Mouthguard Design and Facial Skeletal Profile Effect on Respiratory Function in Athletes

Gebauer D*, Williamson R, Wallman K

Corresponding Author
Dr Dieter Gebauer BDSc MBBS(Hons) Grad Dip OMFS Grad Dip Hosp Dent
Registrar Oral and Maxillofacial Surgery
Department of Oral and Maxillofacial Surgery
Royal Perth Hospital
Wellington Street Campus
PO Box X2213
PERTH 6847
dietergebauer@hotmail.com

Abstract

Mouthguards provide protection from concussion, dento-alveolar injury, and fracture of the facial skeleton. It is also known that some facial skeletal forms do predispose patients to dental trauma. Facial profile type has a significant effect on breathing and airway patency. Many elite athletes refrain from wearing mouthguards during contact sports because of a belief that they make breathing difficult.

Our hypothesis is that a custom mouthguard will have no effect on respiration in athletes either at rest or whilst exercising. The hypothesis will be tested by measuring respiratory functional parameters in athletes in simulated exercise modes with different types and designs of mouthguards in place. This will be done as an unblinded randomised case control cross over study.

31 male subjects were recruited in this study. Skeletal measurements were obtained of the participant by measurements on standard lateral cephalometric radiography. Two mouth guards of different design were fabricated for each subject. Each participant was tested three times either wearing no mouthguard, mouth guard A or mouth guard B. The respiratory data collected include ventilation (**Ve**), Oxygen consumption (**VO2**), and heart rate (**HR**) at mild, moderate and maximum intensity of exercise. Each participant was tested a further two times.

A repeated measure ANOVA found no statistical difference between the three groups of data at minimal, moderate and maximal levels of exercise ($p>0.05$). Secondary endpoints such as skeletal profile and airway dimension were also explored.

The conclusion of this trial is that there is no statistical difference between ventilation, work of breathing or heart rate of an elite athlete and the use or type of custom mouthguard worn and the level of exercise.

Scientific Background

Mouthguards provide protection from concussion, dento-alveolar injury, and fracture of the facial skeleton.* Dento-alveolar and facial trauma is a common and frequent preventable presentation to emergency department in Western Australia in contact sport playing population.

Many elite athletes do not wear mouthguards.* Common reasons for this are that mouthguards have been reported to affect respiration and subjectively increase "air hunger."* Other reasons include gagging and interference with speech and on-field communication.*

There have been a number of studies performed that have assessed the effect of mouthguards on FEV1 / PEF, airway resistance and VO2 Max during exercise.* Results from these studies have been equivocal and may be due to the use of small cohorts, as well as different types of mouthguards.*

Mouthguards can be fabricated both as a custom mould for each individual or as a stock format which is heated up and moulded to the jaw. Custom made mouthguards are considered to be the 'gold standard' when compared to stock mouthguards as they have better shock absorbing capability and are rated higher in terms of fit and comfort.* However there is consensus in mouthguard design in even the custom made group with variation in thickness, occlusal extension and palatal surface area coverage.

Our study has targeted elite athletes as there is an argument that if protective equipment is considered to restrict performance an athlete may not wear it. Elite athletes are role model's to children and other athletes who mimic their on field behaviour, and if the current perceived deficiencies are addressed in mouthguard design then potentially more athletes would wear them. Recent studies have shown no difference in the protective capability of a mouthguard with palatal coverage and one without.* This study will compare mouthguards with the usual palatal surface area coverage against one without palatal surface coverage.

In this study all athletes will have measurements taken of their facial skeletal profile and jaw structure. Jaw structure has been shown to affect the airway patency in individuals who suffer from obstructive sleep apnoea.* Oral and maxillofacial surgeons can alter the oropharyngeal airway with jaw advancement procedures which have been shown to have a beneficial effect on airway patency this patient population.*

Similarly, athletes with narrow airways may be predisposed to difficulty breathing with and without a mouthguard in place.* Perhaps elite athletes performance can be aided by jaw advancement procedures, or the effect of a mouthguard be minimised with an advancement procedure enabling the athlete to wear their protective equipment.
(Denotes annotation for reference – I am currently undergoing training in endnote)*

Aims and Objectives

The aim of this trial is to reduce the incidence of facial trauma (i.e. dento alveolar / facial skeletal and concussion) preventable by the use of mouthguards. The researchers will explore the design of mouthguards, and promote one that will increase mouthguard utilisation in the elite athlete population.

