Efficacy of a Novel Customized Toothbrush in Improving Oral Hygiene and Gingival Health Among Children with Special Health Care Needs - A Randomized Control Trial

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Abstract: Background: Oral health care as part of holistic health is usually unattended in children with special health needs. These children usually lack manual dexterity to maintain oral health care and usually have an array of dental disorders like dental caries, periodontal disease and malocclusion. A tooth brush with improved adaptation skill and complete cleaning of all surfaces which can be educated to these children will have better oral health outcomes.

Aim: To find the efficacy of novel tooth brush in prevention of dental caries and gingivitis in children with special care needs.

Materials & Methods: A randomized controlled trial was conducted among 30 children with special health care needs aged 6–17 years. Participants were allocated into a customized toothbrush group (n=15) and a conventional toothbrush group (n=15). Oral Hygiene Index (OHI), Modified Gingival Index (MGI), Nyvad Index, and toothbrushing ability scores were recorded at baseline, 3 months, and 6 months. Data were analyzed using independent and paired t-tests.

Results: The customized toothbrush group demonstrated significantly greater reductions in OHI, MGI, and Nyvad Index scores at 3 and 6 months compared with the conventional toothbrush group ($p<0.001$). Toothbrushing ability also improved significantly over time, indicating enhanced brushing performance and adaptation.

Conclusion: Within the limitations of this study, the novel customized toothbrush was found to be more effective than a conventional toothbrush in improving oral hygiene status, gingival health, caries activity, and toothbrushing ability among children with special health care needs.

Keywords: Toothbrushing; Dental Caries; Gingivitis; Autism Spectrum Disorder; Child; Oral Hygiene; Toothbrushing; Dental Plaque; Gingivitis; Dental Caries; Oral Health; Disabled Children; Special Needs Population, Pediatric Dentistry

Introduction

Oral health is an integral component of overall health and quality of life. Oral care activities such as toothbrushing are habitual daily occupations that are often considered routine for healthy individuals. However, maintaining adequate oral hygiene remains a significant challenge for children with special health care needs, making oral health one of the most neglected aspects of their overall healthcare management.[1] Although many disabilities affecting these children are not curable, appropriate education, therapeutic interventions, and assistive technologies can help them achieve greater independence and improved quality of life.[2]

Children with special health care needs encompass individuals with physical, developmental, behavioral, sensory, intellectual, or emotional impairments that require specialized healthcare services beyond those required by typically developing children.[3] Many of these conditions are associated with structural abnormalities of the orofacial region, neuromuscular deficits, poor motor coordination, and parafunctional oral habits, predisposing affected children to various oral diseases including dental caries, gingivitis, periodontal disease, malocclusion, bruxism, and developmental enamel defects.[3] Furthermore, difficulties in swallowing, excessive drooling, reduced manual dexterity, and impaired coordination often limit their ability to perform effective oral hygiene procedures independently.[4]

Several studies have reported a significantly higher prevalence of dental caries and gingival diseases among children with special health care needs compared to healthy peers.[5],[6] In addition, medications commonly prescribed for these children, particularly antiepileptic drugs such as phenytoin sodium, have been associated with gingival enlargement, further complicating oral hygiene maintenance and increasing plaque accumulation [10]. Consequently, preventive oral health measures are of paramount importance in this vulnerable population.

Previous investigations have emphasized the role of caregiver-assisted toothbrushing, powered toothbrushes, and adaptive oral hygiene aids in improving plaque control among children with disabilities.[7] Studies by Pilebro and Backman demonstrated that individualized oral hygiene instruction significantly improved oral health outcomes in children with developmental disabilities. Similarly, adaptive toothbrush handles and modified brushing techniques have shown promise in enhancing brushing efficiency among individuals with limited motor skills.[8] However, the available evidence remains limited and predominantly focuses on conventional modifications or caregiver interventions rather than innovative toothbrush designs specifically developed for children with special health care needs.

For these children, routine oral hygiene practices can be challenging due to sensory sensitivities, unique executive functioning patterns, cognitive limitations, and difficulties in understanding and maintaining structured habits.[9], [10], [11] Therefore, there is a need for oral hygiene devices that facilitate easier adaptation, improve brushing efficiency, and encourage independent oral care practices. Customized toothbrushes designed to accommodate the functional limitations of special children may offer a practical solution for enhancing plaque removal and maintaining gingival health.

