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3 **Changes in oral health-related quality of life after treatment of molar**
4 **incisor hypomineralization using Glass Hybrid Restorations**

5
6 **Nihan Tugcu, Berkant Sezer, Cansu Caliskan, Basak Durmus, Betul Kargul**

7 Department of Pediatric Dentistry, Marmara University, Istanbul, Turkey.

8 **Correspondence:** Basak Durmus. **Email:** altinokbasak@yahoo.com

9
10 **Abstract**

11 **Objective:** To assess the changes in children's oral health-related quality of life
12 following the treatment of severely affected molar-incisor hypomineralisation with
13 Glass Hybrid Restorative System (GH) after selective caries removal.

14 **Method:** The observational cross-sectional study was conducted at the Marmara
15 University, School of Dentistry, Department of Pediatric Dentistry. Children aged 11–
16 14 years (n = 55) who were diagnosed with MIH and had finished their dental treatment
17 from November 2018 to December 2019, were included. The children's MIH-affected
18 teeth were treated with GH after SCR. Participants answered the Child Perceptions
19 Questionnaire (CPQ₁₁₋₁₄) prior to their dental treatment and 6 months after the treatment.

20 **Results:** Of the fifty-five patients, 40 patients (24 girls-16 boys) completed baseline and
21 follow-up data. The mean age of the children was 11.85 (± 1.02) years. The overall CPQ
22 score ranged from 3–83 (average 33.27 ± 16.46) at baseline and 0–61 (average $11.67 \pm$
23 11.21) at follow up. The emotional well-being among children was the highest score at
24 baseline. A significant decrease ($p < 0.001$) in the mean values was observed for both
25 the overall CPQ scores and for the scores of the oral symptoms, functional limitations,
26 and social-emotional well-being limitation. All subdomains showed large effect sizes
27 and oral symptom limitation domain presented the greatest effect. Wilcoxon Rank test
28 was used to determine the statistical significance of the changes and the magnitude of
29 change was determined by calculating and classifying the effect size.

30 **Conclusion:** Restorative treatment with GH following selective caries removal
31 positively influenced the oral health-related quality of life of children with severe molar-
32 incisor hypomineralisation.

33 **Key Words:** Health-related quality of life, Dental enamel hypoplasia, Questionnaires,
34 Child, Oral health.

36 **Introduction**

37 Molar incisor hypomineralisation (MIH) is a developmental dental defect that is
38 common in childhood and causes both aesthetic and functional deficiencies.¹ Recent
39 reports show that 13-14% of children are affected by MIH globally.^{2,3} This structural
40 enamel defect affects at least one first permanent molar in children, causing post-
41 eruptive breakdown and a variety of dental problems, such as hypersensitivity, rapid
42 development of atypical carious lesions, insufficient local anaesthesia during treatment,
43 and the need for recurrent dental treatment.^{4,5} Such dental problems disrupt children's
44 daily lives, resulting in negative social and aesthetic consequences in addition to dental
45 pain.^{4,6}

46 The extent and depth of the defect, the age of the child, and their cooperation are the
47 main factors in planning dental restoration of atypical cavitated carious lesions in MIH
48 molars.^{7,8} Numerous studies have shown that selective partial caries removal in vital
49 teeth with deep caries lesions is more beneficial than non-selective complete caries
50 removal, particularly in cases close to the pulp.⁹ Based on this evidence, selective caries
51 removal (SCR) is becoming a popular and preferred method for MIH teeth. SCR is based
52 on the principles of arresting the lesion by sealing active caries activity with a good
53 restoration, and preventing caries progression by isolating the bacteria from the
54 substrate. The technique consists of removal of all proximal caries until the hard dentine
55 is felt, and soft and leathery dentin is left on the cavity walls over the pulp. Thus, the
56 risk of pulp exposure is significantly reduced, especially in paediatric patients, and more
57 complicated treatments, such as root canal treatment, are prevented.^{9,10}

