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Original Article

Evaluation of pain response in children to the SoftClamp™ as an alternative to the metal rubber dam clamp: A randomized clinical trial

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ABSTRACT

Background: The use of a rubber dam is more important than ever in today's COVID-19 era to limit cross infections. In children, the placement of the metal clamp to retain the rubber dam is perceived to be painful and often requiring a local anesthetic injection. This dissuades many clinicians from placing the rubber dam. Hence, this study evaluated the pain response of children to a SoftClamp™ compared to the conventional metal clamp.

Materials and Methods: This was a randomized controlled, equal allocation ratio, split-mouth clinical trial. Forty-two children aged between 8 and 12 years, having two permanent mandibular molars in need of sealants, were divided into Groups A and B (metal clamp and SoftClamp™, respectively). The pain response was recorded using both an objective and a subjective scale i.e., the Faces Legs Activity Cry Consolability (FLACC) scale and the Wong Baker Faces Pain Rating Scale (WBFPRS). The level of significance was set at 5% ($P < 0.05$). The pain response recorded from the WBFPRS and the FLACC scale for the metal and the SoftClamp™ were analyzed using the Wilcoxon signed rank test. The difference in pain response between genders and between two age groups (below and above 10 years of age) was analyzed using the Mann–Whitney *U*-test.

Results: The children reported mild discomfort to clamp placement in both the scales. The *P* values for the FLACC and WBFPRS scores comparing the pain response to the metal and SoftClamp™ were 0.311 and 0.149, respectively.

Conclusion: There was no significant difference in the pain response of children to both the clamps. Good rubber dam application practices in children through the use of behavior guidance and a proper topical anesthesia technique may play a far more important role regardless of the clamp used. But the SoftClamp™, with its more child friendly appearance could be a viable alternative to the metal clamp in children.

Key Words: Child, pain, rubber dams

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INTRODUCTION

The use of a rubber dam for isolation is a long-established technique within the dental profession, having been utilized for over 100 years. Dr. Sanford C Barnum introduced the rubber dam

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into dentistry in the year 1864.[1] From then, a lot of literature has appeared in relation to its practicality and techniques of application.

The rubber dam has several well-established advantages. Preventing moisture contamination during operative procedures, improving the accessibility and visibility of the operator,[2] retraction of the tongue, and reducing procedural time[3] are some of the listed advantages.[4] Ammann P *et al.* observed decreased heart and circulation parameters in dentists using rubber dam and interpreted their results as relaxation.[5]

In addition, the rubber dam has some very specific advantages in children. It provides a physical as well as psychological barrier for children. Children often get the impression that treatment is taking place outside the mouth when the rubber dam is placed and this in turn helps them to tolerate longer appointments.[6]

However, most importantly, it could limit the spread of infectious diseases like measles, tuberculosis, hepatitis and AIDS.[7] This is especially relevant in today's COVID-19 scenario where the formation of aerosols and droplets from air turbines can potentially transmit and cause cross infections.[8] The use of the rubber dam can significantly reduce the microbial content from these air turbines in the operative field.[9]

The rubber dam clamp for retention has to utilize undercuts of the tooth and be pushed towards the gingiva beyond the greatest cervical contour of the tooth. Due to this, the placement of the metal clamp in children is often perceived to be painful, requiring a local anesthetic injection.[5] Furthermore, the sharp metal clamp during application can potentially cause soft tissue damage due to sudden movement by the child.[10] This dissuades many clinicians from placing the rubber dam in children. Clamps produced from alternate soft materials could override these apprehensions. Hence, this study evaluated the pain response of children to a SoftClamp™ compared to the conventional metal clamp.

The null hypothesis was that there would be no significant difference in pain response of children to the placement of the SoftClamp™ compared to the placement of metal clamps.

MATERIALS AND METHODS

This was a randomized controlled, equal allocation ratio, split-mouth clinical trial. The institutional ethical code of the study was 18095. The Clinical Trials Registry India (CTRI) registration number is CTRI/2019/08/020517. The study was conducted in Manipal College of Dental Science, Mangalore, Manipal Academy of Higher Education, India.

