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MAGNETIC FORCES

IN

ORTHODONTICS

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**A thesis submitted in partial fulfilment of the requirements for the degree of Doctorate of
Clinical Dentistry – Orthodontics**

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DEDICATIONS

To my family and Lachy,

Thanks for your support and patience.

I could not have made it without your help.

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DECLARATION

CANDIDATE CERTIFICATE

This is to certify that the candidate carried out the work in this thesis in the Orthodontic Department, University of Sydney and has not been submitted to any other University or Institution for a higher degree.

Angie C. Phelan

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1 ABBREVIATIONS

- ANOVA – Analysis of Variance
- AVC – Active vertical corrector
- B – Magnetic flux density
- BH_{\max} – Maximum energy production
- CAT – Clear Aligner Therapy
- CGS – Centimetre-grams-second system
- °C – degrees Celsius
- EMG - electromyographic
- FMS – Functional magnetic system
- FOMA – Functional orthopaedic magnetic appliance
- FR – Functional regulator
- G – gauss
- g – grams
- H – Magnetic field strength
- IPR – Interproximal reduction
- MAD – Magnetic Activator Device
- MCC – Mandibular condylar cartilage
- mths - Months
- NdFeB – Neodymium Iron Boron
- OMSS – Orthodontic measurement and simulation system
- OPG – Orthopantomogram / panoramic radiograph
- PVS - Polyvinyl-siloxane
- SI units- International system of units
- SmCo – Samarium-cobalt
- SMF – Static magnetic fields

- T – tesla
- T_c – Curie temperature
- 3D – Three-dimensional
- UF – University of Florida
- UNC – University of North Carolina
- UO – University of Otago
- UP – University of Pennsylvania
- wks - Weeks

2 INTRODUCTION

Orthodontics and craniofacial orthopaedics are therapeutic approaches that modify the occlusion, facial form and function through the application of prolonged, mechanical forces. Traditional force delivery systems in orthodontics include the use of wires, springs and elastics. Alternately, magnetic forces can be used to generate the force for tooth movement and orthopaedic treatment. Advantages of magnetic force delivery include good force control at short distances, no friction, and no material fatigue.¹

Magnetic forces have been used in orthodontics for both tooth movement²⁻⁶ and orthopaedic correction⁷⁻¹² with varying degrees of success. Magnetic systems permit precise control of the force levels that are applied, as the force generated can be calculated from specific force-distance diagrams.¹ The magnets initially used were bulky and there were concerns raised about possible toxic effects. However, the current available literature evaluating magnetic fields shows no evidence of any direct or acute toxic effects.¹³⁻¹⁴ Improved safety with better coating and the introduction of rare earth magnets, which led to a dramatic reduction in magnet size, stimulated further interest in the field of orthodontics.¹³⁻¹⁴

The aim of this thesis is to investigate the application of magnet force delivery in two situations – facilitating tooth movement in combination with clear sequential aligners and orthopaedic correction with a new magnetic functional appliance, the Sydney Magnoglide.

The demand for aesthetic orthodontic appliances has increased dramatically in recent years. Consequently, clear aligner therapy has become a popular alternative to fixed appliances. Despite their superior aesthetics this appliance is less effective than fixed appliance therapy.¹⁵ They are quite effective in achieving tipping movements but have limited effectiveness with other types of movements such as bodily movements, rotations, extrusions and severe intrusion of teeth.¹⁶

To overcome some of the limitations of the appliance resin attachments are placed on the teeth. Attachments are generally placed on the teeth to increase the undercuts and retention of the appliance to facilitate the desired tooth movement.¹⁷ However, the current attachments are considered to be only partially effective.¹⁸⁻¹⁹ An improved system utilising small magnetic attachments has been proposed to enhance the capabilities of this appliance.

A laboratory study was performed to examine the physical properties of small neodymium iron boron magnets that could be utilised in this manner, to determine if force levels sufficient to induce tooth movement could be generated. The effect of different magnet morphologies on the force-displacement characteristics was also examined. A case report will demonstrate the clinical application of the technique.

The application of magnetic forces for orthopaedic correction is well documented in the literature. A range of functional appliances utilising magnets have been designed and used successfully for Class II correction.^{8-9,20} A new magnetic functional appliance, the Sydney Magnoglide, has been developed and evolved to improve efficiency and patient comfort. Evaluation of novel therapeutic techniques and appliances are necessary in an evidence-based approach to practice.²¹ In light of this, a prospective clinical study of the effects of the new magnetic functional appliance, the Sydney Magnoglide, was performed. The study was performed to determine the skeletal and dental effects of the magnetic functional appliance compared to a group of untreated Class II controls utilising cephalometrics.

3 REVIEW OF THE LITERATURE

The aim of this literature review is to identify all pertinent research that covers the scope of this project.

3.1 MAGNETS AND MAGNETIC FIELDS

Magnetism, in physics, refers to the effects originating from the electromagnetic interaction of particles.²²⁻²³ It is a physical phenomenon and a form of energy that can be either static or time varying.²⁴

A magnet is an object that exhibits an external magnetic field. Magnets have two poles, a north and a south pole. The north pole is the end that points to the north magnetic pole of the earth when the magnet is freely suspended.²² Magnetic poles have the property that like poles repel each other, and unlike poles attract.^{23,25} The magnetic field that surrounds a magnet emerges from one pole of the magnet, conventionally the north pole, and returns to the other, or south, pole of the magnet.¹³ (Figure 1)

All magnets have a magnetic field that exists in the space around them.^{23,25} The magnet field is a vector which has both magnitude and direction.²² The direction of the magnetic field at any point in space is the direction indicated by the north pole of a small compass needle placed at that point.^{22,25} A magnetic field line as depicted in Figure 1 is a means of visualising the direction of the magnetic field.¹³ They are not real entities, as a magnetic field is a continuous function that exists at every point in space. Magnetic fields are detected by the force they exert on other magnetic materials and moving electric charges.²²

The magnetic field strength, also known as magnetic field intensity or magnetising field, is represented by the symbol H .²³ It may be defined in terms of magnetic poles. At one centimetre from

a unit pole the field strength is one Oersted. The Oersted is the unit of the magnetic field strength in the CGS system and it is measured in amperes per meter (A/m) in SI units.²³

To describe the magnetic properties of a material a quantitative measure of magnetisation must be defined. Magnetic flux is a measure of quantity of magnetism, taking into account the strength and extent of the magnetic field.²⁵ The magnetic flux through a surface is proportional to the total number of magnetic field lines that pass through the surface. Thus, the magnetic field is stronger in regions where the field lines are relatively closer together and weaker where they are relatively far apart.²² It can be measured with a fluxmeter but has largely been superseded by the Hall probe.²⁴ The flux per unit area is called the magnetic flux density or magnetic induction, and is represented by the symbol B.²³ The SI unit of the flux density is the tesla (T). In many circumstances the magnetic field has a value considerably less than one tesla. In these cases, the CGS system magnetic field unit called the gauss (G) is used. 1 gauss = 10⁻⁴ tesla.²² The flux density is proportional to the magnetic field strength.^{23,25}

