along with their family history and other pertinent data for pain assessment, can complicate clinical decision-making. Considering parents' perspectives and judgments in pain assessment may result in more accurate evaluations compared to assessments based solely on the patient's experience and the clinician's observations. This is because parents are familiar with their child's typical pain responses and understand the contextual and systemic information involved. Likewise, studies measured patients' quality of life after dental rehabilitation under GA (DRGA) with a parental questionnaire, and other studies measured post-operative complications **(Rane et al., 2017; Zhang et al., 2020)**.

Today, it is thought that a key indicator of treatment success is the patient's perception of the impact of their care **(Su et al., 2020)**. Accordingly, to measure the infant/child patient-perceived impact consistently across different oral health conditions, this study aimed to assess and compare participants' complaints of pain/discomfort and swelling before they were treated by SSCs and after DRGA. Whether the use of SSCs under GA is beneficial in ECC management or not under multiple factors.

II SUBJECTS& METHODS:

a. Type of Study:

This non-randomized before and after study was conducted alongside another research project to assess the effect of full-mouth rehabilitation with SSCs on the canine occlusal relationship (COR) and the time required for the bite to return to normal.

Comparator:

Patient's pre-operative state before full-mouth rehabilitation.

Outcome:

Pain/discomfort& swelling complaints were recorded after full-mouth rehabilitation with placement of stainless-steel crowns, 4 weeks, and 6 months post-operatively.

Outcome measuring method:

Child pain/discomfort &swelling complaints with a questionnaire given to parents **(Versloot et al., 2006**).

b. Sample size:

A power analysis was designed to have adequate power to apply a two-sided statistical test of the null hypothesis that there is a clinical difference in pain/discomfort and swelling changes after full-mouth rehabilitation and stainless-steel crown placement under GA. By adopting an alpha level of (0.05) and a beta of (0.2), i.e., power=80% and an effect size (d) of (0.211) calculated based on the results of Ghadimi et al, the predicted sample size (n) was a total of (178) cases **(Ghadimi et al., 2019)**. Sample size calculation was performed using G*Power version 3.1.9.7. The number of cases performed by the primary investigator was (90). The rest of the cases will be resumed in the following parts. The number of participants stuck till follow-up in the study was seventy-three, with a retention rate of 81.1%, and seventeen cases dropped out.

c. Study settings:

It took place in the Pediatric Dentistry GA unit -Faculty of Dentistry – Cairo University – Egypt. Out of 800 screened potential participants, only ninety met the inclusion criteria and agreed to take part in the trial, all of whom were aged between 2 and 6. They all required full-mouth rehabilitation with the placement of SSCs under GA. The actual number of participants who finished the 6-month follow-up period was seventy-three participants. The standardization of the GA process helped to eliminate confounding factors. The Operators were staff members of the Paediatric Dentistry Department. The study was sent for approval by the Committee of Research Ethics of the Faculty of Dentistry, Cairo University.

d. Eligibility criteria and selection methods:

The patients were diagnosed at the diagnostic centre of the GA unit by a staff member confirming their need for dental procedures under GA. Patients who met all the eligibility criteria, and required immediate full-mouth rehabilitation under GA were recruited.

e. Inclusion criteria:

Egyptian children with a normal, healthy medical history and no physical or mental health issues. And no preference for a certain sex. From (2 to 6) years old showing uncooperative behaviour. Children requiring dental treatment, including oral rehabilitation under GA and placement of stainless-steel crowns on primary molars due to tooth decay.

f. Exclusion criteria:

Erupted FPM, severe malocclusion (Crossbite, Open bite, etc.), and presence of parafunctional habits, that is, to ensure that those factors did not confound the results. Refusal of participation.

g. Clinical Steps:

The primary investigator administered a questionnaire to the parents to gather information on pre-operative pain, discomfort, and swelling. Information was collected from the parents before treatment, at 4 weeks, and if pain was reported, further assessment was needed during the 6-month follow-up. In addition, the primary investigator completed the patient's assessment chart. Full mouth rehabilitation with SSCs for decayed teeth is done **(Ghadimi et al, 2019)**. Once the patient had been released from the recovery area, and re-establishing facial muscle function, immediate post-GA instructions were given to guardians, and the investigator informed them of the follow-up dates.

h. Data collection, management, and analysis:

Data collection methods:

Patients' assessment charts were filled separately before the GA and stored with pre-operative and follow-up intraoral photos for each patient (**Figure1**).