The ethical committee of the institution approved the clinical investigation. The parents received all information about the study and signed the informed consent before the intervention. The child assent form was also obtained.

This study was performed using the protocol established by the Consolidated Standards of Reporting Trials (CONSORT).[11] Children rated Frankl 3 or 4 in the rating scale, aged between 8 and 12-year-old and free of systemic diseases were included in the study. They were examined to have two permanent mandibular first molars in need of pit and fissure sealants. The teeth had to be classified as one, two, or three under the International Caries Detection and Assessment System (ICDAS) to meet the criteria of requiring a pit and fissure sealant. The ICDAS criteria were used to standardize the selection of teeth for pit and fissure sealants. Participants were excluded if the molars were partially erupted.

The primary outcome of this study was the absolute risk of pain. The sample size was calculated based on a pilot study as there was a lack of similar studies in literature. Based on the pilot study, the standard deviation to the Faces Legs Activity Cry Consolability (FLACC) scores and Wong Baker Faces Pain Rating Scale (WBFPRS) scores [Figure 1] evaluating pain perception were 1 and 2, respectively, for the SoftClamp™ and metal clamp groups. The expected standard deviation was kept as 1.33. Keeping the alpha error as 5%, power of the study as 80%, and keeping a clinically significant difference of 1 unit, the required sample in each group was calculated as 42.Sample size was calculated using the formula: (where the σ stands for the standard deviation and d stands for the clinically significant difference.

$$N = \frac{2(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta})^2 \sigma^2}{d^2}$$

This was a randomized controlled, equal allocation ratio, split-mouth clinical trial. The clamp to be used in each tooth was decided using a computer-generated random number table. An investigator not involved in the implementation of the analysis generated a random

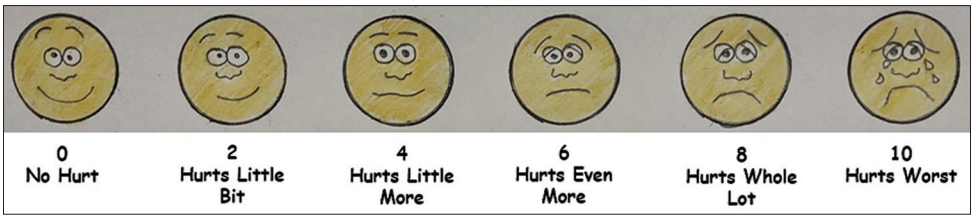

Figure 1: Representation of the wong-baker faces pain rating scale.

sequence. The odd and even numbers were taken to indicate treatment groups A and B, respectively, in which A represented the metal clamp (Hu-Friedy, U.S.A, No 4, winged clamp) (control group) and B the SoftClamp™ (Kerr co-operation, Switzerland) [Figure 2]. The random sequence thus generated (A or B) was placed individually in an opaque, consecutively numbered, and sealed envelope to conceal the allocation. The operator opened the envelopes only immediately before the intervention. The intervention mentioned in the envelope was carried out on the selected tooth in the fourth quadrant (right side) while the alternative clamp was placed on the opposite tooth. The assessor assessing the pain response using the FLACC score was blinded to the objective of the study. The CONSORT flow diagram has been depicted in Figure 3.

Before the clamp placement, the child was instructed, in an age-appropriate language about the rubber dam and its components.

The following steps were performed:

- The quadrants was isolated with cotton rolls and a topical anesthetic gel, 20% Benzocaine (ProGel-B, Septodont Healthcare) was applied. The applicator tip was inserted into the gel container and rotated three times to standardize the amount of the drug used. The gel was applied on the buccal and lingual gingiva of the concerned tooth after drying them with sterile cotton gauze. The gel was rubbed on to the mucosa under moderate pressure for 30 s[12]
- After 2 min, the excess topical anesthetic was removed using a sterile cotton gauze[13]
- The respective clamp after randomization was placed on the tooth followed by the rubber dam sheet. If the child indicated discomfort or displayed deterioration in behavior, the clamp was removed and the procedure was carried out with cotton roll isolation along with the saliva ejector
- After rubber dam application, the sealant procedure was undertaken. Subsequently, in the same appointment the same procedure was carried out on the mandibular first left molar with the alternative clamp. The pain response was recorded immediately after the placement of the clamp using the two different pain scales.

