

## Introduction

- Cleft lip and palate (CLP) is a common congenital diagnosis and has an annual incidence rate around 1-in-1600 in the United States.<sup>1</sup>
- Patients with CLP are more likely to develop a class III malocclusion and may also experience a range of psychological challenges that impact quality of life (QoL).<sup>2</sup>
- The standard of care to treat class III malocclusion is to advance the maxillary bone and dentition by a Le Fort I osteotomy after adolescent growth.<sup>3</sup>
- As an alternative to surgery, maxillary protraction treatment based on procedures modified from Liou and Tsai's protocol<sup>4</sup> can address class III malocclusion for younger patients with CLP.
- Few studies have compared class III treatment outcomes including cost and patient (QoL).

## Objectives

The purpose of this study was to compare the longitudinal self-reported general QoL of patients with CLP from pre-treatment to a year post-treatment and to describe any differences in QoL based on the type of treatment received and the success of the outcome.

## Method

- This was an IRB-approved non-randomized prospective longitudinal cohort study that was conducted at Children's Hospital Los Angeles (CHLA) and Seattle Children's Hospital (SCH).
- Patients and their parents assented/consented, were informed that they may withdraw throughout the course of the study, and were thanked for participating with a \$25 gift cards.

## Measure

- The (SF-12) is a QoL questionnaire includes 12 questions from 8 domains including general health, physical functioning, physical role, body pain, vitality, social functioning, emotional role, and mental health.
  - Two items on overall physical health limitations and two items on emotional problems (yes/no)
  - Degree of pain interference item (not at all, a little bit, moderately, quite a bit, or extremely)
  - Four items assess the frequencies of calmness and peacefulness, energy, downheartedness and bluesness, and interfered social activities (all of the time, most of the time, a good bit of the time, some of the time, a little of the time, or none of the time)
- The Physical Composite Score (PCS) and a Mental Composite Score (MCS) range from 0 to 100<sup>5</sup>.
- The average US population PCS and MCS are 50 (SD = 10) and higher scores reflect higher QoL.

## Study Population and Interventions

- Non-syndromic patients with CLP and class III malocclusion were either part of the maxillary protraction cohort or the orthognathic surgery cohort after meeting the inclusion criteria of being 11-14 years old for the protraction group and 16-21 years old for the surgery group and found acceptable for maxillary protraction or orthognathic surgery based on clinical judgement.
- The protraction cohort were treated using maxillary protraction equipment for 18-24 months.
- The surgery cohort underwent Le Fort I orthognathic surgery.
- Success was determined by the Great Ormond Street London and Oslo) GOSLON yardstick<sup>6</sup> from a baseline rating of 3 to 5 to post-intervention ratings of 1 to 2 or 3 with positive overjet.
- SF-12 data was collected at 4 time points: baseline (T1), at maximal correction (T2), at completion (T3), and at 1-year follow-up (T4).

## Results: Participant Characteristics

Variable	Protraction (n = 53)		Surgery (n = 40)		Total Sample (n = 93)	
	Mean	SD	Mean	SD	Mean	SD
Age	12.15	(0.93)	17.43	(1.30)	14.42	(2.84)
Sex	N	%	N	%	N	%
	Male	30 56.60	21 52.50	51 54.84		
Female	23 43.40	19 47.50	42 45.16			
Race/Ethnicity	Latinx	35 67.31	28 70.00	63 68.48		
	Asian American	11 21.15	6 15.00	17 18.48		
	White/European American	5 9.62	4 10.00	9 9.78		
	Black/African American	0 0.00	2 5.00	2 2.17		
	Unknown	1 1.92	0 0.00	1 1.09		
Insurance	Public	26 49.06	30 75.00	56 60.87		
	Private	26 49.06	10 25.00	36 39.13		
Treatment outcome	Successful	27 50.94	37 92.50	64 68.82		
	Unsuccessful	26 49.06	3 7.50	29 31.18		