The magnetic flux produced by magnets causes them to attract or repel other magnets, and attract materials containing iron.¹³ The force produced by any two magnets is inversely proportional to the square of the distance between them.^{23,25}

$$f \propto \frac{1}{d^2} .$$

This means that the force between any two magnets falls dramatically with distance.¹³ Force-distance diagrams of magnets can be used to calculate the magnetic force level by measuring the gap between magnets.²⁶

3.1.1 Magnetisation

Magnetic fields are produced by moving charges.²² Every atom is a magnet because electrons orbit the nucleus.²⁷ The magnetism produced by electrons within an atom can arise from two motions. Firstly, each electron orbiting the nucleus behaves like an atomic-sized loop of current that generates a small magnetic field. Secondly, each electron possesses a spin that also gives rise to a magnetic field. The net magnetic field is due to the combined fields created by the orbital and spin motions.²² In most substances the electrons are paired and the magnetism produced at the atomic level tends to cancel out with the result that the substance is nonmagnetic.^{22-23,27}

There are some materials, known as ferromagnetic materials, in which the cancellation does not occur for groups of approximately 10^{16} - 10^{19} neighbouring atoms, because they have electron spins that are naturally aligned parallel to each other.²²⁻²³ The result is a small but highly magnetised region called a magnetic domain. Each domain behaves as a small magnet with its own north and south poles. Often the magnetic domains are arranged randomly, so the magnetic fields of each domain cancel each other and no overall magnetism is displayed.^{22,27}

On the application of a magnetic field (H) provided by a permanent magnet or an electromagnet, the domains align and produce a state of magnetism, which will reach a saturation point (Bs).²³ (Figure 2) A state of magnetism is caused by two effects. The domains whose magnetism is parallel or nearly parallel to the external magnetic field grow in size, while the alignment of some domains rotate and become more oriented in the direction of the external field.^{22,27} Magnets can be magnetised in different patterns, which creates different pole arrangements such as axial and radial.²²

In some types of ferromagnetic materials the domains remain aligned when the external magnetic field is removed, and the material becomes permanently magnetised (Br). The magnetisation can be reduced to zero by the application of an equal and opposite magnetic field. The value of H at this point is the intrinsic coercivity (Hc). For a permanent magnet to retain its magnetisation the coercivity

should be as large as possible. By continuing to increase the magnitude of the reversed field, the material can be again saturated, but in a negative value.^{23,28}

If the applied field is reversed between the same positive and negative limits a hysteresis loop is traced. (Figure 2) The behaviour of the material is described by the hysteresis loop. The vertical axis is expressed in terms of magnetic flux density (B) and the horizontal axis in terms of the magnetic field intensity (H).^{23,28} For a permanent magnet, it is the maximum energy product that gives an indication of its power (BH_{\max}).²³ This point is used as an index of the quality for permanent magnets.²⁸ The larger this value, the greater the flux produced by a magnet of a given volume.²³

3.1.2 Magnetic properties of matter

There are three different types of magnetic substances: diamagnetic, paramagnetic and ferromagnetic substances.²²⁻²³

Diamagnetism causes lines of magnetic flux to curve away from the material and creates a magnetic field in opposition to the externally applied magnetic field, a repulsive effect. A diamagnetic substance is weakly repelled and exhibits no permanent magnetism. When the applied field is removed the magnetism disappears. Diamagnetic materials are usually considered to be non-magnetic and include water, wood, most organic compounds and many metals such as bismuth, silver, gold, lead, stainless steel and copper.²³

Paramagnetism is a form of magnetism which occurs only in the presence of an externally applied magnetic field. A paramagnetic substance is one that is weakly attracted to magnets, and therefore will exhibit a small increase in magnetic flux density when an external magnetic field is applied. When an external magnetic field is applied, the dipoles will tend to align with the applied field, resulting in a net magnetic moment in the direction of the applied field. Iron and rare-earth salts are paramagnetic substances, as well as elements such as sodium, potassium and oxygen. Paramagnetic

behaviour can also be observed in ferromagnetic materials that are heated above their Curie temperature.²³

A ferromagnetic substance is one that is strongly attracted to magnets. Ferromagnetism comes from the early association of this behaviour with ferrous or iron containing materials.²³ The magnetic domains are parallel in a ferromagnetic material. Common ferromagnetic materials are iron, nickel, cobalt, chromium dioxide and alnico, an aluminium-nickel-cobalt alloy.²²

Ferromagnetic materials can be termed as either hard or soft depending on how well they retain their magnetic properties after removal of an applied magnetic field.^{23,27-28} A soft magnet can be easily magnetised or demagnetised.²³ An example of such is iron. A hard magnet is able to retain magnetic properties after being magnetised and can be made into permanent magnets.²⁷

3.1.3 Permanent magnets

Permanent magnets create their own persistent magnetic field.²³ All permanent magnets are made from ferromagnetic materials.²² The magnetic properties of materials depend mainly on the chemical composition and on the heat treatment they receive after fabrication.²³ The behaviour of magnetic material is highly sensitive to small amounts of impurities and temperature.¹³

The Curie temperature is an important characteristic of a permanent magnet. The temperature at which any ferromagnetic material loses its magnetism is known as the Curie temperature (T_c). Above this temperature, thermal agitation destroys the magnetic alignment and the magnet become demagnetised.^{13,28}

The following section outlines the properties of permanent magnets that have been reported in the biomedical literature.²⁷⁻²⁸

3.1.3.1 Alnico Magnets

Alnico magnets were the first type of permanent magnets to be used for biomedical purposes.²⁸ Alnico magnets are alloys based on cobalt, aluminium, nickel and iron..^{27,29} These magnets were developed from the 1930s to the 1960s and offered considerable improvements in magnetic hardness compared to the steel magnets that were previously available.²⁸ The Alnicos are two phase alloys, consisting of a strong ferromagnetic phase and a paramagnetic phase.²⁹ They are produced either by casting or by pressing and sintering powder compacts.²⁸

3.1.3.2 Cobalt-platinum Magnets

Cobalt-platinum magnets were available at the same time as Alnico magnets. They were discovered in the 1930s by Jellinghaus and were made available in the 1950s.²⁸⁻²⁹ They consist of equal percentages of cobalt and platinum which forms a continuous solid solution to produce an isotropic magnet.²⁹ They had improved properties and corrosion resistance compared with the Alnicos available at that time. Despite their superior properties they did not gain widespread use in medical or dental applications because of their high cost.^{28,30}

3.1.3.3 Ferrite Magnets

Ferrite or ceramic magnets are the most widely used permanent magnetic material and play an important role in bulk magnet applications.²³ Hard ferrite magnets are not commonly used in biomedical applications.²⁸ They are more resistant to demagnetisation than the Alnico materials which make them suitable for use in complex shaped magnets. They produce a low magnetic field but are very cheap to produce which makes them ideal for their current application.²⁸

