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The use of DryShield versus rubber dam isolation systems among pediatric patients with different airway patency: A randomized clinical trial

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ARTICLE INFO	A B S T R A C T
Keywords: Airway patency Blood pressure Dental isolation Discomfort Heart rate Modified Mallampati Pain Pediatric dentistry Rubber dam	<i>Objectives</i> : This randomized clinical trial aimed to evaluate the impact of DryShield isolation (DSI) and rubber dam isolation (RDI) system usage on vital signs, behavior, pain and discomfort, and chairside time required among children with different airway patencies based on the Modified Mallampati Classification (MMC). <i>Material and methods</i> : Healthy, cooperative children who required fissure sealant in at least two contralateral, fully erupted, permanent first molars were included. Airway patency was determined by two trained and calibrated dentists using the MMC. The participants were categorized based on their MMC scores into patent airways (classes I and II) and non-patent airways (classes III and IV). The dental procedure was videotaped during treatment, and vital signs, including arterial oxygen saturation, heart rate, and blood pressure, were recorded every 3 min. The participants' subjective pain and discomfort were evaluated using a previously validated Arabic interview questionnaire and a validated Arabic version of the Wong–Baker Faces Pain Rating Scale. The participants' behavior and behavioral pain were evaluated utilizing the Frankl Behavior Scale and the face, legs, activity, cry, and consolability scales, respectively. <i>Results</i> : There were no significant differences in any of the vital signs between DSI and RDI. DSI use yielded a significant reduction in chairside time ($P < 0.001$) and was more bothersome ($P < 0.001$) than RDI use among all participants, regardless of airway patency. <i>Conclusion</i> : Irrespective of airway patency, DSI outperformed RDI in terms of behavior, pain, and procedure duration; however, DSI was characterized by noise, pressure on soft tissues, and an increased tendency to induce gag reflexes.

1. Introduction

The use of rubber dam isolation (RDI) has been the most used dental isolation technique for decades in pediatric dentistry (Heintze & Rousson, 2012, Muller-Bolla et al., 2006, Nara et al., 2015). RDI provides protection against cross-infection and aspiration of dental instruments, materials, and debris (Heintze & Rousson, 2012, Muller-Bolla et al., 2006, Nara et al., 2015). However, the use of RDI might affect airflow in the oral and nasal cavities (Odabaş, Deveci, & Ölmez, 2011), which might decrease arterial oxygen saturation (SpO₂) (Gandy, 1995). This is of particular concern during dental procedures, particularly in medically compromised and pediatric patients (Odabaş, Deveci, & Ölmez, 2011).

The impact of RDI use during dental treatment on SpO₂ (Bello, Darwish, & Pedo, 1994, Goodday & Crocker, 2006, Nara et al., 2015, Odabaş, Deveci, & Ölmez, 2011), heart rate (HR) (Ammann et al., 2013, Bagher et al., 2021, Bello, Darwish, & Pedo, 1994, Pol et al., 2018), blood pressure (BP) (Ammann et al., 2013, Bagher et al., 2021, Bello, Darwish, & Pedo, 1994, Pol et al., 2018), and respiratory rate (RR) (Ammann et al., 2013) in healthy adults (Goodday & Crocker, 2006) and children (Ammann et al., 2013, Bello, Darwish, & Pedo, 1994, Nara et al., 2015, Odabaş, Deveci, & Ölmez, 2011) has been investigated by numerous studies.

Newly developed alternative isolation systems such as Isolite system isolation (ISI) and DryShield isolation (DSI) have been introduced in the

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dental market. These systems include a soft silicone attachment that combines a bite block with a cheek and a tongue retractor with high-speed suction (Alhareky et al., 2014, Bagher et al., 2021). Slightly higher but insignificant discomfort and pain were reported with the RDI use than with the DSI use in healthy children (Alhareky et al., 2014, Bagher et al., 2021).

