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UCC
University College Cork, Ireland
Coláiste na hOllscoile Corcaigh

Tooth Wear in Irish Teenagers:

A Laboratory and Epidemiological Study

Volume II of II

This research is presented in fulfilment of the

Degree of Doctor of Philosophy

National University of Ireland, Cork

The research presented in this thesis was conducted at the

Department of Oral Health and Development,

Cork University Dental School & Hospital

By

Mary-Margaret (Máiréad) Antoinette Harding BDS, MDPH

April 2015

Head of Department and School: Professor Martin Kinirons

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Professor David Sheehan, School of Biochemistry and Cell Biology,
College of Science, Engineering and Food Science

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Appendix 1:

Ethical approval letters from the Clinical Research Ethics Committee of the Cork Teaching Hospitals (CREC).

Ethical Approval:
Protocol OHSRC01005
(Cross sectional study 16-year-olds)

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COISTE EITICE UM THAIGHDE CLINICIÚIL
Clinical Research Ethics Committee

Lancaster Hall,
6 Little Hanover Street,
Cork,
Ireland.

Our Ref: ECM 4 (10) 06/12/05

7th December 2005

Dr Helen Whelton
Oral Health Services Research Centre
University Dental School
Wilton
Cork

Re: OHSRC01005. Application to carry out a research project entitled "Toothwear/dental erosion in Irish teenagers; an epidemiological and laboratory investigation".

Dear Dr Whelton

The Clinical Research Ethics Committee of the Cork Teaching Hospitals reviewed your correspondence at its recent meeting held on 6th December 2005.

The Committee approved the protocol.

1. What tests are going to be carried out on the saliva specimens?
2. What insurance is provided in this study?

The Committee approved the following documents:

- Protocol plus appendices
- Consent form (included as Appendix 1 of protocol)
- Protocol Submission Form

The following Committee Members attended the above meeting.

Dr Michael Hyland – (Chairman)
Dr Edward Fitzgerald
Dr Finbarr Allen
Dr Mary Lehane
Sheila McKiernan
Patricia Lydon
Frank Buckley (Lay Member)

The Clinical Research Ethics Committee of the Cork Teaching Hospitals, UCC, is a recognised Ethics Committee under Regulation 7 of the European Communities

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(Clinical Trials on Medicinal Products for Human Use) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

The Committee is fully compliant with the Regulations as they relate to Ethics Committees and the conditions and principles of Good Clinical Practice.

Yours sincerely

Dr Michael Hyland
Chairman
Clinical Research Ethics Committee
of the Cork Teaching Hospitals

Cc: Ms Maria Tobin, Projects Manager, Oral Health Services Research Centre, University Dental School, Wilton, Cork.

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Clinical Research Ethics Committee
2200 Cork Airport Business Park,
Kinsale Road,
Cork,
Ireland.

ORAL HEALTH SERVICES
12 JAN 2006
RESEARCH CENTRE

ECM 3 (k) 07/02/06

Dr Helen Whelton
Oral Health Services Centre
University Dental School
Wilton
Cork

Re: OHSRC01005: Toothwear/dental erosion in Irish teenagers: an epidemiological and laboratory investigation"

Dear Dr Whelton

Thank you for your letter of 4th January 2006.

The Committee has noted the following explanation regarding saliva testing and insurance:

Saliva tests query: Both stimulated and unstimulated saliva samples will be collected, the salivary flow rate will be calculated from the duration taken to collect the unstimulated sample and the weight of saliva collected. The unstimulated saliva sample will be analysed for fluoride levels using a direct ion probe method, calcium and phosphate will be analysed using ion chromatography, this work will be conducted at the Oral Health Services Research Centre (OHSRC).
The salivary proteins present in both the stimulated and unstimulated saliva will be analysed with the assistance of the Department of Biochemistry UCC. Gel electrophoresis will be used to identify proteins, specific proteins present will be identified using Periodic Acid Schiff reagent (PAS) and Western Blotting. Oxidative stress analysis and carbonylation will be conducted on those salivary proteins which exist in those with and without toothwear; dental erosion to ascertain whether differences in oxidation stress and carbonylation are present.

Insurance query: The activities of the Principal Investigator; Dr Helen Whelton and the Researcher; Dr Mairead Harding will be covered by their Professional Indemnity Insurance. UCC Public Liability insurance covers activities of the University insofar as liability may attach to UCC for any injury to a third party as part of a UCC organized event and or a study approved by the Ethics Committee.

Full approval is now granted for this Study.

Yours sincerely

Dr Michael Hyland
Chairman
Clinical Research Ethics Committee
Of the Cork Teaching Hospitals

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COISTE EITICE UM THAIGHDE CLINICIÚIL
Clinical Research Ethics Committee
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Cork,
Ireland.

Our Ref: ECM 2 (q) 06/11/07

7th November 2007

Dr Helen Whelton
Oral Health Services Research Centre
University Dental School
Wilton
Cork

Re: OHSRC01005. Application to carry out a research project entitled "Toothwear/dental erosion in Irish teenagers; an epidemiological and laboratory investigation".

Dear Dr Whelton

The Clinical Research Ethics Committee of the Cork Teaching Hospitals reviewed your correspondence at its recent meeting held on 6th November 2007

The Committee approved the following documents:

- Protocol Amendment dated 19th October 2007
- Assent Form
- Amended Letters to schools and parents.

Yours sincerely

Dr Michael Hyland
Chairman
Clinical Research Ethics Committee
of the Cork Teaching Hospitals

Cc: Ms Maria Tobin, Projects Manager, Oral Health Services Research Centre, University Dental School, Wilton, Cork.

Ethical Approval:
Protocol OHSRC00806
(Longitudinal study 12-year-olds)

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University College Cork, Ireland

COISTE EITICE UM THAIGHDE CLINICIÚIL
Clinical Research Ethics Committee

Lancaster Hall,
6 Little Hanover Street,
Cork,
Ireland.

Our Ref: ECM 5 (11) 01/05/07

2nd May 2007

Dr Helen Whelton
Oral Health Services Research Centre
University Dental School & Hospital
Wilton
Cork

Re: OHSRC00806. Is tooth erosion in primary teeth predictive of tooth wear in permanent teeth? Follow-up to a cross sectional survey of the prevalence and severity of tooth erosion and the prevalence of dental caries in a sample of 5-year old children in the Cork City and County Regions.

Dear Dr Whelton

The Clinical Research Ethics Committee of the Cork Teaching Hospitals reviewed your correspondence at its recent meeting held on 1st May 2007.

Full approval is granted by the Committee to carry out the above study at the following sites:

- Schools in Cork City and county

Subject to receipt of the following:

- The Subject Information and Informed Consent Form should be printed with larger print to make it easier to read
- Assent forms should also be signed by the children who are under 16 years

The Committee approved the following documents:

- Protocol Submission Form
- Protocol Final Version dated 16th April 2007
- Appendix 2 Confidential Medical Questionnaire
- Appendix 3 Oral Hygiene and Dietary Practices Questionnaire
- Appendix 4 Demographic Data Form
- Appendix 5 CRF

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University College Cork, Ireland

COISTE EITICE UM THAIGHDE CLINICIÚIL
Clinical Research Ethics Committee

Lancaster Hall,
6 Little Hanover Street,
Cork,
Ireland.

The following Committee Members attended the above meeting.

Dr Michael Hyland – (Chairman)
Dr Seamus O'Mahony
Dr Finbarr Allen
Dr Seamus Hart
Matt Murphy
Fergus Long (lay person)
Sheila McKiernan

The Clinical Research Ethics Committee of the Cork Teaching Hospitals, UCC, is a recognised Ethics Committee under Regulation 7 of the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

The Committee is fully compliant with the Regulations as they relate to Ethics Committees and the conditions and principles of Good Clinical Practice.

Yours sincerely

Dr Michael Hyland
Chairman
Clinical Research Ethics Committee
of the Cork Teaching Hospitals

Cc: Ms Maria Tobin, Projects Manager, Oral Health Services Research Centre
University Dental School & Hospital, Wilton, Cork.

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COISTE EITICE UM THAIGHDE CLINICIÚIL
Clinical Research Ethics Committee

Lancaster Hall,
6 Little Hanover Street,
Cork,
Ireland.

Our Ref: ECM 3 (jjj) 12/06/07

18th May 2007

Dr Helen Whelton
Oral Health Services Research Centre
University Dental School & Hospital
Wilton
Cork

Re: OHSRC00806. Is tooth erosion in primary teeth predictive of tooth wear in permanent teeth? Follow-up to a cross sectional survey of the prevalence and severity of tooth erosion and the prevalence of dental caries in a sample of 5-year old children in the Cork City and County Regions.

Dear Dr Whelton

The Chairman approved the Child Information and Assent Form and the Parents Information and Informed Consent Form.

Full approval is now granted to carry out the above study at the following sites:

- Schools in Cork City and county

Yours sincerely

Dr Michael Hyland
Chairman
Clinical Research Ethics Committee
of the Cork Teaching Hospitals

Cc: Ms Maria Tobin, Projects Manager, Oral Health Services Research Centre
University Dental School & Hospital, Wilton, Cork.

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COISTE EITICE UM THAIGHDE CLINICIÚIL
Clinical Research Ethics Committee

Lancaster Hall,
6 Little Hanover Street,
Cork,
Ireland.

Our Ref: ECM 3 (j) 03/07/07

1st June 2007

Dr Helen Whelton
Oral Health Services Research Centre
University Dental School & Hospital
Wilton
Cork

Re: OHSRC00806. Is tooth erosion in primary teeth predictive of tooth wear in permanent teeth? Follow-up to a cross sectional survey of the prevalence and severity of tooth erosion and the prevalence of dental caries in a sample of 5-year old children in the Cork City and County Regions.

Dear Dr Whelton

The Chairman approved the protocol amendment to include a provision for the taking of intra-oral photographs in a sub sample of children and the following documents:

- Amendment Submission Form
- Parents Information and Informed Consent Form
- Child Information and Assent Form

Yours sincerely

Dr Michael Hyland
Chairman
Clinical Research Ethics Committee
of the Cork Teaching Hospitals

Cc: Ms Maria Tobin, Projects Manager, Oral Health Services Research Centre
University Dental School & Hospital, Wilton, Cork.

Ethical Approval:
Protocol OHSRC00409
(Longitudinal study 14-year-olds)

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Ireland.

Our Ref: ECM 5 (4) 03/11/09

4th November 2009

Professor Helen Whelton
Oral Health Services Research Centre
University Dental School & Hospital
Wilton
Cork

Re: OHSRC00409: Tooth Wear: A prospective cohort study. A follow-up to a cross sectional survey of the prevalence and severity of tooth wear in the permanent dentition of 12-year-olds, who were also examined as five-year-olds.

Dear Professor Whelton

The Clinical Research Ethics Committee of the Cork Teaching Hospitals reviewed your correspondence at its recent meeting held on 3rd November 2009.

Full approval is granted by the Committee to carry out the above study at the following sites:

- University Dental Hospital, Cork.

The Committee approved the following documents:

- Application Form
- Study Protocol Final Version 19th October 2009.
- Invitation Letter Final Protocol dated 19th October 2009
- Questionnaire version final protocol dated 19th October 2009
- CRF and source documentation version final protocol 19th October 2009
- Information Letter to Parents
- Information Letter to School Principal
- Information Letter to Board of Management / Parents Council
- Parent Information and Informed Consent Form version final protocol dated 19th October 2009
- Child Information and Informed Consent Form version final protocol dated 19th October 2009

The following Committee Members attended the above meeting.

Dr Michael Hyland – (Chairman)
Dr Mike O'Connor
Dr Finbarr Allen
Dr Brian Bird
Raj Chopra
Mary Gilmartin (by phone)
Kieran Doran (lay person)

The Clinical Research Ethics Committee of the Cork Teaching Hospitals, UCC, is a recognised Ethics Committee under Regulation 7 of the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

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The Committee is fully compliant with the Regulations as they relate to Ethics Committees and the conditions and principles of Good Clinical Practice.

Yours sincerely

Dr Michael Hyland
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Clinical Research Ethics Committee
Lancaster Hall,
6 Little Hanover Street,
Cork,
Ireland.

Our Ref: ECM 3 (d) 11/05/10

24th March 2010

Professor Helen Whelton
Oral Health Services Research Centre
University Dental School & Hospital
Wilton
Cork

Re: OHSRC00409: Tooth Wear: A prospective cohort study. A follow-up to a cross sectional survey of the prevalence and severity of tooth wear in the permanent dentition of 12-year-olds, who were also examined as five-year-olds.

Dear Professor Whelton

The Chairman approved the following:

- Amendment 1 Application Form
- Child Information and Assent Form version Amended Final Protocol OHSRC00409 dated xx/03/10
- Parents Information and Informed Consent Form version Amended Final Protocol OHSRC00409 xx/03/10
- Revised Parent/Guardian letter
- Revised Letter to Board of Management / Parents Council
- Revised Letter to School Principal.

Yours sincerely

Dr Michael Hyland
Chairman
Clinical Research Ethics Committee
of the Cork Teaching Hospitals

ORAL HEALTH SERVICES
31 MAR 2010
RESEARCH CENTRE

University College Cork, Ireland
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Harding, M. A. 2015. *Tooth wear in Irish teenagers: a laboratory and epidemiological study*. PhD Thesis, University College Cork.

Please note that Appendix 2 is unavailable due to a restriction requested by the publisher of the following paper.

> Harding M.A., Whelton H., O'Mullane D.M., Cronin M.; (2003) 'Dental erosion in 5-year-old Irish school children and associated factors: a pilot study'. *Community Dental Health*, 20 (3):165-170.

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Appendix 2a:

Oral Hygiene and Dietary Practices Questionnaire 5-year-olds.

Oral Hygiene and Dietary Practices Questionnaire

Instructions to Parents / Guardians.

Please fill out this form for your five-year-old child.

- Most of the questions can be answered by placing a tick (✓) in the box next to the answer that applies to your child.
- You may find that in some questions there may be more than one answer that applies to your child. Please tick all the boxes that apply.
- If you cannot remember, if you do not know or if you are unable to answer a particular question please write 'don't know' or 'can't remember' beside that question.
- Try and answer all questions as accurately as possible. Any information you give will be treated as confidential and will be used for statistical purposes only.
- Please return the completed Forms to the child's teacher *tomorrow* in the envelope provided.



Thank You



Oral Hygiene and Dietary Practices Questionnaire

For Office use only:

Subject Number: ☐☐☐☐☐☐ Name of Primary School: _____ School Number: ☐☐

Parent/Guardian to complete:

Name of child: _____ Age: _____ Date of Birth: ☐☐-☐☐-☐☐
DAY MONTH YEAR

1. **At what age did your 5 year old child stop using a baby bottle?**

   Never used ☐ Less than 12 months ☐ Less than 18 months ☐ 18 to 24 months ☐ 24 months or more ☐ Currently using ☐

2. **How often in the past 12 months has your 5 year old child visited the dentist?**

   Not at all ☐ Once ☐ Twice ☐ Three times or more ☐

3. **Who usually brushes your 5 year old child's teeth?**

   My child's teeth are not usually brushed ☐ My child himself / herself ☐ An Adult ☐ Child and Adult ☐

4. **How often are your 5 year old child's teeth brushed?**

   Never ☐ Once a week ☐ Less than once a week ☐ Once a day ☐ Twice a day ☐ Three or more times a day ☐

5. **At what time(s) of day are your 5 year old child's teeth brushed?**

   Before breakfast ☐ After breakfast ☐ Before other meals ☐ After other meals ☐ After drinking fruit/fizzy drinks ☐

   Before going to bed ☐ Never ☐ Other ☐, please specify :_____

6. **In this question we would like to know what drink(s) your 5 year old child takes and how often they are taken.**
It is helpful to read through the list before answering the questions. Please tick (✓) a box in the *How Often* section, that relates most closely to your child.
Please tick (✓) whether the drink is usually 'Regular', 'Diet' or 'No sugar added' where the choice is given and Still or Fizzy/Sparkling if it applies.
The last column asks you to write in an example of the usual type of drink taken in each group ticked: for example, for Pure Fruit Juice it may be Apple, Fizzy drinks it could be Cola etc.)

List of Drinks	***How Often are the drinks taken***							***Please write in the name of the drink.***
	Never	Once a month	Once or twice a week	Once a day	Twice a day	Three times a day	Four to six times a day	
Pure Fruit Juice (for example, Orange, Apple, Grapefruit etc.)								
Fizzy Drinks (e.g. Cola, lemonade, 7-Up etc.) Please tick whether the drink is usually Regular ☐ Diet ☐								
Fruit Squash (Diluted drinks: Orange, Lemon, Blackcurrant etc.) Please tick whether the drink is usually. Regular ☐ No sugar added ☐								
"Tooth Kind" Drinks (e.g. Ribena ToothKind)								
Bottled water Please tick whichever the child usually has Still ☐ Fizzy/ Sparkling ☐								
Milk								
Other Drink (e.g. Five Alive, Sunny Delight, Capri Sun) Please specify:_____								

7. **When does your 5 year old child have his / her drink(s)? Please place a tick (✓) in each space that relates to your child. There may be more than one tick (✓) on each line.**

List of Drinks	*When is the drink taken*						
	Never	Breakfast	Lunch	At School	Dinner	Between meals	Bed time
Pure Fruit Juice (e.g. Orange, Apple, Grapefruit etc.)							
Fizzy Drinks (e.g. Cola, lemonade, 7-Up etc.)							
Fruit Squash (Diluted drinks: Orange, Lemon, Blackcurrant etc.)							
"Tooth Kind" Drinks (e.g. Ribena ToothKind)							
Bottled water.							
Milk							
Other Drinks (e.g. Five Alive, Sunny Delight Capri Sun) Please specify:_____							

8. **How does your 5 year old child usually take his / her drink?**

From a cup/glass ☐ From a can ☐ Through a straw ☐ Feeder cup ☐ Baby bottle ☐ Other ☐, Please Specify: _____

9. **Please can you estimate how many times your 5 year old child has:** (i)Pure fruit juice in a typical day. ☐ times.

(ii) Fizzy drinks in a typical day. ☐ times.

(iii) Fruit squash (dilutable drinks) in a typical day ☐ times.

10. **How often does your 5 year old child have the following list of foods?**
It is helpful to read through the food list before answering the questions. The first column lists the foods. The second column asks how often the foods are eaten. Please place a tick (✓) in each space that relates most closely to your child.
The final column asks you to write down a typical example of the type of food/snack eaten for each group ticked: (for example, for Citrus Fruits it could be Orange, for Yoghurt it could be Petit Filous, for Sweets, Biscuits, Cakes it could be Lollipops / Jelly babies, Chocolate biscuits, Sponge cake etc.)

Food	***Frequency*** **(How often are the foods eaten)**								***Please write in*** *the name of the 'food'*
	Never	Less than once a month	At least once month	Once or twice a week	Once a day	Twice a day	Three times a day	Four to six times a day	
Citrus Fruits (Oranges, Grapefruits etc.)									
Apples or other fruit									
Yoghurt									
Tomato/Brown sauce									
Vinegar with food									
Spicy food									
Sweets, Biscuits, Cakes									
Crisps, Nuts, Popcorn									

11. **Does your 5 year old child ever have any of the following?**

Stomach Upsets: Yes ☐ No ☐ How often: _____

Frequent Vomiting: Yes ☐ No ☐ How often: _____

12. **Have you ever heard of tooth wear or dental erosion?** Yes ☐ No ☐

13. **If YES, where did you hear about it (e.g. Dentist, Friend, Magazine)?**

_____

14. **Does your family have a medical card?** Yes ☐ No ☐

Thank you for taking the time to complete this questionnaire.



Appendix 3:

Toothwear/Dental Erosion in Irish Teenagers: An Epidemiological and Laboratory Investigation (Protocol OHSRC01005)

Toothwear/Dental Erosion in Irish Teenagers: An Epidemiological and Laboratory Investigation

Approved Research Project Grant PR/2005/267

Oral Health Services Research Centre
National University of Ireland Cork

INTRODUCTION

Recent national surveys indicate that the oral health of children in Ireland has improved over the past thirty years (Whelton et al, 2003), yet there is little to be complacent about. In 16-year-olds toothwear is of growing concern, although this parameter was not measured in the last oral health survey, it is prudent that this be carried out now amid concerns that toothwear is increasing in adolescents.

Toothwear is a descriptive term for the different types of wear, namely abrasion, attrition abfraction and erosion and is described as the loss of mineralised tooth substance from the surface of the tooth as a result of physical or chemical attack. The chemical attack must not be of bacterial origin (Walls, 1996).

The different types of wear are descriptive but also depend on establishing where possible the aetiology.

Abrasion: the loss of dental hard tissue by mechanical forces other than mastication or tooth-to-tooth contacts.

Attrition: the loss of dental hard tissue caused by mastication or contact between occluding or approximal surfaces.

Abfraction: the loss of dental hard tissue cervically due to biomechanical loading forces.

Erosion: the loss of dental hard tissue by a chemical process that does not involve bacteria.

Toothwear occurs throughout life with all processes co-existing; the rate at which toothwear may progress and the extent to which the dentition is affected will be dependent on a number of factors.

At present much of the concern with toothwear, dental erosion in particular is related to the fact that it is being identified in children and young adults. The aetiology is frequently associated with diet and an increase in the consumption and frequency of acidic food and drink, this dietary change has been identified on a population basis (Kelleher et al, 2003). Worryingly surfaces softened by an increased chemical attack will abrade at a faster rate (Kelly and Smith, 1988).