Despite growing awareness regarding oral health disparities among children with special health care needs, there is a paucity of literature evaluating the effectiveness of novel customized toothbrushes in preventing dental caries and gingivitis in this population.[12], To the best of our knowledge, no randomized controlled trial has comprehensively assessed the efficacy of a customized toothbrush specifically developed for children with special health care needs. This constitutes a significant gap in the literature.

Therefore, the present study was undertaken to evaluate and compare the efficacy of a novel customized toothbrush with that of a conventional toothbrush in preventing dental caries and gingivitis among children with special health care needs. The null hypothesis stated that there would be no significant difference in oral hygiene maintenance and gingival health outcomes between children using the customized toothbrush and those using a conventional toothbrush.

MATERIALS AND METHODS

Study Design and Ethical Approval

This single-blinded, randomized intergroup comparative clinical trial was conducted after obtaining approval from the Institutional Ethical Committee of Saveetha Dental College and Hospitals, Chennai (IEC No: IHEC/SDC/FACULTY/22/PEDO/111). The study was performed in accordance with the ethical principles outlined in the Declaration of Helsinki (1975, revised in 2000).[13] The examiners who recorded the clinical indices were blinded to the group allocation of the participants throughout the study period.

The study participants were randomly allocated into two groups:

Group I (Intervention Group): Oral hygiene instructions along with a novel customized toothbrush.

Group II (Control Group): Oral hygiene instructions along with a conventional toothbrush.

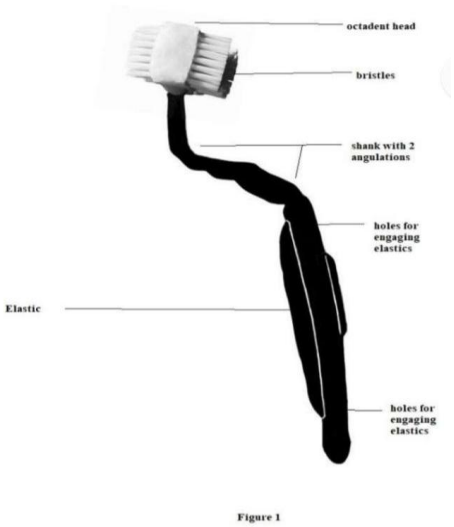

Figure 1: Structural design of the novel customized toothbrush showing the octadent head, multi-surface bristle arrangement, dual-angulated shank, and elastic-assisted handle designed to enhance plaque removal and brushing adaptability in children with special health care needs.

Sample Size Calculation and Participant Selection

The sample size was estimated based on the study conducted by Bozkurt et al.[14]. Using a significance level of 5% ($\alpha = 0.05$), power of 80% ($\beta = 0.20$), $Z\alpha/2$ value of 1.96, and $Z\beta$ value of 0.84, with an average standard deviation of 0.565 and a clinically significant difference of 0.58, the minimum required sample size was calculated as 25 participants per group. Children aged 6–17 years diagnosed with Autism Spectrum Disorder (ASD) and attending the HOPE Child and Adolescent Mental Health Institute were screened for eligibility. Diagnosis and categorization were performed by qualified

psychiatrists using the Childhood Autism Rating Scale, Second Edition–Standard Version (CARS-2ST) [18]. To ensure examiner blinding, participants were assigned unique identification numbers and the severity of autism was concealed from the investigators.

Inclusion Criteria

Children aged 6–17 years diagnosed with Autism Spectrum Disorder according to CART criteria and whose parents or caregivers provided written informed consent were included in the study. Participants and caregivers were required to be willing to comply with the prescribed oral hygiene regimen and attend scheduled follow-up visits.

Exclusion Criteria

Children presenting with associated physical disabilities, severe psychiatric comorbidities, systemic illnesses affecting oral health, or severe behavioral problems that prevented cooperation were excluded. Children whose parents or caregivers were unwilling to provide informed consent or participate in follow-up evaluations were also excluded.

