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Title: International Standardization of the Test of Masticating and Swallowing Solids in Children (TOMASS-C)

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Summary: The Test of Masticating and Swallowing Solids (TOMASS) is a validated assessment tool measuring the efficiency of solid bolus intake by four quantitative parameters: discrete bites, masticatory cycles, swallows, and time to ingest a single cracker. A normative data base for adults (20 - 80+ years) has previously been established. The objective of this study was to investigate the applicability and reliability of the TOMASS in children and adolescents (TOMASS-C) and to establish the normative data base for this younger population. We collected data from 638 participants (male: 311, female: 327) in five age groups (4 - 18 years) with five different but very similar test crackers in four countries. Significant effects of bolus type (cracker), age group and gender on the TOMASS parameters were identified, requiring stratification of the TOMASS-C database by these variables. Intra-rater reliability was excellent (ICC > .94) for all parameters, inter-rater reliability was moderate for 'number of swallows' (ICC = .54), good for 'bites' (ICC = .78) and 'time' (ICC = .82), and excellent for 'masticatory cycles' (ICC = .96). The 'Test of Masticating and Swallowing Solids in Children (TOMASS-C)' was identified to be a reliable diagnostic tool for the comprehensive measurement of discrete oral stage components of solid bolus ingestion, standardized by a large normative data base that covers age groups from preschoolers to young adults. While differences between gender groups were less pronounced than in the adult population, previous results relating to changes in masticatory and swallowing as a function of age are confirmed by our data.

Keywords: mastication, swallowing, solid bolus, normative data, reliability
1. Introduction

Clinical assessment of swallowing is conducted to evaluate the efficiency of oropharyngeal swallowing and to identify signs of dysphagia. Usually, methods of visual and tactile inspection of oral structure and function are applied as well as observation of oral intake. The validity of these methods, however, is limited by the qualitative character of the measurements, as the observations cannot be compared to normative data and the results are highly dependent on the clinical experience of the examiner.

The 'Test of Masticating and Swallowing Solids (TOMASS)' was developed as a high-level assessment method to evaluate oral pharyngeal efficiency for solid bolus intake. Further research has established the validity of the TOMASS in healthy adult male and female participants from 20-80+ years with very good interrater reliability (ICC > .90 for all parameters) and very good convergent validity to instrumental measurements (ICC > .85 for all parameters). Significant differences between different but very similar solid test boluses (crackers) were found, suggesting the need for separate normative data bases for the different test crackers. Additionally, differences in all TOMASS parameters (bites, masticatory cycles, swallows and time needed to ingest the solid bolus) as a function of age and gender were detected in this validation study. Thus, differentiated normative data bases for the age range 20-80+ years, calculated by age and gender, were established across a range of test crackers commercially available in seven different countries. While the TOMASS can be considered an applicable and well-validated tool to assess the effectiveness of solid bolus ingestion in adults, no comparable, comprehensive and easy-to-perform quantitative instrument is available for children so far.

In the paediatric population, the measurement of oropharyngeal function is particularly difficult, as the procedures and instructions must be brief and easy to perform. Furthermore, several factors have to be considered to account for developmental changes during maturation, such as the development of transverse tongue movements and maturation of the swallowing pattern beginning with the infant's first experiences with semi-solid and solid food ingestion. At the age of four, healthy children have acquired a mature swallowing pattern. At the age of six, all deciduous teeth have erupted and none would have been shed. An adult-like chewing pattern, however, is achieved much later when the child is about 12 years
old and is certainly influenced by the eruption of teeth and second dentition that enables the child to fracture different types of foods to an appropriate final bolus particle size for safe swallowing. This period aligns with the end of the first growth phase for height, which has been described to be closely related to mandibular growth velocity. Differences in body growth and cognitive development are related to gender, with girls showing earlier growth and cognitive-psychological spurts during primary school age and boys catching up during puberty. Developmental changes and gender differences in parameters related to oral intake of different bolus types in children from 2 to 8 years have been reported in a series of studies by Gisel and colleagues. They established the reliability of the measurements 'time' (per bite) and 'masticatory cycles' for this age range, reported a decrease of 'masticatory cycles' and 'time' as a function of age and higher 'time / cycle ratios' in their female participants. No data, however, are available for children and adolescents older than 8 years.

