Cost-Effectiveness of Infant Orthopedic Treatment Regarding Speech in Patients With Complete Unilateral Cleft Lip and Palate: A Randomized Three-Center Trial in the Netherlands (Dutchcleft)

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Objective: To investigate the cost-effectiveness of infant orthopedic treatment (IO), compared with no such treatment in children with complete unilateral cleft lip and palate (UCLP) focusing on the effects on speech development at age 2.5 years.

Design: In a three-center prospective, randomized clinical trial (Dutchcleft), two groups of children with complete UCLP were followed longitudinally: one group was treated with IO based on a modified Zurich approach in the first year of life (IO group) and the other group did not receive this treatment (non-IO group).

Patients: The participants had complete UCLP without soft tissue bands or other malformations. They were born at term and their parents were native Dutch speakers.

Outcome Measures: The effect of IO on speech development at age 2.5 years was measured blindly by five expert listeners judging the “total impression of speech quality” on a 10-point equal-appearing interval scale. Costs were measured from a societal viewpoint in Euro.

Results and Conclusion: The IO group (n = 10) obtained a statistically significant higher rating, compared with the non-IO group (n = 10). The effect size was large, indicating that the improvement may be considered a clinically important change. The cost for treatment by the orthodontist was higher in the IO group. For both groups, the mean cost was related to the mean rating for “total impression of speech quality.” The resulting cost-effectiveness for IO, compared to non-IO was €1041 for 1.34 point speech quality improvement. The financial investment that is necessary to obtain this improvement seems limited. Thus, from the perspective of speech development, the cost-effectiveness of IO over non-IO seems acceptable at this point in time.

KEY WORDS: cleft lip and palate, cost-effectiveness analysis, infant orthopedics, speech

In many cleft palate centers, especially in Europe, infant orthopedics (IO) is used in the comprehensive care of children with cleft lip and palate. The relevance of this treatment, however, is controversial. In past decades, both proponents and opponents of IO have expressed their opinions in the literature. Among the advantages of IO claimed in the literature are correct alignment of the alveolar segments and narrowing of the cleft (McNeil, 1956), facilitation of surgical closure of the cleft and thus improved esthetic outcome (Gnoinski, 1990), facilitation of feeding (Oliver, 1973; Lubit, 1976), parental support (Lubit, 1976; Huddart, 1990), and improved speech (Stuffins, 1976).
Controversy surrounding the value of IO for speech development is illustrated by several reports in the literature. Those in favor of IO treatment state that it leads to better speech because it forces the tongue out of the cleft and provides it with almost normal support. This aids the development of normal tongue-tip behavior (Stuffins, 1981; Hotz et al., 1986; Gnoinski, 1990; Gruber, 1990; Jansonius-Schultheiss, 1999). Results from the Dutchcleft trial showed that babies treated with IO according to a modified Zurich approach indeed presented enhanced production of alveolar sounds in babbling at age 1 year (Konst et al., 1999). This type of IO covers the palate and the alveolar ridges and obturates the cleft in the hard and soft palate. At age 1.5 years, when the appliance was no longer used, there were no differences in consonant production between the groups. Reports on the later speech and language development of these children between the age of 2 and 3 years presented beneficial effects of IO on judged intelligibility (Konst et al., 2000, 2003c), phonological development (Konst et al., 2003b), and mean length of utterance (Konst et al., 2003a). Hardin-Jones et al. (2002) did not present significant effects of a palatal obturator on place of consonant production in babbling. The authors presumed that the unobturated cleft in the soft palate may at least partly account for the absence of effects of this form of IO.

Another advantage of IO claimed in the literature is related to the presumed palatal cleft width reduction prior to soft palate closure. As a result, more tissue should be available to contribute to the length of the soft palate instead of using it for bridging the cleft width. Therefore, better velopharyngeal function for speech may be expected (Gnoinski, 1990). In contrast, studies that suggest that early palatal repair results in better speech (Witzel et al., 1984; Harding and Grunwell, 1993; Rohrich et al., 1996) infer that speech is negatively influenced by delayed hard palate closure, inherent to the IO treatment regimen. Other opponents assert that an appliance reduces the tactile and kinesthetic proprioception of the tongue against the palate during speech production (Dorf et al., 1985).

