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Parent Observations of the Health Status of Infants With Clefts of the Lip: Results From Qualitative Interviews

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Abstract

Objective: To explore, using semistructured qualitative interviews, parent observations of their infant's health as they relate to having a cleft lip or cleft lip and cleft palate (CL±P) and/or associated treatments.

Design: Cross-sectional, qualitative study across 3 sites.

Setting: Parents were recruited from 3 academic craniofacial centers. Most interviews were conducted over the telephone, audio-recorded, and transcribed.

Participants: Forty-one parents (31 English-, 10 Spanish-speaking) were interviewed. Parents had a child ages 1 to 35 months diagnosed with CL±P.

Main Outcome Measure(s): Twelve domains reflecting infant health and well-being, likely affected by a CL±P and/or associated treatments, were identified from clinical experience and literature review. Study investigators conducted semistructured interviews based on 12 identified domains. After transcripts of the interviews were reviewed, our multidisciplinary team selected illustrative quotes from each domain that reflected consistent observations made by parents.

Results: Parents' responses covered all 12 domains. Specifically, parents discussed the domain of feeding most frequently, followed by observations about sleep, development, comfort, breathing, and vocalization.

Conclusions: We found that parents of infants with clefts provided caregiver-centered language useful in describing their daily observations. No additional domains of infant health were noted by

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parents. We will use these observations and language to develop and validate a parent-reported observation diary that can augment assessments of the impacts of interventions on infants who are receiving care for CL±P.

Keywords

cleft; infant; parent observations; qualitative research

Introduction

Cleft lip with or without cleft palate (CL±P) is estimated to occur in 1 per 940 live births (Parker et al., 2010). Having a newborn can be a stressful time regardless of a CL±P being present. However, infants with CL±P may experience additional disruption to functions such as feeding, sleeping, breathing, and communication. Timing of treatments is related to craniofacial growth and children typically require multiple interventions during their first years of life. Surgical interventions vary but generally include CL±P repair, tympanostomy tubes, alveolar bone graft, and secondary revisions of the lip, nose, and palate (Figure 1; American Cleft Palate-Craniofacial Association, 2018). The goal of treatment is to optimize form and function. However, the cumulative effect of multiple interventions for CL±P on psychological, behavioral, and physical well-being during infancy and early childhood has not been widely studied.

Although there is consensus among health-care professionals regarding the benefit of interdisciplinary team cleft care, treatment strategies vary greatly across clinics both nationally and worldwide (Figure 1). Despite the diversity of practices, very few outcome studies have been conducted for specific cleft care protocols (Shaw et al., 2005; de Ladeira and Alonso, 2012). This is due in part to a shortage of validated outcome measures for assessing interventions (Strauss, 1998; Semb et al., 2005; Trotman et al., 2007; Sitzman et al., 2008; Long et al., 2011; Kummer et al., 2012), which may partially contribute to a lack of an agreed-upon standardized treatment model. In addition, few studies simultaneously investigate the impact of cleft-related treatments on the multiple areas that could be affected by cleft care. Treatments (eg, nasal stents) designed to improve one area (eg, shape of nose) could be associated with adverse impacts on other aspects of health (eg, breathing).

Outcome studies in cleft-related care should ideally include measures that are specific to infants with CL±P and sensitive to variation in cleft treatments (Patrick, 1997; Matza et al., 2013). Development of measures pertaining to infants with a specific condition relies on systematic observations by care-givers, since infants cannot speak for themselves. Systematic parent observation measures are currently a standard approach in outcome assessment (Matza et al., 2013). Furthermore, researchers utilize qualitative semistructured interviews to explore such observations shared by caregivers or others (eg, Nelson and Hons, 2008; Matza et al., 2013; Alan-sari et al., 2014).

There have been many excellent qualitative studies in individuals with clefting and with parents of children having CL±P (eg, Hall et al., 2013; Hamlet and Harcourt, 2015). For example, a mixed-methods study by Awoyale et al. (2016) shared parents' perspectives, such as reactions to diagnosis and the associated challenges of caring for their child with a cleft.

However, our literature review did not identify a comprehensive approach (ie, instrument) to capture parents' objective observations of an infant's daily routine, treatment for CL±P, and related health. Parents are in the best position to report what they can observe about their infant with a cleft on a daily basis.

As part of a larger study, we conducted an in-depth exploration of parent observations across different areas regarding their child's health. We formulated our interview prompts in 12 well-known areas of health most likely to be impacted by the presence of a CL±P and/or cleft treatments based on literature review and clinical experience (American Cleft Palate-Craniofacial Association, 2009; Chimruang et al., 2011; Losee and Kirschner, 2009). Our ultimate goal is to use these data to aid in the development and validation of a caregiver-reported observational diary measure that will help assess the impact of diverse interventions on young children with CL±P. In this article, we present examples of the responses from parents of infants with CL±P about their observations in each health domain.

Methods

Participants

Using purposive sampling with quotas for the enrollment of English- and Spanish-speaking participants, parents included were at least 18 years of age and had a child less than 3 years of age with CL±P and no additional medical conditions. Parents were recruited from 3 large multidisciplinary craniofacial centers located in urban areas of the United States and that served families from both rural and urban areas. Study procedures were approved by the appropriate institutional review board and conducted in conformity with accepted ethical principles.