Different grading systems have been used to assess patients' anatomical airway characteristics, including the Modified Mallampati Classification (MMC) score, Brodsky Grade Classification, and modified Friedman's Staging System (Lin et al., 2020). The MMC scoring system was selected for this study because it is a quick and easy method for assessing the anatomy of the patient's airways and the size of the base of the tongue in relation to the oropharyngeal opening. It comprises four classes: Class I indicates clear visibility of the soft palate, fauces, uvula, and tonsillar pillars; Class II signifies visibility of the soft palate, fauces, and uvula; Class III is assigned only when the soft palate and base of the uvula are visible; and Class IV is recorded when the soft palate is not visible (Mallampati et al., 1985). However, no study has investigated airway assessment as a predictor of the preferred dental isolation system.

This study aimed to evaluate the effects of the DSI and RDI system usage on SpO₂, HR, BP, behavior, subjective pain and discomfort, and procedure chairside time among healthy children aged 6–12 years with different airway patencies based on their MMC scores. We hypothesized that the RDI system, in comparison to DSI, would result in a significant decrease in SpO₂, an increase in HR, deteriorated behavior, heightened subjective pain and discomfort, and a necessity for increased chairside time in 6–12-year-old healthy children with non-patent airways (MMC scores class III and IV) as opposed to children with patent airways (MMC scores class I and II).

2. Materials and methods

2.1. Ethical approval

Faculty of Dentistry Research Ethics Committee at King Abdulaziz University (134–11-22) provided the ethical permission to conduct this split-mouth randomized clinical trial. This study adhered to the guidelines provided by the Consolidated Standards of Reporting Trials Statement (CONSORT) checklist (Pandis et al., 2017). Data were collected between January and June 2023 at the Pediatric Dentistry Department of King Abdulaziz University Dental Hospital. The study protocol is registered at https://www.clinicaltrials.gov under the identifier NCT06128811.

2.2. Participants' recruitment

Healthy, cooperative, 6–12-year-old children who required fissure sealants in at least two contralateral, fully erupted, permanent first molars were included. Children with partially erupted, previously restored, or carious first molars; children with uncooperative behavior during previous dental treatment; children with fixed orthodontic appliances; and children with nasal obstruction were excluded from the study. Based on previous studies (Bagher et al., 2021, Collette, Wilson, & Sullivan, 2010), a paired *t*-test with a 5 % two-sided significance level was used to estimate that a sample size of 58 participants (29 in each group) would have 80 % power to detect a mean difference in pain and discomfort of 2.7, assuming a standard deviation (SD) of differences being 5.

Before study initiation, each dentist attended training and calibration sessions to perform a clinical examination of 10 randomly selected pediatric patients. Airway patency with the MMC was initially assessed and then re-evaluated after a 2-week interval. The two screening dentists demonstrated inter-examiner reliability (weighted kappa = 0.950) and excellent intra-examiner reliability (NA-weighted kappa = 0.951; NAweighted kappa = 0.948). Two authors conducted an eligibility screening of children who visited the pediatric dentistry clinic during the study period. The guardians of eligible children were approached and informed about the study. Upon agreement to participate, Arabic consent and assent forms were signed, and a treatment appointment was scheduled. Airway patency was assessed by two trained and calibrated dentists (N.A. and N. A.) using the MMC during the screening visit. The participants were asked to sit upright with their chin parallel to the floor, open their mouth to the maximum, and protrude their tongue without phonation to determine their MMC scores ranging from one to four. Based on their MMC scores, participants were categorized into patent (classes I and II) and non-patent airways (classes III and IV). The MMC scores are shown in Fig. 1.

If a participant had more than two contralateral and fully erupted permanent first molars, only one pair was randomly selected for inclusion in the study. Before the treatment appointment, two randomization sequences were generated using a computer program. The first sequence randomly assigned a contralateral permanent first molar to the isolation system, and the second sequence was employed to determine the isolation system that would be used first. The randomization schemes were maintained without dental assistance involved in the study. Participants who received RDI followed by DSI were considered Group 1, while those who received DSI followed by RDI were considered Group 2. Groups one and two consisted of 32 and 28 participants, respectively.

