CLINICAL TRIALS

Randomized Clinical Trial of Interceptive and Comprehensive Orthodontics

G.J. King¹*, C.F. Spiekerman², G.M. Greenlee¹, and G.J. Huang¹

Abstract: *Focusing public insurance programs on interceptive orthodontics (IO) may increase access for low-income children. This report presents outcomes from a randomized clinical trial (RCT) comparing IO with comprehensive orthodontics (CO) in Medicaid patients.*

One hundred seventy pre-adolescents with Medicaid-eligible malocclusions were randomized to IO (n = 86) followed by observation (OBS) or OBS followed by CO (n = 84). One hundred thirty-four completed the trial. Models at pre-treatment (baseline) and following ≤ 2 years of intervention and 2 years of OBS (48 mos) were scored by calibrated examiners using the Peer Assessment Rating (PAR) and Index of Complexity, Outcome and Need (ICON). Overall outcomes and clinically meaningful categorical ICON data on need/acceptability, complexity, and improvement were compared.

At baseline, groups were balanced by age, gender, ethnicity, and PAR/ICON scores. Most were minorities. Most (77%) were rated as difficult-to-very difficult. Scores improved significantly for both groups, but CO more than IO (PAR, 18.6 [95%CI 15.1, 22.1] vs. 10.1 [95%CI 6.7, 13.4]; ICON, 44.8 [95% CI 39.7, 49.9] vs. 35.2 [95%CI 29.7, 40.6], respectively).

On average, IO is effective at reducing malocclusions in Medicaid patients, but less than CO. (ClinicalTrials.gov number CT00067379)

Key Words: access to care, orthodontic therapy, occlusion, patient outcomes, evidence-based dentistry/health care.

Introduction

Access to orthodontics for low-income children is limited (King *et al.*, 2006; Waldman and Perlman, 2006; Im *et al.*, 2007). One strategy to improve access would be to increase the use of simpler interceptive approaches (IO) during the mixed dentition. Studies have shown that these interventions can reduce malocclusion severities, converting from “medically necessary” to elective categories (Mirabelli *et al.*, 2005; Theis *et al.*, 2005; Jolley *et al.*, 2010). Despite orthodontists’ perception that this is beneficial, most recommend a comprehensive second phase in the permanent dentition (CO; King *et al.*, 2006). Nonetheless, surveyed orthodontists who were Medicaid non-participants would consider participating if their main concerns were addressed (*i.e.*, low reimbursements and excessive bureaucracy). Interim

analysis of a randomized clinical trial (RCT) comparing IO with no treatment confirmed that IO is effective in Medicaid patients (Jolley *et al.*, 2010). The purpose of this study is to compare the effectiveness of IO with that of CO.

Materials & Methods

Experimental Design

This RCT compared 170 Washington State Medicaid children randomized to two groups: either interceptive orthodontic treatment followed by observation (IO) or to observation followed by comprehensive treatment (CO). Patients were randomized in chronological blocks of 10, with blocks equally balanced with five patients randomized to each group. Preliminary results, covering the first phase of the study (*i.e.*, early interception *vs.* observation only during the mixed dentition), have been previously reported (Jolley *et al.*, 2010). Those in the IO arm received appropriate interceptive orthodontic treatments, including space management, strategic extractions, dental alignment, growth modification, habit abatement, and corrections of crossbites, overbites, and open bites by both removable and fixed partial appliances, while those in the CO arm received periodic recalls. In the

DOI: 10.1177/0022034512448663. ¹Department of Orthodontics, University of Washington School of Dentistry, Box 357446, Seattle, WA 98195, USA; and ²Department of Oral Health Sciences, University of Washington School of Dentistry, Seattle, USA; *corresponding author, gking@u.washington.edu

A supplemental appendix to this article is published electronically only at <http://jdr.sagepub.com/supplemental>.

© International & American Associations for Dental Research

subsequent 2 yrs, the IO children were retained and periodically observed, while the CO children received comprehensive orthodontics with full appliances.

The protocol was reviewed and approved by the Seattle Children's Hospital Institutional Review Board. A National Institutes of Health External Data and Safety Monitoring Board provided oversight. All patients and guardians provided written consent in accordance with institutional and federal guidelines.