3.1.3.4 Rare earth magnets

Although magnets had dental applications in the 1950s the high cost of magnetic materials was a significant deterrent to their use, until the development of rare earth magnets in the 1970s.²⁸ The

development and availability of rare earth magnetic alloys have led to the increase use of magnets in orthodontics.^{3,31-32}

Rare earth magnets are capable of producing high forces relative to their size due to the property of magnetocrystalline anisotropy.^{13,33} This property allows single crystals to be preferentially aligned in one direction (along the C-axis) which increases the magnetism.³³ The rare earth magnets demonstrate significant improvements in the maximum energy product (BH_{max}) which has led to a dramatic reduction in the size of magnets required to produce a particular magnetic flux.^{13,27} Another advantageous characteristic of the rare earth magnets is their very high coercivity, compared to Alnico and barium ferrite magnets. High coercivity means these magnets have a superior ability to resist demagnetisation. This is the result of their intrinsic properties and the manufacturing process.¹³

There are several types of rare earth magnets – samarium cobalt, neodymium iron boron and samarium iron nitride.²⁸

3.1.3.4.1 Samarium-Cobalt Magnets

Samarium-cobalt (SmCo) magnets were developed in the 1960s and 1970s.³⁴⁻³⁵ Various intermetallic compounds of samarium-cobalt are possible including $SmCo_3$, Sm_2Co_7 , $SmCo_5$ and Sm_2Co_{17} .^{28,33-35}

These magnets are characterised by high saturation magnetisation and Curie temperature.³⁴

Samarium-cobalt magnets have relatively high Curie temperatures, in the range of 500-750 degrees Celsius ($^{\circ}C$) for $SmCo_5$ and 780-850 $^{\circ}C$ for Sm_2Co_{17} .³⁵ They are more costly than other rare earth magnets but are chosen in preference to those with a lower Curie temperature, such as Neodymium, when they are needed for high temperature applications.²⁸

3.1.3.4.2 Neodymium-iron-boron magnets

The high cost associated with samarium-cobalt magnets stimulated further development in this field. Neodymium-iron-boron (NdFeB) magnets arose in response to this need and were first announced in 1984 by two independent groups.³⁶⁻³⁷ $\text{Nd}_2\text{Fe}_{14}\text{B}$ is the basic compound but various partial substitutions and modifications are commonly made. This type of rare earth magnet has an extremely high magnetic saturation, good resistance to demagnetisation and the highest value of energy production. Their excellent magnetic properties allow the production of very small magnets.¹³ They are less costly to produce than Sm-Co alloys and hence are now the main rare earth permanent magnet in use today.²⁸

The main limitation of the neodymium magnet is that it had a low Curie temperature, as low as 300°C, where as SmCo alloys have excellent stability, with a Curie temperature as high as 725°C.³⁵⁻³⁶ This is a distinct disadvantage for dental applications as magnets are embedded in acrylic appliances. On curing methyl methacrylate reaches a temperature of between 80 and 90 degrees.¹³ This could cause a significant amount of flux loss due to the exothermic setting reaction of the acrylic. It is important to ensure that the loss of flux and therefore force is taken into account when preparing these magnets for dental applications.¹³

3.1.3.4.3 Samarium-iron-nitride magnets

Samarium iron nitride permanent magnets are a promising candidate for future applications.²⁷ These magnets may be a superior choice to NdFeB magnets in the future because it has high resistance to demagnetisation, high magnetism and better resistance to temperature and corrosion.²⁷ This material is still under development, but could become available for medical and dental applications in the future.²⁸

3.2 BIOLOGICAL CONSIDERATIONS

Materials designated for clinical use need to be evaluated for any potential side-effects at a local and systemic level.¹³ Testing has been conducted on magnetic materials in cell cultures, various animal models and in clinical studies to assess the biological effects. Biological safety tests of magnetic materials have been performed to investigate the effects of static magnetic fields and possible toxic effects of the materials or their corrosion products.¹³⁻¹⁴ Several studies have shown that magnets have good biocompatibility^{32,38-40} however, cellular changes in response to static magnetic fields and corrosion products have been documented.⁴¹

3.2.1 Surface Oxidation and coating

Rare earth magnets, especially those containing neodymium, are known to be susceptible to corrosion.^{40,42-43} Tsutsui *et al.* reported that the corrosion resistance of SmCo magnets was similar to dental casting alloys, but the acid resistance was relatively low.⁴⁰ The magnet had virtually no toxic or other negative effects on the tissues. Consequently, the authors concluded that the SmCo magnets could be safely used as a dental material if plated or coated.⁴⁰ The corrosive tendency of NdFeB magnets have been shown to be higher than that of SmCo magnets.⁴⁴ Kitsugi *et al.*⁴⁴ compared the corrosion resistance of SmCo and NdFeB magnets and confirmed that the corrosive activity of NdFeB magnets was higher. This finding was supported by the work of Vardimon and Mueller.⁴³

Given the corrosive tendency of magnets in the oral environment it is recommended they be hermetically sealed for dental use.^{40,42,44} Without a coating material oxygen diffuses into the magnet causing a metallurgical change in the surface layer. Drago⁴⁵ reported in a retrospective study that all magnet implants used in various prosthodontic procedures showed evidence of tarnish.

Coating the magnets is advised due to the possible risk of negative biological effects of the corrosion products.³⁸ *In vitro* studies have been performed by several authors to investigate the effects of the corrosion products. The results of these studies have reported a range of effects from “no cytotoxic

effects”^{40,46-47} to “mild cytotoxic effects”.⁴¹⁻⁴² Investigation of the short term effects of NdFeB magnets on osteoblast-like cells (UMR-106) did not appear to have any cytotoxic effects.

Papadopoulos *et al.*⁴⁷ also did not show any significant effect on cellular activity in either attractive or repulsive magnetic fields. On the contrary, Evans and McDonald⁴¹ reported that fibroblasts showed less proliferation in the presence of NdFeB magnetic corrosion products. However, after 12 hours of the experimental period the attachment was not disrupted.

Coating materials are designed to act as a barrier to corrosion. A range of coating materials have been documented in the literature, for example biocompatible epoxy resin,³ stainless steel⁴⁸ or a thin layer of parylene.² Bondemark *et al.* reported that small amounts of water-soluble cytotoxic components were released by partially stainless steel coated samarium-cobalt magnets.⁴² Vardimon and Mueller⁴³ stated that acrylic alone was not an adequate coating material. Parylene (poly-para-xylene) has been used for medical purposes in surgically invasive devices to create a biocompatible surface e.g. cardiac pacemaker.² However, the material itself is not sufficient to survive undamaged in the intra-oral environment.