Figure (1): Pre-operative clinical photos of two participants showing ECC at various stages.

Data Monitoring:

The two supervisors kept a regular eye on the study work results.

Ancillary treatment and post-trial care:

All participants received post-operative care and were provided with preventive measures. Almost all their parents also received the necessary care and attention for treatment in any speciality. Participants who developed new lesions were referred for treatment, and space maintainers were provided to those who needed them.

a. Ethics and Dissemination:

Research ethics approval:

The Medical Biostatistics Unit revised and approved this protocol on 12/2/2021.

The Evidence-Based Committee revised and approved the protocol on 23/6/2021.

Approval of the Paediatric Dentistry and Dental Public Health Department Board was obtained on 24/1/2021.

This study was registered at clinicaltrial.gov with the identifier (clinicaltrials.gov: NCTO4729673).

Ethical approval of the study protocol was obtained from the Committee of Research Ethics, Faculty of Dentistry, Cairo University, on the 27th of July 2021.

Informed Consent: Eligible participants' Names, gender, age, address and contact information were recorded on the consent document. The study presents all the data, but the patient's identity was not disclosed.

III RESULTS:

1. Patient Flow-chart:

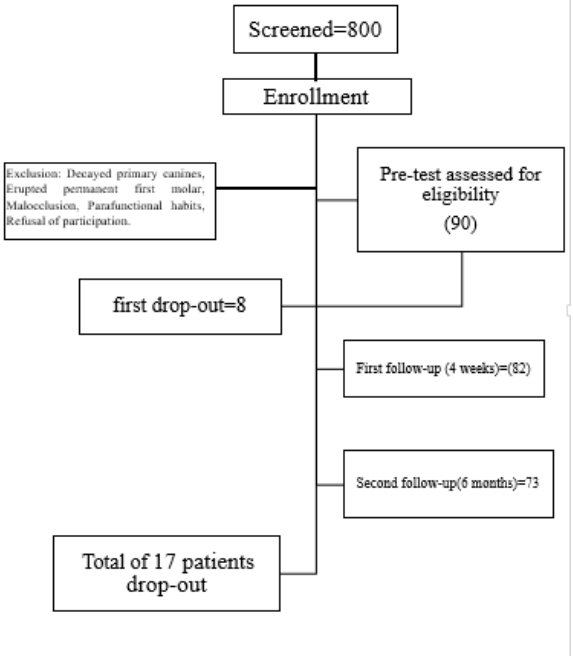

Figure (2):Flowchart showing participants' flow during this trial.

2. Baseline Data:

a. Gender and the number of Stainless-steel crowns:

There were thirty-nine boys and thirty-four girls in the current study, with percentages (53.4%) and (46.6%) respectively **(Table 1).**

In the current study, 27.4% of children received eight crowns, 23.3% received seven crowns, 20.5% received six crowns, 12.3% received five crowns, 12.3% received four crowns, 1.4% received three crowns, and 2.7% received two crowns.

Table (1): Gender distribution and Stainless-steel crowns distribution in children

Variable		Frequency	Percentage
Gender	Boy	39	53.4%
	Girl	34	46.6%
Number of crowns	2	2	2.7%
	3	1	1.4%
	4	9	12.3%
	5	9	12.3%
	6	15	20.5%
	7	17	23.3%
		20	27.4%

3. Child's pain and discomfort complaints before and after treatment:

a. Pain/discomfort:

In the current study, 63% of children showed pain on both sides pre-operatively, 12.3% showed discomfort, and 5.5% showed problems in digestion (**Table 2**). There was a statistically significant difference between preoperative and postoperative pain/discomfort (P < 0.0001) in the first follow-up.

Table (2): Frequency and percentage of pain /discomfort

Pre-operative pain/discomfort	**Frequency**	**Percentage**	**Post-operative pain/discomfort**	**Frequency**	**Percentage**	P value
Pain on both sides	46	63.0 %	Pain on both sides	4	5.5 %	
Discomfort	9	12.3 %	Discomfort	-	-	**P = 0.0015**
Problems in digestion	4	5.5%	Problems in digestion	-	-	

b. Swelling:

In the current study, 80.8% of children showed no signs of preoperative swelling, while 19.2% showed swelling (**Table 3**); 97.3% of children showed no swelling, while 2.7% showed swelling 6-months postoperatively; there was a statistically significant difference between preoperative and post-operative swelling (P = 0.0015).