As a first step in validating the TOMASS for the application in children and adolescents, an initial pilot study was conducted in healthy Dutch children and young adults covering an age span of 4 to 18 years. In this study, significant differences were found between young children (4 – 6 years old) and older children and adolescents (7 – 18 years), suggesting a significant impact of age on quantitative measurements of solid bolus preparation. The objective of this study was to further develop the paediatric version of the TOMASS, the TOMASS-C, by:

1) establishing a normative database for the test in children and adolescents from age 4 to 18 years
2) investigating the influence of age and gender on outcome parameters
3) establishing intra- and interrater reliability.

2. Methods

2.1. Participants

Data were collected from healthy children (4 to 18 years) in five different countries: The Netherlands, Germany, New Zealand, Portugal and Italy. Participants were included if there was no reported history of dysphagia or neurological disease. Children were clustered into five age groups with narrow age ranges to account for
the developmental processes in masticatory and swallowing function: group 1: 4;0 to 5;11 (years;months), group 2: 6;0 to 7;11, group 3: 8;0 to 9;11, group 4: 10;0 to 13;11, and group 5: 14;0 to 17;11. No data in age group 1 (4;00 to 5;11) were collected in Portugal.

2.2. TOMASS-C: Materials and procedure

As with the adult version of the TOMASS, The TOMASS-C involves ingestion of a cracker with the instruction to ‘eat this as quickly as is comfortably possible and when you’re finished, say your name’ 3. While the participant eats the cracker, the examiner observes and counts four parameters associated with effectiveness of oral ingestion: 1) 'number of bites', 2) 'number of masticatory cycles', 3) 'number of swallows', and 4) 'total time' needed to finish the cracker (Table 1). Only crackers that are commercially available and widely used in the respective country were used in this study: the Albert Heijn Basic Cracker™ (The Netherlands), the De Beukelaer TUC Classic™ cracker (Germany), the Arnotts Salada™ cracker (New Zealand) and the Gran Pavesi Salati Salati™ cracker (Portugal and Italy). The crackers chosen from The Netherlands, Portugal / Italy and New Zealand are not identical but very similar in ingredients, size (5 X 5cm, 3.75g) and perceptual characteristics. The German De Beukelaer TUC Classic™ (5 X 6.5cm, 3.75g) is slightly larger than the other crackers. Ingredients of the crackers include: unbleached flour (wheat flour, niacin, reduced iron, thiamine, mononitrate [vitamin B1], riboflavin [vitamin B2], and folic acid), soybean oil, partially hydrogenated cottonseed oil, sea salt, salt, malted barley flour, baking soda, and yeast.

< Table 1: Definition of the TOMASS-C parameters. All measurements refer to numbers taken to finish one cracker >

2.3. Data collection and statistical analysis

Normative data were calculated by age group and gender as mean and 95% confidence intervals (CI) for the 4 TOMASS parameters. Differences between crackers were analysed by conducting a general linear model one-way, fixed factor
MANOVA to determine the need for differentiated normative data for the test crackers. **Effects of age and gender** on the TOMASS variables were analyzed with a general linear model two-way, fixed factor MANOVA and post-hoc comparisons with respect to differences between the five age groups (Bonferroni correction).

**Intra- and inter-rater agreement** were analyzed by (1) comparing the repeated ratings of two raters of the complete Italian dataset (intra-rater), (2) comparing the ratings of two independent raters in the dataset of 140 participants (randomly selected) in the Italian data set (Gran Pavesi™ Cracker) (inter-rater) and (3) comparing ratings of video recordings of the TOMASS by two independent raters (Dutch and German) in a subset of 66 participants (the first 66 included participants, representing all age groups) in the Dutch data set (Albert Heijn Basic Cracker™) (inter-rater). The intraclass correlation coefficient (ICC) with a two-way mixed model, absolute agreement and single measure for analysis (1) (intra-rater reliability), and average measures for experiment (2 and 3) (inter-rater reliability), were used to test the intra- and interrater reliability of the four TOMASS-C parameters. As high reliability has already been established for clinician judgement of test measures, inter-rater reliability for the paediatric test was not completed for all crackers.