58 Oral health and dental therapy can have an impact on how one speaks, eats and looks as
59 well as on the overall quality of life (QOL), which is a multidimensional concept. As a
60 result, there has been an increased clinical emphasis on assessing QOL as a supplement
61 to assessing oral health needs, prioritising care, and evaluating treatment strategy
62 outcomes.¹¹ One of these scales, the Child Perception Questionnaire for children aged
63 11-14 years (CPQ₁₁₋₁₄), was developed¹² to assess the oral health QOL (OHRQOL) of
64 children in that age bracket with various oral and orofacial disorders.¹² The impact of
65 oral and orofacial problems in children is assessed on symptomatic, functional,
66 emotional and social levels in all versions of the questionnaire.¹³ The Turkish version
67 of CPQ₁₁₋₁₄ has also been cross-culturally adapted and validated.¹⁴
68 Although studies have evaluated the relationship between MIH and OHRQOL, there is
69 scarce information on how dental treatment could help to improve the MIH-affected
70 childrens' OHRQOL.¹⁵⁻¹⁷ Therefore, the current study aimed to determine how treating
71 severe MIH teeth with glass hybrid restorations (GH) following SCR affected children's
72 OHRQoL as measured by the Turkish version of the CPQ questionnaire, as well as any
73 differences in OHRQoL before and after treatment according to gender. The study's
74 hypothesis was that treating MIH-affected molars with GH after SCR improved these
75 children's OHRQoL, with gender differences in QHRLQoL.

76

77 **Subjects and methods**

78 The observational cross-sectional study was conducted at the Marmara University,
79 School of Dentistry, Department of Pediatric Dentistry. Children aged 11–14 years (n =
80 55) who were diagnosed with MIH and had finished their dental treatment from
81 November 2018 to December 2019 were included. The study protocol was reviewed
82 and approved by The Marmara University's Research Ethics Committee (Protocol
83 number 2016-43). Children, the parents or guardians were informed verbally and signed
84 a written informed consent form to participate in the study. The reporting of this study
85 is according to the STROBE checklist.¹⁸

86 Children who received a diagnosis of specified MIH lesions were observed prior and 6
87 months after treatment. The modified European Academy of Paediatric Dentistry
88 criteria¹⁹ and the MIH treatment need index (TNI) were used to define MIH.²⁰ The
89 following inclusion criteria were applied: (1) a fully erupted MIH (in occlusion = B
90 code)¹⁹ with cavitation without hypersensitivity, pain or signs of pulp necrosis (MIH
91 TNI 2a–c)²⁰ (2) treatment under local or no anaesthetic was expected; (3) children able
92 to read and write in Turkish.

93 Clinical cases with other types of enamel defects (e.g., moderate/severe dental fluorosis,
94 amelogenesis imperfecta, enamel hypoplasia, enamel tooth malformation linked to
95 syndromes), any dental or facial anomaly other than MIH (e.g., hypodontia, cleft lip and
96 palate), or learning disabilities, or none dental experience were excluded from the study.
97 GH restorations after SCR were performed by a paediatric dentist with 10 years of
98 clinical experience. Using a low-speed rosehead bur, caries was removed from the
99 cavity's lateral walls. SCR on the pulpo-axial walls was preferred, with no need for local
100 anaesthesia, using a sharp spoon, double-ended excavator until leathery or firm dentin
101 (resistant to hand excavator) was reached. The final cavity was washed with water spray
102 and gently dried. GH (Equia Forte, GC, Tokyo, Japan) was used for the restoration
103 according to the manufacturers' instructions and the coat applied on the restoration
104 surface.

105 Sample size calculation was performed to focus on the effect of treatment on OHRQoL.
106 Based on previous studies,^{15,17} the power calculation indicated that at least 40 samples
107 were required to compensate for a 20% drop-out rate at the 5% significance level and
108 80% statistical power.