Oral Hygiene Education and Toothbrushing Practices

All parents and caregivers received a standardized oral health education session emphasizing the importance of maintaining oral hygiene in children with special health care needs. Instructions included proper toothbrushing techniques, use of fluoridated toothpaste, dietary counseling, and preventive oral health measures. The Modified Horizontal Scrub Technique was demonstrated and reinforced during each visit. Caregivers were instructed to supervise or assist toothbrushing twice daily using fluoridated toothpaste. The importance of establishing effective oral hygiene practices early in life was emphasized, particularly because children with special health care needs often exhibit reduced manual dexterity and impaired adaptive skills that compromise plaque removal. All participants were additionally advised to follow a twice-daily rinsing regimen using 0.2% chlorhexidine mouthwash throughout the study period.

Clinical Examination

Baseline clinical examination was performed under natural illumination using sterilized mouth mirrors and explorers. The following indices were recorded at baseline and at the end of the 6-month follow-up period.

Oral Hygiene Index

Oral hygiene status was assessed using the Debris Index-Simplified (DI-S) component of the Simplified Oral Hygiene Index (OHI-S) described by Greene and Vermillion.[15] Scores were categorized as good (0.1–0.9), fair (1.0–1.9), and poor (2.0–3.0).

Modified Gingival Index

Gingival health was assessed using the Modified Gingival Index (MGI) proposed by Lobene et al.[16] The buccal and lingual marginal gingiva and interdental papillae of all teeth were examined and scored from 0 to 4, where 0 indicated absence of inflammation and 4 represented severe inflammation characterized by marked redness, edema, and hypertrophy.

Nyvad Caries Index

Dental caries activity was evaluated using the Nyvad Caries Diagnostic Criteria.[17] The index assesses both lesion severity and activity status through ten diagnostic categories ranging from sound tooth surfaces to active and inactive carious lesions and restorations. The criteria have demonstrated high validity and reliability for monitoring caries progression and arrest.

Toothbrushing Cooperation

Toothbrushing cooperation was evaluated using the Frankl Behavior Rating Scale.[18] Scores ranged from 1 (definitely negative behavior or refusal of toothbrushing) to 4 (definitely positive behavior with excellent cooperation).

Toothbrushing Ability Assessment

Toothbrushing ability was assessed using a structured visual pedagogy protocol adapted from Shin and Saeed [26]. Seven brushing steps were evaluated: brushing of upper anterior teeth, upper left posterior teeth, upper right posterior teeth, lower anterior teeth, lower left posterior teeth, lower right posterior teeth, and rinsing/spitting after brushing.

Each step was scored as follows: Score 0: Unable to complete the task, Score 1: Task completed entirely by parent/caregiver, Score 2: Task completed with prompting and Score 3: Task completed independently. A minimum of ten brushing strokes per quadrant was required for successful completion of each step. The mean score of all seven steps was calculated as the toothbrushing ability score.

Randomization

Following baseline assessment, participants were randomly allocated into either Group I or Group II using a coin-toss randomization method. Allocation concealment was maintained until intervention assignment. Participants in Group I received the novel customized toothbrush along with fluoridated toothpaste and oral hygiene instructions. Participants in Group II received a conventional toothbrush, fluoridated toothpaste, and identical oral hygiene instructions. Caregiver supervision was recommended for all participants irrespective of group allocation.

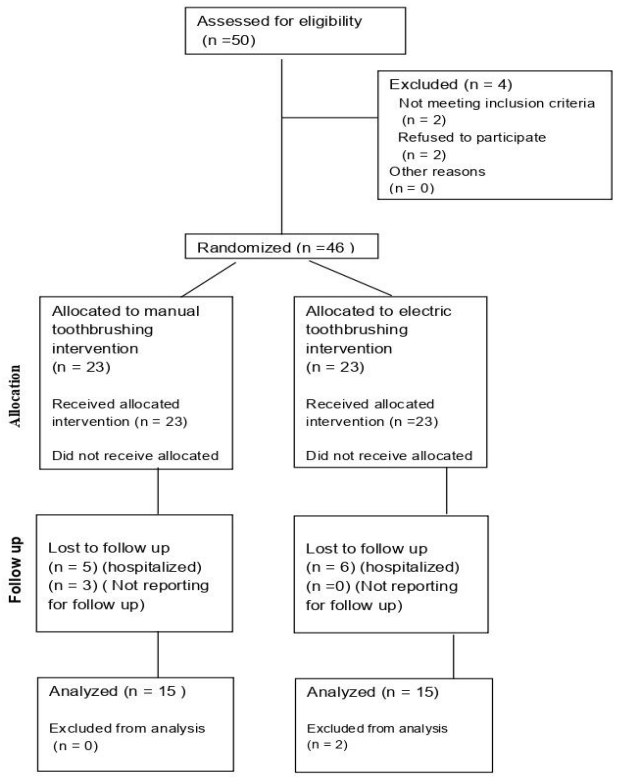

Figure 1: CONSORT diagram showing the flow of participants through each stage of a randomized trial.