Host factors such as saliva both the quality and quantity, and the availability of fluoride are factors which require further investigation with regard to toothwear. Salivary proteins, mucins and non-mucins have a role in tooth remineralisation and demineralisation. Fluoride promotes

enamel remineralisation and inhibits demineralisation; its role in the prevention of dental caries is well understood, but not so clearly in terms of toothwear and erosion, one would expect the effects to be beneficial (Bardsley et al, 2004). Circumstances such as low income have been identified as an indicator of poorer general and dental health (Townsend and Davidson, 1992; Whelton et al, 2003).

This research project proposes to examine the dentition of 16-year-olds, their saliva, demographic factors; including their socioeconomic status and type of water supply and their oral hygiene, dietary habits and behaviours. Investigation at 16 years of age provides an indication of the insults that these permanent teeth have up to that time suffered; ideally this is the dentition that should be maintained into old age.

OBJECTIVES OF THE STUDY

- To measure the prevalence of toothwear in a representative sample of teenagers in Counties Cork and Kerry.
- To investigate demographic factors that may be associated with toothwear.
- To investigate dietary factors that may be associated with toothwear.
- To investigate quantitative and qualitative salivary variables in resting and stimulated saliva samples.

HYPOTHESES

- A high prevalence of toothwear exists in teenagers in Counties Cork and Kerry.
- Those who reside in non-fluoridated areas have a higher prevalence of toothwear.
- Those in the lower socio-economic groups have a higher prevalence of toothwear.
- Toothwear is higher among males than females in the Cork and Kerry region.
- Those who consume acidic foodstuffs have a higher prevalence of toothwear.
- Those who brush less frequently with fluoridated toothpaste have a higher prevalence of toothwear.
- Those individuals exhibiting toothwear have salivary properties which differ from those without toothwear.

SAMPLE SELECTION

The study will be a cross-sectional study using a random representative cluster sample of transition year teenagers in the Cork and Kerry counties. The sample will be stratified on age, gender and school location. A two-stage sampling process will be used to ensure both fluoridated and non-fluoridated schools will be included. Each teenager in each class will have a known probability of being selected.

Teenagers in transition year (TY) will be selected for this study, more and more of this age-group is remaining in full-time education, as transition year has become compulsory in most schools rather than optional which it previously was. All consenting teenagers will be examined, in reality the group will be comprised of teenagers aged 15-17 years with the majority being 16-years-old.

This age group is chosen for this study as the permanent incisors and first permanent molars have been present in the mouth for approximately nine years, and these are the teeth which are most likely to exhibit signs of toothwear, typically dental erosion.

SAMPLE SIZE CALCULATION

The sample size in this study is based on the findings of 'moderate erosion' in a sample of 14-year-old children in Birmingham (Al-Dlaigan et al, 2001), where moderate erosion corresponds to loss of enamel with visible dentine for less the $1/3^{rd}$ of the smooth surface or dentine being just exposed on the incisal surfaces. It is anticipated that 800 teenagers will be examined, 400 who will have a fluoridated water supply and 400 who will have a non-fluoridated water supply.

TIMETABLE

Ethics Approval: Submission to the Clinical Research Ethics Committee of the Cork Teaching Hospitals; November 21^{st} 2005

Training and Calibration: This will be organised for late March or early April 2006 a visiting gold standard will be required to train the examiner (Máiréad Harding) in the use of the index

to record toothwear. Dr. Alexander Milosevic who is experienced in the recording of toothwear for large epidemiological studies will conduct the training and calibration programme. Training will be conducted over three days, on the first day slides and study models will be examined. On the second and third day training and calibration will be conducted in a Cork city school. Fifty subjects will be invited to participate; only those subjects who return the completed informed consent form (Appendix 1) and confidential medical history (Appendix 2) will be invited to participate. On the first school visit subjects will be examined for toothwear and the findings discussed, training will be considered complete when the examiner can correctly identify toothwear and score subjects. On the second day at the school subjects will be examined by both Dr. Alexander Milosevic and Dr. Máiréad Harding and inter-examiner reliability calculated using Kappa statistics. The subjects will be re-examined by Dr. Máiréad Harding and intra-examiner reliability calculated.

The recorder will also participate in training and calibration to identify recording errors. Recoding will be directly to a PC notebook.

Training with regard to the collection, storage and separation of saliva samples will be organised within The Oral Health Services Research Centre (OHSRC), Cork University Dental School and Hospital. The OHSRC has considerable experience in this area. The transfer of samples to the Proteomics Research Group Department of Biochemistry University College Cork will adhere to the same strict standard operating procedures as at The OHSRC.

Saliva samples will be collected from subjects during the training and calibration programme, any problems with collection will be identified and corrected.

The questionnaire on oral hygiene habits, dietary habits and behaviours will be piloted during the training and calibration programme. The questionnaire will be available as a direct data entry system onto a PC notebook at that time, this approach is sought following initial piloting of the questionnaire and as it is recognised that the further away the critical eye of the researcher is, the more honest the answers.

Fieldwork: will commence in September 2006 and will continue into February 2007. This

will consist of an oral examination, saliva collection and questionnaire completion. Only those individuals where informed consent has been provided will be considered for participation. The fieldwork will be conducted in secondary schools in Cork and Kerry.

Analysis of data: Once the subject examinations have been completed analysis of the various groups will be conducted. Those in the fluoridated and non-fluoridated groups will be compared. The salivary properties of those with toothwear of varying severity and those without will be compared. The results of the questionnaire will be compared with respect to the varying degrees of severity of wear.

Writing report: Final submission of this project is anticipated for September 2008.

SEQUENCE OF EXAMINATION

1. Validate informed consent.
2. Check that the confidential medical history questionnaire and demographic data form are completed.
3. Check the inclusion and exclusion criteria.
4. Collection of saliva.
5. Soft tissue examination.
6. Toothwear examination.
7. Questionnaire completion.

EQUIPMENT

Saliva Collection: Test-tubes, funnels, test tube racks, indelible marker, ice packs, styrofoam containers, timer, disposable non-latex gloves, disposable wipes, brown tape, wax pellets.

Oral Examination: Lighting: A portable dental light (Daray) lamp with halogen bulb will be used to illuminate the mouth. These lamps will be clamped to the side of the bench and angled for ease of use. A replacement bulb will be carried at all times.
Hand instruments: The probe to be used will be a cpitn probe.

The mirror will be a size 4 head, silvered front surface.
The teeth will be dried using cotton wool rolls.

Eye Protection: All children will wear protective eyewear. These glasses will be wiped with disinfectant and allowed to dry between examinations.

At the school visits subjects will be asked to lie horizontally on a table, which will first have been covered with a light sheet of foam, taped to the table. A clean disposable towel will be placed in the head area and disposed of after each child.

CROSS INFECTION CONTROL

Rigorous cross infection control procedures will be adhered to throughout the saliva collection and oral examination. Disposable non-latex gloves will be used at all times. Disinfectant wipes will be used to wipe surfaces in the immediate vicinity of the saliva collection area and the examination area.

Gloves will be worn for the examination of each subject and changed for each subject. A facemask will be worn and changed every hour. A disposable paper sheet will be used under each set of instruments and disposed of after each subject. The used cpitn probes and mirrors will be washed and autoclaved at the end of sessions. Two plastic boxes for instruments will be used. One box for transporting sterile instruments only and must be sterilised if contaminated, the other box for contaminated instruments. All contaminated waste will be disposed of into a standard "yellow" bag including used gloves and any tissues or wipes after examination.

INFORMED CONSENT

The Parent or Guardian of each child will be fully informed with regard to the nature of the study. Consenting Parents or Guardians will be asked to sign an informed consent form (Appendix 1) prior to any examination. The confidential medical history questionnaire

(Appendix 2) must be completed prior to the intra-oral examination. The teenagers will be given the opportunity to decide for themselves whether they wish to participate. If participating they too will sign the informed consent form.

INCLUSION CRITERIA

1. Subjects must be adolescents in the selected classes, for whom consent is given by the parent / guardian and themselves.
2. Subjects must be in good general health without any known allergy to commercial dental products or cosmetics.
3. Subjects must be able and willing to co-operate in all study procedures.
4. Parents / guardians of subjects must read, understand and sign the informed consent form.

EXCLUSION CRITERIA

1. Subjects expressing any unwillingness, inability, or lack of motivation to participate in the study procedures as described in the protocol
2. Any subject whose parent / guardian does not give written consent.
3. Severe generalized gingival bleeding or pain.
4. Oral pathology including, but not limited to, acute ulcerative gingivitis, acute herpetic gingivostomatitis.
5. Subjects with a history of cardiac surgery, rheumatic fever, or other circumstances for which a bacteraemia induced by probing the gingiva might pose a threat.
6. Any other condition which the investigator feels should preclude participation in the study (Appendix 3).

PARAMETERS TO BE RECORDED

Toothwear: It is generally agreed that in the teenager toothwear is predominantly although not exclusively associated with an erosive aetiology and the tooth surfaces frequently affected are the smooth surfaces of the anterior teeth and the occlusal surfaces of the first permanent molars. However it must be remembered the affects of abrasion and attrition will be

contributory. The choice of index will be one which will record toothwear on the labial, palatal and incisal surfaces of the upper six and lower six anterior teeth and the occlusal surfaces of the first permanent molars (Steele and Walls, 2000; Bardsley et al, 2004).

Saliva Variables: Unstimulated and stimulated salivary samples will be collected from the consenting participants.

METHODS

Study population: The study will be a cross-sectional study using a random representative cluster sample of transition year teenagers in the Cork and Kerry counties. The sample will be stratified on age, gender and school location. A two-stage sampling process will be used to ensure both fluoridated and non-fluoridated schools will be included. It is proposed to examine 800 children in the Cork and Kerry counties.

DIAGNOSTIC SYSTEMS

Toothwear:
A descriptive partial index will be used to record toothwear, the system will be the index proposed by Dr. Alexander Milosevic (Bardsley et al, 2004). Scores will be recorded on the upper and lower six anterior teeth; upper right canine to upper left canine and lower left canine to lower right canine, on the surfaces labial incisal and palatal and on the occlusal surfaces of the four first permanent molars.

The index teeth will be dried using cotton wool rolls, examination will commence with the upper right first permanent molar and move to the upper right permanent canine, the upper right lateral incisor, the upper right central incisor, the upper left central incisor, the upper left lateral, the upper left canine, the upper left first permanent molar and then move to the lower left first permanent molar along to the six lower anterior teeth and finish with the lower right first permanent molar. A score will be given for the occlusal surface of each first permanent molar, and the labial incisal and palatal/lingual surface of the upper six and lower six anterior teeth. When a tooth is absent or cannot be scored that will be noted (Appendix 4).

Analyses and Laboratory investigation of saliva:

Unstimulated and stimulated salivary samples will be collected from consenting participants. Those participating in the study will be instructed to refrain from toothbrushing from 9 pm on the previous evening (Appendix 1), this will be done in order that fluoride levels can be standardised. Also to ensure standardisation in timing, the collection of saliva will occur at the same time each day, prior to the mid-morning break. It is anticipated that at least 6 teenagers will be sampled together permitting between 20 and 30 samples x 2 (unstimulated and stimulated) to be collected each day.

When taking the unstimulated sample the group will be first asked to swallow the saliva in their mouths, they will then be asked to drool saliva into a receptacle for at least 5 minutes or until 1.5 mls of saliva has been collected. Following collection of the unstimulated sample participants will be given a wax pellet to chew for one minute and asked to swallow all the saliva in their mouths. The participants will then be asked to expectorate all the saliva that accumulates in the mouth into another receptacle while chewing on the wax pellet for a further three minutes. Flow rate will also be calculated from the time taken and weight unstimulated sample. Each receptacle will be marked with the subject identification number, initials, date of birth, date of sampling, type of sampling, time of sampling, the amount of time taken to collect 5mls and whether the sample is stimulated or unstimulated (Appendix 5). The tubes will then be packed in styrofoam boxes with frozen ice packs.

The saliva samples will be transported within 24 hours to the Oral Health Services Research Centre (OHSRC) the receptacles which will have been weighted prior to the collection of unstimulated saliva will be re-weighted. The weight of collected saliva and the time taken to collect it will be used to determine the flow rate. Samples will be frozen at -20^{0} celsius until the time of analyses firstly samples will be analysed for sodium fluoride levels at the OHSRC using a direct method. Measurements will be recorded three times and the average of the second and third reading will be taken as the measurement. If necessary the first reading will be used to determine the appropriate standard interval.

Ion chromatography will be used to determine the calcium and phosphate ion content in the saliva at the OHSRC.

The Department of Biochemistry; The Proteomics Research group will carry out the analyses of salivary proteins mucins and non-mucins using gel electrophoresis (SDS PAGE) and protein will be visualised by staining with Periodic Acid Schiff reagent (PAS). Western

blotting will identify individual proteins.
The oxidative stress and carbonylation of salivary proteins will be conducted by The Proteomics Research Group, such investigations being conducted because such changes in salivary proteins have been associated with pathology (Battino et al, 2002).
The presence, oxidative stress and carbonylation of the different salivary proteins will be related to the other salivary measurements and toothwear on the recorded surfaces.
The collection of saliva will occur prior to the examination for toothwear.

DATA MANAGEMENT

Data in relation to the clinical examination and oral hygiene, dietary habits and behaviours questionnaire (Appendix 6) will be entered directly onto a PC notebook using software specifically designed for this study. The clinical record will be linked to the consent form, medical questionnaire, inclusion and exclusion criteria, demographic data (Appendix 7) oral hygiene, dietary habits and behaviours questionnaire and saliva samples by a unique identifying number.
Data analyses files will be built and the data checked. Back up disks of all data will be maintained.

DATA MEASUREMENT AND RECORDING

General Information: Teenagers' initials, represented by the initial of first name, middle name and then surname, will be entered onto the PC notebook, as follows:

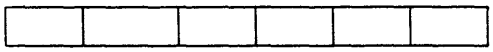
1Initial, 2Initial, Surname

Codes:

Subject Number: Each child will be given a discreet six digit number. This number must be entered onto the PC notebook. The following numbering system will be adopted.

Subject Number:

The six boxes for the subject number should be completed as follows:



School, Class, Child number within the class group.

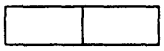
The 1st and 2nd digit will correspond to the number given for each participating school.

The 3rd digit will correspond to the class in which the child is in, at school.

Class in school: Code 1 = Transition year.

The 4th, 5th and 6th digits denote the child being examined. The first child examined will be identified as 001.

School Number: Each School will be given a number. The following system will apply.



School

Schools in non-fluoridated areas will be coded 1 to 30.

Schools in fluoridated areas will be coded 21 to 60.

Examiner Number: The examiner (Máiréad Harding [M.H.]) will be given a two-digit code number: 01

Sex: Male will be recorded: Code 1

Female will be recorded: Code 2.

Reproducibility: Five percent of subjects will be re-examined; each first examination will be designated code 1. Duplicate examinations will be designated code 2. A Kappa statistic will be calculated to determine intra-examiner reproducibility. Only code 1 results will be included in the statistical analyses of prevalence and severity.

Fluoride History: From the demographic data form, the recorder will see if the subject has ever used supplemental fluoride, such as tablets.

No Fluoride: Code 1

Fluoridated water: Code 2

Fluoride Supplements: Code 3

Oral hygiene, dietary habits and behaviours questionnaire: When the subject's toothwear examination is complete, the subject will complete this questionnaire; which will be answered directly onto a PC notebook.

Confidential medical history questionnaire: This will be taken home from school by each participating teenager and completed by the parent / guardian of the teenager.

Social Class: This will be dichotomous. It is established from the demographic data form (whether or not the family possesses a Medical Card a surrogate for disadvantage).

Statistical Analyses: The prevalence of toothwear in both the fluoridated and non-fluoridated groups will be identified; differences between these two groups will be identified using a non-parametric (chi-squared) test. Subjects will be divided into groups dependent on the sites affected and on the severity of toothwear present. Logistic regression analyses will be conducted investigating differences between these groups and the results of the oral hygiene, diet and behaviours questionnaire. Non-parametric tests will be used to investigate differences between groups and their saliva properties.
The level of statistical significance will be 5%.

During the study if oral conditions requiring urgent attention are observed, the parent / guardian of the child will be informed. Whether any soft tissue abnormalities were present will be noted on the soft tissue record form (Appendix 8).

APPENDICES

Appendix 1: Informed consent form for training and calibration

Informed consent form for main study

Letter to Parents / Guardian

Letter to School Principal

Letter to Board of Management or Parents Council

Letter to Parents / Guardian, Re; Training and calibration

Letter to Parents / Guardian, Re; Refrain from toothbrushing

Appendix 2: Confidential medical questionnaire

Appendix 3: Inclusion / Exclusion criteria

Appendix 4: Toothwear Record

Appendix 5: Saliva Sample identification

Appendix 6: Oral healthcare, dietary habits and behaviours.

Appendix 7: Demographic data form

Appendix 8: Soft Tissue Record

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Appendix 4:

Is Tooth Erosion in Primary Teeth Predictive of Tooth Wear in Permanent Teeth? Follow-up to A Cross Sectional Survey Of The Prevalence And Severity Of Tooth Erosion And The Prevalence Of Dental Caries In A Sample Of 5-Year-Old Children In The Cork City And County Regions (Protocol OHSRC00806)

Is Tooth Erosion in Primary Teeth Predictive of Tooth Wear in Permanent Teeth?

Follow-up to A Cross Sectional Survey Of The Prevalence And Severity Of Tooth Erosion And The Prevalence Of Dental Caries In A Sample Of 5-Year-Old Children In The Cork City And County Regions.

Protocol number OHSRC00806

Oral Health Services Research Centre
National University of Ireland, Cork

Is Tooth Wear (Tooth Erosion) in Primary Teeth Predictive of Tooth Wear (Tooth Erosion) in Permanent Teeth?

Follow up to A Cross Sectional Survey Of The Prevalence And Severity Of Tooth Erosion And The Prevalence Of Dental Caries In A Sample Of 5-Year-Old Children In The Cork City And County Regions.

INTRODUCTION:

This study is planned as a follow-up to the study "A Cross Sectional Survey Of The Prevalence And Severity Of Tooth Erosion And The Prevalence Of Dental Caries In A Sample Of 5-Year-Old Children In The Cork City And County Regions" (Protocol number OHSRC00500). That survey, conducted in 2000 / 2001, investigated whether there is an association between dietary habits and the prevalence of caries and tooth erosion in a sample of 200 five-year-old children in the Cork City and County region, and whether water fluoridation affects the prevalence. It also examined prevalence in relation to urban or rural populations and the respondents' socioeconomic status.

The survey found a high prevalence of dental caries and dental erosion in the studied population. Both dental caries and dental erosion were significantly associated with dietary practices, and dental decay was significantly associated with oral hygiene practices and urban / rural domicile (Harding 2001, Harding et al 2003).

This follow-up survey will investigate whether there is an association between the recorded prevalence and severity of tooth wear (tooth erosion) in the primary teeth of these children and observed levels in the permanent teeth. It will also assess the association between dietary habits and the prevalence of tooth wear in the

permanent teeth, and whether water fluoridation affects the prevalence. The survey will also examine prevalence in relation to urban or rural populations and the respondents' socioeconomic status.

BACKGROUND

Tooth wear is an all-encompassing term used to describe the non-carious loss of tooth tissue, which may have occurred due to erosion (the dissolution of teeth by acids), attrition (the wear of tooth against tooth), abrasion (the wear of teeth from other factors) and abfraction (the non-carious loss of cervical tooth tissue, possibly associated with occlusal loading) (Smith et al, 1989; Bartlett et al, 2006).

It is now generally agreed that in epidemiological studies it is not possible to make clear distinctions between these different categories of wear, particularly in the permanent teeth. Tooth wear in this study will therefore be reported collectively rather than by the individual types of wear.

There is concern that tooth wear in children and adolescents is increasing in the recent national survey (2002) of children's oral health in the Republic of Ireland (In press), it was found that 17% of 12-year-olds had tooth wear on their upper central incisors that had progressed into the dentine. .

Although in the national survey no association with diet was identified, the aetiology has been associated with diet and an increase in the consumption and frequency of acidic food and drink, this dietary change has however been identified on a population basis (Kelleher et al, 2003). Worryingly surfaces softened by an increased chemical attack will abrade at a faster rate (Kelly and Smith, 1988).

The Department of Health (DH) Children's Dental Health in the United Kingdom 2003 survey revealed tooth surface loss (tooth wear) to be a problem in the deciduous, mixed and permanent dentitions of the children and young adults examined (http://www.nationalstatistics.org).

Personnel

Investigator

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Principal Investigator	Dr. Helen Whelton
Co-Investigator	Dr. Mairead Harding
Clinical Examiner	Dr. Mairead Harding
Recorder	To be decided
Statistician	To be named

Study Design

This study is a follow up to the study "A Cross Sectional Survey Of The Prevalence And Severity Of Tooth Erosion And The Prevalence Of Dental Caries In A Sample Of 5-Year-Old Children In The Cork City And County Regions" Protocol number OHSRC00500. The study design adopted in OHSRC00500 will be replicated, though in this new study tooth wear rather than tooth wear and dental caries will be examined.

Tooth wear will be measured using an index adapted from the Smith and Knight Tooth Wear Index [TWI] (1984); (Bardsley et al, 2004), and the Exact Tooth Wear Index [ETWI] developed by GlaxoSmithKline Research and Development.

The relationship between dietary habits, oral hygiene practices, gender, fluoride status and socioeconomic status will also be explored.

Sample population

The sample of 200 children examined in study OHSRC00500 will be followed up. These children were aged 5 years when first examined in late 2000 / early 2001, they will be aged 11 / 12 years in late 2006 / early 2007. At age 11 or 12 years, it is expected that eruption of the permanent incisors and first molars will have taken place. Canines and first and second premolars may be erupted. Second molars will probably not be erupted, and third molars will not be erupted.

The children should still be attending National School and will be contacted via their schools in Cork city and County.