Parent characteristics.—Of the 41 participants, most parents were mothers (90.2%). Twenty (48.8%) parents identified as white, 10 (24.4%) multiracial, 7 (17.1%) Hispanic, and 4 (9.8%) as other. Thirty-one interviews were conducted in English (75.6%) and 10 in Spanish (24.4%). The majority of English-speaking participants had completed at least some college education (76.6%) and held private insurance (58.1%). Significantly less Spanish-speaking participants reported the same education (20%) or private insurance (10%). Employment history was similar between groups (56.1%; Table 1).

Child characteristics and interventions.—Mean child age was 13.4 months (range: 1–35 months) and 65.9% were male. Most children were born at term (95%) and had cleft lip and palate (CLP; 76%). Presurgical molding of the lip was common (68%) and included taping (49%) and/or orthodontic device (39%). Post-surgical interventions included nasal stents (22%), hand mitts (20%), and arm or elbow immobilizers (34%; Table 2).

Design and Methodology

Our 11-member research team had experience in cleft care and/or qualitative research in the disciplines of pediatrics, psychology, social work, and sociology. Seven research team members were trained and conducted interviews using our interview protocol according to a standardized interview methodology. Consistency across interview procedures was checked

during weekly research meetings. Spanish interviews were completed by native Spanish-speaking team members, who then translated excerpts into English. We recruited parents for interviews until no new information was obtained over 3 consecutive interviews (Guest et al., 2006).

After initial preinterview eligibility screening, infant and parent characteristics, diagnosis and treatment history were obtained from parents. Parents participated in semistructured interviews in which they described their observations of their child's health and functioning in 12 preselected domains. Interviewers followed the study interview guide and started with general questions to elicit parent observations in each domain and used prompts when needed to elicit more specific observations (Table 3). We also collected specific information about the child's cleft treatments and observed changes associated with these treatments. All but one audio-recorded interview was conducted by telephone, which has been reported to be as reliable as in-person interviews (Rahman, 2015). The study team selected quotes that illustrate parent experiences with their infants for each domain described subsequently.

Data Analysis

Our preselected 12 domains that were believed to be affected by cleft and related treatment included activity, breathing, comfort, communication, development, disposition, feeding, hearing, reflux, skin, sleep, and vocalization. Table 4 lists the rationale for each domain. Thematic analyses within the domains were conducted to identify relevant content. This was performed in 6 phases: (1) familiarization through reading the data, (2) generating and applying categories, (3) searching for themes among categories, (4) reviewing themes, (5) defining and naming themes, and (6) producing the final report (Braun and Clarke, 2006). Blinded audio recordings of interviews were transcribed (VerbalInk.com) and uploaded to a web-based mixed-methods analysis program (Dedoose.com) for content excerption and categorization into each domain. Excerpts were sorted by domain and observations relevant to infant health and well-being were identified. The study team reviewed all excerpts and confirmed domain assignment through consensus.

Results

The 12 domains are listed from highest to lowest number of excerpts by parents (Table 4) and each quote below includes the age, sex, and diagnosis of the child along with parent language.

Feeding

Feeding and weight gain are areas frequently impacted by a CL±P.

During the first 3 weeks, she lost 1 or 2 pounds ... the doctors could not discharge her until she weighed as much as she was born if not a little more. (27 months, female, CLP, Spanish)

It was a slow gain, and she had to be 10 pounds for that first surgery ... we ended up waiting an extra month before we did the first surgery. (20 months, female, CLP, English)

Some participants found that changes in bottle type or formula helped:

They changed my bottle ... since then, he's been gaining weight. They had to change his formula, calorie intake. Ever since then he's starting to gain weight. At first it was difficult. He was losing all the weight instead of gaining. (4 months, male, CLP, English)

I wasn't aware that they were supposed to change my bottles over time. So as he was eating with those bottles, he was burning calories, he wasn't gaining weight. Whatever he was eating, he was burning. (5 months, male, CLP, English)

Many parents talked about the length of time it took for their child to complete a feeding, duration of time between feeds, and observations associated with feeding.

He would last about an hour to finish a bottle, if he could finish it, and it was stressful. (3 months, male, CLP, English)

She was falling asleep before she was done. We kind of knew that was an indication that obviously she must not be getting enough energy because she doesn't even have enough energy to eat. (4 months, female, CLP, English)

Once we switched to the pigeon bottle it got better ... it wasn't taking him 30 minutes to eat 2 ounces. It was about 15-minute feedings every 2 hours, and they were more normal, and he was getting less air, and he seemed more comfortable with it. (4 months, male, CLP, English)

... I know that he's not eating what he's supposed to be eating ... he started to be hungry much shorter than 3 hours in between. It was like every hour we were feeding him. So that's when I said, "Okay, he's not full when he's eating. He's not eating until he's full. He's just eating until he's so tired he can't eat anymore." (5 months, male, CLP, English)

He would sputter and be overwhelmed and kind of gag a bit, because he had too much in his mouth. He got really mad at first. So he'd cry and get beet red ... then he'd act like he didn't want it, or he'd turn his head like he wouldn't want it, but he was just frustrated with the amount of flow he was getting. (12 months, male, CLP, English)

Some parents observed that the use of presurgical devices aided in the pace and ease of feeding, while others felt that such devices adversely affected feeding:

The NAM fit right up in his palate. So he went from taking forever to feed even two or four ounces to once he had the NAM, the bottle was gone in 10 minutes. So the compression really made him be able to squeeze it more and he could drink it as fast as he wanted to. (13 months, male, CLP, English)