Figure 2: CONSORT flow diagram showing participant recruitment and allocation.

Figure 2 CONSORT flow diagram illustrating participant recruitment, allocation, follow-up, and analysis in the randomized controlled trial evaluating the efficacy of a novel customized toothbrush compared with conventional toothbrushing in children with special health care needs. A total of 50 children were assessed for eligibility, of whom 46 were randomized into manual toothbrushing (n = 23) and customized/electric toothbrushing intervention groups (n = 23). Following losses to follow-up, 15 participants in each group completed the study and were included in the final analysis.

Fabrication of the Customized Toothbrush

A novel customized toothbrush was developed by assembling six toothbrush heads in an octagonal configuration to maximize surface contact during brushing. The handle consisted of a soft velvet elastic support system with dual retention loops designed to improve grip stability and manual dexterity in children with special health care needs. The design aimed to facilitate adaptation and improve plaque removal efficiency during toothbrushing.

Statistical Analysis

Data were analyzed using Statistical Package for the Social Sciences (SPSS) software version 26.0 (IBM Corp., Chicago, IL, USA). Descriptive statistics were expressed as mean and standard deviation. Intragroup comparisons between baseline and 6-month follow-up scores were performed using the paired t-test. Intergroup comparisons of Oral Hygiene Index, Modified Gingival Index, Nyvad Index, Frankl Behavior Rating Scale scores, and toothbrushing ability scores were performed using the independent t-test. A p-value <0.05 was considered statistically significant.

RESULTS

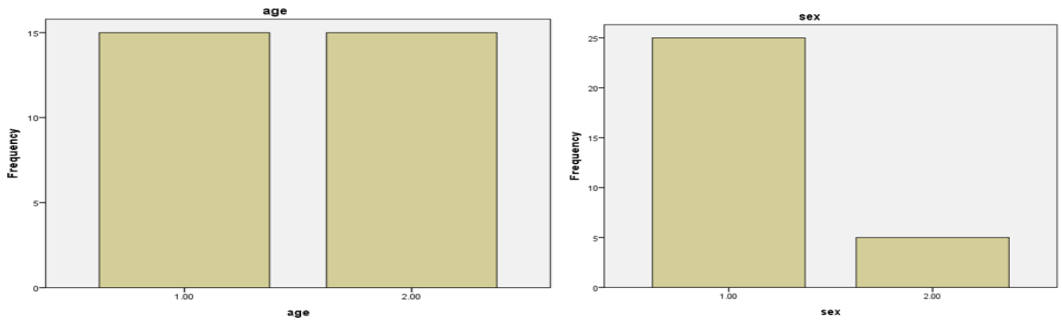

Figure 3: Age and gender distribution of participants in the test and control groups.

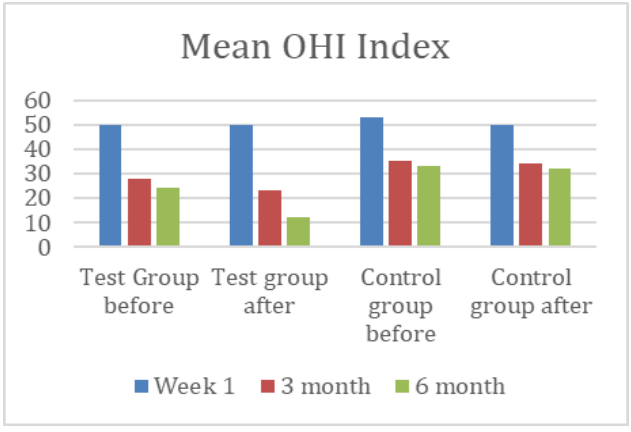

Figure 4: Comparison of mean Oral Hygiene Index (OHI) scores at baseline, 3 months, and 6 months in both groups.