Figure 2: Metal Clamp and SoftClamp™.

Each child quantified the pain experienced during the clamp placement using the WBFPRS. The pain response was also objectively recorded by a blinded and precalibrated observer using the FLACC scale.

All the data were analyzed using SPSS (IBM, version 20.0, Chicago). The level of significance was set at 5% ($P < 0.05$). The pain response recorded from the WBFPRS and the FLACC scale for the metal and the SoftClamp™ were analyzed using the Wilcoxon signed rank test. The difference in pain response between genders and between two age groups (below and above 10 years of age) was analyzed using the Mann–Whitney *U*-test.

RESULTS

A total of 42 participants who met the inclusion criteria were selected for the study. The subjects belonged to the age group of 8–12 years with mean age group of 9.79-year-old. Out of 42 children 21 (50%) were boys and 21 (50%) were girls.

Wilcoxon sign rank test (nonparametric test) was used to compare the pain scores obtained for the metal and SoftClamp™ groups. The children reported mild discomfort to the SoftClamp™ and the metal clamp placement in both the scales. The median values comparing the FLACC and WBFPRS scores were

not statistically significant for metal and SoftClamp™ groups. The mean pain value for the metal clamp was slightly more compared to the SoftClamp™, but clinically it was insignificant. The *P* values were insignificant (0.311 and 0.149) [Table 1].

Thus, the results accept the null hypothesis stating there is no significant difference in pain response of children to the placement of SoftClamp™ compared to the metal clamps.

The difference in the pain response between ages above and below 10 years and between genders was analyzed using the Mann–Whitney *U*-test. There was no statistically significant difference between pain responses recorded for children less than or more than 10 years of age [Table 2]. There was also no statistically significant difference between values analyzed for male or female participants in either control or test group [Table 3].

DISCUSSION

The effectiveness of a rubber dam clamp depends on its ability to tightly grip the tooth, thus preventing the slippage of the clamp or the dam. Hence for better retention, the clamp has to utilize undercuts of teeth[14] and be pushed towards the gingiva beyond the greatest cervical contour of the tooth.[15] One of the reasons for the underuse of the rubber dam in Pediatric Dentistry is the perception that the placement of clamps could lead to pain resulting in negative child behavior.[16]