A-priori significance levels were set at $p < .05$. Data were analyzed with SPSS 24.0 for Windows (SPSS Inc., Chicago, IL, USA).

3. Results

3.1. Normative data

Data from 638 healthy children and adolescents (male= 311; female= 327) and four different test crackers were collected in this study (*Table 2*). A significant main effect of 'cracker' ($F(12,1669.761)= 8.184, p< .001$) was found on each of the four TOMASS-C parameters (bites: $F(3,634)= 3.230, p= .022$; masticatory cycles: $F(3,634)= 14.509, p< .001$; swallows: $F(3,634)= 5.811, p= .001$; time: $F(3,634)= 9.050, p< .001$). Therefore, normative data tables were calculated for each cracker separately. The normative data are presented in the appendix (*Tables I - IV*).
Table 2: Total numbers of participants in the TOMASS-C standardization study by test bolus (cracker), age group (AG years; months) and gender (M: male; F: female)

3.2. Influence of age and gender on the TOMASS parameters

Influence of age and gender across all data sets

Across all data sets we found main effect of age ($F(16,1910.044) = 15.408$, $p < .001$) and a main effect of gender ($F(4,625)= 3.134$, $p = .014$) but no significant age X gender interaction ($F(16,1910.044) = .932$, $p = .532$). Age affected multiple TOMASS-C parameters (bites: $F(4,628)= 42.637$, $p < .001$; masticatory cycles: $F(4,628)= 18.401$, $p < .001$; time: $F(4, 628)= 25.835$, $p < .001$), but not the number of swallows ($F(4,628)= 1.198$, $p = .310$). A gender effect was only evident for the parameter 'number of bites' ($F(1,628)= 10.342$, $p = .001$) with boys needing fewer bites to finish the cracker than girls. Post-hoc analyses of differences between age groups suggest that measurements and data variability decreased as a function of increasing age, with the adolescent participants needing fewer bites, masticatory cycles and time to ingest the cracker than the younger participants (Table 3).

Influence of age-group and gender within the different cracker data sets

Subsequent cracker-wise analysis confirmed the main effects of age in every single data set: Albert Heijn Basic Crackers™ / The Netherlands: $F(16,351.968)= 5.188$, $p < .001$; De Beukelaer TUC Classic™ / Germany: $F(16,266.427)= 5.679$, $p < .001$; Arnotts Salada™ / New Zealand: $F(16,348.913)= 5.117$, $p < .001$; Gran Pavesi Salati™ / Portugal, Italy: $F(16,825.501)= 8.623$, $p < .001$. Not all TOMASS parameters were equally affected by age. Age effects appeared most consistently for
the parameters 'bites', masticatory cycles and 'total time', while 'swallows' was affected by the participants' age in only one data set (Arnotts Salada™ / New Zealand) (Table 4). Significant main effects of gender were found only in the Albert Heijn Basic Crackers™ data set from The Netherlands $F(4,115)= 4.066, p=.004$ without a significant interaction with the participants' age.

<Table 4: Effects of age-group and gender on TOMASS-C parameters; significant effects are highlighted light grey and with an *>

3.3. Intra- and inter-rater reliability

Intra-rater reliability of the two Italian raters who repeated the ratings was excellent with all ICC's above .95. Inter-rater reliability of the two raters of the Italian dataset was excellent for all the parameters (all $ICC > .94$). Inter-rater agreement between the TOMASS measurements of the independent raters from Germany and the Netherlands ranged from moderate for the 'number of swallows' ($ICC= .54$), good for the 'number of bites' ($ICC= .78$,) and 'total time' ($ICC= .82$) to excellent for 'masticatory cycles' ($ICC= .96$).