Eligibility

Inclusion criteria were: Medicaid dental and medical patients; active patient of health care providers; mixed dentition; eligible for Medicaid orthodontic funding.

Exclusions were: the presence of active oral disease; poor compliance; planned move < 4 yrs; unacceptable oral hygiene; craniofacial anomalies; history of orthodontic treatment; posterior crossbite with shift; or unwillingness to randomize.

Treatments

Interceptive treatment plans were presented to the IO patients and parents. These were followed until two orthodontists agreed that the objectives were achieved or until 2 yrs. Dental models were taken at baseline. A second phase consisted of bi-annual observation and retention checks, followed by a second set of models after 48 mos.

Those in the CO arm had baseline models followed by bi-annual observation for 24 mos. The second phase consisted of comprehensive treatments. After 48 mos, models were obtained. Orthodontic graduate students, supervised by faculty, performed all treatments for both groups at the Odessa Brown Children's Clinic and the UW School of Dentistry.

Outcomes

Baseline and 48-month models were scored by calibrated and blinded examiners using the Peer Assessment Rating (PAR; Richmond *et al.*, 1992a,b) and the Index of Complexity, Outcome and Need (ICON; Daniels and Richmond, 2000). Both indices have been

validated and widely used to quantify malocclusions. PAR rates the components of malocclusions, with higher scores indicating greater severity. The components of PAR are: upper and lower incisor irregularity; right and left posterior occlusal relations in sagittal, transverse, and vertical planes; and incisor overjet, overbite, and centerline relationships. Component scores were multiplied by validated weightings (UK) and summed to obtain a total score.

ICON also rates occlusions, with higher scores indicating greater severity. Five dental components were scored: esthetics, upper crowding/spacing, crossbite, anterior vertical, and posterior AP relationships. The sum of weighted ICON scores determined the percentage of patients with need at baseline (> 43) and acceptable outcomes (< 31). The percentage of patients in 5 complexity categories was also calculated: easy < 29; mild 29 > 50; moderate 51 > 63; difficult 64 > 77; very difficult > 77. We calculated ICON improvement scores by multiplying the 48-month score by 4 and subtracting this from baseline (Daniels and Richmond, 2000). More negative numbers represent less improvement. Improvement grade categories are: substantial (> -25), moderate (-26 to -53), minimal (-54 to -84), and none (< -85).

Statistical Methods

Data were compared between groups by independent-samples *t* tests. Paired *t* tests were used for changes over time. Wilcoxon rank-based tests compared distributions of categorical ICON data between groups and time-points. Linear regression modeling estimated group differences at 48 mos, adjusting for age, gender, and treatment complexity at baseline. Proportions with need between groups used Fisher's exact test. Proportions with need between time-points were compared by McNemar's test. Follow-up rates between treatment groups used an uncorrected Pearson Chi-square test. Associations between baseline and acceptable outcomes were modeled by logistic regression. Statistical calculations were performed with

SPSS for Windows, version 16.01 (IBM Corporation, Somers, NY, USA).

Results

Public health dentists and orthodontists referred Medicaid patients. Those meeting inclusion criteria (345) were invited; 170 were consented and randomly allocated (IO = 86; CO = 84). Those completing the trial were IO = 65 and CO = 69. At baseline, 85 sets of casts were scored in the IO group. In CO, 83 were scored for PAR and 81 for ICON. At 48 mos, 65 were scored in IO. In CO, 69 were scored for PAR and 67 for ICON. The failures to score were due to damage or loss. *A priori*, we hypothesized that IO would be slightly less effective than CO. Because of the difficulty of defining how large a shortfall would be considered acceptable, we designed the trial to estimate the difference between average treatment outcomes and based sample-sizes on desired precision of the treatment-difference estimates with estimated widths of the 95% confidence intervals for the mean differences in final PAR using data from the University of Florida Class II RCT (King *et al.*, 2003). We predicted that a sample size of 49/group would have confidence intervals of 5 PAR points. Considering the trial's length and continuity-of-care concerns related to low-income families, we over-recruited. We could maintain sample sizes above 49, even after experiencing a 21% loss. Comparison of baseline characteristics of lost and completed groups indicated that dropouts did not significantly alter the sample (Appendix Table 2). However, we noted trends toward more females (56% *vs.* 51%) and African-Americans (59% *vs.* 37%) and fewer Asians (12% *vs.* 23%) and Hispanics (6% *vs.* 12%) in the dropouts. At 48 mos, data were available for 65 (77%) of the IO patients and 69 (83%) of the CO (*p* = 0.28).