Without the NAM, it takes her about an hour to drink it because she only has that little flap of skin. But with the NAM in ... it's like a 15-minute feeding. (2 months, female, CLP, English)

They were taking 20 minutes to feed. I think the first time he fed, after he had his NAM removed, like 5 minutes. (13 months, male, CLP, English)

... she would do the whole choking, gagging on the milk thing, and we would take [the NAM] out, which would upset her [for] another 10 or 15 minutes, and then she would try to eat again, and it was kind of a vicious cycle ... but she wouldn't eat with it in. (6 months, female, CLP, English)

In addition to presurgical devices, many parents noted positioning affected feeding:

He always had a harder time eating when you weren't holding him at a certain angle. If you were a little bit too far back, he would seem like he was choking on his milk and had little coughing spells ... if he was too far up, the milk would go out the side of his mouth. (14 months, male, CLP, English)

Parents also noted the ease or difficulty that their child experienced when feeding post cleft surgery:

As soon he was done with (lip) surgery ... it was like he took the bottle normally like he would, and I never had a problem. (13 months, male, CL, English)

After the first surgery, it was quicker for him to finish bottles ... But he couldn't eat at first, it was hard for him. Then when the stitches were dissolving, he started to eat better ... About a month ago, he started to actually try to suck. So I feel like that's helping him a lot, he's eating a ton of new stuff. (13 months, male, CLP, English)

Yes, before surgery she would choke on her own milk. She was uncomfortable, and she would cough. When she felt like she was choking, she would move her body, like she would twist. (27 months, female, CLP, Spanish)

We had just started to get to where he was eating a good amount of ... purees. Then we had the lip repair and he almost entirely reverted back. It was 2 weeks before he wanted to eat purees or anything other than breast milk. (15 months, male, CLP, English)

Sleep

Overall, parents described their child's sleep schedule as typical. However, negative effects on their child's duration and quality of sleep were typically attributed to issues with breathing, reflux, surgery, and related treatments. Parents described various approaches, including positioning and self-soothing strategies, used to help support their child's sleep:

When he's propped up on pillows he does better than lying flat in a crib. I used to be really paranoid about that when he was really little. (15 months, male, CLP, English)

He wouldn't sleep in his bed at all. My husband and I had to take turns staying up holding him while he slept, because he would not be put down for any period of time while we were in the hospital. Like you had to hold him, or he was awake and angry and pulling at stuff. (16 months, male, CLP, English)

Since her lip repair we've been able to give her a pacifier and ... she'll go to sleep probably within 10 minutes. (6 months, female, CLP, English)

Some parents worried about their child being unable to breathe while sleeping.

When he was a baby I had to be alert, so he wouldn't choke. Now he sleeps calmly, more comfortably, on whatever side he prefers and how he wants to. (9 months, male, CL, Spanish)

... because when he would snore, ... it just seemed really odd and I was already on alert watching him, like what if he choked. He changed a lot because after surgery, everything was fine, he wasn't snoring, I wasn't as worried that he might choke or that food wouldn't come up his nose. (32 months, male, CLP, Spanish)

Development

Overall, most parents were able to provide specific observations regarding developmental milestones. In addition, most parents felt that their child's development was "normal":

Yeah, she seems to be pretty on track as far as I can tell. We were comparing the progress that she's made to that of her big sister, and they're pretty much both the same. (6 months, female, CLP, English)

Over half of the parents noted how treatment impacted daily routines associated with development, particularly tummy time:

Yeah, I tried to do tummy time quite a bit ... But that was the other thing that was hard with the NAM, he couldn't do tummy time with it in. (12 months, male, CLP, English)

Just preventative stuff. Like, after surgery, we did not let her crawl around too much ... Because she was newly crawling, so she would fall and miss an arm and land on her face, so we kept her up more, held a lot. (21 months, female, CL, English)

Comfort

Parents observed behaviors that indicated their child was experiencing discomfort. Discomfort reportedly resulted from a variety of factors, including internal (eg, gastrointestinal distress) and external (eg, treatment):

He would spit up a couple of times in a 5- to 10-minute period, and you could tell it was uncomfortable because he would cry and cry ... and that was what he did when he was uncomfortable—arch his back. He would pump his legs a lot, and not like that fun, cute, 'I'm going to kick my legs,' loose legs thing.' It was very stiff. (4 months, male, CLP, English)

I think she was more tense. She wasn't able to relax fully. There was some stuff foreign in her mouth still and in her nose. (21 months, female, CL, English)

Some parents noted their child's level of comfort was impacted by an adjustment to new treatment, and several parents described their child as more dependent after surgery, using statements such as, "very needy" and "needed lots of holding and lots of active distractions":

Before the lip repair, anybody could soothe him, anybody could pick him up. Right after lip repair, he didn't want to see anybody, and it took him 2 weeks to be able to

be carried by anybody and not get fussy right away and start crying. The same thing happened after his palate repair. (13 months, male, CLP, English)

A lot of being held. A lot of sleeping up–sitting up, sleeping with her. Or a lot of letting her know she was safe. Earning her trust back that she was in a safe spot, that she wasn't going to be taken away from us and wasn't going to be messed with by people she didn't know. (22 months, female, CL, English)

After surgery, he was scared of being alone ... I would leave him in the room or kitchen and I would move to the side and he cries if he sees that I see him—he just wants to be there attached to me ... He is only where I am and goes wherever I am. (24 months, male, CLP, Spanish)