2.3. Clinical intervention and assessment

At the scheduled appointment, participants' age, sex, and previous experience with dental isolation were recorded. Five minutes after the participant was seated on a dental chair, a pulse oximeter (OxyWatch, ChoiceMMed, Hamburg, Germany) was placed on the right forefinger to record the SpO₂ and HR at baseline, and an automatic BP cuff pressure monitor (Euro Check Digital Blood Pressure Monitor, IndiaMART; Model no-RS-BP-1004) was affixed to the left arm to record the baseline BP. SpO₂, HR, and BP were recorded at 3-min intervals until the isolation system was completely removed. In addition, the chairside time required for the entire dental procedure was measured with a timer; the time required to assemble the RDI and DSI was excluded. Topical anesthetic gel (Bezocaine 20 %) was effective before the RD clamp application. High- and low-volume suction was used to rinse the etchants.

A trained and calibrated dentist administered fissure sealants to both sides during the same appointment. Tell-Show-Do behavior management technique was used for all participants. The dental procedure was videotaped using a high-resolution camera (Nikon D5100, NY, U.S.A) that was securely positioned in the clinic. The recorded videos were used to assess the participants' behavioral pain and discomfort using the face, legs, activity, cry, and consolability (FLACC) scale (Merkel et al., 1997), and behavior was independently assessed using the Frankl Behavior Scale (Frankl, 1962) by two trained and calibrated evaluators. The FLACC scale is used to assess behavioral pain in the children. The scale consists of five categories (cry, legs, face, activity, and consolability), and each category is assigned a score of 0–2, with the total score ranging from 0 to 10, with zero indicating no pain and 10 signifying the most severe pain.

For DSI (KinderDent GmbH, Weyhe, Germany), a pedo-sized mouthpiece was used for all participants. After proper isolation, a fissure sealant (Conseal-FTM SDI) was applied according to the manufacturer's instructions, and the quality of the fissure sealant was checked using an explorer. An additional layer was applied to detect the deficiencies. All participants were positioned with occlusal surfaces approximately 45° to the floor when operating on the manibular molars and perpendicular to the floor when operating on the maxillary molars.

After the fissure sealant procedure, the participants' subjective pain and discomfort were evaluated using a validated Arabic version of the

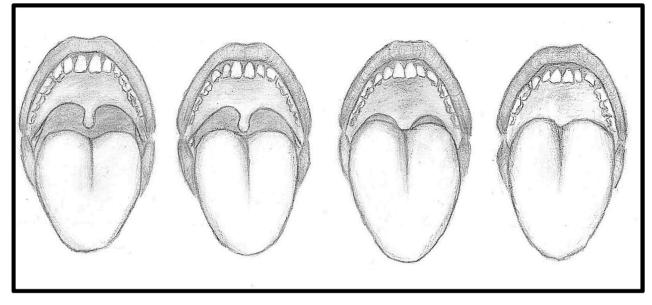


Fig. 1. The Modified Mallampati classification (class I to IV from left to right).

Wong–Baker Faces Pain Rating Scale, in addition to a previously validated Arabic interview questionnaire (Alhareky et al., 2014) (Appendix 1). The questionnaire asked the participants to rate their experience on a numerical scale from zero to 10, with zero indicating "no irritating factor at all" and 10 meaning "presence of irritating factor all the time." These factors include noise, gagging sensation, fluid leakage, stretching, pressure, pain, and discomfort associated with the isolation system.

2.4. Statistical analysis

The Statistical Package for the Social Sciences software for Windows (SPSS, Chicago, IL, USA) was used for statistical analyses. To assess the potential impact of the sequence of application of the isolation system on anxiety and discomfort scores, characteristics of the participant group who underwent dental treatment initially with RDI followed by DSI (group 1) was compared with those of group wherein DSI was followed by RDI (group 2). An independent sample *t*-test was used to compare the data of SpO₂, HR, and BP between the use of RDI and DSI. Furthermore, an evaluation was conducted to assess the changes in the parameters from baseline to mean measurements during the dental procedure using a paired sample *t*-test. The participants were subsequently categorized according to their airway patency, and the readings of the patent and non-patent airway groups were compared.

Pain and behavioral data were evaluated using the split-mouth design, and each participant's DSI and RDI scores were compared. The frequencies of the participants were compared using within-participant analytical approaches, specifically McNemar and Marginal Homogeneity tests. Subsequently, the within-participant differences were compared between the compromised and non-compromised airway groups. The significance threshold was set at 0.05.