Aim of the study

To determine whether tooth erosion in the primary teeth is predictive of tooth wear in the permanent teeth in a sample of 11/12 year old children for whom tooth erosion, dental caries, dietary habits and practices and oral health knowledge, attitudes, and behaviour data was collected at age 5 years.

Objectives:

1. To measure the prevalence of tooth wear in the sample of children previously examined at age 5 years
2. To measure the severity and distribution of tooth wear
3. To assess the association between water fluoridation and tooth wear
4. To assess the dietary habits and practices of the children previously assessed at age 5 years
5. To assess whether there is a relationship between particular dietary habits and tooth wear
6. To assess the relationship between the oral health knowledge, attitudes, and behaviour of the children previously examined at age 5 years and tooth wear
7. To assess the relationship between tooth wear and socioeconomic status
8. To assess whether tooth erosion / tooth wear in the primary teeth is associated with tooth wear in the permanent teeth
9. To provide information for the ongoing monitoring of tooth wear in the Cork City and County regions

Timetable

Ethics Approval: submission 16th April 2007; meeting 1st May 2007.

Training and Calibration Programme: April 2007

Fieldwork to commence. May 2007.

Writing of Report. First Draft September 2007.

Training and Calibration

A Training and Calibration programme will be conducted, study models and photographs will be first used, followed by the examination of three to four subjects, so that the examiner can confidently examine for toothwear using the ETWI. The examiner has previously been trained in a modified TWI developed by Bardsley et al (2004). Ten to fifteen subjects will then be examined to determine the degree of reproducibility between the fieldwork examiner and the trainer. During this exercise the questionnaire will be piloted and problems identified will be corrected. A direct data entry system will be adopted for recording.

Fieldwork

Fieldwork will be conducted during May and June 2007 in National Schools in the Cork City and County areas.

Sequence of Examination:

1. Check Informed Consent is signed.
2. Check Confidential Medical History Questionnaire, Oral Hygiene and Dietary Habits and Practices Questionnaire and Demographic Data Form are completed.
3. Check Inclusion / Exclusion Criteria.
4. Soft Tissue Examination
6. Tooth Wear examination.

Equipment

Lighting; Daray lamps with halogen bulbs will be used to illuminate the mouth. These lamps will be clamped to the side of the bench and angled for ease of use. A replacement bulb will be carried at all times.

Hand instruments; The probe to be used will be a standard W&H periodontal probe. The mirror will be a size 4 head, silvered front surface.

When required the teeth will be dried using sterile cotton wool rolls.

Eye Protection; All children will wear protective eyewear. These glasses must be wiped with disinfectant between examinations.

Cross Infection Control; Latex free examination gloves will be worn for the examination of each subject and changed for each subject. A facemask will be worn and changed every hour. A disposable paper sheet will be used under each set of

instruments and disposed after each subject. The used CPI probes and mirrors will be washed and autoclaved at the end of morning and afternoon sessions. Two plastic boxes for instruments will be used. One box is for transporting sterile instruments only and must be sterilised if contaminated. The other box is for contaminated instruments. All contaminated waste will be disposed of into a standard " yellow" bag with used gloves and any tissues or wipes after examination.

At the school visits subjects will be asked to sit on the portable dental chair (Aseptico Portable Dental Equipment). A clean disposable head rest cover will be placed in the head area and disposed of after each child.

The light will be clamped to the table in a position that will enable it to be angled towards the mouth. Light handles will be wiped with disinfectant wipes between subjects.

Informed Consent

The Parent / Guardian of each child will be fully informed regarding the nature of the study. Consenting Parents / Guardians will be asked to sign an informed consent form (Appendix 1) prior to any examination. The Confidential Medical History Questionnaire (Appendix 2) must be completed prior to the intra-oral examination.

Inclusion Criteria

1. Subjects must be children who participated in the original study, Protocol number OHSRC00500.
2. Subjects must be in good general health without any known allergy to commercial dental products or cosmetics.
3. Subjects must be able and willing to co-operate in all study procedures.
4. Parents / guardians of subjects must read, understand and sign the informed consent form. The child must also indicate his/her assent by signing the consent form.
5. Subjects on inhaled oral steroids will be included they shall be identified from their medical history.
6. Teeth: Surfaces orthodontically banded, abutment teeth, teeth with overhanging or subgingival margins are not scorable.

Exclusion Criteria

1. Subjects expressing any unwillingness, inability, or lack of motivation to participate in the study procedures as described in the protocol
2. Any subject who does not give written assent or whose parent / guardian does not give written consent.
3. Severe generalized gingival bleeding or pain.
4. Oral pathology including, but not limited to, acute ulcerative gingivitis, acute herpetic gingivostomatitis, history of recurrent aphthous ulcerations or systemic disease with oral manifestations.
5. Subjects with a history of Rheumatic fever, prosthetic heart valves or prosthetic joint replacement or other circumstances for which a bacteraemia induced by probing the gingiva might pose a threat.
6. Any other condition which the investigator feels should preclude participation in the study.

Guidelines for diagnostic criteria

Tooth Wear (index adapted from the Smith and Knight Index): The four first permanent molars, the six upper anterior and six lower anterior teeth will be examined. Each tooth surface susceptible to tooth wear is assessed by visual examination. The teeth are dried using cotton wool rolls, and examined under the Daray lamp as light source. The examiner should commence examinations on the upper right, and progress to the upper left, then lower left and continue around the lower arch to finish at the lower right first permanent molar, or the lower right second permanent molar if present. The examiner may have to use clinical judgement regarding tooth morphology, and take into account the subject's previous dental history if doubt exists as to the correct notation for a particular tooth.

All index teeth present will be examined. A tooth is considered to be present once it has penetrated the mucosa. Where teeth cannot be scored, if they are extensively decayed, have large restorations are traumatised, or have orthodontic bands in place they are given the score N, i.e. they cannot be scored but are not missing.

Tooth Status Code:

Existence of teeth

Code	A	Permanent tooth present
	P	Deciduous tooth present
	U	Permanent tooth unerupted
	E	Permanent tooth extracted due to caries
	T	Missing due to trauma
	M	Tooth lost due to other reasons
	C	Crown present
	V	Veneer present

Preface to Surface Condition Score

A condition score will be given to the buccal/labial, lingual/palatal and the occlusal or incisal surface of each index tooth present. Tooth wear will have progressed to dentine before a score is assigned using the index as described by Bardsley et al (2004).

- Score 0 – Loss of enamel surface characteristics but NO dentine visible
- Score 1 – Dentine is visible <1/3rd . Cupping on molar cusp tips. Change in colour
- Score 2 - >1/3rd dentine exposed
- Score 3 – Pulp or secondary dentine exposed
- Score N – Missing/restored/, could not be assessed

*If in doubt a lower score is given, (Direct Data Entry, software programme developed by Alastair Davies 6 Ash Lane Mullingar)

Once the teeth have been scored using the index as described by Bardsley et al (2004), the children will rest for 5 minutes, before the next examination is conducted.

Exact Tooth Wear Index (ETWI) developed by GlaxoSmithKline):
The primary purpose of the new index is to be a research tool for trained examiners, as a method for identifying early tooth wear within enamel and dentine. The index grades all permanent teeth within the mouth except third molars, unless the first or second permanent molars are absent.

For each tooth, the index grades 4 individual surfaces

Buccal- assessment includes the cervical buccal portion

Buccal cervical = cervical 1/3rd of tooth

Palatal /Lingual

Incisal / Occlusal

Where dental restoration(s) occupy greater than 25% (1/4) of the specific surface area, that surface will not be scored and marked 'R'. Tooth wear in the enamel and dentine will be scored separately. The dental examiner is trained to score the enamel first, then dentine and finally the cervical area. For the cervical buccal area tooth wear is assessed in terms of enamel, dentine and depth. The examiner is trained to score tooth wear in enamel first, then dentine and finally depth of any area of wear

(A) ETWI INDEX FOR ENAMEL:

0 - no tooth wear: no loss of enamel characteristics or change in contour

1 - loss of enamel affecting less than 1/10th of the scored surface

2 - enamel loss affecting less than 1/3rd of the scored surface

3 - enamel loss affecting at least 1/3rd but less than 2/3rd of the scored surface

4 - enamel loss affecting 2/3rd or more of the scored surface

(B) ETWI INDEX FOR DENTINE:

0 - no dentinal tooth wear: no loss of dentine

1 - loss of dentine affecting less than 1/10th of the scored surface

2 - dentine loss affecting less than 1/3rd of the scored surface

3 - dentine loss affecting at least 1/3rd but less than 2/3rd of the scored surface

4 - dentine loss affecting 2/3rd or more of the scored surface, no pulpal exposure

5 - secondary dentine formation or pulpal exposure

(C) ETWI INDEX FOR DEPTH ON CERVICAL BUCCAL SURFACES: (measured with a standard W&H periodontal probe)

0 - no tooth wear: no loss of tooth surface

1 - less than 1mm loss of tooth surface depth

2 - tooth surface loss in depth measuring at least 1mm but less than 2mm

3 - tooth surface loss in depth measuring 2mm or greater

At the time of analysis Children will be divided into groups where:

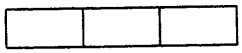
Mild tooth wear, moderate tooth wear and severe tooth wear will be considered.

Data Management

Data will be entered directly onto a lap top PC. Data Analysis Files will be built and the data checked. Back up disks of all data will be maintained.

Data Measurement and Recording

General Information; The Child's initials, represented by initial of first name, middle name and then surname, will be entered at the top of the first page, as follows:



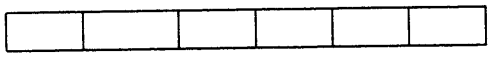
1Initial 2Initial Surname

Codes

Subject Number Each child will be given a discreet six digit number. This number must be entered at the top of each page of the record in the space provided and on the Lap Top data entry screen. The following numbering system will be adopted.

Subject Number

The six boxes for the subject number should be completed as follows:



School, Class, Child number within the class group.

The 1st and 2nd digit will correspond to the number given for each participating school.

The 3rd digit will correspond to the class in which the child was in school at the time of the initial study.

Class in school

Code 1 = Junior Infants

Code 2 = Senior Infants.

The 4th, 5th and 6th digits denote the child being examined. The digits assigned to each child in study OHSRC00500 will be used.

School Number

The school numbers assigned in study OHSRC00500 will be used.

Examiner Number

The examiner will be given a two-digit code number: 01

Sex

Male will be recorded, Male from drop down menu

Female will be recorded, Female from the drop down menu on the direct data entry screen

Reproducibility

5% of subjects will be re-examined. Each first Examination will be designated Code 1. Duplicate examinations will be designated Code 2. A Kappa statistic will be calculated to determine intra-examiner reproducibility. Only Code 1 results will be included in the statistical analyses of prevalence and severity.

Fluoride History

From the consent form, the recorder will see if the subject has ever used supplemental fluoride, such as tablets.

No Fluoride, Code 1

Fluoridated water, Code 2

Fluoride Supplements, Code 3

Oral Hygiene and Dietary Practices Questionnaire

This will be taken home from school by each child and completed by the child at home (Appendix 3).

Confidential Medical History Questionnaire

This will be taken home from school by each child and completed by the Parent / Guardian of the child (Appendix 2)

Social Class

This will be dichotomous. It will be established from the demographic data form (whether or not the family possesses a Medical Card).

Statistical Analysis

Tooth wear

A statistical analysis of the differences between groups will be undertaken using non-parametric (chi-squared) tests. The proportion of children with 1 or more lesions will be compared.

Tooth wear scored using the TWI described by Bardsley et al (2004) will be compared with the findings reported for the children when examined in 2000/2001 and similarly tooth wear scored using the ETWI (GSK Research and Development) will be compared with the findings reported for the children when examined in 2000/2001.

Sample size calculation

A sample size of 200 children was used in study OHSRC00500. This sample will be followed-up in the proposed study.

APPENDICES

Informed Consent Form (Appendix 1)

Confidential Medical Questionnaire (Appendix 2)

Oral Hygiene and Dietary Practices Questionnaire (Appendix 3)

Demographic Data Form (Appendix 4)

CRF (Appendix 5) Direct Data Entry; Software developed by Alastair Davies 6 Ash Lane Mullingar

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Department of Health (DH) Children's Dental Health in the United Kingdom 2003. Department of Health (DH), On-line edition, ONS, UK. . (http://www.nationalstatistics.org.uk/STATBASE/Product.asp?vink=12918)

Harding MA The prevalence of dental caries and tooth wear (dental erosion) in a sample of 5-year-old children and potential risk factors. *Dissertation submitted in part fulfilment of the requirements for the Degree of Master of Dental Public Health in the Faculty of Medicine University College Cork. April 2001*

Harding MA, Whelton H, O'Mullane DM, Cronin M. Dental erosion in 5-year old Irish children and associated factors: a pilot study. *Community Dental Health. 2003 Sep;20(3):165-70*

Kelleher, C., Nic Gabhainn, S., Friel, S., Corrigan, H., Nolan, G., Sixsmith, J., Walsh, O. & Cooke, M (2003). The National Health and Lifestyle Surveys (II) Survey of Lifestyle, Attitudes and Nutrition (SLÁN) and the Irish Health Behaviour in School-Aged children survey (HBSC). Department of Health and Children: Dublin. Department of Health and Children: Dublin.

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Smith, B.G. (1989): Toothwear: aetiology and diagnosis. Dental Update; 16(5):204-212.

H. Whelton, E. Crowley, D. O'Mullane, M. Harding, H. Guiney, M. Cronin, E. Flannery, V. Kelleher. North-South Survey of Children's Oral Health 2002. Oral Health Services Research Centre, University College, Cork, Ireland. (In press)

Protocol Amendment:

Is Tooth Erosion in Primary Teeth Predictive of Tooth Wear in Permanent Teeth? Follow-up to A Cross Sectional Survey Of The Prevalence And Severity Of Tooth Erosion And The Prevalence Of Dental Caries In A Sample Of 5-Year-Old Children In The Cork City And County Regions (Protocol OHSRC00806)

PROTOCOL AMENDMENT

Is Tooth Erosion in Primary Teeth Predictive of Tooth Wear in Permanent Teeth? Follow-up to A Cross Sectional Survey Of The Prevalence And Severity Of Tooth Erosion And The Prevalence Of Dental Caries In A Sample Of 5-Year-Old Children In The Cork City And County Regions.
Protocol No: OHSRC00806

We propose to amend the protocol to include the taking of intra-oral photographs depicting the range of toothwear encountered in a subsample of children to be examined as part of the study.

The study sponsor plans to use these photographs for the purposes of internal staff training and also possibly externally in promotional material for an oral health care product currently under development.

Photographs will be taken using a digital camera and mouth mirrors. No discomfort on the part of the participants is anticipated.
The identity of the participant will not be obvious to anyone viewing the photographs, nor will it be disclosed in any publications that may be made regarding the study.

Signed: _____ Date: _____
Principal Investigator

Signed: _____ Date: _____
Sponsor's Representative

University College Cork, Ireland
Coláiste na hOllscoile Corcaigh

CORA
Cork Open Research Archive
Cartlann Taighde Oscailte Chorcaí

Harding, M. A. 2015. *Tooth wear in Irish teenagers: a laboratory and epidemiological study*. PhD Thesis, University College Cork.

Please note that Appendix 4a is unavailable due to a restriction requested by the publisher of the following paper.

Harding, MA, Whelton, HP, Shirodaria, SC, O'Mullane, DM,Cronin, MS; (2010) 'Is tooth wear in the primary dentition predictive of tooth wear in the permanent dentition? Report from a longitudinal study'. Community Dental Health, 27 :41-45 http://www.cdhjournal.org/view.php?journal_id=26

CORA Cork Open Research Archive http://cora.ucc.ie

University College Cork, Ireland
Coláiste na hOllscoile Corcaigh

CORA
Cork Open Research Archive
Cartlann Taighde Oscailte Chorcaí

Harding, M. A. 2015. *Tooth wear in Irish teenagers: a laboratory and epidemiological study*. PhD Thesis, University College Cork.

Please note that Appendix 4b is unavailable due to a restriction requested by the publisher of the following paper.

Bartlett, D, Harding, M, Sherriff, M, Shirodaria, S, Whelton, H; (2011) 'A new index to measure tooth wear - methodology and practical advice'. Community Dental Health, 28 :182-187
http://dx.doi.org/10.1922/CDH_2552Bartlett06

CORA Cork Open Research Archive http://cora.ucc.ie

Tooth Wear: A Prospective Cohort Study

A Follow-up to A Cross Sectional Survey Of The Prevalence And Severity Of Tooth Wear in the permanent dentition of 12-year-olds, who were also examined as five-year-olds.

Protocol number OHSRC00409

Oral Health Services Research Centre
National University of Ireland, Cork

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Tooth Wear: A Prospective Cohort Study

A Follow-up to A Cross Sectional Survey Of The Prevalence And Severity Of Tooth Wear in the permanent dentition of 12-year-olds, who were first examined as five-year-olds.

INTRODUCTION:

This study is planned as a follow-up to the study 'Is Tooth Erosion in Primary Teeth Predictive of Tooth Wear in Permanent Teeth?' (Protocol number OHSRC00806). That study conducted in 2007/2008 found that 45% had tooth wear with some enamel loss and enamel was worn so that dentine was visible in 40% of the twelve year-olds using the Exact Tooth Wear Index (Fares et al, 2009) and using the TWI as modified by Bardsley et al (2004) 38% had at least one tooth with dentine exposed. Tooth wear is an all-encompassing term used to describe the non-carious loss of tooth tissue, which may have occurred due to erosion (the dissolution of teeth by acids), attrition (the wear of tooth against tooth), abrasion (the wear of teeth from other factors) and abfraction (the non-carious loss of cervical tooth tissue, possibly associated with occlusal loading) (Smith et al, 1989; Bartlett et al, 2006).

As it is now generally agreed that in epidemiological studies it is not possible to make clear distinctions between these different categories of wear, tooth wear in this study similar to the reporting at twelve year of age will be reported collectively rather than by separating out the individual types of wear.

Tooth wear increases with age, national data showed that 17% of 12-year-olds and 29.7% of 15-year-olds had tooth wear that had progressed into the dentine on their

upper central incisors (Whelton et al, 2006). Longitudinal data on tooth wear is limited and we do not have information on the progression in enamel from longitudinal studies. Such information is necessary due to changing dietary practices, children are consuming soft drinks frequently and changing lifestyles have contributed to a more acidic diet. Coupled with increased longevity and the individual's desire to retain their own teeth throughout life, it is critical to increase the knowledge base on tooth wear progression.

From the data collected at the two previous time points of this prospective cohort study we identified that the children with tooth erosion at five years of age were more likely to have tooth wear in their permanent teeth (Harding et al, in press), the study also identified that tooth wear was more likely in males, and in those in possession of a medical card, which is the measure we used for low socio-economic status. Along with our increased concern regarding tooth wear in children and adolescents, dental caries is still of concern in Ireland (Whelton et al, 2006). As dental caries was examined in this group at age 5, we propose recording dental caries also at this time point.

Personnel

Investigator site

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Principal Investigator	Prof.. Helen Whelton
Co-Investigator	Dr. Máiréad Harding
Clinical Examiner	Dr. Máiréad Harding
Recorder	To be decided
Statistician	To be named

Study Design

This study is a follow up to the study "Is tooth erosion in the primary teeth predictive of tooth wear in permanent teeth? A follow-up to a cross-sectional survey of the prevalence and severity of tooth erosion and dental caries in a sample of five-year-old children in the Cork city and county region." (OHSRC00806). The study design adopted in OHSRC00806 will be replicated, although in this new study both tooth wear and dental caries will be examined, similar to the examination at age five.

Tooth wear will be measured using an index adapted from the Smith and Knight Tooth Wear Index [TWI] (1984); (Bardsley et al, 2004), and the Exact Tooth Wear Index [ETWI] (Fares et al, 2009). Dental caries will be measured using standardised methods used in epidemiological surveys.

The relationship between dietary habits, oral hygiene practices, gender, fluoride status and socioeconomic status will also be explored.

Photographs will be taken using a digital camera and mouth mirrors to compare images taken at different time points and to assist with education and training. The identity of the participant will not be obvious to anyone viewing the photographs, nor will it be disclosed in any publications that may be made regarding the study.

Sample population

The sample of 136 children that consented to follow-up in study OHSRC00806 will be invited to participate. The children examined had a mean age of 12.01 (±0.32) years in late 2007. At age 12 years the permanent incisors and first molars were present, canines, first and second premolars had erupted in some subjects. It is expected that at age 14 years the full permanent dentition except third molars will have erupted. All children who consented to examination in study OHSRC00806 will be invited to participate in the next phase although they may not have been examined at age 12 due to absence on the day we visited the school or incomplete forms. The children will have commenced their secondary education and contact will be made through the home address previously provided.

Aim of the study

The aim of this study is to establish the prevalence of tooth wear in a cohort of 14-year-olds, first examined when they were five-years-old and to compare the results

with the findings for tooth wear in their permanent teeth examined at age 12-years and the primary teeth at five years of age.

The prevalence of dental caries in the permanent teeth of the 14-year-olds will be measured and compared with the results at five years of age.

Objectives:

1. To measure the prevalence of tooth wear in the sample of children previously examined at age 12 years.
2. To measure the severity and distribution of tooth wear.
3. To assess the association between tooth wear in those with fluoridated water and those without.
4. To assess the dietary habits and practices of the children previously examined.
5. To assess whether there is a relationship between particular dietary habits and tooth wear.
6. To assess the relationship between the oral health knowledge, attitudes, and behaviour and tooth wear.
7. To assess the relationship between tooth wear and socioeconomic status.
8. To assess whether there is a progression of tooth wear in the period between the examination at age 12 and age 14.
9. To provide information for the ongoing monitoring of tooth wear in the Cork City and County regions.
10. To measure the prevalence of caries in the permanent teeth at age 14 of

subjects previously examined at age 12 and five.