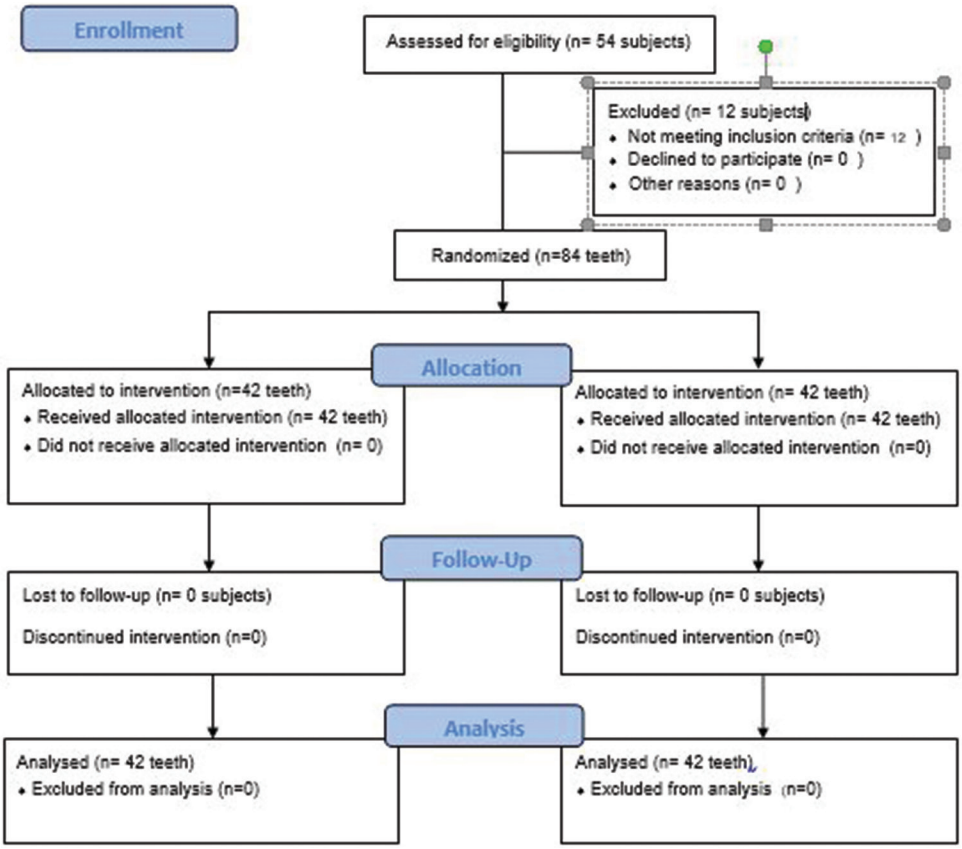

Figure 3: The CONSORT flow diagram. CONSORT: Consolidated Standards of Reporting Trials.

Table 1: Comparison of the pain scores for the metal clamp (control group) and SoftClamp™ (test group) with Faces Legs Activity Cry Consolability and Wong Baker Faces Pain Rating Scale scale using Wilcoxon sign rank test

Pain scales	Clamps	*n*	Mean±SD	Median (IQR)	Range	*Z*	*P*
FLACC	Metal	42	0.86±1.41	0 (0-1)	0-5	−1.013	0.311
	SoftClamp™	42	0.71±1.35	0 (0-1)	0-5		
WBFPRS	Metal	42	2.48±2.45	2 (0-4)	0-8	−1.444	0.149
	SoftClamp™	42	1.95±2.09	2 (0-4)	0-10		

FLACC: Faces Legs Activity Cry Consolability; WBFPRS: Wong Baker Faces Pain Rating Scale; SD: Standard deviation; IQR: Interquartile range

Table 2: Analysis of pain response values in children aged below and above 10 years of age using Mann-Whitney *U*-test

Pain Scales	Age (years)	*n*	Mean±SD	Median (IQR)	Range	Mann-Whitney *U*	*P*
FLACC (metal)	≤10	28	0.96±1.45	0 (0-1)	0-5	168.5	0.411
	>10	14	0.64±1.34	0 (0-1)	0-5		
WBFPRS (metal)	≤10	28	2.5±2.65	2 (0-4)	0-8	188.5	0.835
	>10	14	2.43±2.1	2 (0-4)	0-6		
FLACC (SoftClamp™)	≤10	28	0.75±1.38	0 (0-1)	0-5	192.5	0.912
	>10	14	0.64±1.34	0 (0-1)	0-5		
WBFPRS (SoftClamp™)	≤10	28	1.79±2.27	2 (0-3)	0-10	154.5	0.24
	>10	14	2.29±1.73	2 (2-4)	0-6		

FLACC: Faces Legs Activity Cry Consolability; WBFPRS: Wong Baker Faces Pain Rating Scale; SD: Standard deviation; IQR: Interquartile range

Table 3: Analysis of pain response values between genders using the Mann-Whitney *U*-test

Pain Scales	Sex of the patient	*n*	Mean±SD	Median (IQR)	Range	Mann-Whitney *U*	*P*
FLACC (metal)	Female	21	1±1.55	1 (0-1)	0-5	−1.091	0.516
	Male	21	0.71±1.27	0 (0-1)	0-5		
WBFPRS (metal)	Female	21	3.24±2.64	2 (2-6)	0-8	−0.136	0.049
	Male	21	1.71±2.03	2 (0-2)	0-8		
FLACC (soft)	Female	21	0.71±1.38	0 (0-1)	0-5	−0.352	0.847
	Male	21	0.71±1.35	0 (0-1)	0-5		
WBFPRS (soft)	Female	21	1.81±1.66	2 (0-4)	0-4	−1.066	0.989
	Male	21	2.1±2.49	2 (0-2)	0-10		