## Results

- Two-sample t-tests and ANOVA were performed to first check for any significant differences in patient characteristics between cohorts, with the only difference seen in a greater proportion of participants in the surgery group with public insurance,  $F(1, 90) = 6.20, P = .02$ .
- The SF-12 mean PCS and MCS scores (Table 1) were in the average range clinically across cohorts and time points.
- Other than a baseline (T1) MCS group difference ( $F(1, 91) = 5.37, P = .02$ ) with higher scores for the protraction group than surgery cohort, ANCOVAs showed no other group differences when controlling for insurance across time points comparing protraction to surgery along with treatment outcome.
- Paired t-tests were conducted to evaluate longitudinal difference in the mean PCS and MCS using the whole sample (Table 2) and only including those with successful outcomes (Table 3) with Cohen's d calculated to describe effect size.<sup>6</sup>

Table 1: SF-12 Mean Physical and Mental Composite Scores

	Protraction			Surgery			Total Sample		
	n	Mean	SD	n	Mean	SD	n	Mean	SD
<b>Physical Composite Score</b>									
T1	53	50.27	7.12	40	53.72	5.93	93	51.75	6.82
T2	51	53.06	4.75	38	49.60	7.78	89	51.58	6.42
T3	53	53.68	5.44	38	55.03	4.14	91	54.24	4.96
T4	44	55.03	4.24	23	54.51	4.51	67	54.85	4.31
<b>Mental Composite Score</b>									
T1	53	<b>56.04</b>	<b>7.34</b>	40	<b>51.55</b>	<b>11.41</b>	93	54.11	9.52
T2	51	54.18	8.12	38	51.57	9.62	89	53.07	8.83
T3	53	54.49	7.16	38	52.89	8.95	91	53.82	7.95
T4	44	51.46	10.45	23	52.73	8.54	67	51.89	9.79

- The average costs were:

- Surgery: \$112,779
- Protraction: \$6,815

- The back-of-the-envelope Incremental Cost-Effectiveness Ratio (ICER) (Protraction versus Surgery):

- ICER per PCS: (\$32,806.18)
- ICER per MCS: \$37,979.91

Table 2: Longitudinal SF-12 Mean Differences for Whole Sample

	Difference in Means		t	P	Cohen's d
	Total Sample				
<b>Physical Composite Score</b>					
T1-T2	-0.02	-0.02	0.98	0.98	-0.03
T2-T3	2.56	3.10	<b>0.00**</b>	0.00**	0.46
T3-T4	1.08	1.69	0.10	0.10	0.13
T1-T4	3.33	3.63	<b>0.00**</b>	<b>0.00**</b>	0.53
<b>Mental Composite Score</b>					
T1-T2	-0.98	-1.00	0.32	0.32	-0.11
T2-T3	0.79	0.80	0.43	0.43	0.09
T3-T4	-2.43	-2.21	<b>0.03*</b>	<b>0.03*</b>	-0.22
T1-T4	-3.49	-2.57	<b>0.01*</b>	<b>0.01*</b>	-0.23
<b>Protraction</b>					
<b>Physical Composite Score</b>					
T1-T2	2.99	2.77	<b>0.01**</b>	<b>0.01**</b>	0.46
T2-T3	0.58	0.61	0.55	0.55	0.12
T3-T4	1.66	1.88	0.07	0.07	0.27
T1-T4	4.44	3.56	<b>0.00**</b>	<b>0.00**</b>	0.79
<b>Mental Composite Score</b>					
T1-T2	-1.73	-1.30	0.20	0.20	-0.24
T2-T3	0.23	0.19	0.85	0.85	0.04
T3-T4	-2.90	-2.22	<b>0.03*</b>	<b>0.03*</b>	-0.34
T1-T4	-4.45	-2.47	<b>0.02*</b>	<b>0.02*</b>	-0.52
<b>Surgery</b>					
<b>Physical Composite Score</b>					
T1-T2	-4.06	-2.76	<b>0.01**</b>	<b>0.01**</b>	-0.60
T2-T3	5.28	3.91	<b>0.00**</b>	<b>0.00**</b>	0.87
T3-T4	-0.14	-0.22	0.83	0.83	-0.12
T1-T4	1.21	1.09	0.29	0.29	0.15
<b>Mental Composite Score</b>					
T1-T2	0.02	0.02	0.99	0.99	0.00
T2-T3	1.57	0.92	0.37	0.37	0.14
T3-T4	-1.44	-0.71	0.49	0.49	-0.02
T1-T4	-1.66	-0.86	0.40	0.40	0.11