Timetable

Ethics Approval: submission 19th October 2009; meeting 3rd November 2009.

Training and Calibration Programme: November 2009

Fieldwork to commence. November 2009.

Writing of Report. First Draft March 2010.

Training and Calibration

Dr. Máiréad Harding will conduct the examination, Dr. Harding has been trained and calibrated in each of the indices to be included in the study, further training using photographs and stone models will be undertaken to ensure reliability in identifying the changes in the dental hard tissues. During the study every tenth subject will be re-examined for consistency and reproducibility, an intra-examiner kappa value will be calculated. The questionnaire used at age twelve years will be transferred to an electronic direct data entry format, prior to fieldwork commencing it will be piloted and any problems identified will be corrected. The dental examinations will be entered using the direct data entry system developed for the study at age 12 years.

Fieldwork

Fieldwork will be conducted during November and December 2009 or the early months of 2010 if necessary at the subject's secondary school.

Sequence of Examination:

1. Check Informed Consent is signed.
2. Check Confidential Medical History Questionnaire, Oral Hygiene and Dietary Habits and Practices Questionnaire and Demographic Data Form are completed.
3. Check Inclusion / Exclusion Criteria.
4. Soft Tissue Examination
5. Dental Caries Examination
6. Tooth Wear Examination TWI.
7. Tooth Wear Examination ETWI
8. Photographs of Selected Individuals

Equipment

Lighting; Daray lamps with halogen bulbs will be used to illuminate the mouth. These lamps will be clamped to the side of the bench and angled for ease of use. A replacement bulb will be carried at all times.

Hand instruments; The probe to be used will be a standard W&H probe.

The mirror will be a size 4 head, silvered front surface.

When required the teeth will be dried using sterile cotton wool rolls.

Eye Protection; All children will wear protective eyewear. These glasses must be wiped with disinfectant between examinations.

Cross Infection Control; Personal protective clothing and equipment will be worn by the examiner and recorder; latex free examination gloves will be worn for the examination of each subject and changed for each subject. A facemask will be worn

and changed at frequent intervals. A disposable paper sheet will be used under each set of instruments and disposed of after each subject. All re-usable equipment will be washed and autoclaved at the end of morning and afternoon sessions. All contaminated waste will be disposed of into 'hazardous waste' yellow bags including used gloves, facemasks, cotton wool rolls, tissues or wipes, in accordance with best practice (HSE, 2007).

At the school visits subjects will be asked to sit on the portable dental chair (Aseptico Portable Dental Equipment). A clean disposable head rest cover will be placed in the head area and disposed of after each child.

The light will be clamped to the table in a position that will enable it to be angled towards the mouth. Light handles will be wiped with disinfectant wipes between subjects.

Informed Consent

The Parent / Guardian of each child will be fully informed regarding the nature of the study. Consenting Parents / Guardians will be asked to sign an informed consent form prior to any examination (Appendix 1) and each child will be asked to also sign the informed consent form and an assent form, which will explain to them the nature of the study (Appendix 2). The Confidential Medical History Questionnaire (Appendix 3) must be completed prior to the intra-oral examination.

Inclusion Criteria

1. Subjects must be children who participated in the original study, Protocol number OHSRC00500, and who consented to follow-up in study OHSRC00806.

2. Subjects must be in good general health without any known allergy to commercial dental products or cosmetics.
3. Subjects must be able and willing to co-operate in all study procedures.
4. Parents / guardians of subjects must read, understand and sign the informed consent form. The child must also indicate his/her assent by signing the consent and assent form.
5. Subjects on inhaled oral steroids will be included, they shall be identified from their medical history.
6. Teeth: Surfaces orthodontically banded, abutment teeth, teeth with overhanging or subgingival margins are not scorable.

Exclusion Criteria

1. Subjects expressing any unwillingness, inability, or lack of motivation to participate in the study procedures as described in the protocol
2. Any subject who does not give written assent or whose parent / guardian does not give written consent.
3. Severe generalized gingival bleeding or pain.
4. Oral pathology including, but not limited to, acute ulcerative gingivitis, acute herpetic gingivostomatitis, history of recurrent aphthous ulcerations or systemic disease with oral manifestations.
5. Any other condition which the investigator feels should preclude participation in the study, including at present signs or symptoms of H1N1 virus (Appendix 4)

Guidelines for diagnostic criteria

Dental caries will be recorded first and then tooth wear.

Dental Caries: The examination for caries is largely a visual one. The teeth are examined wet and a CPITN probe is used to remove food debris. The CPITN probe may also be used to confirm cavitation.

The examiner should commence examinations on the upper right, upon the call of the upper right 8 by the recorder. He/she should call the status for each tooth or space following the recorder's call from the upper right 8 (tooth number 1.8) continuing to the upper left (tooth number 2.8). The examiner should then call the status for each lower tooth or space beginning at the lower left 8 (3.8) and proceed to the lower right 8 (4.8). It should be noted that although the FDI international system of numbering teeth has been used the recorder may call 8, 7, 6 etc. to retain simplicity without causing confusion. The examiner may have to use clinical judgement regarding tooth morphology, and take into account the subjects previous dental history if doubt exists as to the correct notation for a particular tooth. However when such doubt exists where there are missing molar teeth the third molar should be assumed to be unerupted rather than recording first or second molar teeth missing due to caries. This will result in an underscoring of caries prevalence rather than an over scoring.

<u>Tooth Status Code -</u>

Existence of Teeth

Code	A	Permanent tooth present
	P	Deciduous tooth present
	U	Permanent tooth unerupted or congenitally absent

E	Permanent tooth extracted due to caries
G	Permanent tooth extracted due to perio disease
M	Permanent tooth missing due to other reasons
R	Deciduous tooth present with a sinus tract

Preface to Surface Conditions Coding

A condition code will be given to each surface of each tooth present. The crown has 4 surfaces; mesial, distal, buccal and lingual, in the case of incisors and canines. Premolars and molars have an extra surface (occlusal). It will be noted, some tooth codes exclude a need for surface condition coding e.g. if a tooth has been extracted or is congenitally missing the surface condition code will be left blank.

In the case of a partially erupted tooth, score all surfaces present and sound unless there is caries on the erupted portion.

If the score is the same for each surface put the condition number in the first box and draw a line through the rest. No distinction need be made between a deciduous and permanent tooth in the surface condition.

Condition Status - CROWN

The teeth will be examined visually. The CPITN probe may be used to confirm a diagnosis of cavitation to check for sealants or to remove food debris.

Code R - Fissure sealant

A fissure sealant is recorded to be present when it is detectable on a surface and when there is no 'probeable' caries on the same surface.

Code S - No Caries

A surface should be considered sound if it shows no evidence of treated or untreated caries, or if it is at the doubtful stage. These scores will also apply in the case of defects not to be counted as caries:

(a) White and/or chalky spots;

(b) Discoloured or rough spots;

(c) Stained pits or fissures in the enamel that catch the explorer but do not have a detectably softened floor, visibly undermined enamel or softening of the walls.

(d) Dark, shiny, hard pitted areas of enamel in a tooth showing signs of moderate to severe fluorosis.

Code V - Visual Caries

Visual caries is recorded when there is definite evidence of caries into dentine, but where there is no 'probeable' cavity through the enamel. The appearance may vary but will usually look like grey or creamy white shadowing under enamel. Where there is any doubt score sound.

Code D - Decayed, cavity

Caries will be considered to be present in a surface when any lesion has a detectably softened floor, undermined enamel, or softened wall. On an approximal surface, the lesion must be visible and the probe point must enter a lesion with certainty. Where any doubt exists, caries should not be diagnosed as being present.

It must be emphasised that clinical caries is a stage in the process of dental caries. Dental caries proceeds from a microscopic lesion, which cannot be diagnosed positively by present clinical methods, to a cavity (or clinical caries) which can be diagnosed by clinical examination. The upper limit for this category is the complete destruction of the crown. Where only roots remain for deciduous teeth, decayed is recorded only when no permanent successor has erupted.

Dental caries affecting enamel only, such as white spot lesions and other conditions similar to the early stages of caries should be deliberately excluded because they cannot be diagnosed positively and reliably.

Decayed is recorded where a surface contains a temporary filling requiring further treatment, or where a complete filling is lost. (See filled or defective filling). For a primary tooth surface, decayed is recorded even though it is about to be exfoliated.

Code K - Filled Amalgam and Primary Decay

A surface should be classified filled and primary decay when a surface has been filled and another area is carious.

Code L – Filled (restoration non-amalgam) and primary decay

Code Y - Filled Amalgam and Secondary Decay

Surface should be classified filled and secondary decay when there is recurrent caries in contact with a filling.

Code Z – Filled (Restoration non-amalgam) and secondary decay

Code F – Filled Amalgam Restoration

Surfaces should be considered filled whenever a filling or any permanent material is present and there is no discrete or recurrent caries. A defective filling where there is no discrete or recurrent caries e.g. cracked or partly missing, is scored F with the appropriate treatment code indicating the replacement restoration required.

Code G – Filled – Non-amalgam restoration

Code C - Crowned

All surfaces should be placed in this category if a tooth has full crown (intended total crown coverage) in a permanent material and including bridge abutments except where the reason for the crown is trauma.

Code Q - Crowned and Decayed

A surface should be scored as crowned and decayed when caries is contiguous with the crown.

Code T - Trauma

A permanent surface should be recorded 'trauma' if part of its substance is missing for reasons other than treated or untreated caries and the latter condition is not present. T is the score for all surfaces where a crown is present due to trauma.

Code X - Excluded

This category should be used for teeth, which cannot be properly examined (i.e. impacted teeth or teeth which have been banded for orthodontic reasons).

Tooth Wear (index adapted from the Smith and Knight Index): The four first permanent molars, the six upper anterior and six lower anterior teeth will be examined. Each tooth surface susceptible to tooth wear is assessed by visual examination. The teeth are dried using cotton wool rolls, and examined under the Daray lamp as light source. The examiner should commence examinations on the upper right, and progress to the upper left, then lower left and continue around the lower arch to finish at the lower right first permanent molar, or the lower right second permanent molar if present. The examiner may have to use clinical judgement regarding tooth morphology, and take into account the subject's previous dental history if doubt exists as to the correct notation for a particular tooth.

All index teeth present will be examined. A tooth is considered to be present once it has penetrated the mucosa. Where teeth cannot be scored, if they are extensively decayed, have large restorations are traumatised, or have orthodontic bands in place they are given the score R, i.e. they cannot be scored but are not missing.

Tooth Status Code:

Existence of teeth

Code	A	Permanent tooth present
	P	Deciduous tooth present
	U	Permanent tooth unerupted
	E	Permanent tooth extracted due to caries
	T	Missing due to trauma
	M	Tooth lost due to other reasons
	C	Crown present
	V	Veneer present

Preface to Surface Condition Score

A condition score will be given to the buccal/labial, lingual/palatal and the occlusal or incisal surface of each index tooth present. A score is assigned using the index as described by Bardsley et al (2004) once tooth wear has progressed to dentine.

0 – Loss of enamel surface characteristics but NO dentine visible

1 – Dentine is visible $<^1/_{3^{rd}}$. Cupping on molar cusp tips. Change in colour

2 - $>^1/_{3^{rd}}$ dentine exposed

3 – Pulp or secondary dentine exposed

R – Missing/restored/, could not be assessed

*If in doubt a lower score is given.

(Direct Data Entry, software programme developed by Alastair Davies, 8 Horseshoe Road, Pangbourne, Reading, UK).

Once the teeth have been scored using the index by Bardsley et al (2004), the children will rest for five minutes, before the next examination is conducted.

Exact Tooth Wear Index (ETWI) (Fares et al, 2009): The primary purpose of this index is to be a research tool for trained examiners, as a method for identifying early tooth wear within enamel and dentine. The index grades all permanent teeth within the mouth except third molars, unless the first or second permanent molars are absent.

For each tooth, the index grades 4 individual surfaces

Buccal- assessment includes the cervical buccal portion

Buccal cervical = cervical 1/3rd of tooth

Palatal /Lingual

Incisal / Occlusal

Where dental restoration(s) occupy greater than 25% ($^1/_4$) of the specific surface area, that surface will not be scored and marked 'R'. Tooth wear in the enamel and dentine will be scored separately. The dental examiner is trained to score the enamel first, then dentine and finally the cervical area. For the cervical buccal area tooth wear is assessed in terms of enamel, dentine and depth.

(A) ETWI INDEX FOR ENAMEL:

0 - No tooth wear: no loss of enamel characteristics or change in contour

1 - Loss of enamel affecting less than $^1/_{10}{}^{th}$ of the scored surface

2 - Enamel loss affecting less than $^1/_3{}^{rd}$ of the scored surface

3 - Enamel loss affecting at least $^{1}/_{3}^{rd}$ but less than $^{2}/_{3}^{rd}$ of the scored surface

4 - Enamel loss affecting $^{2}/_{3}^{rd}$ or more of the scored surface

(B) ETWI INDEX FOR DENTINE:

0 - No dentinal tooth wear: no loss of dentine

1 - Loss of dentine affecting less than $^{1}/_{10}^{th}$ of the scored surface

2 - Dentine loss affecting less than $^{1}/_{3}^{rd}$ of the scored surface

3 - Dentine loss affecting at least $^{1}/_{3}^{rd}$ but less than $^{2}/_{3}^{rd}$ of the scored surface

4 - Dentine loss affecting $^{2}/_{3}^{rd}$ or more of the scored surface, no pulpal exposure

5 - Secondary dentine formation or pulpal exposure

(C) ETWI INDEX FOR DEPTH ON CERVICAL BUCCAL SURFACES: (measured with a standard W&H periodontal probe)

0 - No tooth wear: no loss of tooth surface

1 - Less than 1mm loss of tooth surface depth

2 - Tooth surface loss in depth measuring at least 1mm but less than 2mm

3 - Tooth surface loss in depth measuring 2mm or greater

At the time of analyses children will be divided into groups where:

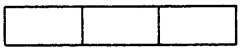
Mild tooth wear, moderate tooth wear and severe tooth wear will be considered.

Data Management

Data will be entered directly onto a personal computer. Data analyses files will be built and the data checked. Back up disks of all data will be maintained.

Data Measurement and Recording

General Information; The Child's initials, represented by initial of first name, middle name and then surname, will be entered at the top of the first page, as follows:



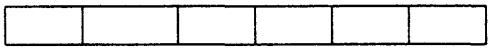
1Initial 2Initial Surname

Codes

Subject Number Each child will be given a discreet six digit number. This number must be entered at the top of each page of the record in the space provided and on the Lap Top data entry screen. The following numbering system will be adopted.

Subject Number

The six boxes for the subject number should be completed as follows:



School, Class, Child number within the class group.

The 1st and 2nd digit will correspond to the number given for each participating school.

The 3rd digit will correspond to the class in which the child was in school at the time of the initial study.

Class in school

Code 1 = Junior Infants

Code 2 = Senior Infants.

The 4th, 5th and 6th digits denote the child being examined. The digits assigned to each child in study OHSRC00500 and OHSRC00806 will be used.

School Number

The school numbers assigned in study OHSRC00500 will be used.

Examiner Number

The examiner will be given a two-digit code number: 01

Sex

Male will be recorded, Male from drop down menu

Female will be recorded, Female from the drop down menu on the direct data entry screen

Reproducibility

Every tenth subject will be re-examined. Each first Examination will be designated Code 1. Duplicate examinations will be designated Code 2. A Kappa statistic will be calculated to determine intra-examiner reproducibility. Only Code 1 results will be included in the statistical analyses of prevalence and severity.

Fluoride History

From the consent form, the recorder will see if the subject has ever used supplemental fluoride, such as tablets.

No Fluoride, Code 1

Fluoridated water, Code 2

Fluoride Supplements, Code 3

Oral Hygiene and Dietary Practices Questionnaire

The questionnaire will be completed at school using a direct data entry system (Appendix 8).

Confidential Medical History Questionnaire

This will be taken home from school by each child and completed by the Parent / Guardian of the child (Appendix 3)

Social Class

This will be dichotomous. It will be established from the demographic data form (whether or not the family possesses a Medical Card) (Appendix 9).

Statistical Analyses

Dental Caries

The proportion of children with and without dental caries will be established and compared. The mean number of decayed missing and filled teeth and surfaces will be calculated for each subject. Comparisons will be made between the two time points using chi-squared tests and student's *t*-test.

Tooth wear

A statistical analysis of the differences between groups will be undertaken using non-parametric (chi-squared) tests. The proportion of children with 1 or more lesions will be compared.

Tooth wear scored using the TWI described by Bardsley et al (2004) will be compared with the findings reported for the children when examined in 2000/2001 and similarly tooth wear scored using the ETWI (Fares et al. 2009) will be compared with the findings reported for the children when examined previously.

Sample size calculation

The sample will be composed of all those who participated in the original study at age 5 years and who consented to follow-up when age 12-years (protocol number OHSRC00806). Any who did not consent to yet further follow-up when examined at age 12yrs will not be invited to participate.

LIST OF APPENDICES

Informed Consent Form (Appendix 1)

Assent Form (Appendix 2)

Confidential Medical Questionnaire (Appendix 3)

Inclusion / Exclusion Criteria (Appendix 4)

Caries Recording Form (Appendix 5)

Tooth Wear Recording Form (Bardsley et al, 2004) (Appendix 6)

Exact Tooth Wear Recording Form (Fares et al, 2009) (Appendix 7)

Oral Hygiene and Dietary Practices Questionnaire (Appendix 8)

Demographic Data Form (Appendix 9)

Soft Tissue Exam Recording Form (Appendix 10

Photograph Recording Form (Appendix 11)

Letters to Parents, School Principals and Schools Boards of Management (Appendix 12)

REFERENCES

Bardsley PF, Taylor S, Milosevic A (2004): Epidemiological studies of tooth wear and dental erosion in 14-year-old children in North West England. Part 1: The relationship with water fluoridation and social deprivation. British Dental Journal; 197: 413-416.

Bartlett DW and Shah P (2006): A Critical Review of Non-carious Cervical (Wear) Lesions and the Role of Abfraction, Erosion and Abrasion. Journal of Dental Research; 85:306-312.

Fares J, Shirodaria S, Chiu K, Ahmad N, Sherriff M, Bartlett D (2009). A New Index of Tooth Wear: Reproducibility and Application to a Sample of 18- to 30-Year-Old University Students. Caries Research; 43:119-125.

Harding MA The prevalence of dental caries and tooth wear (dental erosion) in a sample of 5-year-old children and potential risk factors. Dissertation submitted in part fulfilment of the requirements for the Degree of Master of Dental Public Health in the Faculty of Medicine University College Cork. April 2001.

Harding MA, Whelton HP, O'Mullane DM, Cronin M (2003). Dental erosion in 5-year old Irish children and associated factors: a pilot study. Community Dental Health: 20:165-70.

HSE Code of Practice for Decontamination of Reusable Invasive Medical Devices (RIMD). (2007). http://www.hse.ie/eng/Publications/, [accessed 16th October 2009].

Smith B.G.N, Knight, J.K. (1984). An Index for Measuring the Wear of Teeth. British Dental Journal; 156:435-437.

Smith, B.G. (1989): Toothwear: aetiology and diagnosis. Dental Update; 16:204-212.

Whelton H, Crowley E, O'Mullane D, Harding M, Guiney H, Cronin M, Flannery E, and Kelleher V (2006). North South Survey of Children's Oral Health in Ireland 2002. Dublin, Department of Health and Children. http://www.dohc.ie/publications/pdf/oral_health_report.pdf, [accessed 16th October 2009].

Protocol Amendment:

Tooth Wear: A Prospective Cohort Study. A Follow-up to A Cross Sectional Survey Of The Prevalence And Severity Of Tooth Wear in the permanent dentition of 12-year-olds, who were also examined as five-year-olds (Protocol OHSRC00409).

UNIVERSITY COLLEGE CORK

Clinical Research Ethics Committee Of The Cork Teaching Hospitals

AMENDMENT SUBMISSION FORM

When any revision to an approved research protocol, written consent form and/or advertisement for subject recruitment is desired, an amendment must be filed with the Ethics Committee. The amendment submission form must be completed indicating the changes; revisions may be within the protocol itself, the written consent form or the advertisement. The form should explain what changes have been made and the rationale for the change. Eight copies of the revised pertinent original documents (protocol, consent form, and/or advertisement) should also be submitted with the changes identified using a blue highlighter pen. A cover letter or additional information may also be attached, as necessary.

Amendments to approved protocols may not be initiated until Ethics Committee approval has been obtained, except when necessary to eliminate apparent immediate hazards to the subject. Amendments usually require full Board review at the scheduled monthly meetings; therefore, the submission deadlines must be met. The Ethics Committee reserves the right to determine whether proposed changes are substantive and to request further information or a new protocol submission, as appropriate.

Chief Investigator: Professor Helen Whelton

Department: Oral Health Services Research Centre, Oral Health & Development

Protocol Title: Tooth Wear: A Prospective Cohort Study. A Follow-up to A Cross Sectional Survey Of The Prevalence And Severity Of Tooth Wear in the permanent dentition of 12-year-olds, who were also examined as five-year-olds. OHSRC00409

The following changes are proposed for this protocol:

Chief Investigator	☐	Co-investigator(s)	☐
Dosage	☐	Treatment Procedures	☐
Drug/Device	☐	Study Population	☐
Number of Subjects	☐	Risks	☐
Advertisement	☐	Editorial Corrections	☐

Other √ Site of performance of clinical examination in a subset of subjects

Is a revised protocol necessary as a result of this amendment? Yes ☐ No ☑
If yes, please attach a revised protocol to this amendment.