Table (3): Frequency and percentage of swelling

Pre-operative swelling	**Frequency**	**Percentage**	**Post-operative** Swelling	**Frequency**	**Percentage**	**P value**
No	59	80.8%	No	71	97.3%	
Yes	**14**	**19.2%**	**Yes**	**2**	**2.7%**	**P = 0.0015**

c. Statistical analysis:

Data were analysed using Medcalc software, version 19 for Windows (MedCalc Software Ltd, Ostend, Belgium). Continuous data were explored for normality using the Kolmogorov-Smirnov and Shapiro-Wilk tests. Continuous data showed normal distribution and were described using mean and standard deviation. The intragroup comparison was performed using repeated measures ANOVA followed by tukey post-hoc test, and mean difference was used as an effect size measurement. Descriptive data were described using frequency and percentage, and a comparison between preoperative and postoperative. Data was performed using the chi-square test. A P value less than or equal to 0.05 was considered statistically significant, and all tests were two-tailed.

I. Discussion:

This non-randomized pragmatic before-and-after clinical trial is designed to evaluate interventions' effectiveness in real-life routine practice conditions. It simulated the effects of multiple factors, including operator skill, number of SSCs placed, age & gender effect on patients' symptoms and their standards of life.

It was done in conjunction with another study to evaluate how full-mouth rehabilitation using SSCs affected the occlusal relationship of canines and how long it took for the bite to normalize. The study participants were chosen from the GA unit at the Department of Paediatric Dentistry and Dental Public Health, Faculty of Dentistry, Cairo University. It was conducted with appropriate critical care resources, including a well-equipped operating theatre in the GA unit. Intervention done for the participants throughout the study was conducted by ten different staff members with the help of assistants, i.e., a minimum of four people were required. Including the advantage of different operators augments the idea of pragmatic studies and allows more generalizability of the results (**Zhou et al., 2016)**.

Moreover, the children enrolled in the study were medically free of any abnormal systemic conditions, either physical or mental. They had no chewing or neuromuscular problems to rule out any internal factors affecting the normal masticatory functions, balancing occlusion, and their perception of pain. They were also only of Egyptian nationality, which helped eliminate confounding variables such as diverse ethnic groups **(Marinho et al., 2022)**. After being made aware of the research's goals, methods, advantages, risks, discomforts, and the confidential nature of the data collected, the parents of the participants were invited to take part in the investigation. Which helped in getting their consent. Every parent after the surgery was advised with postoperative instructions and predictive maintenance communicated in detail. For the sake of predicting, controlling, and reducing postoperative complications, decreasing parents' anxiety, and improving the quality of medical care. Furthermore, they were informed of the dates of the recall visits.

The follow-up period was set according to previous studies, some authors suggest that patients with multiple SSCs under DRGA required follow-ups every two to six months following GA to preserve oral health and prevent additional dental procedures **(Van derZee and Van Amerongen, 2010)**. The current study's one-month follow-up period aligned with earlier scientific investigations **(Gallagher et al., 2014; Owais et al., 2019; Nair et al., 2020; Joseph et al., 2020)** The six-month follow-up was corresponding to three previous studies **(Pani et al., 2015**; **Alshareef et al.,2017; Abdallah et al., 2022).**

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Since pain presents a challenge for health professionals when it comes to objectively assessing children's pain, it is a complex and multidimensional phenomenon. Unlike adults who can usually verbalize their pain, children often cannot express their feelings of pain. Additionally, children's cognitive abilities can influence how they experience, comprehend, recall, and communicate pain. Based on these characteristics, specific pain assessment tools have been tailored for different age groups. For neonates and infants, behavioural and physiological indicators are used to evaluate pain. Children between four and seven years old can often provide a self-reported assessment of their pain using a 'facial' scale, despite its limited validity and reliability. When it comes to older children, verbal reports, such as a 0 to 10 verbal rating scale (VRS), are considered the primary method for assessment. Since pain is always a subjective experience, self-reported pain measures represent the standard for assessing children's psychological experience of pain. However, this approach isn't feasible for young children. In these instances, parents play a crucial role in providing information for the assessment of pain **(Versloot et al., 2006)**. Like a study carried out by Radacsi &colleagues where they used both children and parental questionnaires **(Radacsi. et al., 2023)**