The groups reflected local Medicaid populations, with similar ages, genders, and races (Appendix Table 1). The sample was composed primarily of minorities, with African-Americans, Asians, and Hispanics representing 68% of IO and 77% of CO. The "other"

Table 1.

Comparison of PAR and ICON by Treatment Group

	IO			CO				
	N	Mean	SD	N	Mean	SD	Diff.	p Value*
PAR								
BL	85	30.6	8.2	83	31.4	9.0	-0.8	0.56
48 Mo	65	21.0	12.6	69	13.1	12.9	7.9	0.001
Diff	65	10.1	13.4	69	18.6	14.7	-	-
p Value**	-	< 0.001	-	-	< 0.001	-	-	-
ICON								
BL	85	75.1	16.1	81	73.5	14.9	1.6	0.50
48 Mo	65	40.7	21.0	67	28.3	18.9	12.5	0.001
Diff	65	35.2	21.9	67	44.8	20.8	-	-
p Value**	-	< 0.001	-	-	< 0.001	-	-	-

*Two-sample *t* test for differences between treatment groups.**Paired *t* test for differences within groups between time-points; BL = baseline.

category also included minorities. There were no significant associations between PAR or ICON (data not shown) and gender, ethnicity, or age at either time-point.

PAR and ICON are displayed in Table 1. Mean scores were not different at baseline (IO-CO = -0.8 PAR points [$p = 0.56$] and 1.6 ICON points [$p = 0.50$]). However, at 48 mos, group differences (IO-CO) were highly significant ($p = 0.001$), with CO 7.9 PAR and 12.5 ICON points lower than the IO. Both experienced significant reductions in PAR and ICON ($p < 0.001$). IO had a mean reduction of 10.1 PAR points and 35.2 ICON; CO reductions were 18.6 PAR and 44.8 ICON points. Thus, IO experienced 33.0% improvement in PAR and 46.9% in ICON, while the CO had 59.2% for PAR and 60.9% for ICON.

“Clinically meaningful” ICON categories (need/acceptability, complexity, and improvement) are in Tables 2 to 4. No baseline differences in need or acceptability were detected; most had need (98%; Table 2). Both had significant reductions in need by 48 mos ($p < 0.001$; IO = 37%; CO = 21%), but CO need at 48 mos was less than that of IO ($p = 0.055$).

In both groups, complexities were difficult to very difficult at baseline (77%; $p = 0.57$). By 48 mos, both experienced

significant improvements in complexity ratings ($p < 0.001$). Those rated easy-to-mild = 74% for IO and 91% for CO, but the latter had more ($p = 0.011$) in that category (Table 3). More CO (66%; $p < 0.001$) were moderately, substantially, or greatly improved than IO (45%; Table 4).

Several baseline factors were examined for associations with acceptable outcomes (*i.e.*, ICON scores < 31). None had significant interactions at baseline by treatment group. However, combining groups showed significant associations with acceptable outcomes for baseline complexity ($p < 0.034$) and esthetics ($p < 0.023$; Appendix Table 3).

Discussion

This study extends interim findings showing that interceptive mixed-dentition orthodontics provides significant short-term benefits for Medicaid patients (Jolley *et al.*, 2010). This and other studies showing improvement following IO (Pangrazio-Kulbersh *et al.*, 1999; Ngan and Yiu, 2000; King *et al.*, 2003; Mirabelli *et al.*, 2005; Kerosuo *et al.*, 2008) did not consider the possibility for relapse and other negative consequences from continued facial growth. Therefore, the current study follows children who received interceptive treatment for 2

more yrs, with the finding that the PAR improvement did deteriorate slightly [*i.e.*, 15.4 at completion of IO (Jolley *et al.*, 2010) to 21.0 at 48 mos in this study], but remained significant. As expected, CO also improved, but these patients either had just completed treatment or were finishing at 48 mos. Therefore, it is reasonable that CO improvement may also deteriorate during the post-treatment retention phase (de la Cruz *et al.*, 1995; Artun *et al.*, 1996).