3. Results

In this study, 53.3 % of the participants underwent RDI followed by DSI (group 1) and 46.7 % underwent DSI followed by RDI (group 2). The participants were equally distributed among the MMC scores. There were no significant differences between groups in terms of age, sex, MMC score, or prior experience of dental isolation. The demographic characteristics of the participants are presented in Table 1.

Table 2 presents the changes observed in vital signs based on the isolation system. No significant differences were observed in any vital signs when comparing the baseline measurements to the mean

Table 1	
Demographic characteristics of the participants ($N = 60$).	

Variables	Categories	Total N = 60	Group 1 N = 32	$\begin{array}{l} \text{Group 2} \\ N=28 \end{array}$	<i>P</i> - value
Age	$\frac{\text{Mean} \pm}{\text{SD}}$	$\begin{array}{c} 9.0 \pm \\ 1.9 \end{array}$	$\textbf{8.7}\pm\textbf{1.9}$	$\textbf{9.3}\pm\textbf{1.8}$	0.215 [†]
Sex	Male	28 (46.7)	18 (56.3)	10 (35.7)	0.112§
	Female	32 (53.3)	14 (43.8)	18 (64.3)	
MMC score	Class I	15 (25.0)	8 (25.0)	7 (25.0)	1.00 [§]
	Class II	15 (25.0)	8 (25.0)	7 (25.0)	
	Class III	15 (25.0)	8 (25.0)	7 (25.0)	
	Class IV	15 (25.0)	8 (25.0)	7 (25.0)	
Previous experience with dental	Yes	34 (56.7)	19 (59.4)	15 (53.6)	0.651§
isolation	No	26 (43.3)	13 (40.6)	13 (46.4)	

Group 1: Rubber dam then DryShield isolations.

Group 2: DryShield then rubber dam isolations.

MMC: Modified Mallampati Classification

[†] Independent sample *t*-test.

[§] Chi-square test.

measurements taken during the dental procedure within or between the compared dental isolation systems. The utilization of DSI significantly shortened the chairside time of the dental procedure compared to the use of RDI (P < 0.001).

Table 3 shows the comparison of the differences between the isolation systems at baseline and the mean of the measurements taken during the procedure between groups with different airway patency rates. No significant differences were observed between the isolation systems regardless of airway patency. Nevertheless, a significantly longer chairside time was required to complete the dental procedure using the RDI among individuals with both patent (P < 0.001) and non-patent airways (P < 0.001).

All participants reported higher Wong–Baker Faces Pain Ratings with RDI use than with DSI use, and approximately 55 % of the participants exhibited similar behaviors during the utilization of both isolation systems. Furthermore, 36.7 % of the participants demonstrated worse

Table 2

Evaluation of vital signs and chairside time (in minutes) at baseline and during dental procedure based on different dental isolation systems.

-			•	
Variables	Mean	RDI (N = 60)	DSI (N = 60)	P-value [†]
Heart rate	At baseline	88.5 ± 7.7	$\textbf{87.8} \pm \textbf{7.2}$	0.432
	During procedure	$\textbf{88.9} \pm \textbf{6.5}$	$\textbf{87.4} \pm \textbf{6.0}$	0.115
	P-value [§]	0.630	0.569	
Arterial oxygen	At baseline	$\textbf{98.9} \pm \textbf{1.9}$	$\textbf{98.9} \pm \textbf{3.0}$	0.969
saturation	During procedure	98.5 ± 3.5	$\textbf{98.7} \pm \textbf{1.9}$	0.646
	<i>P</i> -value [§]	0.357	0.643	
Systolic blood	At baseline	111.6 \pm	111.1 \pm	0.562
pressure		11.6	11.8	
	During	112.2 \pm	112.3 \pm	0.950
	procedure	10.8	10.4	
	P-value [§]	0.502	0.260	
Diastolic blood pressure	At baseline	$\begin{array}{c} 60.3 \pm \\ 10.9 \end{array}$	59.8 ± 9.7	0.665
	During procedure	61.1 ± 8.6	61.2 ± 8.2	0.852
	P-value [§]	0.489	0.086	
Chairside time (in minutes)		9.7 ± 3.6	$\textbf{4.9} \pm \textbf{1.6}$	<0.001*

RDI: Rubber dam isolation.

DSI: DryShield isolation.