If mouthguards are shown not to affect ventilatory parameters to lobby health insurance bodies to improve mouthguard subsidies and reduce rebates for dento-alveolar trauma sustained whilst engaging in contact sport without wearing protective equipment. The researchers would also like to approach sports administrators to make the use of mouthguards compulsory in elite professional sports.

Study Design and Hypothesis

Our null hypothesis is that there is no difference in respiratory parameters between a custom mouthguard and no mouthguard worn by athletes during various levels of intensity of exercise. This study is an equivalence study. The hypothesis will be tested using an unblinded randomised case control cross over study.

Methodology

1) 31 male subjects who play hockey or water polo either at first division, state level or national level were recruited in the study.

2) Subjects were excluded if they had any respiratory pathology, were smokers or wore a removable dental appliance or had fixed functional orthodontic appliances.

3) Each participant filled in a questionnaire to obtain information about their mouthguard attitudes and utilisation as well as their facial trauma history.

4) The subject's skeletal measurements were then obtained by measurements of standard lateral cephalometric radiography.
    a. Three measurements have been chosen (See Picture 1):
        i. The narrowest point in the oro-pharyngeal airway.
        ii. The mandibular plane angle when compared to Frankfort horizontal plane.
        iii. SNA-SNB (ANB) angle with Class 1 being defined as 0-2 degrees, Class 2 being defined as >4 degrees and Class 3 being defined as less than or equal to 0.

Picture 1(Showing airway diameter / skeletal classification / Frankfort horizontal plane to mandibular plane angle)

5) A blood test was performed to ensure none of the subjects were anaemic.

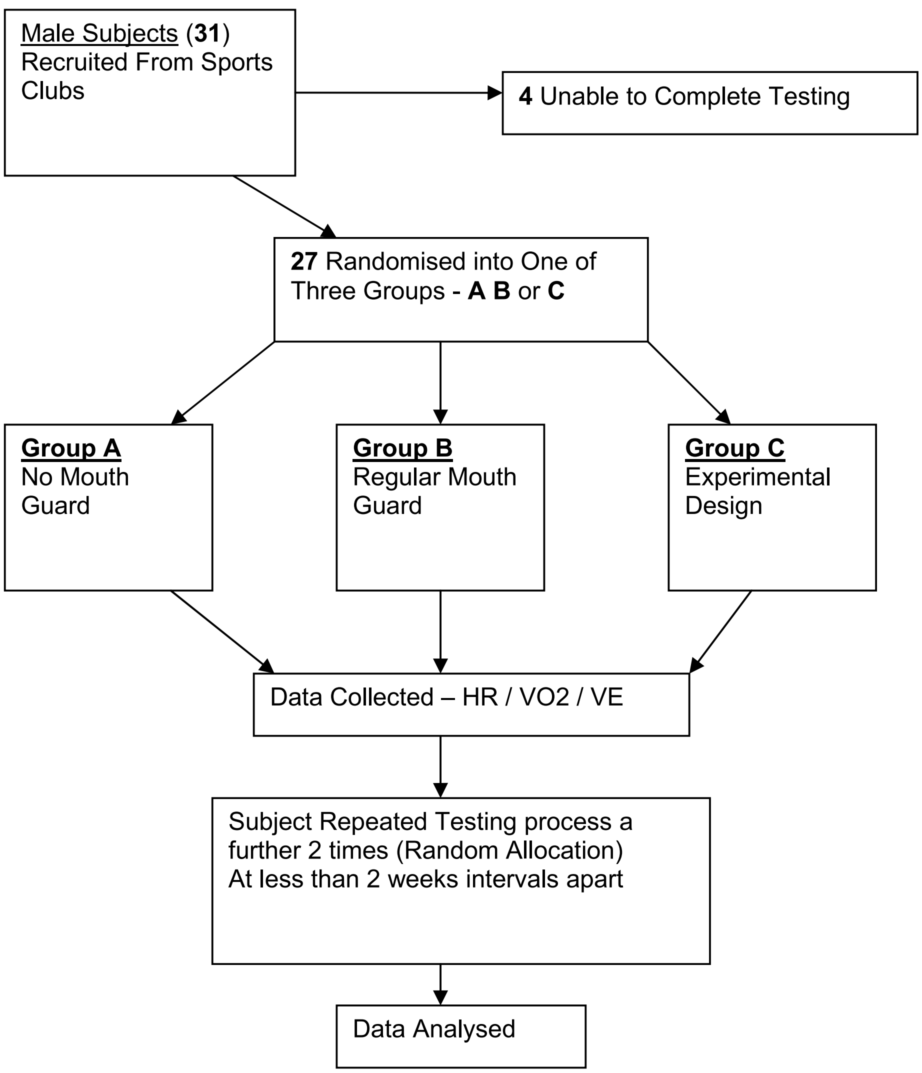
6) Two mouth guards of different design were fabricated for each subject. (See Picture 2)
    a. Mouthguard "1" will be a laminated type with normal palatal surface area coverage.
    b. Mouthguard "2" will have identical thickness but be a laminated type but with palatal coverage 2mm past the gingival margin.