Figure 4 shows the comparison of mean Oral Hygiene Index (OHI) scores between the customized toothbrush group and the conventional toothbrush group at baseline, 3 months, and 6 months. A progressive reduction in OHI scores was observed in both groups, indicating improvement in oral hygiene status over the study period.

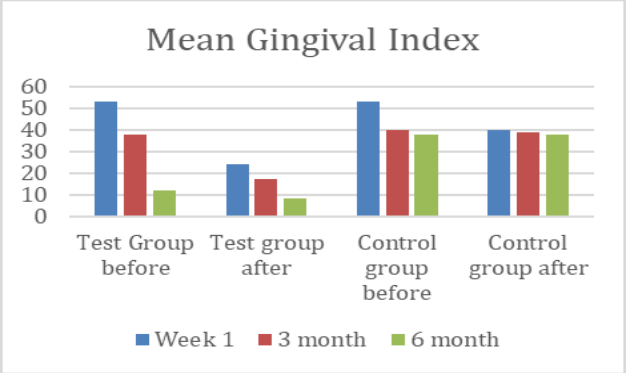

Figure 5: Comparison of mean Modified Gingival Index (MGI) scores at baseline, 3 months, and 6 months in both groups.

Figure 5 shows the comparison of mean Modified Gingival Index (MGI) scores between the customized toothbrush group and the conventional toothbrush group at baseline, 3 months, and 6 months. Both groups demonstrated a reduction in gingival inflammation, with greater improvement observed in the customized toothbrush group.

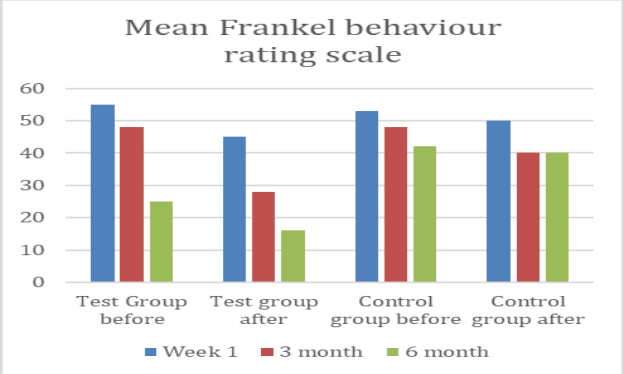

Figure 6: Comparison of Frankl Behavior Rating Scale scores at baseline, 3 months, and 6 months in both groups.

Figure 6 shows the comparison of mean Frankl Behavior Rating Scale scores between the customized toothbrush group and the conventional toothbrush group at baseline, 3 months, and 6 months. An improvement in toothbrushing acceptance and cooperative behavior was observed during the follow-up period in both groups.

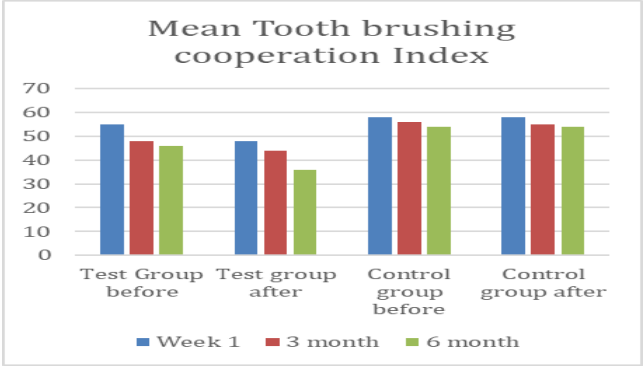

Figure 7: Comparison of Tooth Brushing Cooperation Index scores at baseline, 3 months, and 6 months in both groups.

Figure 7 shows the comparison of mean Tooth Brushing Cooperation Index scores between the customized toothbrush group and the conventional toothbrush group at baseline, 3 months, and 6 months. The customized toothbrush group demonstrated enhanced toothbrushing cooperation and improved brushing performance throughout the study period.

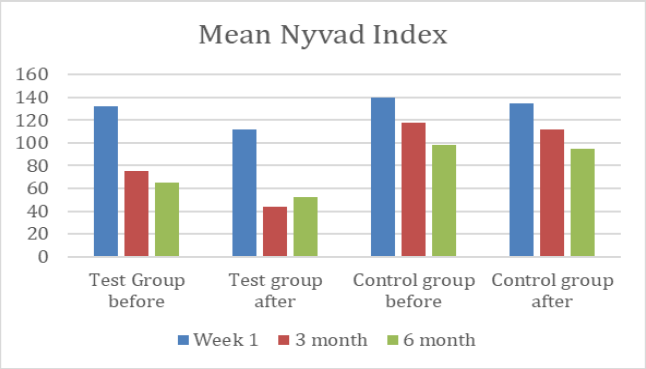

Figure 8: Comparison of mean Nyvad Index scores at baseline, 3 months, and 6 months in both groups.