 † Paired sample *t*-test to assess the pairwise comparison between rubber dam and DryShield isolations.

 $\ensuremath{\$}^{\$}$ Paired sample *t*-test to assess the change of readings from baseline to during the procedure.

Statistically significant (P < 0.05).

Table 3

Comparisons of the mean difference in vital signs and chairside time required (in minutes) at baseline and during dental procedure among groups with different airway patency.

Variables	Mean Difference (RDI minus DSI)	Patent airway [®] N = 30	Non-patent airway [©] N = 30	<i>P</i> -value [‡]
Heart rate	At baseline P-value [§]	$\begin{array}{c} 1.2\pm 6.5\\ 0.310\end{array}$	$\begin{array}{c} 0.2\pm7.5\\ 0.885\end{array}$	0.572
	<i>P</i> -value [®] During procedure <i>P</i> -value [®]	0.310 1.4 ± 6.9 0.273	$0.885 \\ 1.6 \pm 7.7 \\ 0.267$	0.925
Arterial oxygen saturation	At baseline P-value [§]	0.4 ± 4.0 0.562	$\begin{array}{c}-0.5\pm2.2\\0.257\end{array}$	0.290
	During procedure	$egin{array}{c} 0.4 \pm 1.7 \ 0.243 \end{array}$	-0.8 ± 4.8 0.377	0.222
Systolic blood pressure	At baseline P-value [§]	2.0 ± 6.6 0.114	-0.8 ± 0.7 0.582	0.151
Freedor	During procedure	± 7.4 0.422	-1.3 ± 10.9 0.533	0.331
Diastolic blood pressure	At baseline P-value [§]	1.1 ± 10.5 0.570	0.03 ± 9.8 0.985	0.685
r	During procedure P-value [§]	$-0.7 \pm 5.5 \\ 0.476$	$\begin{array}{c} 0.4\pm8.6\\ 0.814\end{array}$	0.559
Chairside time (in minutes)	<i>P</i> -value [§]	4.6 ± 4.2 <0.001*	4.9 ± 2.5 <0.001*	0.740

Mean differences were calculated as RDI reading minus DSI reading. Positive differences indicate higher RDI readings.

Negative differences indicate higher DSI readings.

[‡] Independent sample *t*-test to compare the difference in RDI and DSI with different airway patency.

[§] Paired sample *t*-test to assess the pairwise difference between RDI and DSI with different airway patency.

 * Statistically significant (p < 0.05).

 $^{\omega}$ Patent-airway (classes I and II MMC) and nonpatent-airway (classes III and IV MMC).

behavior with the use of RDI than with that of DSI. A significant difference was observed in the Frankl (P = 0.002) and FALCC scales (P < 0.001), indicating better behavior and less pain with DSI (Table 4).

As presented in Table 5, the use of RDI was associated with significantly higher pain and worse behavior than with DSI use, regardless of airway patency (P < 0.001). The observed difference in Frankl behavior rating scale scores reached statistical significance only among participants with non-patent airways (P = 0.007). Participants expressed a considerably higher level of annoyance with the sounds of the DSI than with those of the RDI (P < 0.001). Additionally, more stretching in the mouth, cheeks, and lips caused higher pressure on the tongue, heightened sensations of vomiting and gagging, an increased sense of fluid leakage, and reports of pain and discomfort were associated with RDI use compared to DSI use, irrespective of airway patency.

4. Discussion

This study aimed to evaluate the impact of the utilization of DSI and RDI systems on SpO₂, HR, BP, behavior, subjective pain and discomfort, and chairside time required among 6–12-year-old healthy children with different airway patencies based on MMC scores. Compared to those of RDI, DSI yielded a significantly shorter procedural chairside time and reported to be more annoying owing to its noise among all participants, regardless of their airway patency. In addition, the DSI was associated with significantly higher Frankl Behavior scores and lower FALCC scores, indicating significantly better behavior and less pain during the placement of fissure sealants.