This finding suggests that a Medicaid focus on IO may increase access for the children of low-income families. This strategy has advantages over CO because it is less complex, less costly, and acceptable to most orthodontists (King *et al.*, 2006). However, the relative cost-effectiveness of the two approaches is unknown (Bresnahan *et al.*, 2010). This study indicates that both approaches are effective, but IO is less than CO. Assuming that IO has lower costs, the relative cost-effectiveness may be quite similar. Superficially, such a finding suggests that IO has little advantage over CO. However, if IO provides greater access without increasing costs, clearly it would be preferred from a public health perspective.

With the ultimate goal of increasing access, one needs to consider that non-providers may not become providers.

Table 2.
ICON Need and Acceptability Ratings

		IO		CO		p Value*
		N	%	N	%	
BL	Need	83	98	79	98	0.67
	Between Need and Acceptable	2	2	1	1	-
	Acceptable	0	0	1	1	-
	Total	85		81		-
48 Mo	Need	24	37	14	21	0.055
	Between Need and Acceptable	16	25	9	13	-
	Acceptable	25	38	44	66	-
	Total	65	-	67	-	-
p Value**		-	<0.001	-	<0.001	

Need = ICON score ≥ 43 ; **Between Need and Acceptable** = ICON score < 43 , > 31 ; **Acceptable** = ICON score ≤ 31 .

* Fisher's exact test for difference in proportions in the need category between treatment groups.

** McNemar's test for difference in proportions in the need category between time-points; BL = baseline.

Table 3.
ICON Complexity Ratings

		BL		48 Mos		
		n	%	n	%	
IO	Easy	0	0	23	35	p < 0.001*
	Mild	6	7	25	38	-
	Moderate	13	15	7	11	-
	Difficult	30	35	6	9	-
	Very Difficult	36	42	4	6	-
CO	Easy	0	0	43	64	p < 0.001*
	Mild	6	7	18	27	-
	Moderate	13	16	2	3	-
	Difficult	32	40	2	3	-
	Very Difficult	30	37	2	3	-
		p = 0.57**		p = 0.001**		

* Wilcoxon signed-rank test for differences within groups between time-points.

** Wilcoxon rank-sum test for differences between groups.

ICON Complexity Categories: **Easy** ≤ 29 ; **Mild** $30 > 50$; **Moderate** $51 > 63$; **Difficult** $64 > 77$; **Very Difficult** > 77 .

Although orthodontists perceive IO as beneficial, they often recommend a second comprehensive phase (King *et al.*, 2006). Hence, many may be uncomfortable with IO programs not offering a second phase.

Some states currently fund a second phase if the patient still meets eligibility requirements, but early partial treatment may eliminate eligibility for a second phase. Many orthodontists may find this

unacceptable. Analysis of the data from the IO group in this study does suggest that this is a real possibility. Moreover, most in the IO group (81%) no longer met Washington State eligibility requirements following their treatment (Jolley *et al.*, 2010). Thus, those patients who desired an elective second phase would be forced to self-finance, delay, or forego treatment. This disadvantage needs to be considered when IO is contemplated as a strategy to increase access. Nonetheless, our modeling suggests that patients with certain antecedent factors are more likely to have acceptable outcomes (*i.e.*, lower initial complexity or esthetic scores), signifying that some are better candidates for IO than others.

The proportion of patients in both groups with no improvement deserves comment. First, comprehensive treatment outcomes from Medicaid and privately financed patients were not different, even after adjustment for baseline differences in severity (King *et al.*, 2011). Hence, lack of improvement from CO, as objectively defined by ICON, cannot be attributed solely to Medicaid. One can speculate that the proportion without improvement may have been lower if seasoned orthodontists in private practice settings had done the treatments, but

Table 4.
ICON Improvement Grades from Baseline to 48 Months

	IO		CO	
	Count	%	Count	%
Not Improved/Worse	30	46	18	27
Minimally Improved	6	9	4	6
Moderately Improved	14	22	5	7
Substantially Improved	10	15	13	19
Greatly Improved	5	8	27	40
Total	65	-	67	-