Bondemark and co-workers³⁸ compared the *in vitro* cytotoxic effects of uncoated and parylene-coated rare earth magnets used in orthodontics. Cytotoxicity was assessed by two *in vitro* methods, the millipore filter method and an extraction method using mouse fibroblasts cells (L929).^{38,42} Uncoated SmCo₅ magnets showed high cytotoxicity and uncoated Sm₂Co₁₇ magnets had moderate cytotoxicity. Parylene coated magnets and uncoated NdFeB magnets demonstrated negligible cytotoxicity.

The use of coating materials is also advocated to preserve the magnetic properties and clinical usefulness of intra-oral magnets.^{38,49-50} Disturbance of the physical properties and tarnishing of the magnets can occur after the corrosion assault.³⁸ Drago⁴⁵ reported that tarnish and corrosion can seriously compromise the long-term effective use of intraoral magnets.

3.2.2 Static magnetic fields

Biological safety testing is generally performed on three levels – *in vitro* testing to establish the toxicity of the material; testing in animals and lastly clinical trials.¹³ Controversy exists in the literature with respect to the effects of static magnetic fields produced by the size and type of magnets used in orthodontics.^{13,38}

The effects of magnetic fields on the growth of cell cultures, both animal and human, have been evaluated. *In vitro* tests have demonstrated that static magnetic fields can affect certain biological parameters, such as stimulate enzymes, cell proliferation and attachment and osteogenesis.^{13,51-53} Tests have been performed on the cytotoxicity of orthodontic SmCo magnets in three states – new, after clinical use and recycled.⁴² Cytotoxicity was assessed by two *in vitro* methods, the millipore filter method and an extraction method.^{38,42} Short term exposure of the magnetic field (2 hours) did not have any deleterious effects on the mouse fibroblast cells utilised in the study. However, there was release of cytotoxic components from new and clinically used magnets.⁴²

The reported effects of magnetic fields on the growth of human cells are inconsistent. Some studies show no significant effects with regard to DNA synthesis, DNA content, cell shape, structure and number⁵⁴ or glycolytic activity.⁵⁵ Linder-Aronson and Lindskog examined the effects of static magnetic fields of a magnitude comparable to clinical use (107 to 230mT) on human periodontal fibroblasts. The results of the study showed progressively impaired attachment and cell growth. However, they did not exclude the possibility of corrosion products from the magnets contributing to the cytotoxic effects.⁵³

A limited number of animal tests have been performed. Blechman and Smiley³² while studying the use of magnetic forces in cats did not find any abnormalities produced by the magnetic fields in samples taken from adjacent tissues and from internal viscera after a 9 month experimentation period. Around the same time Cerny examined the effects of implanting SmCo magnets within animal tissues

and reported no adverse effects in the blood cells⁵⁶, the tissues surrounding the implants⁵⁷, or the dental tissues.³⁹

In vivo studies in rats and monkeys demonstrated a reduction in epithelial thickness with permanent rare-earth magnet exposure. No abnormal healing or osteoblastic activity after implantation of titanium-coated SmCo magnets in dog mandibles was found over a 6 month period.⁵⁸ Bruce *et al.* confirmed a similar finding in another study performed in rabbits.⁵⁹ Linder-Aronson and Lindskog reported that the effect of a static field was a significant increase in resorbing areas underneath repelling and attracting magnets fixed to the tibia of rats. They suggested that the resorbing activity was related to an inhibition of the developing osteoblast.⁶⁰ However, the design of this study was highly criticised in letters to the editor following its publication.

Darendeliler *et al.* examined the effects of static magnetic fields (SMF) and pulsed electromagnetic fields (PEMF) on the rate of tooth movement and showed a significant increase in the rate of tooth movement. Both experimental groups experienced a reduction in the lag phase between the third and sixth day. Blood chemistry showed a reduced serum level of calcium, which was related to an increased rate of osteogenesis and an increase white blood cell count, possibly as a reaction to corrosive products.⁶¹ In a related study Darendeliler *et al.* investigated the effects of SMF and PEMF on the rate and quality of hard tissue repair after osteotomies in guinea pig mandibles. Wound healing was found to be faster in both groups compared to the controls.⁶²

A small number of clinical tests have been performed. Bondemark *et al.*⁶³ examined human buccal mucosa clinical, histological and immunohistochemically after nine months exposure to orthodontic NdFeB magnets. No adverse long term effects were found on human buccal mucosa in contact with an acrylic-coated neodymium iron boron magnets. The minor tissue reaction found in test and control tissues were interpreted to be a result of micro-trauma and not by the SMF, since there was no difference between the two groups.⁶³ Bondemark *et al.*⁶⁴ examined the effects of SMF exposure on seven patients over an eight week period. They found that the SMF produced by rare earth magnets

for orthodontic use did not cause any change in human dental pulp or gingival tissues adjacent to the magnets.⁶⁴

In conclusion, the evidence available from tests of the safety and biological properties of magnets suggest that the risks of biological harm are negligible. The current evidence indicates that coated NdFeB magnets are acceptable for clinical use.¹⁴ Several authors have acknowledged the need for additional studies to be conducted on the biological effects of magnets, as contradictory findings exist in the literature.³⁸

3.3 APPLICATION OF MAGNETIC FORCES IN ORTHODONTICS

Magnets were first used in dentistry to improve the retention of dentures⁶⁵⁻⁶⁶ and maxillofacial prosthesis.⁶⁷⁻⁶⁹ Magnetic forces have been used in orthodontics for both tooth movement²⁻⁶ and orthopaedic correction⁷⁻¹² with varying degrees of success. The use of magnets for generating orthodontic forces has been a subject of increasing interest.^{1,13-14} The following section will review the application of magnets in the field of orthodontics.

Traditional force delivery systems in orthodontics utilise wires, elastics and extra-oral devices.⁷⁰⁻⁷¹ The possibility of using magnetic forces in orthodontics has been advocated as there are numerous benefits. Advantages of magnetic force delivery reported in the literature include good force control over short distances, no friction and no material fatigue.¹ Magnetic systems permit precise control of the force levels that are applied as they can be calculated from specific force-distance diagrams by measuring the distance between magnets.¹ Darendeliler *et al.*⁷² commented that although rare earth magnets offer advantages over traditional fixed appliances with regard to continuous force delivery, these positives have not been significant enough to lead to widespread clinical application.

Several animal and clinical studies have documented the reliability of using magnetic forces for different tooth movements. The following section will summarise the reported application of magnet forces for tooth movement. The literature regarding the use of magnetic forces for orthopaedic correction will be covered in Section 3.7.