109 **Data Collection:** Turkish version of the CPQ₁₁₋₁₄, which consists of 37 general
110 questions spread over 4 OHRQOL dimensions: oral symptoms (6), functional
111 limitations (9), emotional wellbeing (9) and social wellbeing (13).¹⁴ In the Turkish
112 version of the CPQ, the children are asked about the frequency of experiences and
113 emotions experienced due to their teeth, lips and jaws during the preceding 3 months.
114 Each question is answered on a 5-point Likert scale, with options ranging from 0 = never

115 to 4 = every day/almost every day. The total CPQ₁₁₋₁₄ score is calculated by summing
116 up the scores of all the 37 items, and ranges 0-148. Higher scores reflect a more negative
117 OHRQOL. This questionnaire was answered by children prior to their dental treatment
118 and 6 months after the completion of the treatment when they booked for a recall
119 examination.

120 The CPQ₁₁₋₁₄ was administered by two trained examiners in the waiting area of the dental
121 clinic to assist the participants in completing the questionnaire. All participants took a
122 maximum of 10 minutes to complete the questionnaire.

123 With the pre-treatment questionnaire application, we intended to learn the impact of
124 MIH on everyday life activities and emotions of children. Children were recalled six
125 months after treatment and instructed to reflect on post-treatment changes while
126 completing the CPQ₁₁₋₁₄.

127 Impact on OHRQoL represented by the total CPQ score was the dependent variable.
128 Gender, pre-treatment, and post-treatment were the independent variables.

129 **Data Analysis:** Statistical Package for Social Sciences version 22.0 for Windows was
130 utilized for data processing and statistical analysis (SPSS Inc., Chicago, IL, USA). The
131 outcome variables were overall CPQ scores and scores for the subdomains. These were
132 applied as count variables. Wilcoxon Rank test was used to determine the statistical
133 significance of the changes and the magnitude of change was determined by calculating
134 and classifying the effect size. Partial Eta Squared (η^2) was used to calculate effect
135 size. Suggested norms for partial eta-squared are: small = 0.01; medium = 0.06; large =
136 0.14.

137

138 **Results**

139 Sixty children with MIH invited to participate in this study between November 2018
140 and December 2019. Five of these excluded because they did not answer the
141 questionnaires. The remaining 55 children with MIH agreed to take part in the study.
142 The pre-treatment survey included responses from these 55 patients, but there was a
143 drop-out of 15 cases as the patient did not have a follow-up appointment, the primary

144 caregiver declined to complete the post-treatment survey or did not attend the
145 appointment. Therefore, a total of forty children were included in the study, 24 girls and
146 16 boys.(Figure 1).

147 The mean age of the examined children was 11.85 (\pm 1.02) years, ranging from 11 to 14
148 years of age. A total of 86 teeth were treated, all of which had a similar MIH severity
149 (B code; MIH TNI 2a–c). The mean number of DMF-T in total was 3.6 ± 1.22 . Table 1
150 shows the characteristics of the children.

151 Data on the before treatment and following treatment at 6 months period OHRQoL
152 scores, as well as differences in scores with effect sizes, are presented in Table 2. The
153 overall CPQ score ranged from 3–83 (average 33.27 ± 16.46) at baseline and 0–61
154 (average 11.67 ± 11.21) at follow up. The means values of overall CPQ score and its
155 subscale scores show significant reductions after treatment ($p < 0.001$) with effect sizes
156 indicating large changes. The largest effect size was observed in the oral symptoms
157 subscale with an average of 0.70.

158 All children (100%,40) reported an improvement in their OHRQoL after treatments on
159 the over-all CPQ scores. No changes in scores were observed in only 3 children (7.5 %)
160 for oral symptoms, in 4 children (10%) for functional limitation, in 4 children (10%) for
161 emotional well-being, and in 9 children (22%) for social well-being.