Figure 8 shows the comparison of mean Nyvad Caries Activity Index scores between the customized toothbrush group and the conventional toothbrush group at baseline, 3 months, and 6 months. A reduction in Nyvad scores was observed over time, indicating decreased caries activity and improved oral health outcomes following the intervention.

Outcome Variable	Group	Mean Difference	t-value	p-value
Gingival Index	Test	2.033 ± 0.765	14.56	<0.001
Nyvad Index	Test	1.767 ± 0.430	22.494	<0.001
Oral Hygiene Index	Test	2.233 ± 0.430	28.435	<0.001
Gingival Index	Control	0.167 ± 0.874	1.044	0.305
Nyvad Index	Control	1.333 ± 0.479	15.232	<0.001
Oral Hygiene Index	Control	0.500 ± 0.731	3.746	0.001

Table 1: Intragroup comparison of Gingival Index (GI), Nyvad Index, and Oral Hygiene Index (OHI) scores between baseline and 6-month follow-up periods using paired sample t-test analysis.

The paired sample t-test analysis demonstrated in table 1 shows significant improvements in oral health outcomes among participants using the customized toothbrush. The test group showed a significant reduction in Gingival Index (2.033 ± 0.765; $p < 0.001$), Nyvad Index (1.767 ± 0.430; $p < 0.001$), and Oral Hygiene Index (2.233 ± 0.430; $p < 0.001$) after 6 months of intervention. In the control group, significant reductions were observed in the Nyvad Index (1.333 ± 0.479; $p < 0.001$) and Oral Hygiene Index (0.500 ± 0.731; $p = 0.001$), whereas the reduction in Gingival Index was not statistically significant (0.167 ± 0.874; $p = 0.305$). Overall, the customized toothbrush demonstrated greater improvements in oral hygiene status, gingival health, and caries activity compared with the conventional toothbrush over the 6-month follow-up period.

Variable	Time Interval	Customized Toothbrush Group (Mean ± SD)	Conventional Toothbrush Group (Mean ± SD)	p value
Oral Hygiene Index (OHI)	Baseline	2.40 ± 0.504	2.49 ± 0.505	0.699
	3 Months	0.53 ± 0.504	2.45 ± 0.503	<0.001*
	6 Months	0.39 ± 0.493	1.57 ± 0.500	<0.001*
Gingival Index (GI)	Baseline	2.24 ± 0.651	3.45 ± 0.503	<0.001*
	3 Months	1.33 ± 0.476	2.86 ± 0.800	<0.001*
	6 Months	0.45 ± 0.503	1.90 ± 0.728	<0.001*
Nyvad Index	Baseline	2.45 ± 0.503	4.04 ± 1.708	<0.001*
	3 Months	1.47 ± 0.504	3.16 ± 0.703	<0.001*
	6 Months	0.53 ± 0.542	2.20 ± 0.693	<0.001*
Toothbrushing Ability Score†	Baseline	32.8 ± 5.360	32.7 ± 5.365	0.93
	3 Months	19.1 ± 4.482	26.5 ± 6.944	<0.001*
	6 Months	7.9 ± 3.209	11.7 ± 3.727	<0.001*

*Legend: Values are expressed as mean ± standard deviation (SD). Intergroup comparisons were performed using the independent t-test. A p-value <0.05 was considered statistically significant. *Statistically significant difference between groups.*

Table 2: Comparison of Oral Hygiene Index (OHI), Gingival Index (GI), Nyvad Index, and Toothbrushing Ability Scores between the customized toothbrush and conventional toothbrush groups at baseline, 3 months, and 6 months

The customized toothbrush group demonstrated significant improvements in oral hygiene and gingival health throughout the study period as shown in table 2. At baseline, no significant difference was observed in OHI scores between the groups ($p = 0.699$). However, at 3 and 6 months, the customized toothbrush group exhibited significantly lower OHI scores than the conventional toothbrush group ($p < 0.001$). Similarly, significantly lower Gingival Index and Nyvad Index scores were observed in the customized toothbrush group at both follow-up visits ($p < 0.001$). Toothbrushing ability scores also improved significantly over time, with greater improvement observed among children using the customized toothbrush. These findings suggest that the customized toothbrush was more effective in improving oral hygiene status, reducing gingival inflammation, decreasing caries activity, and enhancing toothbrushing performance in children with special health care needs.