3.4 MAGNETIC FORCES FOR TOOTH MOVEMENT

In orthodontics teeth move in response to the application of light continuous forces. Magnets have been used in a variety of configurations for tooth movement. Initial clinical research focused on magnetic brackets or magnets in conjunction with fixed appliances.^{8,32,73} The first magnetic bracket was designed by Kawata *et al.*⁷³ in 1977. These brackets were made from iron-cobalt and chrome but were later replaced by rare earth magnets as they did not generate sufficient forces.⁷⁴⁻⁷⁵ A new magnetic edgewise bracket was introduced by Kawata *et al.*⁵¹ in 1987. The magnetic brackets were chromium and nickel plated SmCo magnets soldered to the base of an edgewise bracket. The brackets allowed mesial and distal movement of teeth only if the inter-bracket distance was less than 3mm and therefore required conventional retraction prior to this.⁵¹

Blechman and Smiley³² demonstrated the use of Alnico magnets for canine distalisation in two cats. Later in a pilot study, Blechman³ reported the successful use of SmCo magnets attached to edgewise appliances for the application of intra and inter-maxillary forces.³ He suggested that magnets were superior to inter-maxillary elastics as they do not require patient compliance and the forces between the magnets fall below clinically useful amounts when the teeth are apart negating some of the unwanted side effects.^{3,13}

Muller used small rectangular magnets directly bonded to the labial aspect of the teeth to close diastemas without archwires. The magnets applied 117.5grams of force but the force was determined by the distance separating the teeth and therefore influenced the size of the magnets used.⁷⁶

Darendeliler and Joho described a similar concept in their Autonomous Magnetic Arch, which also had no brackets or archwires, but used small, SmCo magnets bonded to each tooth to form a continuous force-releasing arch.⁷⁷

3.4.1 Molar distalisation

Several authors have reported on the use of magnets to move molars distally.^{4-6,78-80} In 1988 Gianelly *et al* described a new intra-arch method, whereby distalisation of maxillary first molars was achieved with repelling magnets in combination with a modified Nance appliance cemented on the premolars.⁵ No detailed description or analysis of the force output was presented and weekly activation was performed.⁷⁰ The molars were distalised at a rate of 0.75-1mm per month, without significant anchorage loss. Anchorage loss was calculated as 20 percent.⁴ Molar movement was reported to be faster by at least 1mm/month in the absence of second molars and resulted in less anchorage loss. Treatment time was increased when second molars were present.⁴⁻⁵

Bondemark and Kurol using an analogous system to generate a repelling force of 116 grams at 1mm separation reported a mean crown movement of 4.2mm, 8 degrees of distal tipping and 8.5 degrees of disto-buccal rotation in ten consecutively treated cases.⁷⁸ Blechman and Steger hypothesised that the static magnetic fields generate simultaneous force fields and bio-effects which they claim may explain the possible mechanism of action of repelling, molar distalising magnets.⁸¹

Bondemark and Kurol examined the force output from prefabricated repelling SmCo5 magnets (4x5x2mm) in an experimental model and found that the forces were suitable for distalisation. A pole face distance of 0.5mm was reported to correspond with the recommended force for moving permanent molars distally 180grams. If the molar moved 1mm the force lowered to 100grams. Based on these findings the authors recommended activation of the force system be performed at 4-5 week intervals and recommended the pole distance be carefully checked at each appointment^{70,78} However, there is no consensus regarding the activation in the literature with some authors recommending weekly activation,⁴ while others activate the magnets every 3 to 5 weeks.^{78,82}

Bondemark *et al.* compared the effectiveness of repelling magnets versus superelastic nickel titanium coils in maxillary first and second molar distalisation over a 6 month period.⁶ Eighteen patients were treated with the two systems, one on each side, and were matched to deliver 225 grams of force on

activation. The magnets and springs were activated every 4 weeks, which may have been to the disadvantage of the magnet side as the force level on this side had a more rapid decrease.⁷⁹ Mean distal molar movement was greater for the coils, 3.2mm compared to 2.2mm for the magnets. Complaints of discomfort were more frequent on the magnet side.⁶ A similar study was conducted by Erverdi but with weekly activation of the magnets and nickel-titanium coils were still found to be more effective.⁷⁹ Bondemark conducted a retrospective comparison of two groups of 21 adolescents treated with repelling magnets or a new lingual Ni-Ti coil appliance. The results indicated that the new Ni-Ti appliance was a better choice due to the design preventing molar tipping (2.2 degrees vs. 8.8 degrees) and its single activation.⁸³

Bondemark and Kurol later evaluated radiographically the impact of these treatment techniques on proximal alveolar bone level changes. The treated cases had a statistically significant but small decrease in alveolar bone level (0.2mm versus 0.1mm for the control). There was no statistically significant difference between teeth moved rapidly by magnets or superelastic coils. Thus, with respect to the influence on bone level, the authors concluded that there was no difference between an interrupted continuous force system produced by a magnet and a more continuous force produced by the superelastic nickel-titanium coils.⁸⁴

The advantages espoused for this appliance include no need for patient cooperation, ease of insertion and well tolerated by patients.⁴ Some disadvantages reported in the literature included minor tissue irritation under the acrylic of the Nance⁴, cost of the magnets, bulky appearance and requirement for weekly activation under certain protocols.⁷⁹

3.4.2 Extrusion

Attractive magnets have been used for orthodontic extrusion. The use of magnets to extrude a traumatised incisor and enhance root eruption was reported by McCord and Harvie.⁸⁵ The case report detailed the use of SmCo magnets to extrude the root of an incisor with a subgingival fracture. One

magnet was fixed to the root and one embedded in a removable partial denture. Bondemark *et al.* reported a similar protocol with NdFeB magnets for the extrusion of crown-root fractured teeth.¹ To achieve rapid extrusion forces of 50 to 60 cN are recommended, approximately twice as much as that required for normal extrusion of a single rooted tooth.⁸⁶ The magnetic system consisted of either one or two cylindrical NdFeB magnets (3 mm x 2 mm) placed in each tooth and a larger magnet (5 x 5 x 2mm) in the appliance. The force-distance curve for the magnets demonstrated that the gap between the magnets should not exceed 2mm to ensure a minimum force of 50cN was applied. The roots were successfully extruded 2 to 3mm with a force range from 50 to 240 cN during a treatment period of 9 to 11 weeks.

