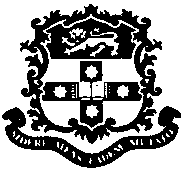
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**Study comparing three different expansion devices**

**INFORMATION FOR ADOLESCENTS (13-16 YEARS)**

**What is the Study about?**

This study is to find if one type of expander (a plate) is better at widening your upper jaw. This expansion plate is needed because you have a narrow upper jaw and the top back teeth bite down inside the bottom back teeth. The expander will be placed on your top teeth and will be one of the following:

1) Hyrax Expander: this is the common type of expander which requires a separate key to turn.

2) Hybrid-Hyrax Expander: this is the normal expander but it also includes two pins placed in the top of the upper jaw (palate)

3) Keles Expander: this is a new type of expander which has a built-in key to turn the expander. This new type of expander is not yet approved by Therapeutic Goods Administration.



Figure 3: Keles Keyless expander

Figure 1: Hyrax expander

Figure 2: Hybrid-Hyrax expander

**Who is doing the Study?**

The study is being conducted within Sydney Dental Hospital by Doctors Gordon Cheung, Shanya Hammond and Simone Mustac. It will be supervised by Professor M Ali Darendeliler and Doctors Oyku Dalci and Alexandra Papadopoulou.

**Which type of expander will I have?**

You will be randomly allocated to one of the three treatment groups and you will be informed of the treatment group at visit 1.

**What do you have to do?**

You will have to come in for multiple appointments where we will make the expander to custom fit your mouth and then glue it in. After we glue the expander in, the expander needs to be turned. Someone will have to do this for you twice a day. While you are turning your expander, we need to see you at the Sydney Dental Hospital once a week. After the turning of the expander has finished, we will see you after 3 months and then again at 6 months. At the 6 month appointment we will remove the expander. We then need to see you one last time 3 months later.

The details of each visit are below:

1. **Visit 1:** Records of your mouth and face will be taken includingnormal photos and 3D photographs, moulds of the upper and lower teeth and **X-rays (cone beam computer tomography)**.
2. **Visit 2.** 4 to 8 small separating elastics will be placed between your back teeth to create spaces so metal bands can be placed in the following visits.
3. **Visit 3.** One week later, the separators will be removed, the metal bands will be fitted on your back teeth for the right size and a mould of your upper teeth will be taken so the laboratory can custom make your expander. The metal bands are then removed and the separating elastics will be replaced.

**If you are in the Hybrid-Hyrax group**, an extra procedure will be required:

1. A numbing cream will be placed on the top of your mouth for approximately one minute then we will use an injection that will numb your mouth .
2. 2 pins will be placed into your palate and then moulds of the pin are taken so the laboratory can custom make your expander
3. **Visit 4.** Two weeks later, the separators will be removed, and the expander will be glued to the teeth. In all expansion groups, you will be instructed to turn the expander using a key. You will need to turn twice a day for 2-3 weeks depending on how narrow your upper jaw is.
4. **Visit 5.** One week later, the appliance will be checked to make sure you are turning the expander properly.
5. **Visit 6.** Weekly reviews will be conducted until your jaw is wide enough. The expander must be kept in the mouth for the next 6 months to stabilise the results.
6. **Visits 7-8.** Three monthly reviews will be conducted for a period of 6 months. The expander and your toothbrushing will be checked at each review appointment.
7. **Visit 9.** Six months after the expansion has finished, we will remove the expander, and the pins from the Hybrid-Hyrax group. We will retake records of your mouth and face at this stage: traditional and 3D photographs, moulds of the upper and lower teeth. **No X-rays will be taken at this visit.**
8. **Visit 10.** Three months after removal of the appliance, records of your mouth and face will be taken includingtraditional photos and 3D photographs, moulds of the upper and lower teeth and **X-rays (cone beam computer tomography).**

The study is now complete.

After the study has been completed, you will continue with your orthodontic treatment in our department with one of the Orthodontic Registrars.

**Do you have to do the Study?**

Participation in this study is entirely voluntary. You do not have to take part in the study. If you do not want to take part and if you change your mind, you can pull out at any time without having to give a reason. Whatever your decision, it will not affect your treatment or relationship with the staff who are caring for you.

**What are the risks of this treatment?**

As with all medical treatment there is some risk of injury. In addition, there may be risks associated with the study that are presently unknown and unforeseeable. Despite us doing all we can, you may have some complications.

The risks of participating in this study are:

* The expander may break
* The expander may be slightly uncomfortable for the tongue and cheeks during the first few days. This may also affect your speech for the first few days.
* Your teeth and jaws may be sore
* Possible side-effects of the pins include
  + Swelling, pain or infection
  + Damage to teeth
  + Damage to your gums, lips and cheeks
  + The pin can break
  + The pin can become loose
  + The pin might need to be replaced
* Possible side-effects of the numbing injection include
  + Bruising
  + Need for more numbing injection
  + Less common side effects include
    - Infection
    - Damage to gums, lips and cheeks
    - Allergy
    - Numbness
  + Rare risks include
    - Too much numbing injection
    - Heart problems
* The expander might not widen your upper jaw enough

**What will this cost?**

It will not cost you anything.

**What if new information arises during this study?**:

Sometimes during the course of a study, new information becomes available about the treatment that is being studied. If this happens, your doctor will tell you about it and discuss with you whether you want your child to continue in the research study. If you decide to withdraw, your doctor will make arrangements for your regular health care to continue. If you decide to continue in the research study you will be asked to sign a new consent form confirming that you have been made aware of the new information.

**Compensation for injuries or complications**If you suffer any injuries or complications as a result of this study, you should contact the study doctor as soon as possible, who will assist you in arranging appropriate medical treatment. If you are eligible for Medicare, your child can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.   
  
In addition, you may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is sufficiently serious and is caused by unsafe drugs or equipment, or by the negligence of one of the parties involved in the study (for example, the researcher, the hospital, or the treating doctor). You do not give up any legal rights to compensation by participating in this study.   
  
In the event of loss or injury, the parties involved in this study agree to be bound by the Medicines Australia Guidelines for Compensation for Injury Resulting from Participation in an Industry-Sponsored Clinical Trial. A copy of these guidelines is available from the Executive Officer of the Ethics Review Committee.

**Confidentiality**All the information collected from you for the study will be treated confidentially, and only the researchers named above will have access to it. This information will be stored for 15 years after the study is completed, or until the child turns 25 years of age, whichever is longer. The study results may be presented at a conference or in a scientific publication, but individual participants will not be identifiable in such a presentation.

**What if you have any questions?**

When you have read this information, Doctors Gordon Cheung, Shanya Hammond or Simone Mustac will talk about it with you further. You can email us at [sdhexpansion@gmail.com](mailto:sdhexpansion@gmail.com).

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This information sheet is for you to keep.

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