Is a revised consent form necessary as a result of this amendment? Yes ☑ No ☐
If yes, please attach a revised consent form to this amendment.

Is a revised advertisement necessary as a result of this amendment? Yes ☐ No ☑
If yes, please attach a revised advertisement to this amendment.

Please list the specific changes from the previously approved protocol and provide sufficient rationale for each change to allow the committee to make a decision. Use additional pages as necessary.

The children in this longitudinal follow-up study have moved from primary to secondary level education since the previous examination at age 12yrs, and we find that they are more widely scattered in different schools than previously. To date we have concentrated on examining in schools with the largest numbers of our target cohort, and so far we have seen 54 children, with another 30 scheduled to be seen within the next week or two. We would like to see the remaining 17 children well before the school summer exams commence in May 2010. But the remaining 17 children are scattered between 11 schools, with one child only in 8 of those schools.

We would like to apply for permission to offer the parents\guardians of these 17 children the option of coming with their child to the Oral Health Services Research Centre outside of school hours, in an attempt to see all children in one or two sessions. This would be much more time and effort efficient than visiting each of the schools to examine one or two children in each. The conditions under which children are seen in their schools would be replicated at the OHSRC.

If implemented, this amendment would necessitate changes to the Parent Informed Consent Form, Child Assent form and covering letter to parents and schools (approved versions and proposed new versions are attached, with proposed changes highlighted).

Investigator _____ Date _____

(This form must bear the original signature of the chief investigator)

Appendix 6:

Fieldwork documents associated with Toothwear/Dental Erosion in Irish Teenagers: An Epidemiological and Laboratory Investigation (Protocol OHSRC01005).

Protocol OHSRC01005:

Letters to School Board of Management, School Principal, Parent/Guardian (Main Study), Parent/Guardian (Training and Calibration)

Board of Management / Parents Council

Dear Chairperson,

The Oral Health Services Research Centre based in University College Cork, conducts research on behalf of the Department of Health and Children, the Health Services Executive, the EU and the oral health care industry.

The Oral Health Services Research Centre is currently involved in a study involving teenage schoolchildren in the Counties of Cork and Kerry. The aim of this study is to obtain information on the amount and severity of toothwear (wearing of the teeth) in 16-year-old teenagers and factors which may influence it. Toothwear can be caused by some foods and drinks, by acid regurgitation and by vomiting. Some individuals may have certain factors which protect against toothwear. The information collected will assist with education, prevention and the planning of future dental services.

Máiréad Harding BDS (NUI), MFGDP (UK), MDPH will carry out the examination of the teenagers, with the assistance of a trained recorder.

I am writing to seek your co-operation in running this study. Teenagers in transition year will be examined. We would require the use of the school hall or a small room for 1 or 2 days depending on the number of teenagers to be examined.

Permission will also be sought from the School Principal and a consent form issued to the Parent/Guardian of each teenager. The Parent/Guardian will also be asked to answer a number of questions to assist in the study and to decide whether the teenager can be included in the study.

The study will have the approval of the Health Service Executive and also full ethical approval prior to commencement. We anticipate that the school visits would commence in September 2006.

Your co-operation with this project would greatly facilitate this research and would be very much appreciated. Should you require any further information regarding this project please contact me at the above number.

Yours sincerely,

Dr Helen Whelton
Director
Oral Health Services Research Centre
University Dental School and Hospital
Wilton
Cork

School Principal

Dear School Principal,

The Oral Health Services Research Centre based in University College Cork conducts research on behalf of the Department of Health and Children, the Health Service Executive, the EU and the oral health care industry.

The Oral Health Services Research Centre is currently involved in a study involving teenage schoolchildren in the Counties of Cork and Kerry. The aim of this study is to obtain information on the amount and severity of toothwear (wearing of the teeth) in 16-year-old teenagers and factors which may influence it. Toothwear can be caused by some foods and drinks, by acid regurgitation and by vomiting. Some individuals may have certain factors which protect against toothwear. The information collected will assist with education, prevention and the planning of future dental services.

Máiréad Harding BDS (NUI), MFGDP (UK), MDPH will conduct the examination of the teenagers, with the assistance of a trained recorder.

I am writing to seek your co-operation in running this study. Teenagers in transition year will be examined. We would require the use of the school hall or small room for 1or 2 days depending on the number of teenagers to be examined.

Permission will also be sought from the Board of Management and a consent form issued to the Parent/Guardian of each transition year teenager. The Parent/Guardian will also be asked to answer a number of questions to assist in the study and to decide whether the teenager can be included in the study.

The study will have the approval of the Health Service Executive and also full ethical approval prior to commencement. We anticipate that the school visits would commence in September 2006.

Your co-operation with this project would greatly facilitate our research and would be very much appreciated. Should you require any further information regarding this project please do not hesitate to contact me at the above number.

Yours sincerely,

_____

Dr. H. Whelton
Director
Oral Health Services Research Centre
Cork University Dental School and Hospital
Cork.

Parent or Guardian
Main Study

Dear Parent / Guardian,

The Oral Health Services Research Centre based in University College Cork conducts research on behalf of the Department of Health and Children, the Health Service Executive, the EU and the oral health care industry.

The Oral Health Services Research Centre is currently involved in a study involving teenage schoolchildren in the Counties of Cork and Kerry. The aim of this study is to obtain information on the amount and severity of toothwear (wearing of the teeth) in teenagers and factors which may influence it. Toothwear can be caused by some foods and drinks, by acid regurgitation and by vomiting. Some individuals may have certain factors which protect against toothwear. The information collected will assist with education, prevention and the planning of future dental services.

A qualified dentist, Ms. Máiréad Harding, will conduct the examination of participating teenagers, with the assistance of a dental nurse and trained recorder. The examination, which will be carried out in the teenager's school, will not involve any risks or discomforts to the teenager. Your teenager would have their teeth examined, they would be asked to provide a sample of saliva and to complete a questionnaire on their oral healthcare, eating, drinking and snacking habits, plus some questions about his or her medical history and awareness of toothwear.

If you are willing to allow your teenager to participate in this study and they are happy to do so, please complete the enclosed Subject Information and Informed Consent Form, Demographic Data Record and Confidential Medical History Questionnaire. These should be returned to the school in the envelope provided within the next 2 or 3 days.

Your co-operation with this project would greatly facilitate our research and would be very much appreciated. Participating teenagers will receive a small gift as a token of our appreciation.

Should you require any further information regarding this project please contact me at the above number.

Yours sincerely,

_____

Dr. Helen Whelton
Director
Oral Health Services Research Centre
University Dental School and Hospital
Wilton
Cork.

Parent or Guardian
Training and Calibration Programme

Dear Parent / Guardian,

The Oral Health Services Research Centre based in University College Cork conducts research on behalf of the Department of Health and Children, the Health Service Executive, the EU and the oral health care industry.

The Oral Health Services Research Centre has planned a study involving teenage schoolchildren in the Counties of Cork and Kerry. The aim of this study is to obtain information on the amount and severity of toothwear (wearing of the teeth) in teenagers and factors which may influence it. Toothwear can be caused by some foods and drinks, by acid regurgitation and by vomiting. Some individuals may have certain factors which protect against toothwear. Before this large study is carried out it is important that the qualified dentist conducting the research can consistently identify toothwear and that the questionnaire being used to collect information from the teenagers is suitable.

A trained expert in measuring toothwear along with the qualified dentist who will conduct the research will examine the participating teenagers. A qualified dental nurse and trained recorder will also be present. The examination, which will be carried out in the teenager's school, will not involve any risks or discomforts to the teenager. Your teenager would have their teeth examined, they would be asked to provide a sample of saliva and to complete a questionnaire on their oral healthcare, eating, drinking and snacking habits, plus some questions about his or her medical history and awareness of toothwear.

If you are willing to allow your teenager to participate in this study and they are happy to do so, please complete the enclosed Subject Information and Informed Consent Form, Demographic Data Record and Confidential Medical History Questionnaire. These should be returned to the school in the envelope provided within the next 2 or 3 days.

Your co-operation with this project would greatly facilitate our research and would be very much appreciated. Participating teenagers will receive a small gift as a token of our appreciation.

Should you require any further information regarding this project please contact me at the above number.

Yours sincerely,

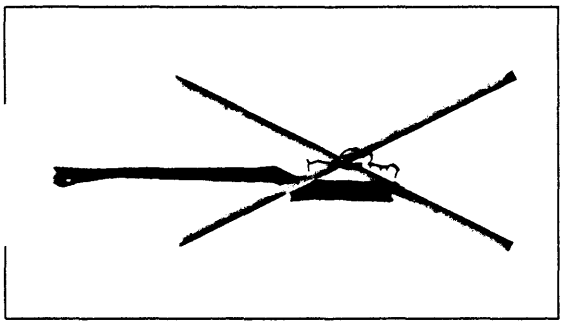
_____

Dr. Helen Whelton
Director
Oral Health Services Research Centre
University Dental School and Hospital
Wilton
Cork.

Parent or Guardian and teenager

Dear Parent and Teenager,

No toothbrushing or toothpaste use after 9.00pm tonight or tomorrow morning please



Some time ago you and your teenager consented to taking part in a research study on toothwear in Irish teenagers. A researcher will be calling to the school tomorrow to carry out the study and collect samples of the teenager's saliva (spit). The saliva will be collected before the morning break.

Usually we encourage teenagers to brush their teeth, but before the researcher calls it is very important that you do not brush for at least 12 hours. I am writing to ask you to ensure that you **do not** brush your teeth after 9.00pm this evening and **not to** brush before school in the morning. This is just for 1 day. Once the researcher has collected the saliva you can return to you normal brushing pattern.

Yours sincerely,

Dr Helen Whelton
Director
Oral Health Services Research Centre
University Dental School and Hospital
Wilton
Cork

Protocol OHSRC01005:

Subject Information and Consent form

Subject Information and Informed Consent Form

Protocol No: OHSRC 01005 **Subject name:**_____

Dentist directing the Research: Dr. Helen Whelton **Subject Number :** ☐☐☐☐☐☐

Your teenager is being invited to participate in a research study. In order to decide whether or not you want your teenager to be a part of this study, you should understand enough about its risks and benefits to make an informed judgement. This process is known as informed consent. This consent form gives detailed information about the research study. Once you understand the study, you will be asked to sign this form if you wish your teenager to participate. Your teenager will also be asked to sign to indicate his / her consent to participate.

We are asking your teenager's class to participate in a study to help us learn more about toothwear (the wearing away of the teeth) in teenagers in Cork and Kerry. The project is designed to find out how common toothwear is in teenagers (15-17 years old) and to estimate the severity of any toothwear present. Toothwear can be caused by some foods and drinks, by acid regurgitation and by vomiting. Some individuals may have certain factors which protect against toothwear.

Participation in this study will involve your teenager having an oral examination, providing a sample of their saliva and filling in a questionnaire relating to his or her oral healthcare, eating, drinking and snacking habits, plus some questions about his or her medical history and awareness of toothwear.

Participation in this study will involve one session at your teenager's school, during which his/her teeth will be examined for toothwear, we will also ask your teenager to provide a sample of his / her saliva and to complete a questionnaire on his / her oral healthcare, eating, drinking and snacking habits along with some questions on their general health. In some cases, photographs of tooth wear will be taken by the dentist. Only the teeth and gums will be in the photo, so nothing would identify your teenager. Photographs would be used by the researchers to educate and train staff on the subject of toothwear. Some of the photos may be used on information leaflets. If you do not wish to have photos taken, your teenager can still take part in the rest of the study. Approximately 5% of participating teenager's will have their teeth examined a second time as a check on the consistency of the examining dentist.

No risks or discomforts are anticipated as a result of participation in this study. There is no expected direct benefit to your teenager, except that if oral conditions requiring urgent attention are observed you will be informed. No treatment will be carried out as part of this project.
It should be noted that procedures conducted during this study do not replace regular dental check-ups. Also, your teenager is free to refrain from participation in this study for any reason. Up to eight hundred teenagers aged 15-17 years will participate.

If you wish your teenager to participate in this study please sign this form. Your teenager should also sign if he / she is willing to take part in the study.

The completed medical questionnaire, demographic data form and this form should be returned to the school in the envelope provided.

The information you give will be treated with the strictest confidence, and will be used for statistical purposes only. Nothing that would identify you or your teenager will be included in the results.
If your teenager completes the study he/she will be presented with a gift of a toothbrush and toothpaste.

Thank you for your interest.

Agreement to Consent

I am aware that participation is voluntary and that I may withdraw my consent at any time. I am aware that my decision not to allow my teenager to participate or to withdraw my teenager will not restrict his/her access to health care services normally available to him/her. Confidentiality of records concerning my teenager's involvement in this project will be maintained in an appropriate manner. When required by law, the records of this research may be reviewed by government agencies and sponsors of the research.

I, the undersigned, hereby consent to allow my teenager to participate as a subject in the above described project to be conducted at his/her school. I have received a copy of this consent form for my records.
I understand that if I have any questions concerning this research or the study procedure I can contact Dr. Helen Whelton at (021) 4901210.
If I have any questions regarding my teenager's rights in connection with the research, I can contact the Clinical Research Ethics Committee of the Cork Teaching Hospitals at 021-4321563.

After reading the entire consent form, if you have no further questions about giving consent, please sign where indicated.

I agree to my teenager taking part in this study, *including* the taking of intra-oral photographs if the dentist feels that they would be useful for the study.

Signature of parent/guardian: _____ Date: _____

Signature of teenager: _____ Date: _____

I agree to my teenager taking part in this study, *but not to* the taking of intra-oral photographs.

Signature of parent/guardian: _____ Date: _____

Signature of teenager: _____ Date: _____

My teenager's details may be entered on a confidential computer database for use by the staff of the Research Centre, who may use it to contact me in the future should my teenager be suitable for inclusion in another trial.

Please tick one box: Yes ☐ No ☐

If I do not wish to have my teenager's details entered on the computer database, I understand that he/she can still participate in this study.

Signature of Parent/Guardian: _____ Date: _____

Protocol OHSRC01005:

Teenager Information and Assent form

Teenager Information and Assent Form

Dentist directing the Research: Dr. Helen Whelton

Protocol No: **OHSRC 01005**

Subject name:_____ Subject No:_____

You have been invited to participate in a research study. This form will explain the study to you. Once you have read the form, if you would like to participate please sign at the bottom of the page.

In this study we would like to gather information on the amount and severity of tooth wear (the wearing away of the teeth) and factors which may influence it in teenagers. Tooth wear can be caused by some foods and drinks, and by acids from the stomach that come into contact with the teeth as a result of heartburn or vomiting. Some people may have factors in their saliva which protect against tooth wear.

The study will involve one visit (of about 20 minutes) at your school, in that time your teeth will be checked for tooth wear by a dentist. The examination is safe and doesn't hurt at all. No treatment will be given. You will also be asked to provide a sample of saliva and complete a questionnaire on your oral health care, eating, drinking and snacking habits, plus some questions about your medical history and awareness of tooth wear.

In some cases, photos of tooth wear will be taken by the dentist. This will be like having a photo taken of part of the inside of your mouth. Your face will not be in the photo, so no-one looking at it would know that it was you. The photos will be used by the researchers to educate and train their staff about tooth wear. Some of the photos may be used on information leaflets. If you do not want to have photos taken, you can still take part in the rest of the study.

To check that the dentist doing the examinations is doing them the same way each time, some of you may be examined a second time.

If you complete the study you will be presented with a gift of a toothbrush and toothpaste.

Thank you for your interest.

After reading the form, and if you have no further questions about participating, please sign one of the choices over the page.

I agree to take part in the study, and I agree to *having* photos taken if the dentist decides it would be useful for the study.

Signature of teenager: _____ Date: _____

I agree to take part in the main part of the study, but I *don't* want to have photos taken

Signature of teenager: _____ Date: _____

Protocol OHSRC01005:

Confidential Medical History Questionnaire

Confidential Medical History Questionnaire

To be completed by parent / guardian

Child's Name: _____ Child's Date of Birth:

D D M M Y Y

Is your child	Yes	No	Please write in the details and the names the of medicines.
1. Attending or receiving treatment from a doctor, hospital, clinic or specialist?			
2. Taking any medicines from his/her doctor? (tablets, inhalers, creams, ointments, injections, other)			
3. Allergic to any medicines, foods or materials?			
Has your child			
1. Had rheumatic fever?			
2. Had jaundice liver disease, kidney disease or hepatitis?			
3. Ever been told he/ she has a heart murmur or heart problem, or high blood pressure?			
4. Been hospitalised? If yes, what for and when?			
5. Had any serious trouble associated with previous dental treatment?			
6. Had surgery for a growth anywhere in his/her body?			
Does your child			
1. Have a pacemaker, or had any form of heart surgery?			
2. Suffer from hay fever, eczema or any other allergy?			
3. Suffer from bronchitis, asthma or other chest conditions?			
4. Have fainting attacks, giddiness, blackouts or epilepsy?			
5. Have diabetes, or a family history of diabetes?			
6. Carry a warning card?			
7. Are there any other aspects concerning your child's health that you think the dentist should know about?			

Signature of Parent / Guardian Signature: _____ Date: _____

Protocol OHSRC01005:

Demographic Data Record

Demographic Data Record

Child's Name _____

Child's Date of Birth _____

Child's Address _____

_____

_____

_____

How long has the child lived at this address? _____Years _____Months

Is your home connected to a public piped water supply? Yes ☐ No ☐

Is your home connected to a group water supply? Yes ☐ No ☐

Previous Addresses at which this child may have lived (if any)

_____

_____

_____

_____

Was the child's previous home connected to a public piped water supply?

Yes ☐ No ☐ Not applicable ☐

Has the child ever taken a course of fluoride tablets or participated in a school fluoride mouthrinse programme? Yes ☐ No ☐

Does your Family have a Medical Card? Yes ☐ No ☐

Thank you for your time and help.

Protocol OHSRC01005:

Soft Tissue Examination Recording Form

SAR ☐☐☐☐☐☐ Date of Exam ☐☐☐☐☐☐

Initials ☐☐☐ Sex ☐ Date of Birth ☐☐☐☐☐☐

Soft Tissue Examination

Were any Soft Tissue Abnormalities detected?

	Yes	No	If yes detail below:
Lips	☐	☐	_____
Bucccal Mucosa	☐	☐	_____
Labial mucosa	☐	☐	_____
Sublingual mucosa	☐	☐	_____
Attatched gingivae	☐	☐	_____
Tongue	☐	☐	_____
Hard/soft palate	☐	☐	_____
Uvula	☐	☐	_____
Oropharynx	☐	☐	_____

General Comment: _____

_____

_____

Examiner: _____ Date: _____

QC: _____ Date: _____

Protocol OHSRC01005:

Toothwear Examination Form

OHSRC 01005

Toothwear Examination

Initials: ☐☐☐ Subject Number: ☐☐☐☐☐☐

Date of Birth: ☐☐ ☐☐ ☐☐ School Number: ☐☐☐

Sex: ☐

Fluoride: ☐ No Fluoride: ☐ Fluoride Supplements: ☐

Date of Examination: ☐☐ ☐☐ ☐☐

Upper Right:

Tooth	Status	Toothwear			Toothwear Area affected		
		B	O/I	L	B	O	L
16							
13							
12							
11							

Upper Left:

Tooth	Status	Toothwear			Toothwear Area affected		
		B	O/I	L	B	O	L
21							
22							
23							
26							

Lower Left:

Tooth	Status	Toothwear			Toothwear Area affected		
		B	O/I	L	B	O	L
36							
33							
32							
31							

Lower Right:

Tooth	Status	Toothwear			Toothwear Area affected		
		B	O/I	L	B	O	L
41							
42							
43							
46							

B = Buccal / Labial O = Occlusal I = Incisal L = Lingual / Palatal

Tooth status code

Code:		
	A	Adult tooth present
	E	Adult tooth extracted due to caries
	T	Missing due to trauma
	M	Missing for other reasons
	C	Crown present
	V	Veneer present

Preface to surface condition code:
A condition score is given to the buccal/labial, lingual/palatal and the occlusal or incisal surface of the first permanent molar, the canine, the lateral incisor and the central incisor in all quadrants. A score is also given for the area affected on the buccal/labial, lingual/palatal and occlusal surfaces.

Toothwear Depth

Score	Criteria	Description
0	Normal no evidence of toothwear	No loss of surface features, no loss of contour
1	Toothwear into enamel	Loss of enamel giving a smooth glazed shiny appearance. Relatively wide shallow concavities on enamel, dentine is not involved. Increased translucency of the tooth due to loss of enamel thickness.
2	Toothwear into dentine	Extensive loss of enamel with dentine involvement Exposure of dentine dentine. Evidence of rimming around the cervical margin. Evidence of cupping on molars.
3	Toothwear into pulp	Extensive loss of enamel and dentine with exposure of the pulp or secondary dentine.
9	Could not be assessed	Extensive caries, large restoration, fractured tooth, missing tooth, crowned tooth.

Toothwear Area

Score	Description
0	Normal
1	Less than 1/3rd of surface involved
2	1/3rd up to 2/3rds of the surface involved
3	More than 2/3rds of the surface involved
9	Could not be assessed.

Protocol OHSRC01005:

Oral Hygiene, Dietary Habits and Behaviours Questionnaire (Paper Transcript of E-Questionnaire)

Hi TY Students,

Thank you for taking the time to participate in our study and complete this questionnaire. Through the questionnaire we would like to learn about oral hygiene practices, dietary choices and lifestyle behaviours in transition year students.

It would be a great help if you could answer each question as accurately as possible. All information which you give will be treated as confidential and nothing that identifies you will be used.

- Most of the questions can be answered by placing a tick (√) beside the answer that most closely applies to you.
- In some questions there may be more than one answer that applies. Please tick (√) all the boxes that apply.
- If you cannot remember, if you do not know or if you are unable to answer a particular question please write 'don't know' or 'can't remember' beside that question.