3.4.3 Magnets and impacted teeth

Treatment options for the management of teeth that fail to erupt include extraction, transplantation, and surgical exposure alone or with the application of orthodontic traction.⁷¹ Attachment to the tooth is usually achieved by bonding a gold chain or stainless steel wire to the tooth.¹³ With traditional orthodontic traction force levels can be difficult to control, techniques such as pinning or lassoing the tooth have been shown to cause damage to the crown, and breaching the mucosa with a gold chain or wire can lead to infection.¹³ Furthermore, problems such as gingival inflammation, reduced attach gingiva, periodontal pockets, exposed cemento-enamel junction and root resorption of the impacted and adjacent teeth have been associated with conventional orthodontic methods.^{2,87}

An alternate option that has been presented in the literature involves the use of magnetic traction. The technique involves surgical exposure of the impacted tooth, after which a magnet is bonded to the tooth surface. The mucosal flap is sutured in place, completely covering the tooth with its bonded magnet. Guided eruption is achieved by means of a second magnet embedded in an appliance and placed in such a way as to attract the sub-mucosal magnet into the ideal place. As the tooth erupts, the magnet held in the appliance can be moved to direct the eruption of the tooth and minimise the risks to adjacent teeth.¹³⁻¹⁴ This technique exploits the unique characteristic of a magnetic field to

prevail between any organic medium.² There does not need to be direct contact between the magnets as they can exert force through mucosa and bone.¹³⁻¹⁴ As the eruptive process is through normal, closed mucoperiosteum it has been stated that this ensures that a healthy periodontium will surround the tooth.²⁴

The technique was first reported by Sandler *et al.* in 1989 for the eruption of a vertically impacted canine in a 12 year old child.⁴⁶ The level of attractive force generated with this system was not stated. Since this first report the application has been used increasingly and has been applied to the eruption of incisors, premolars and molars.^{2,31,88-89}

The application of this approach for the eruption of impacted premolars was described by Sandler 1991. Small neodymium-iron-boron magnets (3x3x1mm) were bonded to the impacted teeth while a second larger magnet (5x5x2 or 3mm) was incorporated into a removable appliance. No reference was made to the force levels generated by this configuration of magnets. Yuksel *et al.* also described the treatment of impacted premolars in several members of the same family with this technique.⁹⁰ Cole *et al.* described the application of magnetic traction to two premolars and six molars in 8 paediatric patients. The failure of one premolar to erupt was attributed to its unfavourable position. In the seven successful cases the distance between the magnets did not exceed 8mm, suggesting that distances up to this magnitude can provide sufficient force to induce tooth movement.³¹

Darendeliler and Friedli combined the use of removable and fixed attraction systems for an impacted canine. The fixed component consisted of a magnet-fixed Ballista type sectional arch. The authors did not observe any side-effects and concluded that the use of magnets was effective for the eruption of impacted teeth and that treatment time and discomfort were reduced.⁸⁷ Vardimon *et al* described the management of several unerupted teeth using edgewise brackets that housed NdFeB magnets between the wings of the bracket in one animal and four patients.² The attracting forces documented by the two authors above varied from 20.4 to 51gm at 2.5mm separation and approximated 45 grams at 1.5mm, respectively.^{2,87}

Recently, Li et al presented a case in which orthodontic traction of an upper left canine was achieved using a magnet⁹¹ in a 15 year old female. A metal bracket was bonded to the impacted tooth after surgical exposure and was under magnetic force, with direction controllable by adjustment of a wire extension arm from a removable appliance. After 12 months two-thirds of the crown had erupted and the patient was ready to receive simple fixed appliance therapy. The authors suggested that magnetic traction with a removable appliance was safe, effective and comfortable.⁹¹

Physical properties of permanent magnets have to be taken into consideration when designing eruptive magnetic devices.² Magnetic attractive forces are forms of energy and obey the inverse square law. This is clinically very important as the threshold force for producing orthodontic tooth movement may not be attained, even at small distances. This has been shown by Vardimon *et al* and Bondemark and Kurol.^{2,24,70}

Mancini et al investigated the attractive forces generated by five different sized NdFeB magnets in a total of nine combinations for tooth extrusion.²⁴ The effect of spatial relationship on force was assessed by varying vertical, transverse and horizontal positions and pole face angles of the magnets. Force levels sufficient to induce the cellular and biomechanical changes required for orthodontic tooth movement could be produced over a reasonable clinical range but the tested magnetic pairs had varying levels of clinical usefulness. The rate of decline of the force was severe when the angle of the pole face of the superior magnet was changed. Offset and angulation significantly reduce pole face overlap directly affecting the magnetic flux density and direction and therefore force of attraction.²⁴

The results of this study suggested that magnets with larger pole face areas and longer magnetic axes provide the best performance with respect to clinical usefulness. A range of 15-200grams was chosen to represent a force that can be considered clinically relevant for tooth movement. The most useful test pairs 3 and 4 commas had the largest pole face areas and magnetic axis lengths of all magnets used (Test pair 3 – 4mm diameter by 2mm combined with 5mm diameter by 3mm and Test pair 4 – 4mm diameter by 2mm and 5 x 5x 2mm). The range of useful activity for test pair 3 was described by

a cone of height 5.5mm and base diameter of 8mm, generating a 440mm² volume of activity.²⁴ The authors also commented that the magnets themselves have thickness which allows the tooth to be further outside the described cone and therefore increased the clinical usefulness of the system.²⁴

Repulsion was detected for all magnetic pairs when in close proximity to one another and with maximal offset. Repulsion occurs when similar pole faces come in contact, which can occur with angulation of the magnet as pole faces of the same sign will be orientated towards each other. The authors did not consider this to be clinically significant as a situation with no vertical separation between the magnets is unlikely to occur and no significant repulsion was detected with vertical separations greater than 2mm. Furthermore, the phenomenon can be avoided if posterior offsets are avoided. It was recommended that the attractive pole face of magnets bonded to unerupted teeth should always be orientated in such a way as to face the opposing magnet.²⁴

The relationship between flux density and attractive force was also investigated. A transverse Hall probe of 1mm thickness and a Gauss meter were used to measure the magnetic flux. A specific relationship between force and flux density for each magnetic pair was generated. This relationship can be used in the clinical management of unerupted teeth to predict the force between the magnets by measuring the magnetic flux density at the mucosal level.²⁴

Vardimon *et al* performed a three-dimensional analysis of the magnetic force systems of the same magnetic bracket attracted by diverse designs of intraoral magnets using the orthodontic measurement and simulation system (OMSS).⁹² It was concluded that a magnet with a large pole surface area exhibited the most efficient guidance and had a greater clinical range.² The authors also commented that the size of the magnet attached to the device could be increased to a certain extent to enhance performance, in contrast to the magnet attached to the tooth.

Guided eruption is one of the most well accepted and promising applications of magnets in orthodontics.⁹⁰ The reported advantages of this technique include: operator and patient ease as there

is no need to attach hooks or elastics, reduction in adjustments, continuous forces over a long period of time, friction-free system, healthy periodontium as the eruptive process is through normal, closed mucoperiosteum and reduced risk of infection.^{13,24,88} There are however a number of limitations with this approach: attractive forces fall rapidly as distances between the magnets increase, the magnets may be subject to corrosion if the coating is damaged and care must be taken to ensure the correct polarity of the magnets.¹³

3.4.4 Retention

Micro-magnetic retainers were introduced by Springate and Sandler in 1992.⁹³ In their case report small (0.8x0.8x1.5mm), NdFeB magnets were bonded to the palatal surfaces of the upper central incisors to prevent a median diastema from opening.⁹³ There has not been any long term follow-up of this technique reported.¹³ Directly bonded magnets have advantages over conventional fixed retainers. Oral hygiene can be maintained as flossing is not prevented and there are no wires close to the gingival margins. The teeth are not splinted which allows normal physiological movement. However, there are potential problems with this approach. The magnets can debond and the friction between the magnets may cause damage to the protective resin coating and expose the magnet which will corrode.¹³

3.5 APPLICATION OF MAGNETIC FORCES FOR TOOTH MOVEMENT IN COMBINATION WITH CLEAR THERMOPLASTIC APPLIANCES

The intention of this thesis is to investigate the application of magnet force delivery in the two principle facets of orthodontic treatment – tooth movement and orthopaedic treatment. The preceding section reviewed the attempts that have been made to apply magnetic forces to orthodontics for tooth movement. In this project the application of magnetic forces for tooth movement in combination with clear sequential aligners will be explored.