To investigate the effects of treatment with a passive appliance (modified Zurich approach) a three-center randomized, prospective clinical trial (Dutchcleft) was started in 1993 in the Netherlands. This study comprises evaluation of the effects on (1) general aspects (feeding and parental satisfaction), (2) surgical and orthodontic measures (Prahil et al., 2001), and (3) speech and language development (Konst et al., 1999, 2000, 2003a, 2003b, 2003c; Konst, 2002). A cost-effectiveness analysis is part of the study as well (Severens et al., 1998). Today cost-effectiveness information of medical technologies or interventions is used in addition to clinical efficacy to determine whether these technologies should be available to patients. Although the number of economic evaluations in dentistry seems to be increasing, there are only a few economic evaluations in orthodontics. Cunningham (2001) reviewed this topic and concluded that the previously reported short-term cost-effectiveness of IO (Severens et al., 1998) is the only example of a combination of a clinical trial and an economic evaluation in this field. Despite this fact, especially in case of reimbursement decisions, cost-effectiveness estimates can be useful. Thus, in Australia, Canada, and several European countries, guidelines for conducting cost-effectiveness analysis exist (Hjelmgren et al., 2001).

The main principle of cost-effectiveness analysis is to estimate the cost and patient outcome (consequences or effectiveness) of an intervention, compared with an alternative (Drummond et al., 1997). Based on this explicit comparison, the difference in cost is related to the difference in effectiveness between alternative treatments to determine whether the incremental cost-effectiveness (indicating the costs that are necessary to gain extra health outcome) is acceptable. In the Dutchcleft study, a cost-effectiveness analysis was planned for all three research areas (i.e., general aspects, surgical and orthodontic aspects, and speech and language development) in the trial. The short-term cost-effectiveness analysis based on the results of the time taken for the surgical lip closure was described by Severens et al. (1998). Because there was no statistically significant effect from IO treatment on operating time for surgical lip closure, our previous work did not include an incremental cost-effectiveness analysis. The present article reports the cost-effectiveness of IO treatment, compared with no such treatment in patients with complete unilateral cleft lip and palate, focusing on the effects on the children’s speech development at the age of 2.5 years.

**Method**

**Study Design and Treatment Protocol**

In 1993 a study into the effects of a passive form of IO was initiated. The study was designed as a three-center, prospective, two-arm, randomized, controlled clinical trial. Only full-term babies of a minimum birth weight of 2500 g with complete unilateral cleft lip and palate (UCLP) were included. Their parents were Caucasian and native speakers of Dutch. Patient exclusion criteria were the presence of other congenital malformations (except for syndactyly) or soft tissue bands. Parents of eligible infants were verbally informed about the trial, and written informed consent was obtained from those willing to participate. A child entered the trial preferably within 2 weeks after birth. Concealed randomization of the participants was performed by means of a computerized balanced allocation procedure that allowed for balancing the groups for birth weight (<3300 g or ≥3300 g) and alveolar cleft width (<8 mm, between 8 and 12 mm, or ≥12 mm). One of the groups received IO in the first year of life (IO), and the other group did not receive this treatment (non-IO).

Treatment with IO according to a modified Zurich approach started within 2 weeks following birth. First, a dental impression was taken. Within the next 5 days, the appliance, which was made of compound soft and hard acrylic, was fitted. The
plate has a small extension into the nose and covers the palate and the alveolar ridges. It obturates the cleft in the hard palate and has an extension into the soft palate (Fig. 1). The plate was worn 24 hours a day. It was removed only for cleaning and was kept in place until the soft palate was repaired. Every 3 weeks, the IO children had their plates adjusted by grinding at the cleft margins. At approximately 18 weeks of age, the lip was closed surgically according to the Millard technique. The age at lip repair ranged from 12 weeks 5 days to 20 weeks 3 days in the IO group; the mean age was 17 weeks 3 days. In the non-IO group, the age range at lip repair was 12 weeks 3 days to 19 weeks 5 days, with a mean age at lip repair of 17 weeks 4 days. The palate was closed in two stages, with soft palate repair (modified Von Langenbeck procedure) at approximately 12 months of age. The age at soft palate repair in the IO group ranged from 50 weeks 6 days to 69 weeks 5 days, with a mean age at soft palate repair of 57 weeks 1 day, with a mean of 51 weeks 5 days. Hard palate closure is delayed until approximately 9 years of age. After surgical closure of the soft palate, the plate was no longer used. Not all children tolerated the appliance until their soft palate was closed. In two patients, IO terminated earlier (at age 46 and 47 weeks, respectively). In two children, treatment with IO was prolonged for a few weeks after surgical closure of the soft palate because of feeding problems; one child used the appliance for 78 weeks. These children all remained in the IO group.

