Objective of the study:
To investigate the occurrence of a range of ecologically and clinically important bacterial species in four distinct oral habitats and evaluate the effects of site, gender, oral hygiene and smoking history using data from Checkerboard DNA-DNA hybridization analysis of oral biofilm samples taken at age 32.

Definitions:
Biofilm - a functionally and structurally organized, matrix-enclosed aggregate of microorganisms which adheres to surfaces such as tooth enamel.

Checkerboard DNA-DNA hybridization (CKB) – a molecular microbiology technique which enables simultaneous determination of the presence of multiple selected bacterial species in multiple microbial specimens.

Microbiota - the microorganisms of a particular site or habitat.

Rationale:
The oral cavity has unique habitats that develop distinct clinically important microbial biofilms. The oral microbiome is diverse, complex, dynamic, and little understood. Additionally, there is a lack of research from population-based samples to characterize the oral microbiota. To the best of the author’s knowledge, this is the first investigation (using CKB analysis) of four separate oral biofilms from a large-scale epidemiologic study of adults.
Data analysis methods:

Nonparametric tests for bivariate associations, principal component analysis

Variables needed at which ages:

Sex
Oral hygiene
Smoking (current/ns)
Plaque bacteria variables

Significance of the Study (for theory, research methods or clinical practice):

Prospective oral health studies that have considered oral microbial ecology are scarce, as are reports from population-based samples characterising the oral microbiota. Also, the CKB analysis used in this research is a molecular technique was chosen because it is considered suitable for large epidemiological studies. This report on the occurrence key ecologically and clinically important bacterial species in four distinct oral habitats and the effects of site, gender, oral hygiene and smoking represents an exceptional opportunity to add to the existing body of scientific knowledge. Additionally this research will lay the foundation for ongoing oral microbial ecological research in the “Dunedin Study” and other birth cohort studies

References:


Zaura E, Keijser BJF, Huse SM, Crielaard W. 2009. Defining the healthy "core
Data Security Agreement

Provisional Paper Title

Proposing Author

Today’s Date

Please keep one copy for your records and return one to the PI Sponsor

Please initial your agreement: (customize as necessary)

<table>
<thead>
<tr>
<th>I am current on Human Subjects Training [CITI <a href="http://www.citigrogram.org">www.citigrogram.org</a>] or equivalent.</th>
</tr>
</thead>
<tbody>
<tr>
<td>My project is covered by the Dunedin Study’s ethics approval OR I have /will obtain ethical approval from my home institution (please specify).</td>
</tr>
<tr>
<td>I will treat all data as “restricted” and store in a secure fashion. My computer or laptop is:</td>
</tr>
<tr>
<td>• encrypted (recommended programs are FileVault2 for Macs, and Bitlocker for Windows machines)</td>
</tr>
<tr>
<td>• password-protected</td>
</tr>
<tr>
<td>• configured to lock-out after 15 minutes of inactivity AND</td>
</tr>
<tr>
<td>• has an antivirus client installed as well as being patched regularly.</td>
</tr>
<tr>
<td>I will not &quot;sync&quot; the data to a mobile device.</td>
</tr>
<tr>
<td>In the event that my laptop with data on it is lost, stolen or hacked, I will immediately contact my PI Sponsor or Study Director, Richie Poulton (<a href="mailto:richie.poulton@otago.ac.nz">richie.poulton@otago.ac.nz</a>).</td>
</tr>
<tr>
<td>I will not share the data with anyone, including my students or other collaborators not specifically listed on this concept paper.</td>
</tr>
<tr>
<td>I will not post data online or submit the data file to a journal for them to post.</td>
</tr>
<tr>
<td>Some journals are now requesting the data file as part of the manuscript submission process. The Dunedin Study Members have not given informed consent for unrestricted open access, so we have a managed-access process. Speak to your PI Sponsor or Richie Poulton for strategies for achieving compliance with data-sharing policies of journals.</td>
</tr>
<tr>
<td>I will delete all data files from my computer after the project is complete. Collaborators and trainees may not take a data file away from the office.</td>
</tr>
<tr>
<td>The data remains the property of the Study and cannot be used for further analyses without an approved concept paper for new analyses.</td>
</tr>
</tbody>
</table>

Signature: ___________________________
# CONCEPT PAPER RESPONSE FORM

A. To be completed by the proposing author:

<table>
<thead>
<tr>
<th>Provisional Paper Title</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Proposing Author</td>
<td></td>
</tr>
<tr>
<td>Other Contributors</td>
<td></td>
</tr>
<tr>
<td>Potential Journals</td>
<td></td>
</tr>
<tr>
<td>Today’s Date</td>
<td></td>
</tr>
<tr>
<td>Intended Submission Date</td>
<td></td>
</tr>
</tbody>
</table>

*Please keep one copy for your records and return one to the proposing author*

B. To be completed by potential co-authors:

- [ ] Approved
- [ ] Not Approved
- [ ] Let’s discuss, I have concerns

Comments:

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

Please check your contribution(s) for authorship:

- Conceptualizing and designing the longitudinal study
- Conceptualizing and collecting one or more variables
- Data collection
- Conceptualizing and designing this specific paper project
- Statistical analyses
- Writing
- Reviewing manuscript drafts
- Final approval before submission for publication
- Acknowledgment only, I will not be a co-author

Signature: ________________________________