ICON Improvement Grade = Baseline – 4 x 48 mos; **Not Improved/Worse** < -85; **Minimally Improved** -85 > -54; **Moderately Improved** -53 > -26; **Substantially Improved** -25 > -1; **Greatly Improved** > -1. Statistically significant difference between treatment groups ($p < 0.001$).

such data are not currently available, and patient self-reports are influenced by satisfaction, rather than by dental criteria. Alternatively, failure rates may indeed be higher than most orthodontists are willing to admit. The proportion without improvement from IO speaks to the challenges that exist for selecting the most appropriate patients for partial mixed-dentition treatments. Analysis of our data suggests that the most complex patients and those with the poorest dental esthetics are at risk of obtaining unacceptable results and may be better served by comprehensive permanent dentition treatment.

Study limitations include losses to follow-up, limited generalizability, and unfinished CO patients at 48 mos. High losses were predicted because of the trial length and poor continuity of care in low-income populations (Horsley *et al.*, 2007; Giannoni and Kass, 2010). More individuals were recruited (72) over our *a priori* sample size estimates (98). The dropout rate was less than expected (21%) and comparable with that in a similar RCT (25%; King *et al.*, 2003). Moreover, baseline characteristics of dropouts were not different from those of completers, despite insignificant trends for greater losses of females and African-Americans.

Races/ethnicities reflected local Medicaid demographics, which had more Asians but fewer Hispanics than

the entire State (Kaiser, 2012). Medicaid demographics and eligibility vary considerably nationwide, suggesting that the data may not be reflective of higher African-American and Hispanic and fewer Asian proportions in other urban centers or rural locales. However, the baseline malocclusion severities and outcomes in our sample did not differ significantly among ethnic groups.

Medicaid patients in Washington are eligible for partial mixed-dentition and/or comprehensive treatment if they meet criteria. The Medicaid program uses a modification of the Handicapping Labiolingual Deviation Index and requires prior authorization (Thies *et al.*, 2005). These criteria were used to select the participants in this trial, and 98% had need at baseline, with 77% categorized as difficult to very difficult. Analysis of these data strongly suggests that these eligibility criteria select for patients with the most severe malocclusions. The majority of patients categorized as less complex had isolated anterior crossbites with gingival recession, a “medically necessary” eligibility. Since eligibility requirements vary markedly among the states, these data may not generalize to all locales or to privately financed patients, who tend to have less complex problems (King *et al.*, 2011).

We previously reported that 62.1% of the CO patients completed treatment in less than 2 yrs (King *et al.*, 2011).

Those who did not finish had higher PAR/ICON scores at 48 mos than those who did, despite adjustment for initial severity, suggesting that even greater group differences may have been evident if CO had been completed on all participants. However, it is important to note that later stages of CO are devoted to finishing. Although time-consuming, finishing changes are subtle. PAR/ICON are less sensitive to minor changes than are other indices [e.g., the American Board of Orthodontics Objective Grading System (Casko *et al.*, 1998)]. Thus, it is reasonable to expect minimal CO changes in PAR/ICON during finishing. Also, patients who did not finish under 2 yrs may have treatment- or compliance-related issues that interfere with their ever achieving acceptable outcomes.

On average, IO is effective at reducing malocclusions in Medicaid patients, but less than CO.

Acknowledgments

We acknowledge: Lynn Wang, Program Coordinator; Lingmei Zhou, Data Manager; Cameron Jolley, Catherine Lee, and Eduardo Santos, model scoring; UW Orthodontic graduate students, treatments; staff and faculty at UW Orthodontic Department and Odessa Brown Children's Clinic; and especially our valued collaborator, Asuman Kiyak, who recently passed away. Research for this article was supported by the NIDCR (grant #U54-DE 014254). The authors declare no potential conflicts of interest with respect to the authorship and/or publication of this article.

