# What are differences in chewing performance of healthy children and children with cerebral palsy.

Published: 21-07-2014
Last updated: 20-04-2024

Using a variety of methods, we try to determine the dynamics of the chewing movements in typically developing children and children with CP. The methods are, in some degree, complementary to each other. Given the limitations of the methods we need…

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Congenital and peripartum neurological conditions |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON40296

**Source**
ToetsingOnline

**Brief title**
Chewing movements of children

### Condition

- Congenital and peripartum neurological conditions

**Synonym**
dysphagia, mastication problems

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Sint Maartenskliniek
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** EMG/kinematica, mastication, observation, ultrasound

## Outcome measures

### Primary outcome

Total score on the MOE (8 items on a 4 point scale)(1):

Ultrasound: frequency and amplitude of (2) left-right tongue movement , (3)

amplitude, and (4) speed of tongue movement

Kinematics; (5) duration chewing cycle, (6) chewing frequency and (7) 3D jaw

movement.

sEMG: (8) outcome M. Masseter and M. Temporalis compared to the maximum bite

force.

### Secondary outcome

information from the parents about the quality of chewing using a

questionnaire (9).

# Study description

### Background summary

Chewing is a rhythmic oral motor activity, in which the coordination of mouth muscles and joints are controlled by the central nervous system (Forster et al., 2006; Lund et al., 2006). An efficient chewing process requires repetitive movements of the mandible in combination with rotational movements of tongue combined with motor activity of lips and cheeks (Sakaguchi et al., 2003; Rogers et al., 2005). The development of the chewing is completely developed at the age of about 6 years (Le Révérend et al., 2013).

Children with cerebral palsy (CP) have constrains in coordination and control of muscles. This results not only in reduced gross motor movement, but also in decreased oral motor movements (Rosenbaum, 2007). One of the consequences is a reduced masticatory function. Children with CP show in their chewing ability:

- reduced chewing speed, with result that eating chewable food costs more time
- reduced coordination with as result less chewed food
- due to the reduced coordination and additional restrictions, these children are at greater risk of choking, impaired digestion and reduced natural dental cleaning.

As a result, children with CP are limited in managing solid food compared to healthy peers (Bell et al., 2010, Matsuo et al., 2008). This has social consequences (participation level), for example, not being able to eat treats or eating at a restaurant.

In clinical practice of speech/language therapists working with children with CP, there is a need for instruments to diagnose and/or evaluate chewing problems during development or after intervention. However, tongue movements and muscle activity of the masseter muscles and jaw movements cannot objectively be measured by observation. To measure mastication, studies with ultrasound, electromyography (sEMG) and kinematics are performed in adults and children. De Felicio et al. (2013) were able to distinct different movements patterns in adults with temporomandibular joint problems compared to healthy subjects using sEMG and kinematics. Also in children from 6 years of age a combination of sEMG and kinematics were used for chewing movements in open bite subjects (e.g. Piancino et al., 2009). Kinematics of jaw movement is applied in infants from 7 months of age (Wilson et al., 2012). These studies concern mostly jaw movement during chewing and present no data of tongue movements. In addition, there are few studies using natural food or studying the reliability of methods and/or to distinguish the minimal differences. Ultrasound is frequently used for images of the tongue during swallowing and articulation (Blissett et al. (2007); Bressmann et al. (2010) . The tongue movement during chewing are limited described with ultrasound. Also, little is known about the methodology used and the methods of analysis.

Previous to this study, an observation instrument to measure the ability to manage solid foods in childen is developed by the researchers.The reliability and discriminative validity of the mastication observation and evaluation instrument (MOE) is determined. Subsequently, the test-retest reliability of measurement of the jaw movement and muscle activity using kinematics and sEMG is established. sEMG makes it possible to determine changes in the activity of individual muscles and the cooperation between the oral muscles (m. Masseter, m. Temporalis and m. Digastricus). With kinematics, the jaw movements (size, direction and speed) are measured in three directions. In addition, a method using ultrasound to determine tongue movements is developed.

Results of the preliminary studies

1. Mastication Observation and evaluation (MOE).

The Mastication Observation and evaluation (MOE) instrument was developed using three Delphi rounds with 15 experts. The final instrument consists of 8 items, to be scored on a 4-point ordinal scale. Based on three bites of bread and three bites of a biscuit of 59 healthy children (6-48 months of age) and 38

CP-children (24-72 months of age), the MOE is assessed on (i) interrater agreement (Gwet's Agreement coefficient = 0.51-0.98), (ii) internal consistency (Cronbach's alpha >. 70), (iii) construct validity (relationship MOE score-age; $r = 0.73$; $p = 0.23$ for healthy children and $r < 0.01$; $p = 0.05$ for CP-children) and (iv) floor and ceiling effects; which were absent (Remijn et al., 2013; Remijn et al., 2014). The MOE is appropriate for assessing chewing. However, the scores give insufficient reliable results on the intra-oral tongue movement during chewing, such as lateral tongue movement and the number of times needed for swallowing the bolus.
(This research was approved by the Medical ethics committee of READE to Amsterdam (number: EN 40472.048.12)

2. Surface electromyography (sEMG)) and kinematics
sEMG and kinematics research is simultaneously used in 12 adult subjects. The aim of this research was to understand normal chewing movements and to establish the test-retest reliability of the relevant parameters. During this study 5 pieces of bread and biscuit in 2 different sizes (large and small) were eaten. Chewing cycles 2-5 were used for the analyses. We looked whether different food consistencies gave different outcomes. The results showed a good test-retest reliability with ICC (two-way random, agreement, average measurement) = 0.80-0.98. For all parameters a Bland & Altman analysis is calculated and Minimal Detectable Differences (MDD) are established. In this pilot the maximum sEMG is measured using the maximum bite force on a plastic tube. This provided a large variation between subjects in the% sEMG of the bites. We expect to determine the maximum bite force more stable with a bite force measurement instrument (Koc et al., 2010).