Thank you for your help

Name: _____ **Subject Number :** ☐☐☐☐☐☐

School Number: ☐☐

Age: _____ **Date of Birth: In the format** ☐☐ ☐☐ ☐☐
Day Month Year

First some questions regarding your oral health practices:

Q1. How often in the past 12 months have you visited the dentist?

(i) Not at all ☐

(ii) Once ☐

(iii) Twice ☐

(iv) Three or more times ☐

(v) Other ☐ Please specify:_____

Q2. How often would you brush your teeth?

(i) Never ☐

(ii) Less than once a day ☐

(iii) Once a day ☐

(iv) Twice a day ☐

(v) Three or more times each day ☐

(vi) Other ☐ Please specify:_____

Q3. When would you brush your teeth?

(i)	Before breakfast	☐
(ii)	After breakfast	☐
(iii)	Before other meals	☐
(iv)	After other meals	☐
(v)	After eating sweet foods or drinks	☐
(vi)	Before going to bed	☐
(vii)	Other	☐ Please specify:_____

Q4. What type are the bristles on the toothbrush you use?

(i)	Hard	☐
(ii)	Medium	☐
(iii)	Soft	☐
(iv)	Other	☐ Please specify:_____

Q5. Do you like the way your teeth look?

(i)	Yes	☐
(ii)	No	☐

Now a few questions regarding your drinking and eating habits:

Q6. How often would you drink fizzy drinks?

(i) Never ☐

(ii) Less than once a week ☐

(iii) At least once a week ☐

(iv) More than once a week ☐

(v) Everyday ☐

(vi) Other ☐ Please specify:_____

Q7. When would you usually have these fizzy drinks?

(i) With meals ☐

(ii) Between meals ☐

(iii) Sipping throughout the day ☐

(iv) At school ☐

(v) At weekends ☐

(vi) After sport / exercising ☐

(vii) Other ☐ Please specify:_____

Q8. In your average week approximately how many cans of fizzy drinks would you have? ☐

Q9. When drinking fizzy drinks would you usually drink?

(i) Low calorie, no sugar added, diet drinks? ☐

(ii) The regular standard drinks ☐

(iii) Other ☐ Please specify:_____

Q10. How often would you drink pure fruit juices which might also be called (breakfast juices, freshly squeezed juices or drinks labelled 100% pure fruit juices)?

(i) Never ☐

(ii) Less than once a week ☐

(iii) At least once a week ☐

(iv) More than once a week ☐

(v) Everyday ☐

(vi) Other ☐ Please specify:_____

Q11. How often would you drink dilutable or ready made fruit drinks, for example Robinsons, Mi-Wadi or ready to drink cartons such as Capri Sun. Regular or the no added sugar variety?

(i) Never ☐

(ii) Less than once a week ☐

(iii) At least once a week ☐

(iv) More than once a week ☐

(v) Everyday ☐

(vii) Other ☐ Please specify:_____

Q12. How do you typically take these drinks?

(i) From a can ☐

(ii) From a bottle ☐

(iii) From a glass or cup ☐

(iv) Through a straw ☐

(v) Other ☐ Please specify:_____

Q13. Here is a question about tea, coffee, and herbal tea. Please read the list of choices and then write in the letter (a), (b), (c) etc which best applies to you.

(a) Never

(b) Less than once a week

(c) At least once a week

(d) More than once a week

(e) Everyday

(f) Other Please specify:_____

Tea ☐

Coffee ☐

Herbal tea ☐

Q14. What type of water do you normally drink?

(i) Plain water from the tap ☐

(ii) Bought still bottled water ☐

(iii) Flavoured still bottled water ☐

(iii) Bottled fizzy / sparkling water ☐

(iii) Flavoured bottled fizzy / sparkling water ☐

(v) Other ☐ Please specify:_____

Q15. During your typical day what kind of drink would you usually have?

_____

Q16. Is milk available in you school for example 'the school milk scheme'?

(i) Yes ☐

(ii) No ☐

(iii) Don't know ☐

Q17. Are there machines available at your school selling fizzy, high energy drinks and fruit drinks?

(i) Yes ☐

(ii) No ☐

(iii) Don't know ☐

Thanks so much for your help so far, please remember all information is confidential, so for a few more questions.

Q18. Do you drink Cider?

(i) Yes ☐

(ii) No ☐

If you answered 'Yes', when would you be most likely to drink cider?

_____

Q26. Do you often suffer from a dry mouth?

(i) Yes ☐

(ii) No ☐

Q27. Are you taking any vitamins or medicines?

(i) Yes ☐

(ii) No ☐

Could you please name the vitamins or medicines that you are taking?

_____

Q28. Do you ever have tummy upsets or vomiting?

(i) Yes ☐

(ii) No ☐

Q29. If you do vomit, how frequently would you vomit?

(v) Hardly ever ☐

(vi) At least every month ☐

(vii) At least every week ☐

(viii) Other ☐ Please specify:_____

Q30. Do you get indigestion or suffer from reflux (would you ever regurgitate acid after eating)?

(i) Yes ☐

(ii) No ☐

(iii) Occasionally ☐

(iv) Don't know ☐

Q31. Do you grind or clench your teeth or have you been told that you grind your teeth at night?

(i) Yes ☐

(ii) No ☐

(iii) Don't know ☐

Q32. Do you bite your nails?

(i) Yes ☐

(ii) No ☐

Q33. How often are you involved in physical and strenuous exercise?

(i) Once a week ☐

(ii) Twice a week ☐

(iii) Three to four times a week ☐

(ii) Everyday ☐

(viii) Other ☐ Please specify:_____

Finally a couple of questions regarding your awareness of tooth wear:

Q34. Before this study had you heard of toothwear or dental erosion?

(i) Yes ☐

(ii) No ☐

Q35. What do you think toothwear or dental erosion is caused by?

(i) Sugar in foods ☐

or

(ii) Acidic Foods ☐

Thank You for taking the time to complete this questionnaire

Your help is greatly appreciated

Appendix 7:

The collection of whole mouth saliva protocol: OHSRC

The collection of whole mouth saliva protocol: OHSRC

1. PURPOSE

To collect both stimulated and unstimulated whole mouth saliva.

2. MATERIALS

35mm plastic funnels

15ml Eppendorf tubes®

Test tube racks

Paraffin wax pellets

Disposable latex-free and powder-free examination gloves

Disinfectant wipes

Black indelible markers

Timer

Tissues

Tape

Styrofoam containers

Ice packs

Waste disposal bags

Each Eppendorf tube® is marked with:

- The participant's identification number
- The participant's initials,
- Date of birth, DD-MM-YY
- Date and time the sample was taken
- Whether stimulated or unstimulated sample

3. APPARATUS

Balance - Calibrated to 0.1mg increments

4. PROCEDURE

4.1 Collection of unstimulated whole mouth saliva

- Unstimulated saliva is collected via passive drool
- Participants sit quietly in a circle with their heads tilted a little forward and their backs to each other to minimise embarrassment and afford some privacy
- Each participant is provided with a pre-weighed labelled tube, a funnel and a disposable wipe
- Participants swallow the saliva in their mouths, and then when asked drool all saliva that collects into the test tube via the funnel for at least 5 minutes or until at least 2 ml of saliva is collected.
- The Eppendorf tube® is closed and collected from participants
- Check cap is secure and that the name, date of birth, sample type and date and duration of time are all recorded on the tube.
- Place on ice in Styrofoam box for transfer

- Weigh tube with saliva on return to OHSRC

4.2 Collection of stimulated whole mouth saliva

- Participants remain seated.
- Each participant is provided with a new pre-weighed labelled test tube, a funnel and a disposable wipe
- Each participant is provided with a paraffin wax pellet to chew for one minute
- The participant is asked to swallow the saliva that has collected in the mouth. Participants continue to chew on the wax pellet and drool the saliva into the test tube via the funnel for a three minute time period
- The Eppendorf tubes® is closed and collected from participants.
- Check cap is secure and that the name, sample type and date details are on the test tube.
- Record the length of time over which the sample is collected
- Place on ice in Styrofoam box for transfer

- Weigh tube with saliva on return to OHSRC

Appendix 8:

Fieldwork documents associated with the longitudinal study of 12- and 14-year-olds (Protocols OHSRC00806 and OHSRC00409)

Longitudinal study of 12-year-olds (Protocol OHSRC00806)

Protocol OHSRC00806:

Cover Letter to Parents/Guardians

Coláiste na hOllscoile Corcaigh, Éire
UNIVERSITY COLLEGE CORK, IRELAND

Aonad Taighde Seirbhísí Sláinte Béil
Oral Health Services Research Centre
University Dental School, Wilton, Cork.
Telephone: +353 21 4901210
Facsimile: +353 21 4545391
E-mail: oral_health@ucc.ie
Web: http//ohsrc.ucc.ie

Dr. Helen Whelton BDS, PhD, MDPH, MFPHM
Professor Denis O'Mullane BDS, PhD, FDSRCS (Ed), FFDRCSI

Dear Parent/Guardian,

When your child was five years of age you kindly agreed to allow them participate in a study to examine the 'baby teeth' for signs of tooth wear. At that time we also asked you whether you would mind being contacted in the future.

We would now like to see your child again and examine the 'adult teeth' for tooth wear. The study is explained in greater detail in the informed consent which accompanies this note.

I would be very grateful if you would complete the informed consent, your child's details on the enclosed sheet and the confidential medical questionnaire. The medical questionnaire is so that we will know whether it is correct for your child to participate in the study.

I would also ask you to ask your child to complete the enclosed form explaining the study to them and the questionnaire on their oral hygiene habits and diet.

Your child will be presented with a toothbrush and toothpaste as a token of appreciation.

Thanking you in anticipation of your co-operation.

Yours faithfully,

Mairead Harding BDS, MFGDP (UK), MDPH

Protocol OHSRC00806:

Parent Information and Consent form

Parents Information and Informed Consent Form

Protocol No: OHSRC00806 **Subject name:**_____

Dentist directing the Research: Dr. Helen Whelton **Subject No:**_____

Your child is being invited to participate in a research study. In order to decide whether or not you want your child to be a part of this study, you should understand enough about its risks and benefits to make an informed judgement. This process is known as informed consent. This consent form gives detailed information about the research study. Once you understand the study, you will be asked to sign this form if you wish your child to participate. The study is also explained to your child in child-appropriate terms in the enclosed Child Information and Assent form.

This study is a follow-up to a study your child participated in during 2001, when he/she was aged approximately 5 years. In that study, your child's teeth were examined for signs of decay and tooth erosion a type of tooth wear. This study will look at tooth wear in children who participated in the earlier study and will compare results to that study in order to find out whether children who had some tooth erosion in their primary ("baby") teeth are more likely to have tooth wear on their permanent ("adult") teeth, and to estimate the severity of any tooth wear present. This research will help us to learn more about tooth wear and in the long term the research may provide information for the planning of dental services.

Participation in this study will involve one session (of approximately 20 minutes) at your child's school, during which his/her teeth will be examined for tooth wear. In some schools, photographs will be taken by the dentist of the range of tooth wear seen in children on this study. Photographs will be of the inside of the mouth only, so the identity of the child would not be obvious to anyone viewing the photographs. Photographs will be taken using a digital camera and dentist's mirror. No discomfort for the child is anticipated. The study sponsor plans to use these photographs for the purposes of internal staff training and also possibly externally in promotional material for an oral health care product currently under development. The names of children will not be used in any publications. If you or your child do not wish to have photographs taken, your child can still participate in the main part of the study.

Your child will also be asked to complete a questionnaire relating to his / her oral health care, eating, drinking and snacking habits. Approximately 5% of participating children will be examined a second time as a check on the consistency of the examining dentist. No risks or discomforts are anticipated as a result of participation in this study. There is no expected direct benefit to your child, except for the possibility of early diagnosis of tooth wear. If signs of significant tooth wear or other oral health problems are detected, you will be informed. No treatment will be carried out as part of this project.

It should be noted that procedures conducted during this study do not replace regular dental check-ups. Also, your child is free to refrain from participation in this study for any reason. Up to two hundred children will participate.

If you wish your child to participate in this study please complete this form, the Demographic Data form, and the questionnaires relating to the general health of your child. Please ask your child to complete the

questionnaire on his / her oral healthcare, dietary, drinking and snacking habits. Please return all forms to the child's teacher in the envelope provided. The information you give will be treated with the strictest confidence, and will be used for statistical purposes only. Nothing that would identify you or your child will be included in the results.

If your child completes the study he/she will be presented with a gift of a toothbrush and toothpaste.

Thank you for your interest.

Agreement to Consent

I am aware that participation is voluntary and that I may withdraw my consent at any time. I am aware that my decision not to allow my child to participate or to withdraw my child will not restrict his/her access to health care services normally available to him/her. Confidentiality of records concerning my child's involvement in this project will be maintained in an appropriate manner. When required by law, the records of this research may be reviewed by government agencies and sponsors of the research.

I, the undersigned, hereby consent to allow my child to participate as a subject in the above described project to be conducted at his/her school. I have received a copy of this consent form for my records. I understand that if I have any questions concerning this research, I can contact the dentist listed above. If I have any questions concerning my child's rights in connection with the research, I can contact the Clinical Research Ethics Committee of the Cork Teaching Hospitals at 021-4345599. If I have any queries about the study procedure I can contact Dr. Helen Whelton at (021) 4901210.

After reading the entire consent form, if you have no further questions about giving consent, please sign where indicated.

I agree to my child taking part in this study, including the taking of intra-oral photographs if the dentist feels that they would be useful for the study.

Signature of parent/guardian: _____ Date: _____

I agree to my child taking part in this study, but not to the taking of intra-oral photographs.

Signature of parent/guardian: _____ Date: _____

My child's details may be entered on a confidential computer database for use by the staff of the Research Centre, who may use it to contact me in the future should my child be suitable for inclusion in another trial or as a follow up to this study.

Please tick one box: Yes ☐ No☐

If I do not wish to have my child's details entered on the computer database, I understand that he/she can still participate in this study.

Signature of Parent/Guardian: _____ Date: _____

Protocol OHSRC00806:

Child Information and Assent form

Child Information and Assent Form

Dentist directing the Research: Dr. Helen Whelton

Protocol No: OHSRC00806

Subject name:_____ Subject No:_____

You have been invited to participate in a research study. This form will explain the study to you. Once you have read the form, if you would like to participate please will you sign at the bottom of the page.

This study is a follow-up to a study you took part in, when you were approximately 5 years old and in junior or senior infants.
In the last study, your 'baby teeth' were examined for signs of tooth wear and holes in the teeth caused by acidic foods and drinks. This study will look at your 'adult teeth' for signs of tooth wear. Tooth wear happens when acids from foods and drinks wear away the surface of teeth.

The study will involve one visit (of about 20 minutes) at your school, in that time your teeth will be checked for tooth wear by a dentist. The examination is safe and doesn't hurt at all. No treatment will be given. In some cases, photos of tooth wear will be taken by the dentist. This will be like having a photo taken of part of the inside of your mouth. Your face will not be in the photo, so no-one looking at it would know that it was you. The photos will be used by the company who are paying for the study to train their staff about tooth wear. Some of the photos may be used in ads for a new product the company are planning to make. If you do not want to have photos taken, you can still take part in the rest of the study.

We would also like you to answer some written questions relating to how you care for your teeth and some questions on the food and drink you like to have.
The questionnaire is included in the envelope and can be filled out at home and brought back with all the forms to school tomorrow.

To check that the dentist doing the examinations is doing them the same way each time, some of you may be examined a second time.

If you complete the study you will be presented with a gift of a toothbrush and toothpaste.

Thank you for your interest.

After reading the form, and if you have no further questions about participating, please sign one of the choices over the page.

I agree to take part in the study, and I agree to having photos taken if the dentist decides it would be useful for the study.

Signature of child: _____ Date: _____

I agree to take part in the main part of the study, but I don't want to have photos taken

Signature of child: _____ Date: _____

Protocol OHSRC00806:

Confidential Medical History Questionnaire

Confidential Medical History Questionnaire

To be completed by Parent / Guardian

Child's Name: _____ Child's Date of Birth:

D D M M Y Y

Is Your child	Yes	No	Please write in details and the names of medicines.
1. Attending or receiving treatment from a doctor, hospital, clinic or specialist?			
2. Taking any medicines from his/her doctor? (tablets, inhalers, creams, ointments, injections, other)			
3. Allergic to any medicines, foods or materials?			
Has your child			
1. Had rheumatic fever?			
2. Had jaundice liver disease, kidney disease or hepatitis?			
3. Ever been told he/ she has a heart murmur or heart problem, or high blood pressure?			
4. Been hospitalised? If yes, what for and when?			
5. Had any serious trouble associated with previous dental treatment?			
6. Had surgery for a growth anywhere in his/her body?			
Does Your Child			
1. Have a pacemaker, or had any form of heart surgery?			
2. Suffer from hay fever, eczema or any other allergy?			
3. Suffer from bronchitis, asthma or other chest conditions?			
4. Have fainting attacks, giddiness, blackouts or epilepsy?			
5. Have diabetes, or a family history of diabetes?			
6. Carry a warning card?			
7. Are there any other aspects concerning your child's health that you think the dentist should know about?			

Signature of Parent / Guardian: _____ Date: _____

Protocol OHSRC00806:

Demographic Data Record

Demographic Data Record

Child's Name _____

Child's Date Of Birth _____

Child's Address _____

_____

_____

_____

How long has the child lived at this address? _____Years _____Months

Is the child's home connected to a public piped water supply? Yes ☐ No ☐

Is the child's home connected to a group water supply? Yes ☐ No ☐

Child's Previous Address (if any) _____

_____

_____

_____

Was the child's previous home connected to a public piped water supply?

Yes ☐ No ☐ Not applicable ☐

Is the child currently taking a course of fluoride tablets? Yes ☐ No ☐

Has the child ever taken a course of fluoride tablets? Yes ☐ No ☐

Does your family have a medical card? Yes ☐ No ☐

Thank you for your time and co-operation.





Protocol OHSRC00806:

Soft Tissue Examination Recording Form

SCR ☐☐☐ Date of Exam ☐☐☐☐☐☐

Initials ☐☐☐ Sex ☐ Date of Birth ☐☐☐☐☐☐

Soft Tissue Examination

Were any Soft Tissue Abnormalities detected?

	Yes	No	If yes detail below:
Lips	☐	☐	_____
Bucccal Mucosa	☐	☐	_____
Labial mucosa	☐	☐	_____
Sublingual mucosa	☐	☐	_____
Attatched gingivae	☐	☐	_____
Tongue	☐	☐	_____
Hard/soft palate	☐	☐	_____
Uvula	☐	☐	_____
Oropharynx	☐	☐	_____

General Comment: _____

_____

_____

Examiner: _____ Date: _____

QC: _____ Date: _____

Protocol OHSRC00806:

Toothwear Examination Form

Toothwear Examination

Initials: ☐☐☐ Subject Number: ☐☐☐☐☐☐

Date of Birth: ☐☐ ☐☐ ☐☐ School Number: ☐☐☐

Sex: ☐

Fluoride: ☐ No Fluoride: ☐ Fluoride Supplements: ☐

Date of Examination: ☐☐ ☐☐ ☐☐

Upper Right:

Tooth	Status	Toothwear				
			B	C 1/3rd	O/I	L
16		Enamel				
		Dentine				
		Bucc.Cer. 1/3rd Depth				
15		Enamel				
		Dentine				
		Bucc.Cer. 1/3rd Depth				
14		Enamel				
		Dentine				
		Bucc.Cer. 1/3rd Depth				
13		Enamel				
		Dentine				
		Bucc.Cer. 1/3rd Depth				
12		Enamel				
		Dentine				
		Bucc.Cer. 1/3rd Depth				
11		Enamel				
		Dentine				
		Bucc.Cer. 1/3rd Depth				

Upper Left:

Tooth	Status	Toothwear				
[redacted]			B	C 1/3rd	O/I	L
21		Enamel				
[redacted]		Dentine				
[redacted]		Bucc.Cer. 1/3rd Depth				
22		Enamel				
[redacted]		Dentine				
[redacted]						
23		Enamel				
[redacted]		Dentine				
[redacted]		Bucc.Cer. 1/3rd Depth				
24		Enamel				
[redacted]		Dentine				
[redacted]		Bucc.Cer. 1/3rd Depth				
25		Enamel				
[redacted]		Dentine				
[redacted]		Bucc.Cer. 1/3rd Depth				
26		Enamel				
[redacted]		Dentine				
[redacted]		Bucc.Cer. 1/3rd Depth				

Lower Left:

Tooth	Status	Toothwear				
[redacted]			B	C 1/3rd	O/I	L
36		Enamel				
[redacted]		Dentine				
[redacted]		Bucc.Cer. 1/3rd Depth				
35		Enamel				
[redacted]		Dentine				
[redacted]						
34		Enamel				
[redacted]		Dentine				
[redacted]		Bucc.Cer. 1/3rd Depth				
33		Enamel				
[redacted]		Dentine				
[redacted]		Bucc.Cer. 1/3rd Depth				
32		Enamel				
[redacted]		Dentine				
[redacted]		Bucc.Cer. 1/3rd Depth				
31		Enamel				
[redacted]		Dentine				
[redacted]		Bucc.Cer. 1/3rd Depth				

Lower Right:

Tooth	Status	Toothwear				
			B	C 1/3rd	O/I	L
41		Enamel				
		Dentine				
		Bucc.Cer. 1/3rd Depth				
42		Enamel				
		Dentine				
43		Enamel				
		Dentine				
		Bucc.Cer. 1/3rd Depth				
44		Enamel				
		Dentine				
		Bucc.Cer. 1/3rd Depth				
45		Enamel				
		Dentine				
		Bucc.Cer. 1/3rd Depth				
46		Enamel				
		Dentine				
		Bucc.Cer. 1/3rd Depth				

B = Buccal / Labial O = Occlusal I = Incisal L = Lingual / Palatal C1/3rd = Buccal-Cervical 1/3rd

Tooth status code

Code: A Adult tooth present
E Adult tooth extracted due to caries
T Missing due to trauma
M Missing for other reasons
C Crown present
V Veneer present
R Tooth / Surface cannot be scored

Preface to surface condition code:
A condition score is given to the buccal/labial, lingual/palatal and the occlusal or incisal surface of all erupted permanent teeth in all quadrants. The index grades 4 individual surfaces:
Buccal- assessment includes the cervical buccal portion
Buccal-Cervical = cervical 1/3rd of tooth
Palatal /Lingual
Incisal / Occlusal

Where dental restoration(s) occupy greater than 1/4 of the specific surface area, that surface will not be scored and marked 'R'.