    (All mouth guards covered the occlusal surfaces of the upper first molar)

Picture 2 (Mouthguard 1 on Left / Mouthguard 2 on Right)

7) The subject will be randomized into one of three groups. (See Figure 1)
   a. Group "A" performs the test without a mouthguard in place.
   b. Group "B" performs the test with the standard design of mouthguard.
   c. Group "C" is tested wearing the palate free design.

   (Subjects will be randomly tested with the mouth guard in or out first to avoid any error due to becoming used to the testing equipment.)



8) The subjects will then be placed on a treadmill with variable torque control. The respiratory data that will be collected include ventilation (**VE**), heart rate (**HR**) Oxygen consumption (**VO2**) at minimal, moderate and maximal effort as modelled on previous trials in our department. These parameters will be the deemed the primary outcomes. Other parameters such as height and weight will be measured. (See Picture 3)


Picture 3


Picture 4

9) All parameters will be collected using a face mask covering the nasal and oral aperture. No restrictions on head posture will be made to simulate "real life." (See Picture 4)

10) The volume if the mouthguards that have been fabricated will be measured and recorded. Additionally, after each test the subject will be asked to rate the mouthguard out of ten on a visual analogue scale.

11) Statistical analysis was performed on the data.

12) The subject is tested a further two times randomly allocated to the remaining two groups.

Statistical Methods and Preliminary Results

Pre trial sample size calculations were performed to preliminary assesses the number required to results that were adequately powered. Base line statistical data was obtained from the Australian Institute of Sport and 30 subjects (paired comparison) was deemed to detect an equivalent measurement of +/- 2% difference in VO2max to p=0.01 with a power of 95%.

Descriptive statistics (See Table 1) of have been reported as a mean with 95% confidence intervals on either side. Skeletal classification was reported as a percentage of total participants.

Table 1

Sport Played	Water polo – 8 / 27 = 29.66% Hockey – 19 / 27 = 70.37%
Height	X = 182.13 (178.81 : 185.44) 95% CI
Weight	X = 81.66 (78.22 / 85.11) 95% CI
BMI	X = 24.63 (23.78 / 25.48) 95% CI
HGB	X = 149.74 (147.02 / 152.46) 95% CI
Age	X = 23.51 (21.99 / 25.03) 95% CI
Skeletal Classification	Class 1 - 14 / 27 = 51.85% Class 2 - 10 / 27 = 37.04% Class 3 - 3 / 27 = 11.11%

The primary outcomes of this trial deal with comparison of group A, B and C data comparing **HR**, **VO2max** and **VE**. Professional statistical advice and support was obtained from the Western Australian Institute for Medical Research. A repeated measures analysis of variance (ANOVA) of effect of mouthguard (i.e. A vs. B vs. C) on **VO2max**, **VE**, and **HR** at different levels of exercise was used to compare each group. Below are preliminary results for **VO2max**, **VE** and **HR** in tabulated form (Table 2 / Table 3 / Table 4). The p value is listed at the bottom of the table. A level of significance was set at $p < 0.05$.

Table 2

VO2 (Drift) (mL.kg.min)	**Min**	**Mod**	**Max**
A (X +/- SD)	36.89 +/-2.88	45.88 +/- 3.77	56.09 +/- 4.82
B(X +/- SD)	37.69 +/- 2.20	47.58 +/- 6.45	57.22 +/- 6.14
C(X +/- SD)	38.35 +/- 3.45	46.80+/- 3.33	56.76 +/- 6.33
A vs. B vs. C (P Value)	0.1436	0.4401	0.7952