Ultrasonography (Ultrasound).
Ultrasound measurements of the tongue movement during chewing were established. Ultrasound movements of the transverse and sagittal cross section of the tongue are shown at the same time (see Figure 2). The transverse and sagittal section of ultrasound measurements of four healthy subjects and two persons with CP (3 trials per person) are manually drawn by two raters. The value of the ICCs showed a good intra-and inter-rateragreement (0.79-0.91 or 0.75-0.87) for drawing of the contour lines. There are indications of differences in the transverse tongue movements between healthy subjects and adults with CP concerning the movement and speed of displacement of the highest point of the tongue and the frequency of up and down movement and left-right movement. The sagittal tongue movements showed limited differences on these parameters. The moment of swallowing is determined afterwards in the analysis. As a result, the duration of the analysis is not sufficiently reliable. To increase the reliability of duration of chewing it is necessary to determine the start of the swallowing phase objectively. Hereby we propose to use an acoustic signal for the setting of the swallowing phase in a further study (Borr et al., 2007). (Remijn, Weijers, Nijhuis-van der Sanden, Groen & de Korte; paper in progress)

## Study objective

Using a variety of methods, we try to determine the dynamics of the chewing movements in typically developing children and children with CP. The methods are, in some degree, complementary to each other. Given the limitations of the methods we need all methods to complete the insight in the mastication process. In clinical practice the MOE is the most accessible and feasible instrument, so we want to validate the MOE with the other methods.

Research questions:
1. Is it possible to measure chewing movements in healthy children and children with CP with MOE, sEMG, kinematics and ultrasound?
2. Is it possible to discriminate between normal and abnormal chewing movements with the results of the MOE and objective measurement methods (sEMG, kinematics and ultrasound) ?

## Study design

Children visit once the SMK for the measurements. Two sessions will take place. Per session 5 (2 reserve) pieces of wheat bread and pate or chocolate spread (depending on the taste preference) and 5 (2 reserve) pieces of a biscuit are offered. The reserve pieces are offered if necessary to obtain at least 5 to analyse. The size of the pieces of bread and biscuit is 1.5 cm2 . In total, 3/4 slice of bread without crusts and 1* biscuit will be eaten. In addition, the child will chew 20 times on a waxtablet (a kind of chewing gum) (plasticine modelling wax, non-toxic DIN en-71). The consistency of the waxtablet does not change during mastication. This value is considered as a reference value for the chewing movements of bread and biscuit. After 20 chewing movements, the waxtablet is removed from the mouth. There is no health risk when the waxtablet is accidentally swallowed. In a previous study in children (5-12 years) with a muscular disorder this waxtablet was already used. Parents are asked to be present during the entire session and are asked to offer the food. Between both sessions there is a short break for relaxation. The order of the sessions are presented ad random.

Session 1: Ultrasound in combination with video recording for the observation tool MOE. The transducer of the ultrasound is held under the chin and the stethoscope is held on the side of the neck against the larynx during eating. Both devices provide a minimal pressure on the chin and neck and do not influence the chewing. Simultaneously a video is recorded for post-hoc analysis of the mastication with the MOE. This session will take approximately 20 minutes.
Session 2. Att first, the kinematics markers and sEMG boxes are fixed on the head. The maximum bite force is determined by the bite force measurement as a reference value for the relative muscle activity. The stethoscope is held next to the larynx during swallowing. This replaces the sEMG sticker under the chin.

This session will take approximately 45 minutes due to fixing process of the markers.

### Study burden and risks

The burden for the children is 2 hours for the research. The children are asked to eat for them well-known products, namely bread and biscuit. The parent is allowed to be present during the session and are asked to offer the food to the child. EMG markers are placed on the face of the child. The markers are associated with a for the child attractive cartoon character. In addition, the child has to chew on a waxtablet. The risk of choking is equal to the risk of choking in the regular mealtimes at home. No additional activities are executed in the mouth. There is no interference of the research session with the treatment. Parents and child have to visit the Sint Maartenskliniek once.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

**Age**
Children (2-11 years)

### Inclusion criteria

cerebral palsy, aged 5-12 years
spastic CP with oral motor problems
used to eat bread and biscuit

### Exclusion criteria

food intolerance for wheat
not being in good condition
not used to eat bread and biscuit
problems with teeth
no informed consent
hypersensibility in the face

## Study design

### Design

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| Study type: | Observational non invasive |
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Diagnostic |

### Recruitment

NL

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| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 27-10-2014 |
| Enrollment: | 20 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 21-07-2014 |
| Application type: | First submission |
| Review commission: | METC Slotervaartziekenhuis en Reade (Amsterdam) |
| Approved WMO Date: | 23-10-2014 |
| Application type: | Amendment |
| Review commission: | METC Slotervaartziekenhuis en Reade (Amsterdam) |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| CCMO | NL47397.048.14 |