Several parents observed that increased physical contact and other soothing methods were important for the child's comfort:

Oh, yes, I would give him massages (when he was crying), I would carry him and walk around with him, and he would calm down. It was easy. (32 months, male, CLP, Spanish)

So every time she would hit her[self]—make contact with her face (after lip surgery), she would start crying. We could usually soothe her pretty quick. She really loved her pacifier, so we could soothe her with the pacifier for maybe 5 minutes. So, it wasn't that big of a deal. But it was clearly uncomfortable. (5 months, female, CLP, English)

He loved his NAM device. It was like a pacifier, so when he took it out he'd want it back—when you put it back in he would suck on it like a pacifier. I think a lot of his difficulty after the lip repair was he couldn't have that soothing mechanism anymore. (13 months, male, CLP, English)

Breathing

Most parents reported that their child's CL and the associated change in nostril shape impacted their child's breathing:

He was gasping for air at night as a newborn. I think one nostril is regular, but his other nostril was basically shutting down. (9 months, male, CL, English)

She always has been a very noisy mouth breather ... I think since she only has one nostril, it's just easier for her to breathe in and out of her mouth ... (10 months, female, CLP, English)

It was really scary at first because you don't really know how to help them—it just feels like their nose, their normal mechanism for breathing, is closed off. (12 months, male, CLP, English)

Yeah, his breathing seems completely normal ... His left side of his nostril is pretty flat, so I would think he would have problems with it, but I don't see it holding him back. (14 months, male, CLP, English)

Several parents ascribed negative effects on other areas of functioning, such as feeding and sleeping, to breathing difficulties.

She would turn bright red (while feeding), like she wanted to scream but couldn't. She would kind of try to suck in. And then once she figured out that, she would let out a big scream. Then that would kind of trigger her to know that, "Oh, I can breathe." (12 months, female, CLP, English)

He just can't get comfortable enough to get into a deep sleep because at a certain point he's not breathing well enough and so he wakes himself up. (7 months, male, CLP, English)

Some parents specifically described choking during discussion about breathing:

Yes, as we would feed him, he would turn purple, it would go to his nose I think and so he couldn't breathe unless it was out of his mouth ... and that's what scared us, we have never seen a baby that would arch it's back all the way, like it was the exorcist ... and we had to put him on his stomach so that it would come out of his mouth. (7 months, male, CLP, Spanish)

Some parents observed an impact of treatments such as presurgical molding and postoperative nasal stents on the child's breathing.

With the NAM, we had the real issue. She was wheezing, is the best way to describe it. But it wasn't like a chest wheeze; it was she was trying to breathe, and the NAM was basically getting in her way. (6 months, female, CLP, English)

I think the stents after surgery were the hardest in regards to her nose. But it wasn't long-lasting. It was a small discomfort. Once the [stents] were taken out you could definitely see relief because it was one less thing to mess with on her face. It affected breathing after surgery because you have tubes up your nose that are halting or making that narrow passage even narrower. (21 months, female, CL, English)

I felt he was short of breath (with the nasal stents in) because when I see that he likes to play peekaboo a lot and you can see that he seems short of breath and starts kicking, stretching his hand, getting desperate. (12 months, male, CLP, Spanish)

Parents observed positive and negative changes in breathing after lip and/or palate surgery.

It was like she was breathing through her nose, almost like, "Oh, this is kind of cool, I have two places to breathe through." (6 months, female, CLP, English)

When she was born, it was majority through her mouth, and that was all kind of one cavity for her. After her lip repair, she was still mostly breathing through her mouth. She figured out she could wrinkle her nose up and stuff like that, but she didn't use it for forcing air in and out at all until after palate surgery. (20 months, female, CLP, English)

While improvements in breathing were noted by some parents after lip repair, "*Every once in a while he'll snore, but it used to be all the time,*" worsening of breathing was more common after palate repair, where one parent noted her infant, "*snored like a freight train.*"

Vocalization

Parents frequently observed that their infants could not make pressure consonants (eg, ba, da, pa), and attempts sounded “*more like a ‘Mamama’*” After cleft palate surgery, there was parent agreement that their child produced a variety of new sounds, such as “d” and “b.”

He can (now) say ‘mama’ and ‘dada’, and we’re working on the B sound with ‘ball’ ... So he’s getting different sounds out that he didn’t have before the palate repair ... (14 months, male, CLP, English)

Before the surgery, she sounds like she had air, like her breathing was faltering and now that she had the operation, the sound sounds complete. (13 months, female, CLP, English)

Disposition

Several participants observed changes in their child’s disposition after surgery.

I don’t think she has had many issues because of the cleft. She’s been an easy baby. Although, the surgery caused the biggest shift in her personality, (just with the clinginess) and relearning to eat. (6 months, female, CLP, English)

His irritability went up from the first surgery and he never really quite recovered from that. He’s always been way moodier, and it gets really bad right after surgery. (14 months, male, CLP, English)

I told my mom at one point it was like they took part of his soul when they did his lip repair. It’s like his whole demeanor changed. He couldn’t get comfortable. It was very strange. I mean he had it and now he’s back to normal. I think being a young kid the pain, affected him (15 months, male, CLP, English)

I believe that since surgery he remained scared, because after surgery, he would look at the doctors and cry and cry, as if he was very frightened of the doctors. After surgery, he would wake up sometimes at night crying, as if he remembered his surgery. I believe that it was a little traumatic, his surgery, being so little. (31 months, male, CL, Spanish)

Some parents indicated no changes in their child’s disposition with treatments. For example, one parent remarked that the infant was “*really just very tolerant*” and “*just kind of lets us do whatever it is the doctors say we need to do.*”

Hearing and Eustachian Tube Function

Parents identified the following observations associated with ear infections:

I believe we’ve had 6 ear infections since birth. It was after his first set of tubes at 3 months old and then it feels constant. (8 months, male, CLP, English)

It started, with fever [and] with crying a lot without stopping, he would start to pull his ears. (8 months, male, CLP, Spanish)

It was a time where she had become very fussy and kept crying ... and something just told me to look in her ear, and I saw some discharge. (11 months, female, CLP, English)

In addition, some parents noted their child was not responding to sounds as expected, along with changes that they observed after treatment with tympanostomy tubes.