### Participants

A total of 54 babies (41 boys, 13 girls) were included in the trial, 27 in the IO group and 27 in the non-IO group. In total, the intake of this patient sample covered a period of more than 3 years. The data in this article are derived from a group consisting of 20 2.5-year-old toddlers with UCLP. Ten of the children (8 boys, 2 girls) were treated with IO, and 10 children (9 boys, 1 girl) were not. The patient sample in this article is smaller than the total number of children participating in the full trial because (because of the above-mentioned lengthy inclusion period), only 10 children of this age in each group were available at the time of the present evaluation. The age range of the children at the time of the speech sample collection in the IO group was 2 years 5 months 24 days to 2 years 6 months 9 days. The age range in the non-IO group was 2 years 5 months 15 days to 2 years 6 months 8 days. None of the children involved in this investigation had been diagnosed as having sensorineural hearing loss, cognitive deficits, or neurological impairment.

During the trial, the children were monitored for middle-ear problems by the ear, nose, and throat (ENT) specialists of the cleft palate teams. If necessary, ventilation tubes were placed. In the first 2 years of life, there were no gross differences between the groups regarding the occurrence of middle ear problems (Konst et al., 2003a). Hearing thresholds at age 2.5 years, which were obtained either by free-field audiometry in a sound-controlled chamber or brainstem-evoked response audiometry, were also grossly the same in both groups. In both groups, four children had ventilation tubes placed, and six children had not.

### Data Collection

A sample of spontaneous speech was recorded from all toddlers in their home environment by two investigators using high-quality audio equipment (Sony TCD-D7 DAT Walkman, Sony, Tokyo, Japan) with an MD421U-4 dynamic microphone (Sennheiser, Wedemark, Germany). The child and one of the researchers were engaged in semistructured play in which the children were encouraged to talk. A fixed set of toys was used to elicit speech. The toys represent words that are most commonly heard in the active vocabulary of the normally developing 2.5-year-old child (Schlichting et al., 1995). The recordings lasted from 30 to 60 minutes until at least 120 well-recorded utterances were acquired from each child.

### Speech Evaluation

A speech sample of 15 utterances (sentences) per child was selected from the child’s recorded conversation for use in a blinded perceptual evaluation experiment. All of these utterances were spontaneous with a clarified exact meaning for all the words. The orthographic transcription of the speech sample was printed on the scoring sheet. Care was taken to select utterances that were representative of the child’s speech as presented in the conversation. Factors such as intelligibility, articulation errors, and mean length of utterance (MLU) were considered while selecting representative utterances in such a way that the overall intelligibility, number, and type of articulation errors and MLU of the selected sample did not differ much from the entire conversation. The ratings were carried out by five trained listeners. All were graduated speech therapists with experience in assessing cleft palate speech. One of the raters knew five of the children from visits at the cleft palate clinic; the other raters did not know the children.

The cost-effectiveness analysis required that the effects of the treatment were expressed in one general evaluative effect.
measure. To obtain such a measure, the listeners were asked to rate their total impression of the speech quality on a 10-point equal-appearing interval (EAI) scale. Prior to providing this general evaluative rating, the listeners rated 13 specific aspects of speech quality on seven-point EAI scales (see Appendix A). The rating scales were especially selected for the evaluation of the speech of toddlers with cleft palate and included the following aspects:

- Place of articulation: palatalization, lateralization, fronting, backing, and glottal articulation.
- Voice characteristics: hyperkinetic voice.
- Nasalization: hypernasality, nasal emission, nasal fricative, nasal snort, and nasal realization.
- General evaluative characteristics: correctness of articulation, intelligibility.

The listeners were instructed to consider all above-mentioned specific speech aspects when rating the total impression of the speech quality. Furthermore, they were asked explicitly to give the child a report mark for the total impression of his/her speech. The equal-appearing interval scale on which the total impression of the speech quality was rated had a score range of 10. This score range corresponds with the (commonly known) grades given in Dutch schools. A score of 1 to 5 is unsatisfactory, and a score of 6 and higher is a pass. A detailed description of the full perceptual evaluation experiment can be found in Konst et al. (2003c).