Variable	Time Interval	Customized Toothbrush Group (Mean ± SD)	Conventional Toothbrush Group (Mean ± SD)	p value
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*Legend: Values are expressed as mean ± standard deviation (SD). Intergroup comparisons were performed using the independent t-test. A p-value <0.05 was considered statistically significant. *Statistically significant difference between groups. † Verify the toothbrushing ability scoring system, as the reported scores exceed the maximum score described in the methodology section and may represent cumulative scores rather than mean scores.*

Table 3: Comparison of Oral Hygiene Index (OHI), Gingival Index (GI), Nyvad Index, and Toothbrushing Ability Scores between the customized toothbrush and conventional toothbrush groups at baseline, 3 months, and 6 months

Table 3 shows that the customized toothbrush group demonstrated significant improvements in oral hygiene and gingival health throughout the study period. At baseline, no significant difference was observed in OHI scores between the groups ($p = 0.699$). However, at 3 and 6 months, the customized toothbrush group exhibited significantly lower OHI scores than the conventional toothbrush group ($p < 0.001$). Similarly, significantly lower Gingival Index and Nyvad Index scores were observed in the customized toothbrush group at both follow-up visits ($p < 0.001$). Toothbrushing ability scores also improved significantly over time, with greater improvement observed among children using the customized toothbrush. Overall, the findings suggest that the customized toothbrush was more effective in improving oral hygiene status, reducing gingival inflammation, decreasing caries activity, and enhancing toothbrushing performance in children with special health care needs.

DISCUSSION

Children with special health care needs (CSHCN) frequently experience poor oral health outcomes owing to impaired motor coordination, reduced manual dexterity, sensory challenges, and dependence on caregivers for daily oral hygiene procedures. These limitations often predispose them to increased plaque accumulation, gingival inflammation, and dental caries. The present study evaluated the effectiveness of a novel customized toothbrush in improving oral hygiene status, gingival health, caries activity, and toothbrushing ability among children with special health care needs. The findings demonstrated significantly greater improvements in Oral Hygiene Index (OHI), Gingival Index (GI), Nyvad Index, and toothbrushing ability scores in the customized toothbrush group compared with the conventional toothbrush group over a 6-month follow-up period.

The significant reduction in OHI scores observed in the customized toothbrush group is consistent with the findings of Al-Batayneh et al. [19], who demonstrated that structured toothbrushing interventions utilizing visual communication methods significantly improved gingival health and oral hygiene among children with autism spectrum disorder (ASD). While their intervention focused on behavioral training using the Picture Exchange Communication System (PECS), the present study suggests that modifying the brushing device itself may further enhance plaque removal efficiency in children with limited motor skills.

Subhashree et al.[20] reported significant improvements in toothbrushing skills and oral hygiene following the implementation of toothbrushing visual pedagogy among children with ASD. Our findings complement these observations by demonstrating that improved adaptation to the toothbrush, in conjunction with caregiver guidance and repeated reinforcement, can substantially improve oral hygiene outcomes. The marked reduction in OHI scores from baseline to 6 months in the customized toothbrush group supports the role of adaptive oral hygiene devices in promoting effective plaque control.

Pawar et al.[21] compared manual and powered toothbrushes in autistic children and found superior plaque removal with powered toothbrushes. Vajawat and Deepika[22] reported significant reductions in plaque and gingival scores following the use of powered toothbrushes. Although our study did not compare the customized toothbrush with a powered toothbrush, the magnitude of improvement observed suggests that enhancing grip stability and access to multiple tooth surfaces may provide benefits comparable to technologically advanced toothbrushes while remaining economically feasible and easy to use.