Table 3

VE (L.min^{-1})	**Min**	**Mod**	**Max**
A (X +/- SD)	63.08 +/- 10.24	83.33 +/- 14.37	124.19 +/- 15.62
B(X +/- SD)	64.45 +/- 9.93	84.28 +/- 14.12	122.51 +/- 18.80
C(X +/- SD)	64.72 +/- 9.47	85.86+/- 13.47	124.22 +/- 14.68
A vs. B vs. C (P Value)	0.5002	0.4744	0.4975

Table 4

HR (bpm)	**Min**	**Mod**	**Max**
A (X +/- SD)	156.70 +/-11.50	174.11 +/- 10.84	191.37 +/- 8.04
B(X +/- SD)	156.00 +/- 11.80	174.14 +/- 9.65	190.81 +/- 9.31
C(X +/- SD)	157.33 +/- 12.44	175.55 +/- 11.14	191.96 +/-9.17
A vs. B vs. C (P Value)	0.7589	0.5484	0.5912

The secondary endpoints of mouthguard weight, rate and airway diameter, skeletal classification and mandibular plane angle will be analysed statistically. Student t-tests have been used to compare the means between the two mouthguards types. (See Table 5)

Table 5

Current Mouth Guard Rate	7.29 (6.45 : 8.14) 95% CI
Mouth Guard A Rate (MGA)	6.71 (6.08 : 7.34) 95%CI
Mouth Guard B Rate (MGB)	8.21 (7.64 : 8.78) 95%CI
Average Weight Mouthguard A (MGA)	11.52g (10.97 : 12.06) 95%CI
Average Weight Mouthguard B (MGB)	9.47g (8.92 : 10.01) 95%CI

Rate MGA vs. MGB is statistically significant (**p<0.0007**)
Weight MGA vs. MGB is statistically significant (**p<0.0001**)

A repeated measure ANOVA was used to examine whether there is a relationship between the skeletal classification / airway diameter and mandibular plane angle and ventilatory parameters in athletes wearing mouthguards and exercising without one. Increased airway diameter is significantly associated with increased **VE / VO2max** (*p<0.001*). Both mouthguard B and C are similarly and significantly associated with an increased **VE** but as airway diameter increases its influence grows less as indicated by the significant negative interaction for both mouthguards. Skeletal classification and mandibular plane angle is not associated with **VE** or **VO2max** nor does it interact with exercise level or mouthguard.

Research Ethics

Justification (Merit and Integrity) – This study has the potential to benefit a significant number of people who participate in contact sport in both the professional and amateur arena. Information in this trial, if utilised by administrative sporting bodies or health insurers would have immediate public health effects. The research team is familiar in dealing with facial and dentoalveolar trauma and reconstruction of lost dentition. The research team has conducted previous mouthguard trials and has had experience if managing elite athletes in their research centre with similar testing protocols.

Justice
Women have been excluded from this trial as the primary target group. This was done as anecdotally males appear to be overrepresented in the emergency departments being admitted after being injured without wearing protective equipment. This may be due to a greater proportion of the male population engaging in contact sport, a greater proportion of male exhibiting “macho” behaviour and not wearing protective equipment and such putting themselves at risk or the nature of male contact sport being such when collisions occur etc. that greater force is transmitted and more injuries are sustained.
No burden was placed on the participants who enrolled in this trial. In fact they received free mouthguards at the end of the trial and most were interested to see what their physiological parameters were to compare against other team members. Unless a participant was an Australian Institute of Sport athlete on a full scholarship, testing opportunities such as the one offered in this trial are rare. Each participant was offered a print out of his results at the end of the trial to compare with their team mates if they wished.

Beneficence
Precautions were taken to ensure safe participation of subjects in the exercise protocol ensuring that no injuries are encountered. All athletes were asked to warm up in a manner that they usually do prior to training. A research assistant was recruited to assist the principle researcher so that

additional personnel were available to stop the testing equipment and assist the athlete in the event of an emergency. An orientation session of the equipment was completed with the athlete prior to testing including the location of the emergency stop button on the apparatus.

Respect
Each participant obtained information about the trial prior to consenting to participation, explaining that entry into the trial is completely voluntary and they were able to withdraw from the trial at any time. If the test results are released to coaches of the athletes will this may affect their selection in team. Participation or a poor test result in our trial may potentially affect selection to representative teams. To combat this issue results were only released to the individual participant themselves and it was up to them to allow their coaches or other team mates to view their data. All of the data collected from the subjects was stored in a locked secure environment.