He didn't really respond to sounds. If my husband was across the room and saying something, he didn't suddenly turn and look at my husband. He didn't really care or notice that he came in the room, and we didn't necessarily pick up on that. (12 months, male, CLP, English)

It [ear tubes] seemed to unlock a whole different part of his world, and he'd get bright eyed at all kinds of thing and like, "Wow!" Just the amazement that he would express when he would hear different tones ... like knowing what his dad's voice was and get excited when he heard it. (11 months, male, CLP, English)

We could tell his hearing was a lot better, because he would turn more to noises, would react, and it seemed to be normal up until he was 10 months old when we noticed he wasn't turning as much to noises; he got his next hearing test right around that time too ... he needed new tube ... right after his surgery, we noticed he's turning more to noises again. (13 months, male, CLP, English)

Activity

Some parents noted a change in their child's activity level immediately following surgery. A few parents raised concerns about the potential for infant self-harm after surgery and used methods to prevent injury.

We put her in the walker quite a bit after surgery because it was ... a way for her to be mobile without possibly falling on her face. (21 months, female, CL, English)

Yes, in the first 3, 4 weeks that he had the lip [surgery] he didn't move much because he was on medication and all. But after that he was the same. (7 months, male, CLP, Spanish)

Gastroesophageal Reflux

For the few parents who made observations suggestive of gastroesophageal reflux, the volume and frequency of spit up appeared to be most concerning.

It would start probably 15 minutes to anywhere up to an hour after a bottle, ... It was almost a measurable amount. I could have scooped it up and it would have been half an ounce. He was throwing up, up to half of what he was eating. (4 months, male, CLP, English)

Anytime I noticed him having trouble with gagging and choking, it was because he had formula coming up in his throat. Or, he was spitting up and it was coming out of his nose. I think it was all related to the reflux because now that we have that under control we don't have any problems. (5 months, male, CLP, English)

It was daily ... it lasted about 8 weeks. It's when I changed the formula ... but the powder one didn't sit well. We started to give her the one that was already prepared, and ... it was then that the reflux completely stopped. (12 months, female, CLP, Spanish)

Additionally, some parents explained that the presence of gastroesophageal reflux greatly affected sleep. Parents reported that optimally positioning their child reduced the frequency of these episodes:

It would wake him up at night sometimes if I laid him down too soon. If I waited 30 minutes or whatever, it was less likely to disrupt his sleep. (7 months, male, CLP, English)

We kept him upright, or at least at a pretty good angle, for up to 30 minutes after his bottle. Because if we laid him down or even put him in this baby lounger, which is at a lower angle, it would all just come up the minute you laid him down ... (4 months, male, CLP, English)

He couldn't sleep ... because he would get reflux ... We tried to put him to sleep a little more upright (sitting) ... (21 months, male, CL, Spanish)

Skin

Among the parents whose infants used presurgical molding, some parents did not notice changes while others observed "raw" and "red" skin.

We tried to do (taping) as much as possible when we got home and did it as much as we could in the first 2 months. But the tape on her cheeks just made her red, raw, and dry. (5 months, female, CLP, English)

We did it for a few weeks and it was awful, 'cause he hated it, you could tell ... we would take it off and it would be so raw under the tape that we were told that we could let it breathe for a couple of days. So he would be used to not having this giant rubber band constricting thing on his face, and then he would breathe and drink better, all of that. Then as soon as he started to heal we would slap it back on. (21 months, male, CLP, English)

Communication

Most parents observed their child vocalizing to get attention from adults or to express wants and needs:

He just says "uh" a lot and he does a lot of throat noises when he's mad and throws fits. He throws himself back. (13 months, male, CLP, English)

It's not just babbling for the fun of it. It's, "I'm trying to tell you something," whether it's a story, or, "I want something." (20 months, female, CLP, English)

Similarly, parents observed nonverbal communication through actions or gestures such as, *"shaking her head," "pushing her hand," or "licking his lips."* One parent described a particular gesture that, *"... If he sees something he wants, he'll just like point to it and then move his tongue all over his lips."*

Other

We asked parents to identify observations or areas of health that they felt were impacted by the presence of a CL±P or treatments. No additional domains were suggested by parents, such that no new topics were mentioned during interviews with enough frequency to warrant the creation of any new domains.

Discussion

We explored parent's observations of the impact of CL±P and cleft-related treatments on the health of infants. Parents reported detailed and consistent observations of their infants specifically related to cleft, treatment, and related functioning under each health domain. Some observations also apply to children without cleft, but this is true of most condition-specific measures.