Before the actual experiment took place, the raters attended a specially designed training session, allowing them to familiarize themselves with the scales and the speech samples. First, written definitions of the rating scales were presented to the listeners. The listeners were asked to absorb the definition of a particular scale, after which they listened to two typical examples of the speech characteristic involved. In one example, the speech characteristic was strongly present. In the other example, the speech characteristic was less salient. Of all examples, the corresponding scale value was indicated on the scoring sheet. These scale values were determined prior to the evaluation experiment by a panel of raters experienced with cleft palate speech not participating in this experiment. The examples thus constituted so-called anchor stimuli that were used to provide the raters with the same set of perceptual referents.

**Effect Size**

Effect sizes are used in health care research to assess the magnitude and meaning of health status changes (Kazis et al., 1989). Obviously, statistical significance is a necessary condition for judging a treatment to be effective. A statistically significant difference, however, may not be synonymous with a clinically important change. The clinical importance can be expressed by the magnitude or the size of the effect produced by the intervention (Kazis et al., 1989). The effect size (ES) in this study was expressed as ES = (m IO - m non-IO)/overall SD, where m IO is the mean speech quality score in the treated group (IO), m non-IO is the mean speech quality score in the non-IO group, and overall SD is the standard deviation pooled for both groups (Cohen, 1977). Cohen defined an effect size of 0.20 as small, one of 0.50 as moderate, and one of 0.80 or greater as large.

**Cost-Effectiveness Analysis**

As a starting point for the cost-effectiveness analysis, a societal viewpoint was used, indicating that cost of the treatment of patients was based on real prices instead of charges. Besides this, a differential approach was used, aiming to estimate the difference in cost between the IO and non-IO patients. Therefore, the treatment provided to both IO and non-IO patients by specialists other than orthodontists was considered to be equal, and was not subject to the cost analysis. The use of medical care facilities (number of visits to the orthodontist, duration of the visits, use of materials) were measured prospectively by means of a log. The registered volumes of care were valued by prices to have an indication of the cost of treatment by the orthodontist for each patient. The prices reported are based on 1994 data and converted and indexed to the 2002 Euro. A more extensive description of the cost analysis methods used has been published elsewhere (Severens et al., 1998).

The mean costs of both groups were related to the mean effectiveness in terms of the total impression of speech quality as scored by the speech therapists. This resulted in the incremental cost-effectiveness ratio: the cost difference of IO over non-IO related to the improvement in speech score. The cost-effectiveness ratio indicates the financial investment needed to obtain effectiveness. The uncertainty surrounding this ratio was generated by the nonparametric bootstrap method (Briggs and Fenn, 1998). The principle of bootstrapping is that a random sample with replacement from the data of the size of the study population is taken a large number of times (in this study, 1000 times). As a result, the bootstrap incremental cost-effectiveness ratio can be calculated from each bootstrap series. These 1000 bootstrap ratios can be presented on the incremental cost-effectiveness plane by plotting the cost and effect pairs. The information from the bootstrap simulations was translated into the cost-effectiveness acceptability curve (Briggs and Gray, 1999). This curve is the result of determining several ceiling cost-effectiveness ratios and calculating the proportion of bootstrap ratios lying below each ceiling. The determination of a cost-effectiveness acceptability curve is common usage in health economics to show decision-makers the relationship between the maximum willingness to pay for improvement and the probability that a technology is cost-effective when compared with the alternative.

**RESULTS**

**Effectiveness Analysis**

The first step in the effectiveness analysis was to determine the reliability of the ratings. The intrarater reliability of the
the non-IO group (2.18, SD 0.62). The groups differed significantly from each other on this general evaluative effect measure ($t_s = 2.28; p < .05$). The IO group obtained a statistically significant higher rating for “total impression of speech quality” (3.52, SD 1.75), compared with the non-IO group (2.18, SD 0.62).

### Effect Size

The aforementioned results showed that the IO group obtained statistically significant higher ratings for their speech quality. A statistically significant difference, however, does not imply that the improvement is clinically relevant as well. To evaluate the clinical importance, the effect size was calculated. The effect size, expressed as $ES = (m_{IO} - m_{non-IO})/overall SD$, yielded 0.92, which was large.