162 At baseline, boys and girls had similar overall and subscale domain scores on the CPQ
163 questionnaires (oral symptoms, functional limitations, emotional limitations, and social
164 well-being).The mean values of both the overall CPQ score and the subscale scores
165 showed significant reductions after treatment in both genders ($p < 0.05$) (Table 3).
166 There was no time-gender interaction in overall CPQ score and the subscale
167 scores.($p < 0,05$) (Table 4)

168

169 Discussion

170 It is critical to assess the impact of MIH, which has emerged as a major public health
171 issue affecting children's OHRQOL. This evaluation helps to determine the needs
172 perceived by the patient in the early stages of the disease and to develop preventive

173 dentistry policy and practices. The negative effect of MIH on children's OHRQOL had
174 been demonstrated in some previous studies.^{4,15-17} However, clinical-based studies are
175 rare.^{15, 21-23} To the best of our knowledge, the current study is the first to investigate the
176 potential relationship between OHRQOL and treatment using SCR technique of first
177 permanent molars with MIH in Turkish children using the Turkish version of the CPO₁₁.
178 14.

179 Teeth affected by MIH may be hypersensitive to thermal and mechanical stimuli during
180 dental treatments. Furthermore, teeth that have been severely affected by MIH are more
181 prone to restoration failure and repeated treatments.^{7,8} This combination may have an
182 impact on these children's QOL and increase their risk of developing behaviour
183 management issues. When compared to conventional caries removal, the advantages of
184 SCR-GH in clinical practice, particularly in public dental clinics, are its ease of
185 administration, shorter procedure time, and better handling of behavioural problems in
186 MIH.¹⁰ In 2015, a newer class of restorative materials^{24,25}, the Glass hybrid restorative
187 system was launched and showed to be a reliable treatment option for MIH affected
188 teeth.²⁶

189 In our study, we observed that treating hypomineralised molars improved children's
190 OHRQOL overall. Despite the fact that all domains had large effect sizes, the oral
191 symptoms subscale showed the greatest improvement, with an effect size of 0.70. The
192 subscale asked about symptoms, such as pain, bad breath and food impaction. Children
193 may experience symptoms, such as pain, bad breath, food impaction, and subsequent
194 atypical caries due to the hypomineralised structure of the enamel of MIH-affected first
195 permanent molars. Aside from caries, the post-enamel breakdown areas create a surface
196 suitable for dental plaque, and dental plaque accumulation increases due to ineffective
197 brushing due to sensitivity. Dental plaque can foster the development of caries as well
198 as cause bad breath and bleeding gums in children. It is encouraging to see the highest
199 effect due to the reduction of symptoms in this subscale after the treatment of dental
200 caries, and it shows the success of the treatment from the children's point of view.

201 The social wellbeing subscale asks about the effects of children's oral and dental health
202 on school activities and their relationships with peers. Previous research found that
203 children with opacities in their permanent incisors due to MIH experienced aesthetic
204 concerns and were teased by their peers. These aesthetic concerns caused consequences,
205 such as shyness, lack of self-confidence and avoiding smiling. Hasmun *et al.*²¹ stated
206 that after minimally invasive treatment of opacities in permanent incisors, QOL scores
207 increased significantly, and the greatest improvement was in the social-emotional
208 wellbeing subscale depending on the improvement of aesthetics. But in the current
209 study, social and emotional wellbeing subscales had a lower effect size than other
210 domains. This can be explained by not taking into consideration any aesthetic approach
211 regarding opacities in the permanent incisors.