Note: \*P<.05; \*\*P<.01

Table 3: Longitudinal SF-12 Mean Differences for Successful Treatment

	Difference in Means		t	P	Cohen's d
	Total Sample				
<b>Physical Composite Score</b>					
T1-T2	-1.55	-1.31	0.19*	0.19*	-0.24
T2-T3	3.73	3.93	<b>0.00**</b>	<b>0.00**</b>	0.69
T3-T4	0.14	0.26	0.79	0.79	-0.04
T1-T4	1.98	1.80	0.08	0.08	0.35
<b>Mental Composite Score</b>					
T1-T2	-0.06	-0.06	0.95	0.95	-0.01
T2-T3	0.64	0.55	0.58	0.58	0.06
T3-T4	-2.44	-1.58	0.12	0.12	-0.17
T1-T4	-2.61	-1.64	0.11	0.11	-0.10
<b>Protraction</b>					
<b>Physical Composite Score</b>					
T1-T2	2.33	1.55	0.13	0.13	0.40
T2-T3	1.30	1.42	0.17	0.17	0.34
T3-T4	0.43	0.56	0.58	0.58	0.10
T1-T4	2.85	1.61	0.12	0.12	0.65
<b>Mental Composite Score</b>					
T1-T2	-0.70	-0.53	0.60	0.60	-0.10
T2-T3	-0.37	-0.32	0.75	0.75	-0.05
T3-T4	-3.01	-1.46	0.16	0.16	-0.38
T1-T4	-3.37	-1.45	0.16	0.16	-0.45
<b>Surgery</b>					
<b>Physical Composite Score</b>					
T1-T2	-4.43	-2.81	<b>0.01**</b>	<b>0.01**</b>	-0.64
T2-T3	5.59	3.84	<b>0.00**</b>	<b>0.00**</b>	0.90
T3-T4	-0.19	-0.25	0.81	0.81	-0.16
T1-T4	1.05	0.83	0.42	0.42	0.09
<b>Mental Composite Score</b>					
T1-T2	0.41	0.27	0.79	0.79	0.04
T2-T3	1.42	0.77	0.45	0.45	0.12
T3-T4	-1.77	-0.74	0.47	0.47	-0.03
T1-T4	-1.81	-0.82	0.42	0.42	0.12

Note: \*P<.05; \*\*P<.01

## Conclusions

- Patients with CLP and class III malocclusion in this sample had average range QoL.
- Although there was higher baseline MCS for the younger protraction cohort, QoL did not otherwise vary by treatment approach or outcome.
- For the total sample, PCS increased from baseline to a year post treatment with a medium effect size.
- PCS also improved for the total sample from maximal correction to treatment completion with an effect size approaching medium.
- Conversely, there were small effect sizes in drops in the MCS scores for the total sample from treatment completion to a year later and from baseline to a year post treatment.
- Overall, both treatments improved physical functioning, but not mental health.
- Success was higher in the surgery group, which also had higher costs.
- The ICER preferred protraction to surgery with a negative ICER on PCS and a cost-effective ICER on MCS at a \$50,000 willingness-to-pay threshold.
- Generic QoL measures may not capture cleft-specific variables impacting psychosocial adjustment.
- Study limitations include sample attrition over time, lack of randomization, and differences in age required by the interventions.

## References

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