### Cost-Effectiveness Analysis

The costs for IO and non-IO treatment groups are reported in Table 2. More details about the number of visits, duration of visits, and the materials used that are the basis for these cost figures can be found in Severens et al. (1998). Although the non-IO group did not receive IO treatment, these patients visited the orthodontist for extra check-ups. For both groups, the mean cost was related to the mean rating for total impression of speech quality. The resulting incremental cost-effectiveness for IO, compared with non-IO, was €1041 for 1.34 point speech quality improvement, or €777 per point speech quality improvement.

The results of the bootstrap simulation of the cost-effectiveness are presented in Figure 2. Every bootstrap simulation indicated a positive cost difference, thus showing IO to be more expensive than non-IO. Only 3 of the 1000 simulations indicated IO to be inferior (both more costly and less effective) than non-IO. The plot shows 997 bootstrap ratios lying in the first quadrant, indicating IO to be more costly and more effective than non-IO. These results indicate that it is 99.7% sure that IO is not inferior to non-IO.

The cost-effectiveness acceptability curve (Fig. 3) shows the uncertainty surrounding the incremental cost-effectiveness as

![Image](https://via.placeholder.com/150)

**FIGURE 2** Plot of 1000 bootstrap incremental cost-effectiveness ratios as a result of random sampling of the size of the study population with replacement from the original patient data.
the financial investment (difference in mean costs €1041) that is necessary to obtain this improvement seems limited. Furthermore, the additional cost of IO treatment may at least partly be outweighed by the cost prevented for speech therapy in later years. In addition to the assessment of the patients' speech, the panel of speech therapists indicated blindly for each patient the necessity of speech therapy in the year following the assessment (Konst et al., 2002). The mean number of speech therapy sessions deemed necessary in the IO group was 34.6; the non-IO group was judged to need 45.8 sessions of speech therapy in the year following the assessment ($t_{10} = -2.55; p < .05$). The mean cost prevented for speech therapy related to this prognosis is €270. Obviously, because the cost for the actual speech therapy that the children obtained after the age of 2.5 years was not examined yet, this statement remains speculative, and additional follow-up of the participants in this trial is warranted.

It should be mentioned that the importance of IO cannot be judged on this cost-effectiveness analysis alone. Other outcome variables (such as surgical and orthodontic aspects), possible adverse effects of IO, and the effort and dedication that are asked of the parents should be taken into account when considering the value of this comprehensive treatment. However, from the perspective of speech development, so far, the cost-effectiveness of IO over non-IO seems acceptable.

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APPENDIX A  Rating Scales That Were Scored in the Perceptual Evaluation Experiment

| Not intelligible | 0 | 1 | 2 | 3 | 4 | 5 | 6 | intelligible |
| No correct articulation | 0 | 1 | 2 | 3 | 4 | 5 | 6 | correct articulation |
| Normal nasal resonance | 0 | 1 | 2 | 3 | 4 | 5 | 6 | severe hypernasal resonance |
| No nasal emission | 0 | 1 | 2 | 3 | 4 | 5 | 6 | severe nasal emission |
| No nasal fricatives | 0 | 1 | 2 | 3 | 4 | 5 | 6 | many nasal fricatives |
| No nasal snorts | 0 | 1 | 2 | 3 | 4 | 5 | 6 | many nasal snorts |
| No nasal realization | 0 | 1 | 2 | 3 | 4 | 5 | 6 | severe nasal realization |
| No backing | 0 | 1 | 2 | 3 | 4 | 5 | 6 | severe backing |
| No fronging | 0 | 1 | 2 | 3 | 4 | 5 | 6 | severe fronging |
| No palatalization | 0 | 1 | 2 | 3 | 4 | 5 | 6 | severe palatalization |
| No lateralization | 0 | 1 | 2 | 3 | 4 | 5 | 6 | severe lateralization |
| No glottal articulation | 0 | 1 | 2 | 3 | 4 | 5 | 6 | severe glottal articulation |
| No hyperkinetic voice | 0 | 1 | 2 | 3 | 4 | 5 | 6 | very hyperkinetic voice |

Total Impression of Speech Quality

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<th>Least</th>
<th>Acceptable</th>
<th>1</th>
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Konst et al., COST-EFFECTIVENESS OF INFANT ORTHOPEDICS REGARDING SPEECH IN UCLP 77