To mitigate the potential impact of confounding variables on the study findings, nearly equal numbers of participants were included in each isolation system group and within each MMC group. No statistically significant differences were observed between groups in terms of age, sex, MMC score, or prior experience with dental isolation. Compared to the use of RDI, using DSI in the current study resulted in a significantly shorter chairside time. This finding is consistent with previously published research showing that DSI and ISI require much less chairside time than that of other isolation systems (Alhareky et al., 2014, Bagher et al., 2021, Collette, Wilson, & Sullivan, 2010). Several reasons have been suggested for the shorter chairside times; for instance, good behavior of the participants when using DSI might facilitate faster completion of the dental procedure, and the high- and low-volume suction adjustments required under and above the dam may also require extra time compared to that with DSI use.

In addition to the results of the current study, numerous prior studies (Alhareky et al., 2014, Bagher et al., 2021, Collette, Wilson, & Sullivan, 2010) revealed that children were more annoyed by the noise associated with DSI and ISI compared with that of other isolation systems; however, upon further analysis, there was no significant difference in the extent to which they were annoyed by the sounds, irrespective of their airway patency.

The Wong–Baker Faces Pain Rating Scale was used to evaluate pain and discomfort, and all participants reported experiencing more pain and discomfort with RDI, regardless of their airway patency. In a study conducted by Bagher et al. in 2021, participants reported slightly less, but non-significant, pain and discomfort when using the DSI than when using the RDI. This can be attributed to the fact that the children included in this study were 6–12 years old, with a mean age of 9 years, whereas the children included in the previous study were older, with a mean age of 11.54 years. This is supported by a recent systematic review on the levels of pain and discomfort associated with the use of RDI, particularly in younger patients (Afshari et al., 2023). Clamp pressure on the tooth and gingiva and dam pressure are among the main causes of pain associated with the use of RDI.

The Frankl Behavior Scale and FLACC were used to evaluate participants' behavior during fissure sealant application. The participants performed significantly better on the DSI. The ability to easily remove DSI and its flexibility may be the reason for its superior behavior. However, this finding is inconsistent with that of a study conducted by Current et al. (2022) to evaluate the behavior of moderately sedated pediatric patients treated using RDI and IsoVac isolation, and better

Table 4

Pairwise comparison of the difference in pain and behavior between different dental isolation systems.

Variables		$RDI \; N = 60$	$DSI \; N = 60$	Same score in both systems	Higher score in RDI N (%)	Higher score in DSI N (%)	P-value
Wong-Baker Faces Pain Rating	0	0 (0.00)	30 (50.0)	0	60 (100)	0	NA
Scale	2	30 (50.0)	30 (50.0)				
	4	30 (50.0)	0 (0.00)				
	6,8,10	0 (0.00)	0 (0.00)				
FLACC	0	0	0	38 (63.3)	21 (35.0)	1 (1.7)	<0.001*§
	1	23 (38.3)	40 (66.7)				
	2	15 (25.0)	9 (15.0)				
	3	15 (25.0)	8 (13.3)				
	4	7 (11.7)	3 (5.0)				
	5–10	0 (0.00)	0 (0.00)				
Frankl Behavior Scale	1	28 (46.7)	45 (75.0)	33 (55.0)	22 (36.7)	5 (8.3)	0.002*∝
	2	32 (53.3	15 (25.0)				
	3 or 4	0 (0.00)	0 (0.00)				

RDI: Rubber dam isolation

DSI: DryShield isolation

FLACC - Face, legs, activity, cry, consolability behavioral pain assessment scale.

[∝] McNemar test.

[§] Marginal Homogeneity test.

Table 5

Comparisons of mean difference in pain, behavior, and subjective pain and discomfort between different dental isolation systems among participants with different airway patency.