4. DISCUSSION:

The aim of this study was to extend the application of the Test of Masticating and Swallowing Solids (TOMASS)³, a newly developed quantitative measure of discrete components of solid bolus texture ingestion to a younger population of children and adolescents. A normative data base was developed for individuals between 4 and 18 years, calculated by age and gender for four different test crackers that adds to the already established adult data base. Differences between younger and older participants were found in this large cohort that confirm previous findings in a Dutch pilot study¹⁶ and that are consistent with the adult data sets. Although the test boluses (crackers) were very similar, our data confirmed cracker-related differences that were previously reported when the TOMASS was applied in adults³. This emphasizes the rationale to calculate normative data with a differentiation of different
cracker types, age and gender as conducted previously for adults and now also for the younger population.

To our knowledge, this is the largest normative data study on masticatory and swallowing-related parameters in a cohort of children and adolescents. These data cover an age range from preschoolers to young adults and compare parameters of oral ingestion across a range of similar solid bolus types in different countries. Our data complement the previous results by Gisel and colleagues\textsuperscript{13-15} by considerably expanding the age range of available data.

4.1. Age effects

Differences between the younger and the older participants were found for 'number of bites', 'masticatory cycles' and the total 'time' needed to finish the cracker, while there was no difference between age groups with respect to the number of swallows. In the light of the developmental milestones of masticatory and swallowing function, this result is not surprising, as most participants had likely already acquired a mature swallowing pattern by the age of four years\textsuperscript{4-6}. Therefore, the number of swallows required to ingest a single cracker was not different in younger vs. older children. Masticatory function, however, underlies continuous developmental processes until an adult-like pattern is achieved by the age of about 12 years. Thus, the continuous decrease in the number of bites, masticatory cycles and total time in our study sample might reflect milestones of masticatory development and, thus, the progression in oropharyngeal solid bolus ingestion. Previous findings by Schwaab and colleagues in a study with 2 - 5 year old children, reported a decrease of 'masticatory cycles' and even more pronounced decrease for 'time' as a function of age\textsuperscript{15}, suggesting that this dynamic developmental process begins even earlier when the child begins to gain experiences with solid food textures.

4.2. Gender effects

In line with results of the adult TOMASS validation study with adults, we found a main effect of gender in our younger population with boys needing less 'bites' to finish the cracker than girls. Previous results by Gisel and colleagues\textsuperscript{13}, who found higher 'time / cycle ratios' in girls, were not replicated as we did not find gender-
related differences in the parameters 'masticatory cycles' and 'time'. This might be explained by the larger age range included in our study sample. A close relationship between body growth and mandibular growth velocity as well as gender-related differences in body growth and cognitive development have been described earlier \(^{10-12}\). Thus, developmental factors such as growth and cognitive spurts might have obscured differentiated gender effects in our study.

4.3. Reliability

As an extension to the previous standardization study with adults, good intra- and interrater agreement in applying the TOMASS-C was also demonstrated for the application in younger participants in this study. In comparison to the excellent reliability (\(ICC > .90\)) for all four TOMASS parameters in the adult population study, rating agreement was found to be slightly lower (sufficient to good) when the TOMASS is applied in the younger population. This was most evident for the parameter 'number of swallows' with only moderate inter-rater reliability. Of interest, this is the only parameter that did not differ as a function of age. While swallowing-related laryngeal movements are more difficult to observe with the less prominent thyroid cartilage in smaller children, the reliability of swallowing observations might also be reduced by a more restless and lively behaviour of the younger children that was frequently observed during data collection.