Tooth wear in the enamel and dentine will be scored separately. The dental examiner is trained to score the enamel first, then dentine and finally the cervical area. For the cervical buccal area tooth wear is assessed in terms of enamel, dentine and depth. The examiner is trained to score tooth wear in enamel first, then dentine and finally depth of area of wear

(A) ETWI INDEX FOR ENAMEL:

0 - no tooth wear: no loss of enamel characteristics or change in contour

1 - loss of enamel affecting less than $1/10^{th}$ of the scored surface

2 - enamel loss affecting less than $1/3^{rd}$ of the scored surface

3 - enamel loss affecting at least $1/3^{rd}$ but less than $2/3^{rd}$ of the scored surface

4 - enamel loss affecting $2/3^{rd}$ or more of the scored surface

(B) ETWI INDEX FOR DENTINE:

0 - no dentinal tooth wear: no loss of dentine

1 - loss of dentine affecting less than $1/10^{th}$ of the scored surface

2 - dentine loss affecting less than $1/3^{rd}$ of the scored surface

3 - dentine loss affecting at least $1/3^{rd}$ but less than $2/3^{rd}$ of the scored surface

4 - dentine loss affecting $2/3^{rd}$ or more of the scored surface, no pulpal exposure

5 - secondary dentine formation or pulpal exposure

(C) ETWI INDEX FOR DEPTH ON CERVICAL BUCCAL SURFACES: (measured with a standard W&H periodontal probe)

0 - no tooth wear: no loss of tooth surface

1 - less than 1mm loss of tooth surface depth

2 - tooth surface loss in depth measuring at least 1mm but less than 2mm

3 - tooth surface loss greater in depth than 2mm

Protocol OHSRC00806:

Tooth Erosion Examination Form

Tooth Erosion Examination

Initials: ☐☐☐ Subject Number: ☐☐☐☐☐☐

Date of Birth: ☐☐ ☐☐ ☐☐ Age: ☐☐ Ask child what age are You?

Sex: ☐

School: _____ School Number: ☐☐

No Fluoride: ☐ Fluoridated water: ☐ Fluoride Supplements: ☐

Examiner Number: ☐☐ Duplication: ☐

Examination Date: ☐☐ ☐☐ ☐☐

Tooth		Status	Tooth Wear Depth			Tooth Wear Area		
			B	O/I	L	B	O/I	L
1.6	■							
1.5	E							
1.4	D							
1.3	C						■	
1.2	B						■	
1.1	A						■	

Tooth		Status	Tooth Wear Depth			Tooth Wear Area		
			B	O/I	L	B	O/I	L
4.6	■							
4.5	E							
4.4	D							
4.3	C						■	
4.2	B						■	
4.1	A						■	

Tooth		Status	Tooth Wear Depth			Tooth Wear Area		
			B	O/I	L	B	O/I	L
2.1	A						■	
2.2	B						■	
2.3	C						■	
2.4	D							
2.5	E							
2.6	■							

Tooth		Status	Tooth Wear Depth			Tooth Wear Area		
			B	O/I	L	B	O/I	L
3.1	A						■	
3.2	B						■	
3.3	C						■	
3.4	D							
3.5	E							
3.6	■							

B=Buccal/Labial
O=Occlusal
I=Incisal
L=Lingual/Palatal

Protocol OHSRC00806:

Oral Hygiene, Dietary Habits and Behaviours Questionnaire

Oral Hygiene and Dietary Practices Questionnaire

Instructions to Children taking part in the study.

Hi Students please can you take some time to answer a few questions

- Most of the questions can be answered by placing a tick (✓) in the box next to the answer that is nearest to what you usually do.
- You may find that in some questions there is more than one answer. Please tick all the boxes that apply.
- If you cannot remember, if you do not know or if you are unable to answer a particular question please write 'don't know' or 'can't remember' beside that question.
- Try and answer all questions as truthfully as possible. Any information you give will be treated as top secret and you will not be identified in any way.
- Please return the completed Forms to your teacher *tomorrow* in the envelope provided.



Thank You



Oral Hygiene and Dietary Practices Questionnaire

For Office use only:

Subject Number: ☐☐☐☐☐☐ Name of Primary School: _____ School Number: ☐☐

Student to complete:

Name of child: _____ Age: _____ Date of Birth: ☐☐-☐☐-☐☐
DAY MONTH YEAR

1. **How often since the last school summer holidays have you visited the dentist?**

   Not at all ☐ Once ☐ Twice ☐ Three times or more ☐

2. **Who usually brushes your teeth?**

   My teeth are not usually brushed ☐ I do myself ☐ An Adult ☐ Myself and an Adult ☐

3. **How often are your teeth brushed?**

   Never ☐ Once a week ☐ Less than once a week ☐ Once a day ☐ Twice a day ☐ Three or more times a day ☐

5. **At what time(s) of day are your teeth brushed?**

   Before breakfast ☐ After breakfast ☐ Before other meals ☐ After other meals ☐ After drinking fruit/fizzy drinks ☐

   Before going to bed ☐ Never ☐ Other ☐ , please write down if you brush at another time: _____

6. **In this question I would like to know what drink(s) you take and how often you have them.**
It is helpful to read through the list before answering the questions. Please tick (✓) a box in the *How Often* section, that is closes to what you do.
Please tick (✓) whether the drink is usually 'Regular', 'Diet' or 'No sugar added' where the choice is given and Still or Fizzy/Sparkling if that applies.

List of Drinks	***How Often are the drinks taken***							
	Never	Once a month	Once or twice a week	Once a day	Twice a day	Three times a day	Four to six times a day	
Pure Fruit Juice (for example, Orange, Apple, Grapefruit etc.)								
Fizzy Drinks (e.g. Cola, lemonade, 7-Up etc.) Please tick whether the drink is usually Regular ☐ Diet ☐								
Fruit Squash (Diluted drinks: Orange, Lemon, Blackcurrant etc.) Please tick whether the drink is usually. Regular ☐ No sugar added ☐								
"Tooth Kind" Drinks (e.g. Ribena ToothKind)								
Bottled water Please tick whichever the child usually has Still ☐ Fizzy/ Sparkling ☐								
Milk								
Other Drink Please write it on the line:_____								

7. When do you have your drink(s)? Please place a tick (✓) in each space that is closest to what you do. There may be more than one tick (✓) on each line.

List of Drinks	***When is the drink taken***						
	Never	Breakfast	Lunch	At School	Dinner	Between meals	Bed time
Pure Fruit Juice (e.g. Orange, Apple, Grapefruit etc.)							
Fizzy Drinks (e.g. Cola, lemonade, 7-Up etc.)							
Fruit Squash (Diluted drinks: Orange, Lemon, Blackcurrant etc.)							
"Tooth Kind" Drinks (e.g. Ribena ToothKind)							
Bottled water.							
Milk							
Other Drinks (e.g. Five Alive, Sunny Delight Capri Sun) Please specify:_____							

8. How do you usually take your drink?

From a cup/glass ☐ From a can ☐ Through a straw ☐ From the bottle ☐
Other☐, If there is another way please write it down: _____

9. Please can you estimate how many times you have:

(i) Pure fruit juice in a typical day ☐ times.

(ii) Fizzy drinks in a typical day. ☐ times.

(iii) Fruit squash (dilutable drinks) in a typical day ☐ times.

10. How often do you have the following list of foods?
It is helpful to read through the food list before answering the questions. The first column lists the foods. The second column asks how often the foods are eaten. Please place a tick (✓) in each space that is closest to what you do
The final column asks you to write down a typical example of the type of food/snack eaten for each group ticked: (for example, for Citrus Fruits it could be Orange, for Yoghurt it could be Petit Filous, for spicy food it could be curry.)

Food	***Frequency*** **(How often are the foods eaten)**								***Please write in*** *the name of the 'food'*
	Never	Less than once a month	At least once month	Once or twice a week	Once a day	Twice a day	Three times a day	Four to six times a day	
Citrus Fruits (Oranges, Grapefruits etc.)									
Apples or other fruit									
Yoghurt									
Tomato/Brown sauce									
Vinegar with food									
Spicy food									

11. **Do you ever have any of the following?**

Stomach Upsets: Yes ☐ No ☐ How often: _____

Frequent Vomiting: Yes ☐ No ☐ How often: _____

12. **Do you take vitamin tablets?** Yes ☐ No ☐

13. **Are your teeth sensitive?** Yes ☐ No ☐

14. **Do you get tooth freeze when eating normally everyday foods?** Yes ☐ No ☐

15. **Had you ever heard of tooth wear or dental erosion before this study?** Yes ☐ No ☐

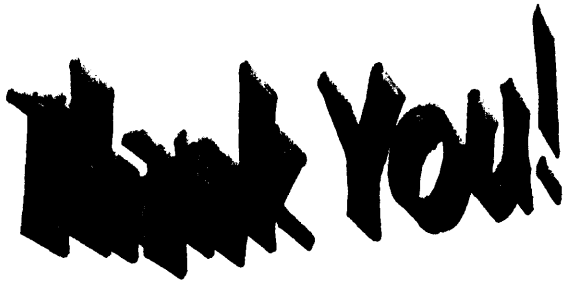
16. **If YES, where did you hear about it (e.g. Dentist, Friend, Magazine, T.V.)?**

_____

Thank you for taking the time to complete this questionnaire.



Don't forget to put it in the envelope and bring it back to your teacher at school tomorrow.



Longitudinal study of 14-year-olds (Protocol OHSRC00409)

Protocol OHSRC00409:

Cover Letter to Parents/Guardians

Dear Parent/Guardian,

When your child was five years old and again when they were twelve years old you kindly agreed to allow them participate in a study to examine their teeth for signs of tooth wear (wear from the tooth surface) and also at age five for dental decay (holes in their teeth). At that time we also asked you whether you would mind being contacted in the future.

We would now like to see your child again and examine the 'adult teeth' for tooth wear and dental decay. The study is explained in greater detail in the informed consent which accompanies this note.

Since being examined at age 12 years, the children in this study have moved from primary to secondary schools. As the children are more spread out amongst the secondary schools, this means that there are several cases where only one or two children in the study are attending a particular school. Your child's school is one of these. Because of that, we would like if possible to see your child here at the Oral Health Services Research Centre, attached to the University Dental School & Hospital in Wilton. Your child would need to be accompanied by a parent or guardian, and the visit would take place outside of school hours. You would be compensated for any travel expenses incurred. However, your child's continued participation in the study is important to us, and if you prefer, we will come to your child's school and conduct the examination there.

I would be very grateful if you would complete the informed consent, your child's details on the enclosed forms and the confidential medical questionnaire. The medical questionnaire is so that we will know whether it is correct for your child to participate in the study. Please also complete the attached slip to indicate whether you are willing to attend the Oral Health Services Research Centre with your child.
I would also like you to ask your child to complete the enclosed assent form which explains the study to them.

Please return all completed forms to the Oral Health Services Research Centre using the stamped addressed envelope provided.

Your child will be presented with a toothbrush and toothpaste as a token of appreciation.

Thanking you in anticipation of your co-operation, and continued support.

Yours faithfully,

_____

Mairead Harding BDS, MFGDP (UK), MDPH

Protocol No: OHSRC00409

Child's name: _____

Please complete one of the options below:

I am willing to attend the Oral Health Services Research Centre (attached to the University Dental School & Hospital in Wilton) with my child at a date and time convenient to both my family and the study staff. I understand that if I choose this option, any travel expenses incurred by me will be reimbursed.

Signature of parent/guardian: _____ Date: _____

OR

I will not be able to attend to the Oral Health Services Research Centre with my child. I would prefer that my child be examined in his/her school.

Signature of parent/guardian: _____ Date: _____

Protocol OHSRC00409:

Parent Information and Consent form

To be printed on OHSRC headed notepaper

Parents Information and Informed Consent Form

Protocol No: OHSRC00409 **Subject name:**_____

Dentist directing the research: Prof. Helen Whelton **Subject No:**_____

Your child is being invited to participate in a research study. In order to decide whether or not you want your child to be a part of this study, you should understand enough about its risks and benefits to make an informed judgement. This process is known as informed consent. This consent form gives detailed information about the research study. Once you understand the study, you will be asked to sign this form if you wish your child to participate. The study is also explained to your child in child-appropriate terms in the enclosed Child Information and Assent form.

This study is a follow-up to two studies your child participated in: during 2001, when he/she was aged approximately 5 years; and again in 2007, when he/she was aged approximately 12 years. In both those studies, your child's teeth were examined for signs of tooth wear and tooth erosion, a type of tooth wear. And in the first study, your child's teeth were also examined for dental decay. This study will look at tooth wear and dental decay in children who participated in the earlier studies and will compare results to those studies in order to find out whether there are any changes. This research will help us to learn more about tooth wear and dental decay, and in the long term the research may provide information for the planning of dental services.

Participation in this study will involve one session (of approximately 20 minutes) at your child's school or at the Oral Health Services Research Centre, University Dental School & Hospital, Wilton, during which his/her teeth will be examined for tooth wear and dental decay. Photographs will be taken to compare with those taken in the previous study, and to assist with education and training. Photographs will be of the inside of the mouth only, so the identity of the child would not be obvious to anyone viewing the photographs. Photographs will be taken using a digital camera and dentist's mirror. The names of children will not be used in any publications, you and your child may agree or not to the taking of photographs.

Your child will also be asked to complete a questionnaire on a laptop computer relating to his / her oral health care, eating, drinking and snacking habits. Approximately 10% of participating children will be examined a second time as a check on the consistency of the examining dentist. No risks or discomforts are anticipated as a result of participation in this study. There is no expected direct benefit to your child, except for the possibility of early diagnosis of tooth wear and dental decay. If signs of significant oral health problems are detected, you will be informed. No treatment will be carried out as part of this project.

It should be noted that procedures conducted during this study do not replace regular dental check-ups. Also, your child is free to refrain from participation in this study for any reason. Up to two hundred children will participate.

If you wish your child to participate in this study please complete this form, the Demographic Data form, and the questionnaire relating to the general health of your child. Please return all forms to the Oral Health Services Research Centre in the stamped addressed envelope provided. The information you give will be treated with the strictest confidence, and will be used for statistical purposes only. Nothing that would identify you or your child will be included in the results.

If your child completes the study he/she will be presented with a gift of a toothbrush and toothpaste.

Thank you for your interest.

Agreement to Consent

I am aware that participation is voluntary and that I may withdraw my consent at any time. I am aware that my decision not to allow my child to participate or to withdraw my child will not restrict his/her access to health care services normally available to him/her. Confidentiality of records concerning my child's involvement in this project will be maintained in an appropriate manner. When required by law, the records of this research may be reviewed by government agencies and sponsors of the research.

I, the undersigned, hereby consent to allow my child to participate as a subject in the above described project to be conducted at his/her school or at the Oral Health Services Research Centre, University Dental School & Hospital, Wilton. I have received a copy of this consent form for my records. I understand that if I have any questions concerning this research, I can contact the dentist listed above. If I have any questions concerning my child's rights in connection with the research, I can contact the Clinical Research Ethics Committee of the Cork Teaching Hospitals at 021-4345599. If I have any queries about the study procedure I can contact Prof. Helen Whelton at (021) 4901210.

After reading the entire consent form, if you have no further questions about giving consent, please sign where indicated.

I agree to my child's participation in the study and the taking of photographs:

Signature of parent/guardian: _____ Date: _____

OR

I agree to my child's participation in the study but not the taking of photographs:

Signature of parent/guardian: _____ Date: _____

Signature of child: _____ Date: _____

My child's details may be entered on a confidential computer database for use by the staff of the Research Centre, who may use it to contact me in the future should my child be suitable for inclusion in another trial or as a follow up to this study.

Please tick one box: Yes ☐ No☐

If I do not wish to have my child's details entered on the computer database, I understand that he/she can still participate in this study.

Signature of Parent/Guardian: _____ Date: _____

To be printed on OHSRC headed notepaper

Parents Information and Informed Consent Form

Protocol No: OHSRC00409 **Subject name:**_____

Dentist directing the research: Prof. Helen Whelton **Subject No:**_____

Your child is being invited to participate in a research study. In order to decide whether or not you want your child to be a part of this study, you should understand enough about its risks and benefits to make an informed judgement. This process is known as informed consent. This consent form gives detailed information about the research study. Once you understand the study, you will be asked to sign this form if you wish your child to participate. The study is also explained to your child in child-appropriate terms in the enclosed Child Information and Assent form.

This study is a follow-up to two studies your child participated in: during 2001, when he/she was aged approximately 5 years; and again in 2007, when he/she was aged approximately 12 years. In both those studies, your child's teeth were examined for signs of tooth wear and tooth erosion, a type of tooth wear. And in the first study, your child's teeth were also examined for dental decay. This study will look at tooth wear and dental decay in children who participated in the earlier studies and will compare results to those studies in order to find out whether there are any changes. This research will help us to learn more about tooth wear and dental decay, and in the long term the research may provide information for the planning of dental services.

Participation in this study will involve one session (of approximately 20 minutes) at your child's school, during which his/her teeth will be examined for tooth wear and dental decay. Photographs will be taken to compare with those taken in the previous study, and to assist with education and training. Photographs will be of the inside of the mouth only, so the identity of the child would not be obvious to anyone viewing the photographs. Photographs will be taken using a digital camera and dentist's mirror. The names of children will not be used in any publications, you and your child may agree or not to the taking of photographs.

Your child will also be asked to complete a questionnaire on a laptop computer relating to his / her oral health care, eating, drinking and snacking habits. Approximately 10% of participating children will be examined a second time as a check on the consistency of the examining dentist. No risks or discomforts are anticipated as a result of participation in this study. There is no expected direct benefit to your child, except for the possibility of early diagnosis of tooth wear and dental decay. If signs of significant oral health problems are detected, you will be informed. No treatment will be carried out as part of this project.

It should be noted that procedures conducted during this study do not replace regular dental check-ups. Also, your child is free to refrain from participation in this study for any reason. Up to two hundred children will participate.

If you wish your child to participate in this study please complete this form, the Demographic Data form, and the questionnaire relating to the general health of your child. Please return all forms to the child's teacher in the envelope provided. The information you give will be treated with the strictest confidence, and will be used for statistical purposes only. Nothing that would identify you or your child will be included in the results.

If your child completes the study he/she will be presented with a gift of a toothbrush and toothpaste.

Thank you for your interest.

Agreement to Consent

I am aware that participation is voluntary and that I may withdraw my consent at any time. I am aware that my decision not to allow my child to participate or to withdraw my child will not restrict his/her access to health care services normally available to him/her. Confidentiality of records concerning my child's involvement in this project will be maintained in an appropriate manner. When required by law, the records of this research may be reviewed by government agencies and sponsors of the research.

I, the undersigned, hereby consent to allow my child to participate as a subject in the above described project to be conducted at his/her school. I have received a copy of this consent form for my records. I understand that if I have any questions concerning this research, I can contact the dentist listed above. If I have any questions concerning my child's rights in connection with the research, I can contact the Clinical Research Ethics Committee of the Cork Teaching Hospitals at 021-4345599. If I have any queries about the study procedure I can contact Prof. Helen Whelton at (021) 4901210.

After reading the entire consent form, if you have no further questions about giving consent, please sign where indicated.

I agree to my child's participation in the study and the taking of photographs:

Signature of parent/guardian: _____ Date: _____

OR

I agree to my child's participation in the study but not the taking of photographs:

Signature of parent/guardian: _____ Date: _____

Signature of child: _____ Date: _____

My child's details may be entered on a confidential computer database for use by the staff of the Research Centre, who may use it to contact me in the future should my child be suitable for inclusion in another trial or as a follow up to this study.

Please tick one box: Yes ☐ No☐

If I do not wish to have my child's details entered on the computer database, I understand that he/she can still participate in this study.

Signature of Parent/Guardian: _____ Date: _____

Protocol OHSRC00409:

Child Information and Assent form

To be printed on OHSRC headed paper

Child Information and Assent Form

Dentist directing the Research: Prof. Helen Whelton
Protocol No: OHSRC00409

Subject name:_____ Subject No:_____

You have been invited to participate in a research study. This form will explain the study to you. Once you have read the form, if you would like to participate please will you sign at the bottom of the page.

This study is a follow-up to two studies you took part in, when you were approximately 5 years old and again when you were approximately 12 years old.
In the first study, your 'baby teeth' were examined for signs of tooth wear caused by acidic foods and drinks, and tooth decay ('bad teeth'). The second study looked at your 'adult teeth' for signs of tooth wear. This new study will look at your teeth for signs of both tooth wear and tooth decay to see if there are any differences from the previous studies.
The study will involve one visit (of about 20 minutes) at your school or at the Oral Health Services Research Centre in Wilton, in that time your teeth will be checked for tooth wear and dental decay by a dentist. The examination is safe and doesn't hurt at all. No treatment will be given. Photos of tooth wear may be taken by the dentist to compare with the photos taken in the previous study, and to help with training and educating dentists and the employees of the sponsoring company about tooth wear. This will be like having a photo taken of part of the inside of your mouth. Your face will not be in the photo, so no-one looking at it would know that it was you.
We would also like you to complete a simple questionnaire relating to how you care for your teeth and some questions on the foods and drinks you like. You will complete the questionnaire using a laptop computer that we will provide for your use on the day of examination.
To check that the dentist doing the examinations is doing the exam the same way each time, some of you may be examined a second time.