Variables	Patent airway ⁶⁹ N = 30 Mean difference (RDI minus DSI)	Non-patent airway $^{\mbox{\tiny GP}}$ $N=30$ Mean difference (RDI minus DSI)	<i>P</i> - value [‡]
Wong-Baker Faces Pain Rating Scale	2.0 ± 0.0	2.0 ± 0.0	NA
<i>P</i> -value ^{**}	<0.001*	<0.001*	
FLACC	0.7 ± 0.9	0.4 ± 0.9	0.119
P-value ^{**}	<0.001*	0.031*	
Frankl's Behavior Scale	0.2 ± 0.6	0.4 ± 0.6	0.296
P-value ^{**}	0.146	0.007*	
To what degree were you annoyed by the sounds from the isolation system?	$-$ 2.9 \pm 1.7	$-$ 2.6 \pm 2.2	0.598
<i>P</i> -value [§]	<0.001*	<0.001*	
To what degree did the isolation system cause stretching in the mouth, cheeks, and lips?	2.0 ± 1.9	1.3 ± 2.6	0.222
<i>P</i> -value [§]	<0.001*	0.012*	
To what degree did you feel pressure on the tongue while using the isolation system?	1.8 ± 1.8	1.2 ± 2.5	0.266
<i>P</i> -value [§]	<0.001*	0.016*	
To what degree did you feel that you want to vomit/gag because of the isolation system?	3.2 ± 1.7	2.5 ± 3.0	0.253
<i>P</i> -value [§]	<0.001*	<0.001*	
To what degree did you feel leaking fluids into your mouth during using the isolation	3.4 ± 1.4	3.2 ± 2.7	0.812
system?	<0.001*	<0.001*	
P-value ⁸			
To what degree did you feel pain and discomfort during using the isolation system?	3.8 ± 1.5	3.4 ± 3.3	0.622
<i>P</i> -value [§]	<0.001*	<0.001*	

Mean differences were calculated as RDI reading minus DSI reading.

Positive differences indicate higher RDI readings.

Negative differences indicate higher DSI readings.

FLACC - Face, legs, activity, cry, consolability behavioral pain assessment scale.

NA: Not applicable because all participants (n = 60) had the same value (difference of 2 between RDI and DSI).

**Related samples Wilcoxon Signed Rank Test to assess the pairwise difference between RDI and DSI within different airway patency.

 $^{\$}$ Paired sample *t*-test to assess the pairwise difference between RDI and DSI within different airway patency.

[‡] Independent sample *t*-test to compare the difference in RDI and DSI between different airway patency.

⁶⁰ Patent-airway (classes I and II MMC) and nonpatent-airway (classes III and IV MMC).

* Statistically significant.

overall behavior with RDI was reported. This difference might be because the participants in the previous study were sedated, and their level of consciousness might have influenced the outcome (Current et al., 2022).

No statistically significant changes were observed in any vital signs when comparing the baseline measurements with the mean readings obtained during the dental procedure within and between the compared dental isolation systems. This finding is consistent with those of previously published studies which no significant changes in SpO₂ (Bello, Darwish, & Pedo, 1994, Nara et al., 2015, Odabaş, Deveci, & Ölmez, 2011), HR (Ammann et al., 2013), and BP (Ammann et al., 2013, Bello, Darwish, & Pedo, 1994) were observed following efficient RDI application in children; however, this outcome is inconsistent with that of a study by Bello and Darwish et al. (2014) who reported a significant increase in HR during routine dental treatment with RDI in children (Bello, Darwish, & Pedo, 1994).

In this study, MMC was used as it is a common, quick, and noninvasive airway assessment tool that has been used for decades (Lesavoy et al., 2022). However, the use of this method alone is not adequate for independently predicting a difficult airway (Roth et al., 2018). Herein, tonsillar hypertrophy, the most common cause of upper airway obstruction in children measured using the Brodsky grade, was not assessed (Simsek et al., 2015). Therefore, further studies are required to evaluate airway patency by combining MMC and Brodsky grades.

The results of this study should be interpreted with consideration of its limitations. First, data were collected from a single dental hospital, which may have affected the generalizability of the results. Second, although the study design was randomized, it was not possible to blind the participants and clinicians who performed the dental procedures to intervention allocation. Third, the RR was not measured, which could have provided significant additional to this study. Finally, a single highresolution camera was utilized, aimed at capturing the entire body as much as possible. Future studies should prioritize the implementation of a multicenter project, introduce blindness into the methodology to minimize bias, and include RR as part of the measured vital signs.

5. Conclusion

Regardless of airway patency, the use of DSI significantly shortened the chairside time of the dental procedure, when compared to RDI use, and induced better behavior and less pain. Participants experienced more stretching in the mouth, cheeks, and lips with higher pressure on the tongue, heightened sensations of vomiting and gagging, increased sense of fluid leakage, and pain and discomfort with the use of the RDI than with DSI use. However, the participants expressed a higher level of annoyance with the noise generated by the DSI. No significant changes were observed in any of the vital signs when comparing the baseline measurements with the mean readings taken during the dental procedure within and between the dental isolation systems.