FLACC: Faces Legs Activity Cry Consolability; WBFPRS: Wong Baker Faces Pain Rating Scale; SD: Standard deviation; IQR: Interquartile range

Many modifications have been attempted to the metal clamp to counter the above disadvantages.[17-20] Clamp accessories such as cushees[21] were found to be effective in reducing pain and impingement of the clamp prongs to the gingiva.

The SoftClamp™ is made up of radio opaque high performance polymer.[22] Unlike a metal clamp, this clamp has no sharp edges, thereby reducing the possibility of damage to soft tissues or tooth structure.[14] The grip-tight coating of the clamp jaws allows the soft clamp to engage the tooth surface gently but firmly, minimizing the risk of slippage and eliminating the cause of patient discomfort and iatrogenic damage to the teeth. The SoftClamp™ also has a more child friendly appearance compared to the metal clamp. This study intended to evaluate if these features of the SoftClamp™ decreased the pain associated with clamp placement.

A split-mouth study design was used to prevent bias between study subjects. Two separate pain scales, the FLACC and the WBFPRS scale were used in the study to provide both an objective and subjective assessment of the pain responses. The WBFPRS[23-26] scale is helpful in determining the severity of pain for pediatric patients because of its simplicity. Although subjective assessment of pain is generally considered the gold standard when measuring pain, Von Baeyer *et al*.[27] reported that children's evaluation of pain might be exaggerated or unreliable. For objective evaluation, we also used the FLACC scale which has been shown to have excellent validity and reliability for pain evaluation in young children.[28,29]

The subjective pain responses were recorded immediately after clamp placement by the children so that almost real time data could be obtained without a time lapse.

The results of the study showed no significant difference in pain response values by the children to a metal clamp or to the SoftClamp™. The meticulous protocol followed for topical anesthetic application could have played an important role in negating the pain difference between the two clamps. The use of various topical anesthetic agents before clamp placement have been reported in literature[30-32] including lidocaine, prilocaine,[2] and light-cured tetracaine[33] which have all yielded promising results. In our study we used 20% benzocaine anesthetic gel before clamp placement. Regardless of the topical anesthetic used, the results of this study emphasize the importance of following the correct topical anesthetic protocol.[12] Its application on a dry mucosa and a waiting period of at least two minutes[13] before clamp

application may have contributed to a comfortable clamp placement experience with both types of clamps.

The clinical implication of the study is that false perceptions about metal clamp placement being painful should not be a deterrent for the clinician to apply rubber dam routinely in children. The benefits of the rubber dam far outweigh any trivial disadvantages propagated. Good rubber dam application practices in children include the use of Tell–Show–Do, use of euphemisms, proper topical anesthesia technique, use of good rubber dam equipment, and the intent of wanting to apply the dam. These may play a far more important role than demonizing the metal clamp as a reason for not applying the dam. But, the SoftClamp™ with a more child friendly appearance could be a viable alternative to the metal clamp in children.

The limitation of this study was that it evaluated only children in the 8–12 year age group for their pain response to the two clamps. Further studies can evaluate this clinical problem in younger age groups. The retentive ability of the SoftClamp™ on the teeth and their durability are further avenues for research.

CONCLUSION

Based on the inferences from the study, it was concluded that there was no significant difference in pain response for the metal clamps compared to the SoftClamp™ Good rubber dam application practices in children through the use of behavior guidance and a proper topical anesthesia technique may play a far more important role regardless of the clamp used. But, the SoftClamp™ with its more child friendly appearance could be considered a viable alternative to the metal clamp in children.

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Conflicts of interest
The authors of this manuscript declare that they have no conflicts of interest, real or perceived, financial or non-financial in this article.

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