212 Dantas-Neta *et al.*⁴ stated that girls had higher CPQ scores in oral health and functional
213 limitations subscales than boys; thus, MIH affected girls' OHRQOL more than boys'.
214 Similar studies from Mexico and Colombia found that girls with MIH had poorer
215 OHRQOL than boys.^{15,16} This difference observed between genders in the past studies
216 might be because females are more concerned about their appearance and what others
217 think about them compared to males. On the other hand, Hasmun *et al.*²¹ reported that
218 their investigation did not reveal any significant gender differences in reported
219 OHRQoL, either before or after aesthetic treatment. In parallel with that study, in the
220 current study, no gender difference was observed between the baseline and post-
221 treatment scores. The colour and size of opacities present in the permanent incisors of
222 children may affect social and emotional subscale scores and can lead to different results
223 in OHRQOL than expected. For this reason, the classification of opacities in future
224 studies may also be useful in evaluating gender-based differences.

225 However, the results of this study, should be analyzed with caution because of the size
226 of the sample and short follow-up time. In our study, noteworthy improvements were
227 observed in the total and all subscale mean scores of the CPQ scale after treatment which
228 enable clinicians to assess the quality and success of their treatment from the patient's
229 point of view. Also, the OHRQoL of children was measured 6 months following the

230 dental treatment, and it is possible that the results found could be different at different
231 time points. Even so, this result shows us that the responsiveness of the Turkish version
232 of the CPQ to treatment in the MIH patient group is satisfactory. Further OHRQoL
233 analysis with various treatment techniques should be determined to gain a better
234 understanding of how to improve the daily lives of MIH-affected children.

235

236 **Conclusion**

237 Treating MIH-affected molars with Glass Hybrid restorations after SCR improved these
238 children's OHRQoL with no gender differences in QHRLQoL. The CPQ₁₁₋₁₄
239 demonstrated responsiveness to treatment in children with MIH. The results of this study
240 can be used to encourage interventions on oral health in this special group.

241

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243 **Conflict of Interest:** None.

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245

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Table 1: Patient characteristics (n = 40)

n (%)	Mean ±SD
Age	
Girls n=24 (60%)	11.79 ±1.06
Boys n=16 (40%)	11.93 ±0.99
Age (years)	
11-12 n=30 (75%)	11.33±0.48
13-14 n=10 (25%)	13.4 ± 0.52
Total n: 40	11.85 ±1.02
DMF-T	
Boys	3.56 ± 1.02
Girls	3.75 ± 1.45
Total	3.6 ± 1.22

328 SD: Standard deviation, DMF-T: Decayed, missing and filled teeth.

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Table 2: Mean values of total CPQ₁₁₋₁₄ scores and subscales at baseline and 6 months after treatment (n = 40).

CPQ ₁₁₋₁₄	Baseline Mean (SD)	Follow-up Mean (SD)	Difference Mean (SD)	Effect size (ES)**	p-value
Oral symptoms	9.20± 4.24	3.52± 2.82	5.67±3.73	0,70	0,001*
Functional limitation	7.20± 5.03	3.35± 2.79	3.85±3.95	0,49	0,001*

Emotional well-being	11.87± 8.73	3.18± 5.87	8.70±7.47	0,58	0,001*
Social well-being	5.00± 6.00	1.62± 4.05	3.37±4.28	0,39	0,001*
Overall CPQ ₁₁₋₁₄	33.27± 16.46	11.67± 11.21	21.6±12.44	0,76	0,001*

334 *p<0,05, Wilcoxon rank test†

335 ** Partial Eta Squared (η^2)

336 SD: Standard deviation, CPQ₁₁₋₁₄: Child perceptions questionnaire for children aged 11-14 years.

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Table 3: Baseline and follow-up CPQ₁₁₋₁₄ scores according to gender.