The questionnaire of the current study was modified on the basis of previous research like Versloot & colleagues. The parent pre-operatively and in the recall visits was asked if he/she ever noticed that the child had a toothache, this question could be answered

with: 'never', 'sometimes' or 'often'. If the parent answered, 'sometimes' or 'often', they were asked when: either during meals, during daytime or nighttime (several alternatives possible). Also, there were questions concerned with different behaviours possibly associated with toothache or discomfort due to caries, e.g., crying during meals or chewing or digestion problems. For each item, the parent was asked to rate how often their child showed a given specific behaviour like never, sometimes, or often **(Versloot et al., 2006).** One of the questionnaire-based studies was Radasci et al., where it is unlikely, that they used the parental questionnaire post-operatively only **(Radasci et al., 2023).**

More than half of the study participants were boys; thirty-nine (53.4%) and thirty-four (46.6%) were girls. This finding agreed with previous investigations like studies conducted in Egypt in Mansoura and El-Gharbia governorates (23, 24). Males were found to have more caries than females, with (73.7%) males and (26.3%) females, according to the findings worldwide. This may reflect that boys have not developed the coping mechanisms necessary to handle in-office dental treatment and mature psychologically more slowly **(Stephen et al., 2017)**. Unlikely, the child's sex and ECC did not significantly correlate. Nevertheless, the plausibility of biological factors such as sex being risk factors for ECC is hard to understand **(Christensen, 2004; Shih et al., 2022; Radasci et al., 2023)**. Further studies may require investigating sex in caries risk practices or tooth anatomy differences.

Usually, dentists consider oral rehabilitation as restoring all teeth in each mouth. However, when merely the faulty teeth are restored, that too could be described as oral rehabilitation **(DuPont., 2013)**. As a form of full mouth rehabilitation, patients enrolled in this study had had multiple SSCs, dental restorations and extractions. As a result, twenty (27.4%) of children received eight crowns, seventeen (23.3%) received seven crowns, fifteen (20.5%) received six crowns, nine (12.3%) received five crowns, the same as four crowns, one participant (1.4%) received three crowns, and two participants (2.7%) received two crowns. Nearly the study by Ghadimi et al. agreed with these counts, where more than 50% of the children received four or more SSCs, and 48.3% had received four or fewer SSCs **(Ghadimi et al., 2019)**. The number of SSCs in the current study was higher than Ghadimi et al. by thirteen and higher than Gallagher et al. by fifty-three SSCs. At the same time, it was higher than Van der Zee and Van Amerongen by almost two hundred& ninety crowns **(Gallagher et al.**, **2014**; **Ghadimi et al., 2019**; **Joseph et al., 2020**).

The full-mouth rehabilitation involved the placement of eight SSCs for the highest number of participants, and this number decreased consecutively to two SSCs for the fewest participants. While Ghadimi et al. included children receiving only one crown as the least number of crowns (**Ghadimi et al., 2019**). The range of SSC numbers assessed in the current study helped detect any effect on patients' signs and symptoms of pain/discomfort. And accentuated the idea of the pragmatic study. Contrary to other studies where all molars were covered with SSCs opposing each other to eliminate the effect of natural teeth occluding against an SSC, the MOBF was recorded after placing eight SSCs in each participant **(Alshareef et al., 2017)**. This may counteract the aim of assessing any minute effect on pain response, discomfort, and swelling.

In the current study, the mean age of children was 3.9 ± 1.1 years. Participants were in the primary dentition stage, both early and late. The subjects had full dentition without the eruption of the FPM. Two years old was included as the Cs and Es would have been fully erupted. Besides the canine class I relationship and the absence of erupting first permanent molars. In contrast to Ghadimi et al., their study included 8.3% of children whose primary second molars had not erupted or occluded **(Ghadimi et al., 2019)**.

Post-operative complications of comprehensive treatment of severely worn dentition like (ECC) may agitate pedodontists to be concerned with causes and prevention. Complications like postoperative pain, weariness, discomfort, and agitation. Reasons speculated by Zhang et al. was the duration of the procedure which was significantly related to postoperative pain. Long duration means rendering complex treatments, such as pulp therapy or

extractions. The longer the duration is, the more difficult the procedure. The accumulation of discomfort causes the child to feel pain.