4.4. Limitations

Although we were able to collect a large data set across four different test crackers, stratification of the data according to cracker, age and gender leads to small numbers of participants in some cells of the normative data base. During data collection, we used the same TOMASS instruction as for adults, however, the youngest children, in particular, sometimes talked or laughed during eating the cracker. Furthermore, oral residues after finishing the cracker were observed in some of the younger children and it remains unclear whether this was due to an inability to understand the instruction or anatomical or functional reasons. Therefore, we cannot fully exclude that this might have contributed to the age effects we found in the data sets.
5. Conclusion

In summary, this study provides a standardization of the 'Test of Masticating and Swallowing Solids in Children (TOMASS-C)' for the comprehensive measurement of discrete oral stage components of solid bolus ingestion. In clinical application, the normative data base that has been established in this project will allow for a differential evaluation of four different components of oral solid bolus ingestion. For application in paediatric patients with swallowing impairments, we suggest complementing the TOMASS with other quantitative tests of mastication, such as overall performance with the 'Karaduman Chewing Performance Scale' or endurance in mastication with the '6 - Minute Mastication Test'. This package could provide a complete and quantitative overview of the oral efficiency for solid bolus intake in order to develop tailor-made therapy.

Appendix: <Tables I - IV>

- Table I.: Normative data consisting of mean, standard deviations and 95% confidence intervals by age and gender for Albert Heijn Basic Crackers™ (The Netherlands)
- Table II.: Normative data consisting of mean, standard deviations and 95% confidence intervals by age and gender for De Beukelaer TUC Classic™ (Germany)
- Table III.: Normative data consisting of mean, standard deviations and 95% confidence intervals by age and gender for Arnotts Salada™ (New Zealand)
- Table IV: Normative data consisting of mean, standard deviations and 95% confidence intervals by age and gender for Gran Pavesi Salati™ (Portugal, Italy)

Compliance with ethical standards: The study was approved by the regional ethical committees in The Netherlands, Germany, New Zealand, Portugal and Italy. Informed consent was obtained from the participants and from their parents or legal representatives.
Conflict of interests:

The authors declare that they have no conflict of interests

References:


Table 1: Definition of the TOMASS-C parameters. All measurements refer to numbers taken to finish one cracker.

<table>
<thead>
<tr>
<th>TOMASS-C PARAMETERS</th>
<th>DEFINITION</th>
</tr>
</thead>
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<tr>
<td>bites</td>
<td>number of bites taken to finish the cracker</td>
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<tr>
<td>masticatory cycles</td>
<td>up-down movement of the jaw&lt;br&gt;does not include the rotatory jaw and tongue&lt;br&gt;movements used to clear residue in the oral cavity</td>
</tr>
<tr>
<td>swallows</td>
<td>observed from the movement of the thyroid cartilage</td>
</tr>
<tr>
<td>time</td>
<td>duration of time needed to finish the cracker&lt;br&gt;measured with a digital stopwatch&lt;br&gt;START: when the cracker reaches the patient's lips&lt;br&gt;STOP: when the patient says his / her name</td>
</tr>
</tbody>
</table>
Table 2: Total numbers of participants in the TOMASS-C standardization study by test bolus (cracker), age group (AG years; months) and gender (M: male; F: female)

<table>
<thead>
<tr>
<th>Country</th>
<th>Cracker</th>
<th>Gender</th>
<th>AG 1 4;00-5;11</th>
<th>AG 2 6;00-7;11</th>
<th>AG 3 8;00-9;11</th>
<th>AG 4 10;00-13;11</th>
<th>AG 5 14;00-17;11</th>
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<th>total</th>
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<td>13</td>
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<tr>
<td></td>
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<td>9</td>
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<td>16</td>
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<td>10</td>
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Table 3: Post-hoc comparisons (mean differences and p-values) between age groups across all test cracker data sets. TOMASS-C parameters: bites, masticatory cycles and time. AG= age group; AG1: 4:00 - 5:11, AG2: 6:00 - 7:11, AG3: 8:00 - 9:11, AG4 10:00 - 13:11, AG 5 14:00 - 17:11; significant differences (Bonferroni-adjusted p < .0125) are highlighted light grey and with an *.