Parents provided precise content in their own language for each of the domains. They did not identify additional domains. Parents talked most frequently about challenges in the feeding domain. They noted that structural differences in an infant's nose and mouth impacted breathing while feeding; they also noted challenges with frequent spitting up and/or regurgitation of milk through the nose. Long and challenging feedings were distressing to parents. Parents who sought feeding help from their cleft team frequently expressed appreciation for the recommended adjustments, which often resulted in shorter, more efficient feeding and better weight gain.

Parents also reported many positive and negative observations across domains. For example, breathing difficulties often adversely affected the child's ability to sleep and feed. Conversely, parents noted that interventions designed to improve one area of functioning often positively affected other areas. For example, keeping an infant in an elevated position in order to alleviate gastroesophageal reflux was also associated with improvements in the child's breathing and sleeping.

Parents observed mixed effects from cleft-related treatment across multiple domains. Many parents attributed their child's irritated facial skin to the use of tape in presurgical molding. While some parents noted that the use of presurgical molding led to respiratory and feeding difficulties, others associated the treatment with improved breathing and feeding. These results reinforce the need for providers to be mindful of the variable effects that treatments can have on infants and that treatments designed to address one aspect of cleft-related care may have collateral effects on other aspects of health.

As anticipated, CL±P surgeries were associated with postoperative behaviors that suggest infants experienced irritability, pain, and need for increased comforting. Many parents observed initial difficulty with feeding postoperatively, which resolved over time. The majority of respondents noted changes in the types and frequency of vocalizations from pre- (eg, mmmm) to post- (eg, da) palate surgery, as well as an increase in responsiveness to sounds after placement of tympanostomy tubes.

Limitations

While participants from diverse backgrounds shared a great deal of information regarding their children's health and experiences related to cleft treatment, limitations were also identified. Infants and young children cannot report on their own experiences; therefore, the findings for this study were based on parent observations. Observer-reported outcome is an accepted way to obtain information on how a medical condition and related treatment affect daily functioning for young children (Edwards et al., 2017; United States Food and Drug Administration, 2012), but may still be limiting because we are not receiving the child's own feedback.

Furthermore, it is likely that parents' characteristics (eg, parental belief systems, educational/socioeconomic levels, experiences with medical care, and personal stress) may have affected interpretations of their child's behaviors. It would have been interesting to gather more data about the parents' feelings and experiences related to caring for a child with cleft; however, this was beyond the scope of this research. Additionally, parents were often asked to describe retrospective observations, and while their children were still young, recall of information may have been affected by passage of time. Finally, observations were typically collected from one parent. It would have been helpful to gather information from a second parent to better understand the child's experience from another adult's perspective.

Due to the nature of telephone interviews, participants' non-verbal communication as well as opportunities for follow-up inquiries may have been missed (Rahman, 2015). Although we recruited the proposed number of Spanish-speaking families, there was a lower participation rate within this group than the English-speaking group. This may reflect a lack of trust in the medical and/or research community or possibly discomfort sharing personal experiences over the phone with someone unfamiliar (Maldonado-Duran et al., 2002). Furthermore, while we attempted to accurately translate interview questions with cultural sensitivity through qualified bilingual researchers, some language or intent of questions may not have been translated accurately.

Future Directions

Parents provided many observations within each domain of infant health that we will use in the next phases of the instrument development process. Ultimately, these data will be used to develop a clinical measure to guide clinical cleft-related care for patients, parents, and providers that will be piloted with a greater number of parents.

We will also continue to incorporate culturally appropriate language into this research and determine how these differences might impact the care. Ideally, the future parent-reported outcome measure will be useful for parents who speak a variety of languages.

Cleft teams have the capacity to honor the concept that all providers, alongside with patients and families, can make meaningful contributions to the treatment and management of cleft care (Strauss, 2002). Furthermore, appropriate family involvement can increase the effectiveness of treatment and enhance adherence to provider recommendations (Pannbacker and Scheuerle, 1993). Data from this study support the use of parent observations to assess infant health in response to treatment and to help inform treatment options.

Conclusion

Semistructured interviews provided rich qualitative data based on parents' observations of their infants in a variety of areas during an active period of cleft-related interventions. Proxy observations are critical for developing an assessment tool examining the effects of CL±P and related interventions on young children. We highlight the necessity for clinical practice to take into account not only the child's medical needs but also their overall health. In future studies, we will use this information, in combination with expertise of health-care providers, to develop a valid, reliable, and sensitive quantitative assessment tool to assess overall health in infants with CL±P.

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Figure 1.
Examples of possible treatments in the period before and after cleft lip repair.

Table 1.

Parent Characteristics.