. However, this practice has raised questions about its impact on the mouth and consequently on patients' symptoms and overall dental health. They deduced that the placement of SSCs significantly improved their standard of life (**Zhou et al., 2016).**

Throughout the questionnaire, parents showed a sense of guilt toward their children. Children who experienced dental pain woke their mothers up in the middle of the night. Furthermore, some mothers noted having to prepare food chopped in a blender that rendered food does not require chewing or swallowing it without chewing so the child could finish the meal **(Elkhadem and Nagi, 2019)**. Fortunately, most parents or caregivers regarded the GA experience as positive and became more accepted by parents nowadays than earlier. There was a statistically significant reduction in the parent's sense of guilt toward their children. Besides, there was an absolute reduction in the time lost income and time taken off work to deal with the consequences of dental caries **(el Sayed, 2018)**.

In the current study, parents reported pre-operatively that their children suffered from discomfort when consuming hot or cold foods or sweets; forty-six (63%) of children showed pain on both sides, nine (12.3%) showed discomfort, and four (5.5%) showed problems in digestion. Fourteen participants complained of pre-operative swelling.

Elkhadem & Nagi stated that in pre-operative pain, up to 65% of children experienced occasional pain or problems, and 37% of these children were unable to finish their meals **(Elkhadem and Nagi, 2019)**. The percentage was much higher in El Sayed's cross-sectional study, where pain was the most reported item for the child before GA treatment (81.7 %). Followed by difficulty eating (66.7%) and drinking hot or cold drinks (61.7%). It coincided with an overview that included twenty-one papers concerning the same issue conducted by Oubenyahya and Bouhabba, stating the same degree of pre-operative complaints of pain **(el Sayed, 2018; Oubenyahya and Bouhabba, 2019).**

Luckily, most of the patients reported no post-operative pain there was an exciting finding: seventy eight out of eighty-two (95.1%) patients had no pain, and four participants (5.5%) complained of pain on both sides post-operatively at the 4-week follow-up and none of them complained of swelling. They were referred for dental treatment. The reported pain four weeks later could be attributed to either recurrent decay of anterior teeth, failure of one of the pulp therapies, or formation of a peri-apical abscess, developing new lesions, besides the parents' non-sticking to the oral hygiene measures and good dietary habits that led to gingivitis around the crowns.

For the second follow-up (6 months) about sixty nine out of seventy-three (94.5%) of the study participants had no complaints of pain, and seventy-one (97.3%) patients did not complain of recurrent swelling. Just two patients were complaining of severe marginal gingivitis of teeth with SSCs due to plaque accumulation. The remaining two (2.7%) complained of recurrent swelling where extraction was the treatment of choice. Likewise in a previous study, a decrease in the post-operative complaints of pain (9.4%) following difficulty in eating (14.4%), was explained on the basis that the child used to avoid eating due to multiple teeth extraction **(el Sayed, 2018).**

On the contrary, 82% of other study participants complained of postoperative pain; associated with the total number of teeth treated; it was more common post-operative dental morbidity than bleeding **(Hu et al., 2018)** but their pain subsided after three days.

One of the results in a study in 2020, the most prevalent complication was postoperative pain (62.70%), followed by weariness, agitation, masticatory problems, drowsiness, oral bleeding, coughing, fever, sore throat, nausea, constipation, epistaxis, vomiting, excitement, and diarrhoea **(Zhang et al., 2020)**.

Moreover, about 65.1% of private clinic patients complained of pain due to ECC in 2022 **(Marinho et al., 2022).** Surprisingly, all these studies and the current study had the same outcome of diminished pain/discomfort with significant

improvement in the OHRQoL of children, a crystal-clear positive effect of ECC treatment with SSCs under GA **(el Sayed, 2018; Elkhadem and Nagi, 2019; Oubenyahya and Bouhabba, 2019 Marinho et al., 2022)**.

In summary, both the current study and previous research found no direct link between the number of SSCs placed, operator skill, patient gender, and age on post-operative complaints reported by parents. Overall, using SSCs during ECC treatment under GA reduces pain and discomfort, positively impacting management during recall periods. (**Van der Zee and Van Amerongen, 2010**; **el Sayed, 2018; Oubenyahya and Bouhabba, 2019; Elkhadem and Nagi, 2019**).

V. *CONCLUSION:*

With 94.5% of participants reporting no pain, the quality of life for the participants significantly improved.

- **Conflict of interest:** No conflict of interest.

- **Funding:** This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sector.

- **Ethics:** This study protocol was approved by the ethical committee of the faculty of dentistry- at Cairo University on 27th of July 2021, approval number: 7 7 21.

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