References

- Artun J, Garol JD, Little RM (1996). Long-term stability of mandibular incisors following successful treatment of Class II, Division 1, malocclusions. *Angle Orthod* 66:229-238.
- Bresnahan BW, Kiyak HA, Masters SH, McGorray SP, Lincoln A, King G (2010). Quality of life and economic burdens of malocclusion in U.S. patients enrolled in Medicaid. *J Am Dent Assoc* 141:1202-1212.
- Casko JS, Vaden JL, Kokich VG, Damone J, James RD, Cangialosi TJ, *et al.* (1998). Objective grading system for dental casts

- and panoramic radiographs. American Board of Orthodontics. *Am J Orthod Dentofacial Orthop* 114:589-599.
- Daniels C, Richmond S (2000). The development of the index of complexity, outcome and need (ICON). *J Orthod* 27:149-162.
- de la Cruz A, Sampson P, Little RM, Artun J, Shapiro PA (1995). Long-term changes in arch form after orthodontic treatment and retention. *Am J Orthod Dentofacial Orthop* 107:518-530.
- Giannoni PP, Kass PH (2010). Risk factors associated with children lost to care in a state early childhood intervention program. *Res Dev Disabil* 31:914-923.
- Horsley BP, Lindauer SJ, Shroff B, Tufekci E, Abubaker AO, Fowler CE, *et al.* (2007). Appointment keeping behavior of Medicaid vs non-Medicaid orthodontic patients. *Am J Orthod Dentofacial Orthop* 132:49-53.
- Im JL, Phillips C, Lee J, Beane R (2007). The North Carolina Medicaid program: participation and perceptions among practicing orthodontists. *Am J Orthod Dentofacial Orthop* 132:144.e15-21.
- Jolley CJ, Huang GJ, Greenlee GM, Spiekerman C, Kiyak HA, King GJ (2010). Dental effects of interceptive orthodontic treatment in a Medicaid population: interim results from a randomized clinical trial. *Am J Orthod Dentofacial Orthop* 137:324-333.
- Kaiser HF (2012). Distribution of the nonelderly with Medicaid by race/ethnicity, states (2009-2010) US. URL accessed on 4/25/12 at: <http://www.statehealthfacts.org/comparebar.jsp?ind=158&cat=3>.
- Kerosuo H, Vakiparta M, Nystrom M, Heikinheimo K (2008). The seven-year outcome of an early orthodontic treatment strategy. *J Dent Res* 87:584-588.
- King GJ, McGorray SP, Wheeler TT, Dolce C, Taylor M (2003). Comparison of peer assessment ratings (PAR) from 1-phase and 2-phase treatment protocols for Class II malocclusions. *Am J Orthod Dentofacial Orthop* 123:489-496.
- King GJ, Hall CV, Milgrom P, Grembowski DE (2006). Early orthodontic treatment as a means to increase access for children enrolled in Medicaid in Washington State. *J Am Dent Assoc* 137:86-94.
- King GJ, Kiyak HA, Greenlee GM, Huang GJ, Spiekerman CF (2011). Medicaid and privately financed orthodontic patients have similar occlusal and psychosocial outcomes. *J Public Health Dent* [Epub ahead of print 10/17/2011; DOI: 10.1111/j.1752-7325.2011.00288.x] (in press).
- Mirabelli JT, Huang GJ, Siu CH, King GJ, Omnell L (2005). The effectiveness of phase I orthodontic treatment in a Medicaid population. *Am J Orthod Dentofacial Orthop* 127:592-598.
- Ngan P, Yiu C (2000). Evaluation of treatment and posttreatment changes of protraction facemask treatment using the PAR index. *Am J Orthod Dentofacial Orthop* 118:414-420.
- Pangrazio-Kulbersh V, Kaczynski R, Shunock M (1999). Early treatment outcome assessed by the Peer Assessment Rating index. *Am J Orthod Dentofacial Orthop* 115:544-550.
- Richmond S, Shaw WC, O'Brien KD, Buchanan IB, Jones R, Stephens CD, *et al.* (1992a). The development of the PAR Index (Peer Assessment Rating): reliability and validity. *Eur J Orthod* 14:125-139.
- Richmond S, Shaw WC, Roberts CT, Andrews M (1992b). The PAR Index (Peer Assessment Rating): methods to determine outcome of orthodontic treatment in terms of improvement and standards. *Eur J Orthod* 14:180-187.
- Theis JE, Huang GJ, King GJ, Omnell ML (2005). Eligibility for publicly funded orthodontic treatment determined by the Handicapping Labiolingual Deviation Index. *Am J Orthod Dentofacial Orthop* 128:708-715.
- Waldman HB, Perlman SP (2006). Dental needs assessment and access to care for adolescents. *Dent Clin North Am* 50:1-16, v.