Characteristics of the Parents	n (%)	English Interview	Spanish Interview
Total, N	41 (100)	31 (75.6)	10 (24.4)
Type of caregiver interviewed			
Mother	37 (90.2)	29 (93.5)	8 (80.0)
Father	3 (7.3)	1 (3.2)	2 (20.0)
Both parents	1 (2.4)	1 (3.2)	0 (0.0)
Race/ethnicity			
Single designation of race or ethnicity			
White	20 (48.8)	20 (64.5)	0 (0.0)
Hispanic	7 (17.1)	2 (6.5)	5 (50.0)
Other	4 (9.8)	4 (12.9)	0 (0.0)
Multidesignation of race or ethnicity			
Hispanic + white	8 (19.5)	5 (16.1)	3 (30.0)
Hispanic + other	2 (4.9)	0 (0.0)	2 (20.0)
Education			
12th grade	3 (7.3)	1 (3.3)	2 (20.0)
High school grad/GED	12 (29.3)	6 (20.0)	6 (60.0)
Some college (no degree)	5 (12.2)	4 (13.3)	1 (10.0)
Associate degree	7 (17.1)	6 (20.0)	1 (10.0)
Bachelor's degree	6 (14.6)	6 (20.0)	0 (0.0)
Master's/professional/doctoral degree	7 (17.1)	7 (23.3)	0 (0.0)
Missing/unknown	1 (2.4)	1 (2.4)	0 (0.0)
Employment status			
Employed	23 (56.1)	17 (54.8)	6 (60.0)
Not employed	18 (43.9)	14 (45.2)	4 (40.0)
Primary language			
English	27 (65.9)		
Spanish	10 (24.4)		
Other language	1 (2.4)		
Missing/unknown	3 (7.3)		
Insurance status			
Private	19 (46.4)	18 (58.1)	1 (10.0)
Public (eg, Medicaid)	20 (48.8)	12 (38.7)	8 (80.0)
Military health care	2 (4.9)	2 (6.5)	0 (0.0)
Uncompensated care	3 (7.3)	3 (9.7)	0 (0.0)
Other insurance/coverage	1 (2.4)	1 (3.2)	0 (0.0)
Missing/unknown	1 (2.4)	0 (0.0)	1 (10.0)
Marital status			
Single	5 (12.2)	3 (9.7)	2 (22.2)
Married or with long-term live-in partner	30 (73.1)	26 (83.9)	4 (44.4)

Abbreviation: GED, general education diploma.

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Table 2.

Characteristics of the Infants/Children.

Characteristics of the Infants/Children	n	%
Total, N	41	100.0%
Sex		
Male	27	65.9%
Age at interview		
Age in months (mean, SD)	13.4	8.8
0–6 months	13	31.7%
7–12 months	12	29.3%
13–18 months	5	12.2%
19–24 months	6	14.6%
25–35 months	5	12.2%
Cleft type		
Cleft lip/alveolus only	10	24.4%
Unilateral	8	80.0%
Bilateral	2	20.0%
Cleft lip and palate	31	75.6%
Unilateral	24	77.4%
Bilateral	6	19.4%
Race/ethnicity		
Single designation of race or ethnicity		
White	10	24.4%
Hispanic	8	19.5%
Other	3	7.3%
Multidesignation of race or ethnicity		
Hispanic + white	9	22.0%
Hispanic + other	0	0.0%
Multiracial	1	2.4%
Missing/unknown	10	24.4%
Birth weight		
Weight in grams (mean, SD)	3314.8	514.5
<2500 g	3	7.3%
2500 g	33	80.5%
Missing/unknown	5	12.2%
Estimated gestational age at birth		
Gestational age in weeks (mean, SD)	38.8	5.7
<37 weeks	2	4.9%
37 weeks	39	95.1%
Age of infant at time of first visit to a cleft/craniofacial team		
Age in months (mean, SD)	0.7	0.6
At birth	2	4.9%

Characteristics of the Infants/Children	n	%
6 months	31	75.6%
Missing/unknown	8	19.5%
Presurgical intervention(s)		
No	13	32.0%
Yes (see details)	28	68.0%
Presurgical molding		
Nasoalveolar molding (NAM)	12	29.3%
Seattle alveolar molding (SAM)	4	9.8%
Taping	20	48.8%
Surgeries		
Cleft lip repair	33	80.5%
Cleft palate repair	16	39.0%
Ear tubes (tympanostomy tubes)	9	22.0%
Postsurgical		
Nasal stents	9	22.0%
Hand mitts	8	19.5%
Arm or elbow restraints	14	34.1%

Abbreviation: SD, standard deviation.

Table 3.**Interview Prompts for Each Domain Used When Needed to Elicit More Specific Observations.**

General examples of prompting for observations:

- Can you describe what it looked like as he was _____? I'd like to learn more specifically about what you saw or heard.
- What did you see with the new bottle that made you feel like, "This is working well"?
- What were you seeing or hearing that made it seem that he was uncomfortable?

Activity

- ☐ How would you describe your baby's activity/movement?
- ☐ Did your baby move a lot, always kicking/wiggling, or was baby more likely to be still or move more carefully/deliberately?

Breathing

- ☐ Did you see anything that made you worry about his/her breathing? If yes, what types of things did you observe? Noisy breathing? Change in color? Signs of working to breathe?
- ☐ Did your baby ever seem to stop breathing for short periods of time?
- ☐ Did your baby wake up because of choking, gagging, arching, or seem uncomfortable?
- ☐ Was there anything that seemed to prompt the difficulty?
- ☐ Did your baby ever seem to have difficulty breathing when you were feeding her/him (choking, gasping?)
- ☐ How did your baby breathe when he/she had a cold?

Comfort

- ☐ How often did your baby cry?
- ☐ How long did it last when he/she did cry?
- ☐ What kinds of things seemed to prompt fussiness or crying?
- ☐ How easy/hard was your baby to soothe?

Communication

- ☐ Does your baby communicate nonverbally with actions, gestures, games?
 - ☐ Actions—shrugs, smacks lips if something tastes good, points, reaches out to give you something
 - ☐ Games—patty cake, so big, peekaboo
 - ☐ Gestures—"hush" to be quiet
- ☐ Do you know when your child is happy and when they are upset?
- ☐ Does your child smile or laugh when they are looking at you?
- ☐ Do you feel that your baby makes good eye contact?