<table>
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<th>AG 2</th>
<th>AG 3</th>
<th>AG 4</th>
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<td>18.28</td>
<td>18.15</td>
<td>11.82</td>
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<td>p&lt; .001*</td>
<td>p&lt; .001*</td>
<td>p&lt; .001*</td>
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<td>time</td>
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<td>p&lt; .001*</td>
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<td>7.04</td>
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<td>p = .005*</td>
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<td>p = .699</td>
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<td>p&lt; .001*</td>
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<tr>
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<td>p&lt; .001*</td>
<td>p=.005*</td>
<td>p=.699</td>
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<tr>
<td>AG 5</td>
<td>23.77</td>
<td>15.83</td>
<td>12.36</td>
<td>8.79</td>
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</tr>
<tr>
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<td>p&lt; .001*</td>
<td>p&lt; .001*</td>
<td>p&lt; .001*</td>
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Table 4: Effects of age and gender on TOMASS-C parameters within the different cracker data sets; significant effects are highlighted light grey and with an *

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<th>TOMASS-C parameters - Univariate ANOVAs</th>
<th>bites</th>
<th>masticatory cycles</th>
<th>swallows</th>
<th>time</th>
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<tbody>
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<tr>
<td><strong>A. Heijn Basic Crackers™</strong></td>
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<td></td>
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</tr>
<tr>
<td>The Netherlands</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>AGE</strong></td>
<td>F(4,118)= 15.181</td>
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<td>F(4,118)= 2.19</td>
<td>F(4,118)= 7.156</td>
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<tr>
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<td>p = .153</td>
<td>p = .073</td>
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<tr>
<td><strong>GENDER</strong></td>
<td>F(1,118)= 10.953</td>
<td>F(1,118)= 3.001</td>
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<tr>
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<td><strong>De Beukelaer TUC Classic™</strong></td>
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</tr>
<tr>
<td>Germany</td>
<td></td>
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<td></td>
</tr>
<tr>
<td><strong>AGE</strong></td>
<td>F(4,90)= 11.95</td>
<td>F(4,90)= 9.389</td>
<td>F(4,90)= .594</td>
<td>F(4,90)= 11.851</td>
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<td>p&lt; .001*</td>
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<tr>
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<tr>
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<td><strong>Arnotts Salada™</strong></td>
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<td></td>
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<tr>
<td>New Zealand</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td><strong>AGE</strong></td>
<td>F(4,117)= 11.960</td>
<td>F(4,117)= 10.850</td>
<td>F(4,117)= 3.525</td>
<td>F(4,117)= 17.998</td>
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<tr>
<td></td>
<td>p&lt; .001*</td>
<td>p&lt; .001*</td>
<td>p&lt; .009*</td>
<td>p&lt; .001*</td>
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<tr>
<td><strong>GENDER</strong></td>
<td>F(1,117)= 1.855</td>
<td>F(1,117)= .174</td>
<td>F(1,117)= .117</td>
<td>F(1,117)= 2.827</td>
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<tr>
<td><strong>Gran Pavesi Salati™</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Portugal / Italy</td>
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<td></td>
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</tr>
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<td><strong>AGE</strong></td>
<td>F(4,273)= 16.970</td>
<td>F(4,273)= 10.437</td>
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<tr>
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<td>p&lt; .001*</td>
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<td><strong>GENDER</strong></td>
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Appendix: Table I.: Normative data consisting of mean, standard deviations and 95% confidence intervals by age and gender for Albert Heijn Basic Crackers™ (The Netherlands)