Clear sequential aligner therapy has become a popular alternative to fixed appliances in recent years with the increased demand for aesthetic treatment options. Clear aligner therapy or clear sequential aligner treatment refers to a sequence of clear thermoplastic appliances made on a series of casts with reset teeth, each incorporating another small amount of tooth movement.⁷¹ Despite their superior aesthetics this appliances is less effective than fixed appliance therapy.¹⁵

To overcome some of the limitations of the appliance composite resin attachments are placed on the teeth. Attachments are generally placed on the teeth to increase the undercuts and retention of the appliance to facilitate the desired tooth movement.⁷¹ However, the current attachments are considered to be only partially effective.¹⁸⁻¹⁹

An improved system utilising small magnetic attachments has been proposed to enhance the capabilities of this appliance. In this system a sequential orthodontic appliance is combined with at least one magnetic attachment positioned in an attractive or repulsive configuration bonded to the surface of a tooth and a magnet encased in the body of the thermoplastic material. (Figure 3) The magnets used in this system are neodymium iron boron (NdFeB) rare earth magnets which have the highest energy per unit volume of any commercially available magnetic material.¹³

A laboratory based study was performed to examine the three-dimensional physical properties of small neodymium iron boron magnets that could be utilised in this manner, to determine if force levels sufficient to induce tooth movement could be generated and to examine the effect of different magnet morphologies on the force-displacement characteristics.

The application of magnetic forces to clear aligner therapy would create a magnetic force interaction that can theoretically make the movement of teeth in any direction possible and easier. With this objective in mind the following section of this literature review deals with the use of clear thermoplastics in orthodontics. The current literature regarding the efficacy of the appliance is examined to highlight the need for enhancement of this system.

3.6 CLEAR THERMOPLASTIC APPLICANCES

In recent years the demand for aesthetic orthodontic appliances has increased dramatically.

Consequently, sequential clear thermoplastic aligners have become a popular alternative to fixed appliances. The concept of aligning teeth with thermoplastic appliances is not new. The use of a flexible removable orthodontic appliance for minor tooth movement was first introduced by Kesling in 1945.⁹⁴ The “tooth positioning appliance” was initially made from rubber and was a one-piece flexible appliance that covered the surfaces of the upper and lower teeth. It allowed active tooth movement -and was indicated for the treatment of mild relapse and for use as a retainer.⁹⁴

With the advent of vacuum-formed clear thermoplastic sheets it became apparent that if teeth were reset slightly and the vacuum-formed sheet was made to fit the reset teeth, a tooth moving device would be the result. Nahoum described his “vacuum formed dental contour appliance” in 1964 and was one of the first to apply elastics and utilise attachments.⁹⁵ Ponitz in 1971 introduced the concept of the “invisible retainer” and acknowledged that these thin thermoplastic appliances could be used to move teeth.⁹⁶ McNamara also discussed the use of invisible retainers for minor tooth movement.⁹⁷ Such devices became known as “aligners” because the typical use was to bring mildly misplaced teeth back into alignment.⁷¹

The early appliances were manufactured with vacuum-form machines that sucked the heat-softened thermoplastic material onto the model. The vacuum method was found to have inaccuracies in areas where the vacuum pressure was unable to reach effectively.⁹⁸ Within the last decade machines which use compressed air to blow the material onto the cast have improved the accuracy.¹⁷ Commercially available pressure machines include Biostar, Erkopress and Trutain.⁹⁸

Only small amounts of tooth movement are possible with a single aligner because of the stiffness of the plastic material. To obtain more than minor changes, it is necessary either to reshape the aligner or make a new one on a cast with the teeth reset to a greater degree. A sequence of several aligners made

on a series of casts with reset teeth, each incorporating another small amount of tooth movement, is referred to as clear aligner therapy or clear sequential aligner treatment. Different systems have evolved to facilitate a broader range of tooth movement with clear aligner therapy.⁷¹

Essix developed a technique whereby clear pressure-formed thermoplastic appliances are used to perform minor tooth movements and this became known as the “Essix Appliance”.⁹⁹ In the early 1990s Sheridan popularised the Essix appliance.¹⁰⁰⁻¹⁰¹ The appliances are constructed from unaltered plaster casts of the patients’ teeth and tooth movement is achieved by placement of a divot which applies pressure to the tooth when the appliance is in place. Space within the appliance is obtained by blocking out the working cast or cutting a window in the appliance. The movements are limited to a maximum of 3mm (in 1mm increments) as the plastic becomes too thin to exert force after this.⁷¹ This system avoided the cost and complexity of having to make multiple new aligners.¹⁰⁰ Despite the improvements, reshaped aligners are not considered a practical way to manage orthodontic problems of any complexity.⁷¹

3.6.1 Commercially available systems

Three commercial systems involving the use of a series of clear thermoplastic appliances for sequential tooth movement in the treatment of malocclusions have been available in Australia: ClearSmile, Simply 5™ and Invisalign®.

ClearSmile Pty Ltd was formed by a team of orthodontists and technicians in NSW.¹⁰² In this system thermoplastic appliances known as “correctors” are used to treat malocclusions. From a single polyvinyl-siloxane (PVS) impression, a technician manually resets teeth in sequential stages on the plaster model and fabricates a series of correctors. Each appliance is designed to move the teeth in approximately 0.5mm increments.¹⁰³ ClearSmile list the applicability of their appliances as follows: Class I molar relationship, crowding less than 4mm, spacing less than 5mm, overjet less than 5mm and openbite of less than 1mm. Although a sequence of modified dental casts can be produced

manually in a standard dental laboratory, this is time consuming and difficult.⁷¹ The company has recently ceased operations.