If you complete the study you will be presented with a gift of a toothbrush and toothpaste.
Thank you for your interest.

After reading the form, and if you have no further questions about participating, please sign below.

I agree to take part in the study, and I agree to having photos taken if the dentist decides it would be useful for the study.

Signature of child: _____ Date: _____

I agree to take part in the main part of the study, but I don't want to have photos taken

Signature of child: _____ Date: _____

To be printed on OHSRC headed paper

Child Information and Assent Form

Dentist directing the Research: Prof. Helen Whelton
Protocol No: OHSRC00409

Subject name:_____ Subject No:_____

You have been invited to participate in a research study. This form will explain the study to you. Once you have read the form, if you would like to participate please will you sign at the bottom of the page.

This study is a follow-up to two studies you took part in, when you were approximately 5 years old and again when you were approximately 12 years old.
In the first study, your 'baby teeth' were examined for signs of tooth wear caused by acidic foods and drinks, and tooth decay ('bad teeth'). The second study looked at your 'adult teeth' for signs of tooth wear. This new study will look at your teeth for signs of both tooth wear and tooth decay to see if there are any differences from the previous studies.
The study will involve one visit (of about 20 minutes) at your school, in that time your teeth will be checked for tooth wear and dental decay by a dentist. The examination is safe and doesn't hurt at all. No treatment will be given. Photos of tooth wear may be taken by the dentist to compare with the photos taken in the previous study, and to help with training and educating dentists and the employees of the sponsoring company about tooth wear. This will be like having a photo taken of part of the inside of your mouth. Your face will not be in the photo, so no-one looking at it would know that it was you.
We would also like you to complete a simple questionnaire relating to how you care for your teeth and some questions on the foods and drinks you like. You will complete the questionnaire using a laptop computer that we will provide for your use on the day of examination.
To check that the dentist doing the examinations is doing the exam the same way each time, some of you may be examined a second time.

If you complete the study you will be presented with a gift of a toothbrush and toothpaste.
Thank you for your interest.

After reading the form, and if you have no further questions about participating, please sign below.

I agree to take part in the study, and I agree to having photos taken if the dentist decides it would be useful for the study.

Signature of child: _____ Date: _____

I agree to take part in the main part of the study, but I don't want to have photos taken

Signature of child: _____ Date: _____

Protocol OHSRC00409:

Confidential Medical History Questionnaire

Confidential Medical History Questionnaire

To be completed by Parent / Guardian

Child's Name: _____ Child's Date of Birth: ☐☐☐☐☐☐ D D M M Y Y

Is Your child	Yes	No	Please write in details and the names of medicines.
1. Attending or receiving treatment from a doctor, hospital, clinic or specialist?			
2. Taking any medicines from his/her doctor? (tablets, inhalers, creams, ointments, injections, other)			
3. Allergic to any medicines, foods or materials?			
Has your child			
1. Had rheumatic fever?			
2. Had jaundice liver disease, kidney disease or hepatitis?			
3. Ever been told he/ she has a heart murmur or heart problem, or high blood pressure?			
4. Been hospitalised? If yes, what for and when?			
5. Had any serious trouble associated with previous dental treatment?			
6. Had surgery for a growth anywhere in his/her body?			
Does Your Child			
1. Have a pacemaker, or had any form of heart surgery?			
2. Suffer from hay fever, eczema or any other allergy?			
3. Suffer from bronchitis, asthma or other chest conditions?			
4. Have fainting attacks, giddiness, blackouts or epilepsy?			
5. Have diabetes, or a family history of diabetes?			
6. Carry a warning card?			
7. Are there any other aspects concerning your child's health that you think the dentist should know about?			

Signature of Parent / Guardian: _____ Date: _____

Protocol OHSRC00409:

Demographic Data Record

Demographic Data Record

OHSRC00409

Child's Name _____

Child's Date of Birth _____

Child's Address _____

_____

_____

_____

How long has the child lived at this address? _____Years _____Months

Is the child's home connected to a public piped water supply? Yes ☐ No ☐

Is the child's home connected to your own private well or a group water supply?

Yes ☐ No ☐

Child's Previous Address (if any) _____

_____

_____

_____

Was the child's previous home connected to a public piped water supply?

Yes ☐ No ☐ Not applicable ☐

Is the child currently taking a course of fluoride tablets? Yes ☐ No ☐

Has the child ever taken a course of fluoride tablets? Yes ☐ No ☐

Does your family have a medical card? Yes ☐ No ☐

Thank you for your time and help.





Protocol OHSRC00409:

Soft Tissue Examination Recording Form

SCR ☐☐☐ Date of Exam ☐☐☐☐☐☐

Initials ☐☐☐ Sex ☐ Date of Birth ☐☐☐☐☐☐

Soft Tissue Examination

Were any Soft Tissue Abnormalities detected?

	Yes	No	If yes detail below:
Lips	☐	☐	_____
Bucccal Mucosa	☐	☐	_____
Labial mucosa	☐	☐	_____
Sublingual mucosa	☐	☐	_____
Attatched gingivae	☐	☐	_____
Tongue	☐	☐	_____
Hard/soft palate	☐	☐	_____
Uvula	☐	☐	_____
Oropharynx	☐	☐	_____

General Comment: _____

_____

_____

Examiner: _____ Date: _____

QC: _____ Date: _____

Protocol OHSRC00409:

Toothwear Examination Form

OHSRC00409

Toothwear Examination

Initials: ☐☐☐ Subject Number: ☐☐☐☐☐☐

Date of Birth: ☐☐ ☐☐ ☐☐ School Number: ☐☐☐

Sex: ☐

Fluoride: ☐ No Fluoride: ☐ Fluoride Supplements: ☐

Date of Examination: ☐☐ ☐☐ ☐☐

Upper Right:

Tooth	Status		Toothwear			
			B	C 1/3rd	O/I	L
16		Enamel				
		Dentine				
		Bucc.Cer. 1/3rd Depth				
15		Enamel				
		Dentine				
		Bucc.Cer. 1/3rd Depth				
14		Enamel				
		Dentine				
		Bucc.Cer. 1/3rd Depth				
13		Enamel				
		Dentine				
		Bucc.Cer. 1/3rd Depth				
12		Enamel				
		Dentine				
		Bucc.Cer. 1/3rd Depth				
11		Enamel				
		Dentine				
		Bucc.Cer. 1/3rd Depth				

Upper Left:

Tooth	Status	Toothwear				
[redacted]		[redacted]	B	C 1/3rd	O/I	L
21		Enamel				
[redacted]		Dentine				
[redacted]		Bucc.Cer. 1/3rd Depth				
22		Enamel				
[redacted]		Dentine				
[redacted]						
23		Enamel				
[redacted]		Dentine				
[redacted]		Bucc.Cer. 1/3rd Depth				
24		Enamel				
[redacted]		Dentine				
[redacted]		Bucc.Cer. 1/3rd Depth				
25		Enamel				
[redacted]		Dentine				
[redacted]		Bucc.Cer. 1/3rd Depth				
26		Enamel				
[redacted]		Dentine				
[redacted]		Bucc.Cer. 1/3rd Depth				

Lower Left:

Tooth	Status	Toothwear				
[redacted]		[redacted]	B	C 1/3rd	O/I	L
36		Enamel				
[redacted]		Dentine				
[redacted]		Bucc.Cer. 1/3rd Depth				
35		Enamel				
[redacted]		Dentine				
[redacted]						
34		Enamel				
[redacted]		Dentine				
[redacted]		Bucc.Cer. 1/3rd Depth				
33		Enamel				
[redacted]		Dentine				
[redacted]		Bucc.Cer. 1/3rd Depth				
32		Enamel				
[redacted]		Dentine				
[redacted]		Bucc.Cer. 1/3rd Depth				
31		Enamel				
[redacted]		Dentine				
[redacted]		Bucc.Cer. 1/3rd Depth				

Q31. Are your teeth sensitive or do you get tooth freeze with normal everyday foods?

(i) Yes ☐

(ii) No ☐

Q32. How often are you involved in physical and strenuous exercise?

(i) Once a week ☐

(ii) Twice a week ☐

(iii) Three to four times a week ☐

(ii) Everyday ☐

(viii) Other ☐ Please specify:_____

Finally a couple of questions regarding your awareness of tooth wear:

Q33. Before this study had you heard of toothwear or dental erosion?

(i) Yes ☐

(ii) No ☐

Q34. What do you think toothwear or dental erosion is caused by?

(i) Sugar in foods ☐

or

(ii) Acidic Foods ☐

Thank You for taking the time to complete this questionnaire
Your help is greatly appreciated

Appendix 9:

Protein concentration, carbonyl concentration, ratio and inorganic ion concentration, where available in the unstimulated whole saliva of participants selected for 2-DE with no or moderate tooth wear scores.

Protein concentration, carbonyl concentration, ratio and inorganic ion concentration in unstimulated whole saliva samples selected for participants with moderate tooth wear scores

ID Number gender (Moderate Wear)	Protein Concentration µg µml^{-1}	Carbonyl Concentration mM	Carbonyl : Protein Ratio	Salive flow ml min^{-1}	F mmoll^{-1}	P mmoll^{-1}	Ca mmoll^{-1}
281020 male	1.3858	0.0116*	0.0084	0.40	0.062	6.06	0.38
301003 male	1.2868	0.0120*	0.0094	0.60	nd	nd	nd
271009 male	0.8249	0.0241~	0.0292	0.53	nd	nd	nd

Protein concentration, carbonyl concentration, ratio and inorganic ion concentration in unstimulated whole saliva samples selected for participants with moderate tooth wear scores

ID Number gender molar tooth wear score in dentine	Protein Concentration µg/µml	Carbonyl Concentration mM	Carbonyl/Protein Ratio	Saliva flow ml/min	F mmoll^{-1}	P mmoll-1	Ca mmoll-1
231008 female	1.0009	0.0243~	0.0242	0.31	nd	x	x
251009 male	1.3473	0.0235~	0.0174	0.31	0.169	6.68	1.34
331012 female	1.1054	0.0111*	0.0100	0.21	x	x	x

Protein concentration, carbonyl concentration, ratio and inorganic ion concentration in unstimulated whole saliva samples selected for participants with no tooth wear

ID Number 'no' tooth wear	Protein Concentration µg/µml	Carbonyl Concentration mM	Carbonyl/Protein Ratio	Saliva flow ml/min	F mmoll-1	P mmoll-1	Ca mmoll-1
241060 male water F	0.8789	0.0103*	0.0117	0.36	0.052	6.92	1.56
321001 Male no F water	0.2594	0.0111*	0.0430	0.17	nd	nd	nd
281011 female water F	0.6618	0.0109*	0.0164	0.68	0.11	7.86	0.78

Low Carbonyl Concentration
~High Carbonyl Concentration
Nd not determined - X Insufficient sample to analyse

Appendix 10:

Salivary fluoride, phosphate and calcium ion concentration for each individual.

Participants with no tooth wear

Participants with no tooth wear. ID, Gender, unstimulated flow rate, stimulated flow rate and fluoride, phosphate and calcium concentrations in unstimulated and stimulated saliva.

Survey ID	Gender	Unstimulated Flow Rate(ml/min)	Stimulated Flow Rate(ml/min)	Fluoride (u) ppm /mMol l^{-1}	Phosphate (u) ppm /mMol l^{-1}	Calcium (u) ppm /mMol l^{-1}	Fluoride (s) ppm /mMol l^{-1}	Phosphate (s) ppm /mMol l^{-1}	Calcium (s) ppm /mMol l^{-1}
211003	F	0.36	1.83	2.43 / 0.13	598.05 / 6.30	35.19 / 0.88	0.80 / 0.042	643.34 / 6.77	61.40 / 1.53
231005	F	0.5	1.60	1.8 / 0.10	260.95 / 2.75	47.38 / 1.18	1.99 / 0.11	262.93 / 2.77	38.37 / 0.96
251003	M	0.26	1.97	3.75 / 0.20	327.33 / 3.45	20.18 / 0.50	1.98 / 0.10	226.57 / 2.39	45.66 / 1.14
251007	M	0.5	3.63	2.72 / 0.14	772.15 / 8.13	64.60 / 1.61	0.97 / 0.05	374.4 / 3.94	68.93 / 1.72
251015	M	0.58	2.70	2.65 / 0.14	372.64 / 3.92	33.25 / 0.83	1.15 / 0.06	227.05 / 2.39	40.22 / 1.00
251016	M	1.24	2.73	1.03 / 0.05	367.98 / 3.87	54.68 / 1.36	0.58 / 0.03	212.60 / 2.24	47.33 / 1.18
261010	M	0.5	2.67	0.77 / 0.04	229.88 / 2.42	18.06 / 0.45	0.94 / 0.05	181.21 / 1.91	38.35 / 0.96
271030	M	0.96	2.83	4.30 / 0.23	492.61 / 5.19	46.37 / 1.16	1.23 / 0.07	435.73 / 4.59	55.31 / 1.38
271032	M	0.7	1.97	4.39 / 0.23	417.73 / 4.40	29.48 / 0.74	1.18 / 0.06	317.42 / 3.34	34.73 / 0.87

Survey ID	Gender	Unstimulated Flow Rate(ml/min)	Stimulated Flow Rate(ml/min)	Fluoride (u) ppm /mMol l^{-1}	Phosphate (u) ppm /mMol l^{-1}	Calcium (u) ppm /mMol l^{-1}	Fluoride (s) ppm /mMol l^{-1}	Phosphate (s) ppm /mMol l^{-1}	Calcium (s) ppm /mMol l^{-1}
271033	M	0.28	1.30	4.58 / 0.24	506.51 / 5.33	28.50 / 0.71	1.89 / 0.10	424.39 / 4.47	26.49 / 0.66
281015	M	0.5	3.00	2.47 / 0.13	691.26 / 7.28	31.86 / 0.79	2.19 / 0.12	328.16 / 3.46	38.72 / 0.97
281018	M	0.5	1.00	3.45 / 0.18	668.80 / 7.04	47.80 / 1.19	0.68 / 0.04	670.64 / 7.06	56.41 / 1.41
301022	F	0.23	0.30	1.42 / 0.08	248.62 / 2.62	18.71 / 0.47	Insufficient Sample		
331001	F	0.22	0.70	2.71 / 0.14	518.53 / 5.46	37.33 / 0.93	2.21 / 0.12	407.67 / 4.29	29.52 / 0.74
331004	F	0.22	1.50	3.45 / 0.18	360.95 / 3.80	28.24 / 0.70	1.86 / 0.1	271.66 / 2.86	40.56 / 1.01
331032	F	0.82	3.17	1.67 / 0.09	314.73 / 3.31	79.23 / 1.98	Insufficient Sample		
341005	F	0.3	1.50	2.24 / 0.12	408.29 / 4.30	18.72 / 0.47	0.09 / 0.01	171.67 / 1.81	29.18 / 0.73
341012	F	0.31	2.50	1.70 / 0.09	350.93 / 3.70	13.58 / 0.34	0.25 / 0.01	276.73 / 2.91	61.15 / 1.53
361004	F	1	5.13	0.3 / 0.02	314.19 / 3.31	44.59 / 1.11	0.63 /0.03	202.79 / 2.14	52.83 / 1.32
361006	F	0.31	0.67	0.6 / 0.03	342.92 / 3.61	23.54 / 0.59	0.81 / 0.04	223.64 / 2.35	43.02 / 1.07
361019	F	0.38	2.17	1.12 / 0.06	450.12 / 4.74	32.62 / 0.81	1.18 / 0.06	458.38 / 4.83	34.64 / 0.86
361025	F	0.8	1.83	1.55 / 0.08	462.91 / 4.87	20.41 / 0.51	2.12 / 0.11	401.63 / 4.23	37.59 / 0.94

Survey ID	Gender	Unstimulated Flow Rate(ml/min)	Stimulated Flow Rate(ml/min)	Fluoride (u) ppm /mMol l^{-1}	Phosphate (u) ppm /mMol l^{-1}	Calcium (u) ppm /mMol l^{-1}	Fluoride (s) ppm /mMol l^{-1}	Phosphate (s) ppm /mMol l^{-1}	Calcium (s) ppm /mMol l^{-1}
3o1029	F	0.54	1.00	1.00 / 0.53	628.07 / 6.61	34.13 / 0.85	0.87 / 0.05	476.15 / 5.01	38.07 / 0.95
3o1031	F	0.53	1.50	1.66 / 0.09	460.25 / 4.85	23.85 / 0.60	0.78 / 0.04	398.33 / 4.19	23.45 / 0.59
3o1033	F	0.58	0.67	1.71 / 0.09	355.69 / 3.75	44.95 / 1.12	1.29 / 0.07	262.98 / 2.77	38.24 / 0.95
3o1039	F	0.5	2.5	2.52 / 0.13	365.08 / 3.84	27.36 / 0.68	1.04 / 0.06	301.12 / 3.17	26.31 / 0.66

Participants with moderate tooth wear

Participants with moderate tooth wear. ID, Gender, unstimulated flow rate, stimulated flow rate and fluoride, phosphate and calcium concentrations in unstimulated and stimulated saliva.

Survey ID	Gender	Unstimulated flow rate ml min^{-1}	Stimulated flow rate ml min^{-1}	Fluoride (u) ppm/mmol l^{-1}	Phosphate (u) ppm/mmol l^{-1}	Calcium (u) ppm/mmol l^{-1}	Fluoride (s) ppm/mmol l^{-1}	Phosphate (s) ppm/mmol l^{-1}	Calcium (s) ppm/mmol l^{-1}
211014	F	0.14	3.67	8.80 / 0.46	859.12 / 9.05	69.65 / 1.74	2.88 / 0.15	743.02 / 7.82	42.29 / 1.06
231010	F	1	3.00	1.99 / 0.11	285.17 / 3.00	51.59 / 1.29	0.63 / 0.03	270.22 / 2.85	29.42 / 0.73
251009	M	0.31	2.17	3.20 / 0.17	634.77 / 6.68	53.71 / 1.34	0.92 / 0.05	386.57 / 4.07	43.78 / 1.09
251012	M	0.36	2.43	2.55 / 0.13	732.29 / 7.71	59.09 / 1.47	0.88 / 0.05	426.12 / 4.49	35.65 / 0.89
261005	M	0.64	2.13	2.62 / 0.14	492.23 / 5.18	44.87 / 1.12	2.55 / 0.13	435.37 / 4.58	64.94 / 1.62
261012	F	0.7	1.90	4.47 / 0.24	366.91 / 3.86	79.72 / 1.99	3.24 / 0.17	305.31 / 3.21	43.49 / 1.09
271016	M	0.54	1.43	1.94 / 0.10	407.42 / 4.29	28.82 / 0.72	0.05 / 0.003	395.19 / 4.16	35.49 / 0.89
281012	M	0.35	2.37	2.47 / 0.13	542.70 / 5.71	51.19 / 1.28	0.83 / 0.04	268.45 / 2.83	36.11 / 0.90
281020	M	0.4	2.33	1.17 / 0.06	575.92 / 6.06	15.33 / 0.38	1.23 / 0.07	472.18 / 4.97	29.19 / 0.73
281034	M	0.76	2.13	1.83 / 0.10	590.45 / 6.22	48.72 / 1.22	0.91 / 0.05	348.78 / 3.67	37.08 / 0.93
311001	M	1.02	2.63	2.01 / 0.11	343.21 / 3.61	65.61 / 1.64	0.13 / 0.01	283.84 / 2.99	68.65 / 1.71

Survey ID	Gender	Unstimulated flow rate ml min $^{-1}$	Stimulated flow rate ml min $^{-1}$	Fluoride (u) ppm/mmol l $^{-1}$	Phosphate (u) ppm/mmol l $^{-1}$	Calcium (u) ppm/mmol l $^{-1}$	Fluoride (s) ppm/mmol l $^{-1}$	Phosphate (s) ppm/mmol l $^{-1}$	Calcium (s) ppm/mmol l $^{-1}$
311003	M	0.6	2.50	2.32 / 0.12	536.60 / 5.65	56.75 / 1.42	0.65 / 0.03	426.38 / 4.49	73.28 / 1.83
331004	F	0.58	2.30	3.45 / 0.18	360.95 / 3.80	28.24 / 0.70	1.86 / 0.1	271.66 / 2.86	40.56 / 1.01
321006	F	0.38	2.60	3.61 / 0.19	661.09 / 6.96	37.20 / 0.93	1.07 / 0.06	375.54 / 3.95	31.73 / 0.79
321018	M	0.34	2.67	4.84 / 0.26	724.98 / 7.63	50.04 / 1.25	1.12 / 0.06	505.15 / 5.32	31.51 / 0.79
331006	F	0.15	1.50	4.67 / 0.25	576.73 / 6.07	69.77 / 1.74	1.99 / 0.10	445.66 / 4.69	77.80 / 1.94
341001	M	0.343	1.80	1.83 / 0.10	453.59 / 4.78	45.57 / 1.14	0.04 / 0.002	231.86 / 2.44	38.57 / 0.96
341003	F	0.357	1.13	0.46 / 0.02	236.42 / 2.49	39.58 / 0.99	0.09 / 0.005	171.67 / 1.81	29.18 / 0.73
341007	F	0.92	2.23	1.16 / 0.06	440.41 / 4.64	65.51 / 1.63	1.23 / 0.07	362.87 / 3.82	24.73 / 0.62