	Oral Symptoms	Functional Limitation	Emotional Well-being	Social Well-being	Overall CPQ ₁₁₋₁₄
Girls (n=24)					
Baseline score	8.58±3.65	6.38±4.91	11.5±8.95	4.87±6.87	31.33±17.45
Follow-up scores	3.75±3.04	3.25±2.95	3.38±6.35	2.13±5.11	12.5±13.09
p-value	0,001*‡	0,001*‡	0,001*‡	0,002*‡	0,001*‡
Boys (n=16)					
Baseline scores	10.12±4.97	8.43±5.11	12.44±8.65	5.19±4.66	36.19±14.92
Follow-up scores	3.18±2.53	3.5±2.63	2.88±5.26	0.88±1.31	10.44±7.85
p-value	0,001*†	0,001*†	0,001*‡	0,002*	0,001*†

341 *p<0,05

342 †Paired t test

343 ‡Wilcoxon rank test

344 CPQ₁₁₋₁₄: Child Perceptions Questionnaire for children aged 11-14 years.

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Table 4: Time-related changes between baseline and follow-up CPQ₁₁₋₁₄ scores according to gender

		Baseline Mean±SD	Follow-up Mean±SD	Gender p
Oral Symptoms	Boys	10.12±4.97	3.18±2.53	0,629
	Girls	8.58±3.65	3.75±3.04	
	Time p		0,001*	0,080†
Functional Limitation	Boys	8.43±5.11	3.5±2.63	0,320
	Girls	6.38±4.91	3.25±2.95	
	Time p		0,001*	0,159†
Emotional Well-being	Boys	12.44±8.65	2.88±5.26	0,918
	Girls	11.5±8.95	3.38±6.35	
	Time p		0,001*	0,558†
Social Well-being	Boys	5.19±4.66	0.88±1.31	0,264
	Girls	4.87±6.87	2.13±5.11	
	Time p		0,001*	0,760†
Overall CPQ ₁₁₋₁₄	Boys	36.19±14.92	10.44±7.85	0,737
	Girls	31.33±17.45	12.5±13.09	

	Time p		0,655	0,085 [†]
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350 *p<0,05, two way repeated measures analysis of variance (ANOVA)

351 [†]gender and time interaction

352 SD: Standard deviation, CPQ₁₁₋₁₄: Child Perceptions Questionnaire for children aged
 353 11-14 years

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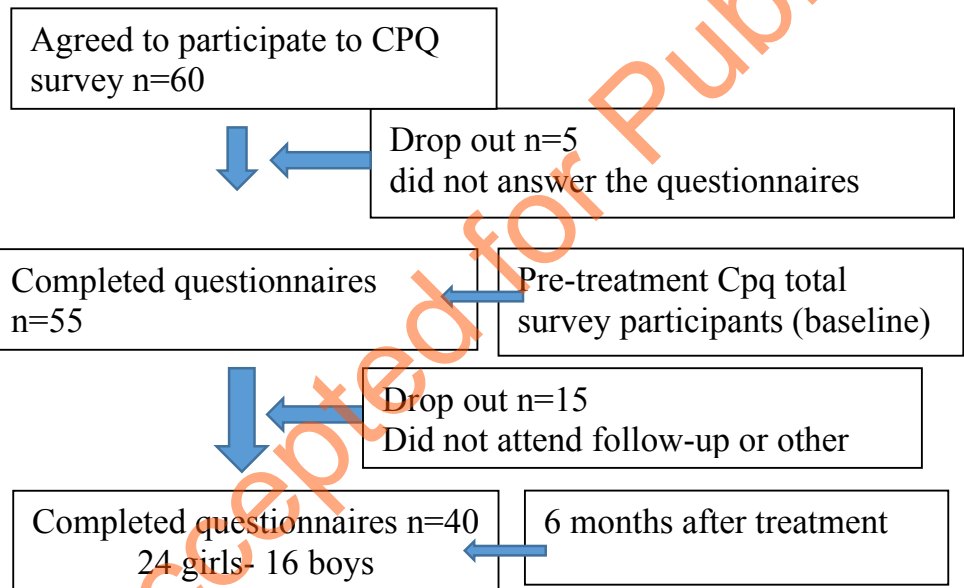
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370 **Figure 1: Flowchart of the recruitment, inclusion and drop-out at follow-up of**
 371 **participants.**

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