Research Governance
Ethics committee approval was sort from the University of Western Australia and approval for the trial was granted. As part of the approval, annual reports need to be submitted during the duration of the trial to satisfy the governance criterion. A complaints procedure is in place and contacts details of where to complain are made available to the participants in the trial on their information sheet. Similarly annual progress reports need to be submitted to the University of Western Australia about the progress of the research by the supervisors of the trial.

Practical Applications and Translational Aspects

There is no statistical difference between the respiratory data of no mouth guard, mouthguard of regular design and a mouthguard of a palate free design. This study has shown that there in no impedance of physiological performance when a mouthguard is worn. The complaint that mouthguards "affect breathing" has no scientific basis and cannot be used and an excuse to refrain from wearing one.

The players enrolled in this trial rated the mouthguard with a palate free design significantly higher suggesting that this design is more likely to be worn without compromising its protective capability. If mouthguards are to be fabricated for elite athletes then one should be made with a palate free design to encourage utilisation.

This study could be used by professional sports health bodies and dental associations to lobby health insurers to subsidise mouthguards heavily so that cost is not a factor in preventing access to having one professionally fitted. As respiratory performance is not affected in the professional arena, injuries sustained when a mouthguard is not worn, should not be covered by the insurer / sporting body.

Additionally, due to the findings in this trial the researchers will recommend that sporting bodies mandate the use of mouthguards during professional sporting activity that are classified as contact sports. Hopefully this has a trickle down effect to the general population who look up to this group and change their behaviour and reduce the general incidence of dento-alveolar trauma, facial fracture and concussion rates to emergency departments. This would have an overall cost saving effect on the taxpayer.

Further research is required to explore the relationship of athletic performance and orthognathic surgery to see is there is benefit in jaw advancement procedure on airway patency and a follow on effect to enhanced performance.

Budget

	Rate		
Personnel			
Academic	$95 837	X 0.1	9 583
Research Assistant	$12.00 / hr	X 23.25 hrs	279
Dental Assistant	$14.00 / hr	X 6 hrs	84
Equipment			
Blood Testing	$12.50 / Test	X 31	387.5
Physiology Lab Hire	$80.00 / hr	X 23.25 hrs	1860
Dental Chair Hire	$15.00 / hr	X 6 hrs	90
Consumables			
Mouth Guard Fabrication	$120 Unit	X (31 x 2)	7440
Stationary	$300		300
		Total	**$20 023.5**

References

1. Amis T, Di Somma E, Bacha F, Wheatley J. Influence of intra-oral maxillary sports mouthguards on the airflow dynamics of oral breathing. Medicine and Science in Sports and Exercise. 2000; 32(2):284-290.
2. Bourdin M, Brunet-Patru I, Hager PE, Allard Y, Hager JP, Lacour JR, et al. Influence of maxillary mouthguards on physiological parameters. Medicine and Science in Sports and Exercise. 2006; 38(8):1500-1504.
3. Cole P, Forsyth R, Haight JSJ. RESPIRATORY RESISTANCE OF THE ORAL AIRWAY. American Review of Respiratory Disease. 1982; 125(3):363-365.
4. Craig RG, Godwin WC. Properties of athletic mouth protectors and materials. Journal of Oral Rehabilitation. 2002; 29(2):146-150.
5. Delaney JS, Montgomery DL. Effect of non-custom bimolar mouthguards on peak ventilation in ice hockey players. Clinical Journal of Sport Medicine. 2005; 15(3):154-157.
6. Duhaime CF, Whitmyer CC, Butler RS, Kuban B. Comparison of forces transmitted through different EVA mouthguards. Dental Traumatology. 2006; 22(4):186-192.
7. Jaeger MJ, Matthys H. PATTERN OF FLOW IN UPPER HUMAN AIRWAYS. Respiration Physiology. 1968; 6(1):113.
8. Kececi AD, Cetin C, Eroglu E, Baydar ML. Do custom-made mouth guards have negative effects on aerobic performance capacity of athletes? Dental Traumatology. 2005; 21(5):276-280.
9. Kragskov J, Bosch C, Gyldensted C, SindetPedersen S. Comparison of the reliability of craniofacial anatomic landmarks based on cephalometric radiographs and three-dimensional CT scans. Cleft Palate-Craniofacial Journal. 1997; 34(2):111-116.
10. Maeda Y, Machi H, Tsugawa T. Influences of palatal side design and finishing on the wearability and retention of mouthguards. British Journal of Sports Medicine. 2006; 40(12):1006-1008.
11. Niinimaa V, Cole P, Mintz S, Shephard RJ. ORONASAL DISTRIBUTION OF RESPIRATORY AIR-FLOW. Respiration Physiology. 1981; 43(1):69-75.
12. Schwartz R, Collins BJ, Fong C. Effects of a single and double commercial athletic mouthpiece on expiratory peak flow: A pilot study. Cranio-the Journal of Craniomandibular Practice. 2000; 18(1):23-29.
13. Spann RW, Hyatt RE. FACTORS AFFECTING UPPER AIRWAY RESISTANCE IN CONSCIOUS MAN. Journal of Applied Physiology. 1971; 31(5):708.
14. Taylor G, Kaplan R, Luke R. THE EFFECTS OF MOUTHGUARDS ON AIR-FLOW. Journal of Dental Research. 1982; 61(4):610-610.
15. von Arx T, Flury R, Tschan J, Buergin W, Geiser T. Exercise capacity in athletes with mouthguards. International Journal of Sports Medicine. 2008; 29(5):435-438.
16. Wheatley JR, Amis TC, Engel LA. ORONASAL PARTITIONING OF VENTILATION DURING EXERCISE IN HUMANS. Journal of Applied Physiology. 1991; 71(2):546-551.
17. Yamada J, Maeda Y, Satoh H, Miura J. Anterior palatal mouthguard margin location and its effect on shock-absorbing capability. Dental Traumatology. 2006; 22(3):139-144.