Development

- ☐ How often did you put your baby on his/her tummy in the first few months?
- ☐ How did your baby respond to tummy time?
- ☐ When did your baby roll over?
- ☐ Sit? Crawl? Pull to stand? Cruise?
- ☐ When did your baby begin to reach for toys?
- ☐ Move toys from hand to hand? Put hands or toys in mouth?
- ☐ Pick up small objects?
- ☐ When did your baby start smiling?
- ☐ Is/was your baby receiving any early intervention services?
- ☐ What kind, how often?
- ☐ Do you have any concerns about your baby's development?

☐ If yes, why do you think your child has had difficulty?

Disposition

☐ Did he/she go easily to people he/she didn't know well in the first few months?

☐ Did she/he smile at people easily or was she/he more cautious?

☐ Have you seen your baby become more hesitant about going to unfamiliar people/more comfortable? If yes, when did that start?

Feeding

☐ How did you feed your child in the first few months of life? a. Bottle(s) _____ type _____ b. Breast c. Other (cup, syringe, NG tube/feed etc)

☐ How long were feedings? How often?

☐ How many ounces were in the bottle each time and how much was taken?

☐ Were feedings challenging? How so?

☐ Did your baby have difficulty gaining weight?

Hearing

☐ Did your baby have ear infections? How many?

☐ Were you ever told your baby had hearing loss?

☐ Did your baby have ear tubes? (How early, how many sets?)

☐ Did you have trouble with your baby's ears draining?

☐ How often did your baby receive antibiotics or ear drops?

☐ How could you tell that your baby's ears were infected or bothering him/her?

Gastroesophageal reflux

☐ If reflux: Ask if can see anything before baby spits up.

Skin

☐ If received taping treatment: What have you noticed about his skin? Any skin issues related to taping?

☐ What happened if you removed the taping?

☐ Did you notice any physical changes (eg, rashes, bleeding, bumps, irritation) on your baby's facial skin at any point?

Sleep

☐ Did your baby take regular naps? How often? Length?

☐ How did your baby sleep at night?

☐ How hard was it to get your baby to sleep?

☐ What routines did you use to get your baby to sleep (eg, rocking/ feeding/letting baby cry it out)?

☐ How often did he/she wake up during the night?

☐ What did you do when baby woke up (eg, feed, diaper change, walk/ rock)?

☐ Where did your baby sleep during the first months of life? (eg, bassinet, crib, parent bed, same room as parents, separate room)?

☐ How often did your baby wake up during the night?

Vocalization

☐ Did your baby coo, make sounds like ooo/ah/eee, squeal, or may sounds like /ma/, /ni/, /ya/, /da/, /ga/

☐ Did he/she watch you when you talked?

☐ Try to imitate your sounds?

☐ When did he/she seem to recognize his/her name?

☐ Recognize names of family members?

☐ How much/how often did/does your baby vocalize? When? when baby is hungry, first wakes up, first sees you, fussy/crying. Vocalize outside of crying?

☐ Canonical (ba ba ba, daba) sounds?

- ☐ Did/does your child sound different than other children?
- ☐ If child is speaking, how old were they when they said their first word?
- ☐ How old were they when they put 2 words together?
- ☐ Who do they vocalize to?

Examples for probing for observations:

- ☐ Can you describe what it looked like as he was _____ ? I'd like to learn more specifically about what you saw or heard.
- ☐ What did you see with the faster flow that made you feel like, "This is working well"?
- ☐ What were you seeing or hearing that you came to the point where you were wearing him most of the time?

Treatment related

- ☐ Ask about each treatment aspect separately regarding:
 - ☐ Ask what the caregiver saw or heard in relation to each domain above
 - ☐ The treatment or use of the device itself
 - ☐ Changes before and after treatment (eg, NAM, lip surgery, palate surgery, taping)
 - ☐ Was there anything about your child's cleft or treatments related to the cleft that you feel impacted your child in this area?

Other

- ☐ Ask if there were any other areas of functioning not discussed that caregiver observed are important for their child's health and well-being.
- ☐ If so: How has this area been impacted by CL±P and related treatment

Abbreviations: CL±P; cleft lip with or without cleft palate; NAM, nasoalveolar molding.

Table 4.

Domains, Rationale, and Number of Excerpts Elicited.

Domain	Rationale	Number of Excerpts
Feeding	Challenges related to latching and creating suction; need for special bottles or feeding techniques	581
Sleep	Increased risk for sleep-disordered breathing or sleep disruption due to treatment (eg, surgery, nasal stents, etc)	233
Development	Treatment and recovery process impact ability to move around and progress in development (eg, immobilizers)	222
Comfort	Influenced by treatment	212
Breathing	Affected by anatomy of CL±P and treatments	201
Vocalization	Presence of CP impacts speech and language development	198
Disposition	May impact cooperation or be influenced by treatments	154
Hearing	Increased frequency of Eustachian tube dysfunction, hearing loss, and tympanostomy tubes	85
Activity	Activity level might be altered by treatment (eg, immobilizers)	83
Gastrointestinal reflux	Incidence may be higher with CL±P	58
Skin	Dryness of exposed oral mucosa and irritation of facial skin from taping used for presurgical molding	37
Communication	May be impacted by cleft palate and difficulties verbalizing wants and needs	31

Abbreviation: CL±P; cleft lip with or without cleft palate; CP, cleft palate.