The reduction in gingival inflammation observed in the present study is in agreement with the meta-analysis by Davidovich et al.[23], which concluded that improved plaque removal directly translates into better gingival health outcomes. The customized toothbrush group demonstrated a substantial reduction in GI scores, indicating that improved plaque disruption effectively reduced gingival inflammation. The Modified Gingival Index was selected because it permits non-invasive evaluation without provoking bleeding, making it particularly suitable for children with special health care needs.

Educational and visual interventions have also been shown to improve oral health outcomes in children with developmental disabilities. Godbole et al.[24] reported that picture-based toothbrushing interventions significantly improved plaque scores, gingival health, and brushing behavior.[25],[26] Although our study primarily focused on the toothbrush design rather than visual training, the observed improvements in toothbrushing ability suggest that adaptive devices and behavioral reinforcement may work synergistically to improve oral hygiene outcomes.

The importance of caregiver involvement has been emphasized by Fenning et al.[27], who reported significant improvements in oral hygiene practices following parent-training programs. A subsequent study by the same authors[28] demonstrated that optimized parent-training approaches enhanced both feasibility and oral hygiene outcomes. In the present study, all participants received caregiver supervision and standardized oral hygiene instructions. However, children using the customized toothbrush achieved greater improvements despite similar caregiver support, indicating that device design may play an independent role in facilitating oral hygiene performance.

An interesting finding of the present study was the improvement in toothbrushing ability scores over time. The reduction in assistance required by participants suggests that the customized toothbrush enhanced self-performance and adaptability. This observation is supported by France et al.[29], who demonstrated improved brushing frequency and compliance following the use of a smart electric toothbrush among children with ASD. Although the technology employed differs substantially, both studies emphasize the importance of improving user engagement and brushing independence.

The present findings are further supported by the systematic review conducted by Rajaei et al.[30], which concluded that oral health interventions incorporating visual pedagogy, educational tools, adaptive technologies, and powered toothbrushing significantly improved oral hygiene and gingival health among children with ASD.[31] This customized toothbrush represents a novel adaptive technology designed specifically to address manual dexterity limitations and may therefore contribute to the growing body of evidence supporting individualized oral health interventions.

Balian et al.[32] reported significant improvements in debris scores and gingival health following visual pedagogy-based interventions. Usilla et al.[33] found that structured oral health education programs significantly enhanced oral hygiene awareness and oral hygiene practices among children with ASD. Although these studies primarily focused on educational interventions, the present study extends these findings by demonstrating that physical modifications to oral hygiene devices may further improve clinical outcomes.

The significant reduction in Nyvad Index scores observed in the customized toothbrush group indicates a reduction in caries activity. Since dental plaque is the primary etiological factor in dental caries, improved plaque removal likely contributed to the observed decrease in active carious lesions. This finding reinforces the concept that preventive oral health strategies tailored to the functional limitations of children with special health care needs can substantially reduce disease burden.

Another noteworthy observation was the apparent increase in independent toothbrushing behavior among participants using the customized toothbrush. The modified handle design improved grip stability and reduced the need for complex wrist movements, potentially enabling children with impaired motor coordination to perform brushing more effectively. While this outcome was not objectively measured using validated independence scales, it represents a promising avenue for future research.

However, the study had certain limitations, including a relatively small sample size, single-center design, and lack of objective assessment of caregiver involvement and brushing independence. Another limitation is that it was not registered with the Clinical Trials Registry–India (CTRI). Furthermore, comparisons with powered toothbrushes were not performed. A major strength of this study is the evaluation of a novel customized toothbrush specifically designed to address manual dexterity challenges encountered by children with special health care needs. The randomized controlled design, six-month follow-up period, and assessment of multiple clinical and behavioral outcomes further strengthen the validity of the findings. Future multicenter studies with larger sample sizes, longer follow-up periods, objective behavioral assessments, and direct comparisons with

powered toothbrushes are recommended to validate the long-term effectiveness and clinical applicability of customized toothbrushes in children with special health care needs.

CONCLUSION

Within the limitations of this study, the novel customized toothbrush was more effective than a conventional toothbrush in improving oral hygiene status, gingival health, caries activity, and toothbrushing ability among children with special health care needs. The customized design facilitated better plaque control and may promote greater independence during toothbrushing. These findings emphasize the importance of adaptive oral hygiene aids, caregiver education, and preventive oral health programs in improving the long-term oral health outcomes of children with special health care needs.

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CONFLICT OF INTEREST: There are no conflicts of interest...

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