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<th>Sex</th>
<th>Age</th>
<th>Discrete bites per cracker</th>
<th>Masticatory cycles per cracker</th>
<th>Swallows per cracker</th>
<th>Total time (in sec)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td>Mean 95% CI</td>
<td>Mean 95% CI</td>
<td>Mean 95% CI</td>
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<tr>
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<td>41.10 29.52-52.67</td>
<td>2.20 1.63-2.76</td>
<td>48.70 36.44-60.95</td>
</tr>
<tr>
<td></td>
<td>6;00 - 7;11</td>
<td>3.50 2.83-4.16</td>
<td>41.38 35.46-47.31</td>
<td>1.88 1.55-2.22</td>
<td>34.77 29.77-39.78</td>
</tr>
<tr>
<td>Males</td>
<td>8;00 - 9;11</td>
<td>2.30 1.71-2.88</td>
<td>36.60 31.31-41.88</td>
<td>1.90 1.37-2.42</td>
<td>31.60 28.02-35.17</td>
</tr>
<tr>
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<td>10;00 - 13;11</td>
<td>3.07 2.50-3.65</td>
<td>35.76 27.69-43.84</td>
<td>2.15 1.73-2.57</td>
<td>33.30 27.88-38.73</td>
</tr>
<tr>
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<td>2.54 1.62-3.46</td>
<td>37.09 29.71-44.47</td>
<td>2.36 1.40-3.32</td>
<td>35.27 29.12-41.41</td>
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<td>7.00 3.83-10.16</td>
<td>48.55 41.58-55.52</td>
<td>2.00 1.14-2.85</td>
<td>51.00 40.02-61.97</td>
</tr>
<tr>
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<td>5.55 3.21-7.89</td>
<td>42.44 31.64-53.24</td>
<td>1.88 1.17-2.60</td>
<td>40.66 33.04-48.28</td>
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<td>3.40 2.85-3.94</td>
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<td>42.40 35.23-49.56</td>
</tr>
<tr>
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<td>10;00 - 13;11</td>
<td>2.75 2.25-3.24</td>
<td>37.93 31.10-44.76</td>
<td>2.56 2.08-3.03</td>
<td>34.56 29.85-39.27</td>
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<td>14;00 - 17;11</td>
<td>2.88 2.37-3.39</td>
<td>37.76 32.52-43.00</td>
<td>2.94 2.32-3.55</td>
<td>35.82 31.07-40.57</td>
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**Appendix: Table II.:** Normative data consisting of mean, standard deviations and 95% confidence intervals by age and gender for 
De Beukelaer TUC Classic™ (Germany)

<table>
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<th>Sex</th>
<th>Age</th>
<th>Discrete bites per cracker</th>
<th>Masticatory cycles per cracker</th>
<th>Swallows per cracker</th>
<th>Total time (in sec)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td>Mean</td>
<td>95% CI</td>
<td>Mean</td>
<td>95% CI</td>
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<td>Males</td>
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<td>4.84-7.95</td>
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<td>48.13-75.66</td>
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<tr>
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<td>6:00 - 7:11</td>
<td>3.70</td>
<td>2.48-4.91</td>
<td>44.00</td>
<td>34.85-53.14</td>
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<tr>
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<td>8:00 - 9:11</td>
<td>4.60</td>
<td>3.57-5.62</td>
<td>45.00</td>
<td>35.23-54.76</td>
</tr>
<tr>
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<td>10:00 - 13:11</td>
<td>3.50</td>
<td>2.42-4.57</td>
<td>44.60</td>
<td>34.85-53.14</td>
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<tr>
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<td>14:00 - 17:11</td>
<td>2.90</td>
<td>2.49-3.30</td>
<td>35.10</td>
<td>28.42-41.77</td>
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<tr>
<td>Females</td>
<td>4:00 - 5:11</td>
<td>7.40</td>
<td>5.57-9.22</td>
<td>68.00</td>
<td>51.16-84.83</td>
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<tr>
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<td>6:00 - 7:11</td>
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<td>47.91-76.48</td>
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<td>32.03-51.96</td>
</tr>
<tr>
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<td>10:00 - 13:11</td>
<td>3.90</td>
<td>3.18-4.61</td>
<td>38.80</td>
<td>31.30-46.29</td>
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<tr>
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<td>14:00 - 17:11</td>
<td>3.50</td>
<td>2.89-4.10</td>
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<td>31.87-40.72</td>
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Appendix: Table III.: Normative data consisting of mean, standard deviations and 95% confidence intervals by age and gender for Arnotts Salada™ (New Zealand)