CRediT authorship contribution statement

Sara M. Bagher: Conceptualization, Writing – original draft, Writing – review & editing, Investigation, Methodology, Supervision. Ghalia Y. Bhadila: Conceptualization, Writing – original draft, Writing – review & editing, Investigation, Methodology, Supervision. Njood H. Alqahtani: Data curation, Writing – original draft, Investigation. Njood H. Alharbi: Data curation, Writing – original draft, Investigation. Osama M. Felemban: Conceptualization, Writing – original draft, Writing – review & editing, Investigation, Formal analysis, Methodology, Supervision.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Validated arabic version of wong-baker pain rating scale



Wong-Baker FACES® Pain Rating Scale

Appendix B. Subjective pain, discomfort Arabic validated questionnaire.

				1.0									
1-To what degree were you annoyed by the n Zero= The noise didn't annoy me at all 10= The noise annoyed me all the time	(015C a55	0	1	2	3	4	5	6 sys	7	8	9	10	*
2- To what degree, did the isolation system s	timulat	ed y	our	gag	ging	sens	atio	n du	ring	gtr	eatn	nent?	8
Zero= It did not stimulate my gagging sensation at all	+	+	+	-	+	+	+	+	+	+	+	-	+
10= It stimulated my gagging sensation all the time		0	1	2	3	4	5	6	7	8	9	10	
3- To what degree, did you feel fluid leaking	into yo	ur n	out	h du	ring	tre	atmo	nt?					
Zero= I did not feel fluid leaking into my mouth at all	+	+	+	+	+	+	+	+	+	+	-		-
10= I felt fluid leaking into my mouth all the time		0	1	2	3	4	5	6	7	8	9	10	
1- To what degree, did the isolation system ca	aused st	rete	hing	z in y	your	mo	uth,	che	cks	and	lips		
during treatment? Zero= It did not cause caused stretching in my mouth, ch	ecks and			g in y	your	mo	uth,	chee	cks	and	lips		
4- To what degree, did the isolation system ca during treatment? Zero= It did not cause caused stretching in my mouth, ch 10= It caused stretching in my mouth, checks and lips all	ecks and			; in ;	your	mo	uth,	chee	cks :	and	lips	-1	
during treatment? Zero= It did not cause caused stretching in my mouth, ch 10= It caused stretching in my mouth, checks and lips all 5- To what degree, did the solation system ca	ecks and the time	lips a	t all	1 2	3	4	1	6	+ 7	8	9	10	
during treatment? Zero= It did not cause caused stretching in my mouth, ch 10= It caused stretching in my mouth, checks and lips all 5- To what degree, did the solation system ca Zero= It did not cause pressure on my tongue at all	ecks and the time	lips a	t all	1 2	3	4	1	6	+ 7	8	9	10	→ →
Auring treatment? Zero= It did not cause caused stretching in my mouth, chi I0= It caused stretching in my mouth, checks and lips all 5- To what degree, did the solation system ca Zero= It did not cause pressure on my tongue at all	ecks and the time	lips a	t all	1 2	3	4	1	6	+ 7	8	9	10	→ →
during treatment? Zero= It did not cause caused stretching in my mouth, ch 10= It caused stretching in my mouth, checks and lips all 5- To what degree, did the solation system ca Zero= It did not cause pressure on my tongue at all 10= It caused pressure on my tongue all the time 6- To what degree, were you comfortable with	ecks and the time the time	0 0 0	t all 1 are o 1	+ 2 2 9 1 2	+ 3 0ur 1 + 3	+ 4 10ng + 4	 5 ue d 5	 6 6	 7 19 17 7	eatr 8	9 men 9	10 t?	→ →
during treatment? Zero= It did not cause caused stretching in my mouth, ch 10= It caused stretching in my mouth, checks and lips all 5- To what degree, did the solation system ca	ecks and the time the time	0 0 0	t all 1 are o 1	+ 2 2 9 1 2	+ 3 0ur 1 + 3	+ 4 10ng + 4	 5 ue d 5	 6 6	 7 19 17 7	eatr 8	9 men 9	10 t?	→ →

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