-Research Participant Information Sheet and Consent Form-

Please read the following information carefully and if in agreement with all the information provided, please sign at the bottom of this document.

Why are we doing the study?

Using a mouthguard can prevent facial trauma, yet many athletes do not wear one because of a belief that it restricts breathing. To date, there have been no well-designed studies that have explored the relationship between breathing and mouth guards. This study will look at the effect of mouth guards as well as the relationships of facial profile and mouth guard design on breathing.

If this research finds that mouth guards do not affect breathing, this information can be used to mandate that wearing a mouthguard should be compulsory in all contact sports. If in fact mouth guards do affect breathing, information about which type of mouth guard will least affect breathing would be available, which in turn may revolutionise mouth guard design. (You will receive two types of mouthguards)

You have been chosen to participate in this study because of the following reasons:

1) You play hockey or water polo– all sports that there are overrepresented in presentations to hospitals due to facial trauma.
2) All sports required a high level of fitness to play and rely on aerobic metabolism.
3) You are considered to be an elite level athlete.

What does the study involve as a participant?

As a participant in this study you will receive two free custom fitted mouthguards. Each participant is randomly allocated to one of three scenarios, no mouthguard, a regular mouthguard and an experimental mouthguard. We are looking to see if there is a difference depending on the type of mouthguard you wear. Additionally, you will be asked to participate in graded exercise test in order to determine your cardiovascular fitness (VO2max) and respiratory rate. This information may be of use to yourself and your coach in order to monitor you fitness.

At the end of the test only you and the researcher will view the VO2max test result. You can choose to show it to your coach. The research team will not disclose any of the results to a third party and all the results will be treated similarly to a confidential medical record.
You will be required to make an appointment at the Oral Health Centre of West Australia to take mouth guard moulds and fill in a questionnaire. A routine blood test an x-ray will be taken at this appointment. This appointment will take approximately 20 mins.

An x-ray is taken as part of a standard screening examination of your facial skeleton, and this is done as standard practice for all patients who attend an orthodontist's office. The x-ray involves the use of a low dose x-rays about equal to one twentieth of the background radiation you would receive in one year living in Perth. For comparison the total background radiation in Western Australia is about 2mSV per year and the radiation dose from cosmic rays from flying in a jet from Perth to London is approximately 0.1mSv. You will be receiving approximately 0.097mSv with the proposed x-ray.

Three further appointments will be required in order for you to undergo physiological testing in order to assess you body's ability to utilise oxygen. This test involves a graded exercise test performed on a treadmill / bicycle. Testing is performed in the School of Sports Science, Exercise and Health (formerly Human Movement and Exercise Science), which is next to the University of Western Australia's water polo pool. The two tests take about 30 mins each and required you to run on an ergometer and have your respiratory gases collected by a metabolic cart. One of these tests will be performed with a mouth guard in place, and one with out the mouthguard to see if there is a difference in breathing patterns. To minimise human variation, these two tests cannot be performed more than two weeks apart.

Before you sign up to participate – the research team would like to know if you have any questions are queries about the research? If so please ask your researcher now?