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<th>Sex</th>
<th>Age</th>
<th>Discrete bites per cracker</th>
<th>Masticatory cycles per cracker</th>
<th>Swallows per cracker</th>
<th>Total time (in sec)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Mean 95% CI</td>
<td>Mean 95% CI</td>
<td>Mean 95% CI</td>
<td>Mean 95% CI</td>
</tr>
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<td>4;00 - 5;11</td>
<td>6.33  4.05-8.60</td>
<td>66.11  42.02-90.19</td>
<td>2.66  1.80-3.52</td>
<td>56.55  44.28-68.83</td>
</tr>
<tr>
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<td>6;00 - 7;11</td>
<td>5.07  3.31-6.83</td>
<td>61.28  49.62-72.94</td>
<td>3.28  2.48-4.08</td>
<td>44.78  37.94-51.62</td>
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<tr>
<td></td>
<td>8;00 - 9;11</td>
<td>4.10  2.46-5.73</td>
<td>44.40  40.05-48.74</td>
<td>3.00  2.10-3.89</td>
<td>36.70  31.00-42.39</td>
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<tr>
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<td>10;00 - 13;11</td>
<td>3.00  1.98-4.01</td>
<td>48.20  40.36-56.03</td>
<td>2.90  1.71-4.08</td>
<td>44.00  33.82-54.17</td>
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<td></td>
<td>14;00 - 17;11</td>
<td>1.50  0.86-2.13</td>
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<td>48.77  39.78-57.77</td>
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<td>2.52  1.95-3.10</td>
<td>39.11  33.84-44.38</td>
<td>2.05  1.47-2.64</td>
<td>32.41  27.00-37.82</td>
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Appendix: Table IV: Normative data consisting of mean, standard deviations and 95% confidence intervals by age and gender for Gran Pavesi Salati™ (Portugal, Italy)

<table>
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<th>Sex</th>
<th>Age</th>
<th>Discrete bites per cracker</th>
<th>Masticatory cycles per cracker</th>
<th>Swallows per cracker</th>
<th>Total time (in sec)</th>
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<tbody>
<tr>
<td></td>
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<td>Mean 95% CI</td>
<td>Mean 95% CI</td>
<td>Mean 95% CI</td>
<td>Mean 95% CI</td>
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<td>2.30 1.62-2.98</td>
<td>53.40 39.61-67.19</td>
</tr>
<tr>
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<td>6:00 - 7;11</td>
<td>4.50 3.36-5.64</td>
<td>60.42 48.63-72.22</td>
<td>2.26 1.84-2.68</td>
<td>53.23 46.57-59.89</td>
</tr>
<tr>
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<td>8:00 - 9;11</td>
<td>3.74 3.31-4.16</td>
<td>61.23 55.97-66.49</td>
<td>2.29 1.98-2.61</td>
<td>48.00 43.36-52.64</td>
</tr>
<tr>
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<td>10;00 - 13;11</td>
<td>4.18 3.40-4.96</td>
<td>52.27 43.01-61.53</td>
<td>2.60 2.06-3.14</td>
<td>43.42 35.83-51.02</td>
</tr>
<tr>
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<td>14:00 - 17;11</td>
<td>2.23 1.82-2.64</td>
<td>37.91 32.83-42.99</td>
<td>2.31 1.87-2.75</td>
<td>35.91 31.07-40.75</td>
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<tr>
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<td>2.00 1.17-2.82</td>
<td>46.60 37.51-55.69</td>
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<td>4.31 3.52-5.11</td>
<td>56.62 46.29-66.95</td>
<td>2.17 1.79-2.55</td>
<td>51.62 40.62-62.63</td>
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<td>8:00 - 9;11</td>
<td>4.56 3.51-5.79</td>
<td>62.50 53.49-71.51</td>
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<td>48.15 40.48-55.82</td>
</tr>
<tr>
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<td>10;00 - 13;11</td>
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<td>53.21 46.11-60.32</td>
<td>3.00 2.43-3.56</td>
<td>46.90 40.64-53.17</td>
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<tr>
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<td>14:00 - 17;11</td>
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<td>1.92 1.35-2.50</td>
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</table>