Another commercially available aligner system is Simpli 5TM manufactured by AOA Orthodontic Laboratory, Inc and marketed by Ormco Pty Ltd.¹⁰⁴ It is designed to treat patients with mild to moderate anterior crowding or spacing, or those who have experienced orthodontic relapse and have a stable posterior occlusion and no TMD. It is a laboratory generated product that delivers five sets of sequential trays for anterior correction that require up to 2.5 mm of movement per arch from impressions or models. The reported advantages of Simpli5 include speed, flexibility, simplicity and economy.¹⁰⁴

3.6.2 Invisalign

The Invisalign® System was introduced by Align Technology Inc (Santa Clara, California) in 1999. In this system a series of clear, removable, plastic appliances that are worn sequentially by a patient are used to correct a malocclusion.^{17,105} Align Technology Inc computerised the process of producing sequential aligners. Traditional laboratory methods are labour intensive and require detailed setups to be done by a technician. Consequently, this technique is used for simple malocclusions and is difficult to apply to a large patient population. By developing a computer-based manufacturing process Align Technology was able to resolve some of the difficulties.¹⁰⁵⁻¹⁰⁶

The Invisalign® System requires a CT scan of a PVS impression creating a digital model and uses 3-D computer software to manipulate the position of the teeth on the digital model. Sequential stereolithographic resin models are created with a computer-programmed laser. From these models, a series of vacuum-formed appliances known as “aligners” are constructed. The movement programmed into each aligner is 0.25 to 0.33mm.^{17-18,71,107-108} The aligners are worn for a minimum of 20 hours per day and changed every two weeks.¹⁷⁻¹⁸

Since its advent Invisalign® has grown rapidly in worldwide consumer demand and professional use. Currently over one million patients have been treated with Invisalign.¹⁰⁹ Meier *et al.* conducted a prospective study to define a profile of patients who were interested in Invisalign®. They found women aged between 20 and 29 years were most frequently interested in Invisalign treatment. 97% of those surveyed gave aesthetic concerns as their primary motivation for treatment. The demand for aesthetic treatment options were also reflected in the finding that 62% would not consider orthodontic treatment with visible appliances.¹¹⁰

Vicens and Russo recently investigated the use of Invisalign by orthodontist and general dentists within a 35-mile radius of Stony Brook University. Interestingly, for both groups, the longer the practitioners were certified in Invisalign, the fewer cases they started over the last 12 months. The authors suggested that for these practitioners the novelty of the technique had diminished and that its limitations relative to fixed appliance treatment are beginning to discourage them from using it as much as they originally did.¹¹¹

3.6.2.1 Indications

Align Technology provides guidelines for cases that can be successfully treated with Invisalign. Cases for which Invisalign is recommended include the following features: Mild to moderate crowding (1-6mm), mild to moderate spacing (1-6mm), non-skeletal constricted arches and relapse after fixed appliances. The case selection criteria of Align Technology are merely guidelines. Each clinician must apply their own clinical judgement regarding the suitability of the case, as they are responsible for the treatment outcome.^{15,112}

Several case reports have documented successful treatment of mild to moderate malocclusions with the Invisalign® system.¹¹³⁻¹¹⁵ Boyd *et al.* published the first case reports of treatment with the Invisalign system in 2000. The first cases treated with Invisalign were adult patients with mild (3 to 6mm) spacing and crowding.¹¹⁴ Early studies demonstrated limitations in the treatment of complex cases with the Invisalign system. During the first four years of appliance development significant

problems were accounted with accomplishing bodily movements, root torque, extrusion and derotation of canines and premolars.¹¹⁶⁻¹¹⁷

Controversy still exists over whether moderate to difficult orthodontic treatment can be completed routinely with Invisalign.¹¹⁶ In recent times case reports of successful management of moderate to difficult malocclusions with Invisalign have appeared in the literature.¹¹⁸ Patients with more complex malocclusions including premolar extractions, deep overbites, Class II malocclusions, molar distalisation and open bites have been treated with the Invisalign system.^{116,118-124} Despite this, a recent survey reported that most orthodontists and general practitioners would not treat severe Class I malocclusions with Invisalign.¹¹¹

The inability to control root movement limits the use of the Invisalign system in malocclusions requiring premolar extractions.¹²⁵ This is considered to be one of the most significant limitations of the appliance.¹²⁶ Case reports by Giancotti *et al.* and Miller *et al.* which involved premolar extractions highlight this problem, as both required fixed appliances to upright the molars, premolars and canines at the completion of aligner therapy.^{125,127} Honn and Goz presented a case report of a successful premolar extraction treatment with Invisalign. One aspect favouring the use of the system was that limited bodily movement was required, only minor rotations and no extrusion, intrusion or torque movements. The authors' highlighted that the success of Invisalign treatment is largely dependent on which tooth movements are required to correct the clinical situation and the importance of understanding the range of indications for the appliance.¹²⁰

Based on clinical experience Joffe advised that the Invisalign system has difficulty treating the following cases:

- Crowding or spacing over 5mm
- Sagittal discrepancies more than 2mm from a Class I canine relationship
- Large discrepancies between centric relation and centric occlusion

- Teeth that are rotated more than 20 degrees
- Open bites
- Cases requiring extrusion
- Teeth that are tipped more than 45 degrees
- Short clinical crowns
- Multiple missing teeth.¹⁸

Although certain aspects of a malocclusion are difficult to manage with Invisalign, it does not preclude the use of the system completely, as it is possible to undertake combined treatment. It can be used to treat one arch or alternately it can be used in a staged treatment with fixed appliances.^{18,126}

Invisalign has also been used sequentially with a functional appliance and a Carriere distalising appliance.¹²⁸⁻¹²⁹

3.6.2.2 Efficacy of clear aligner therapy

Given that clear sequential aligner systems are fundamentally similar, the systems will be considered collectively with regard to the advantages, disadvantages, efficacy and tooth movements that can be achieved. Certain tooth movements are performed more predictably than others with clear aligner therapy.¹²³

As the demand and professional use of clear sequential aligners continues to grow the efficacy of the system needs to be examined. Adequate assessment of the effectiveness of Invisalign treatment is difficult as insufficient clinical research has been published.¹¹² Lagravere and Flores-Mir performed a systematic review of the literature regarding the Invisalign system and found that scientific evidence regarding the indications, efficacy, limitations and treatment effects were lacking. Two articles fulfilled the inclusion criteria of a clinical trial but the authors determined that they did not adequately evaluate the treatment effects of the system.¹³⁰ The majority of articles in the literature are case reports, material studies, commentaries and descriptions of the use of the system.^{106,112} The authors

reported that no strong conclusions regarding the treatment effects of Invisalign appliances could be made.¹³⁰

The two clinical trials by Bollen *et al.* and Clements *et al.* used different aligner material to Invisalign's current system, which minimises their importance.^{16,112,117,131} The first study by Bollen *et al.* investigated the effects of activation time and material stiffness on the patient's ability to complete Invisalign treatment.¹³¹ The results of the study supported the current recommendation for a 14 day wear period as a 2-week activation time almost doubled the likelihood of successful completion of the aligners, compared to the 1-week activation. High PAR scores and planned extractions significantly decreased the likelihood that the aligners would be completed. Clements *et al.* conducted the second clinical trial which examined the effects that activation time and material stiffness had on the quality of the dental movements as measured by changes in the PAR scores.¹¹⁷ The authors concluded that the "aligners were most successful in improving anterior alignment, moderately successful at improving the overjet and midline, and least successful in improving buccal occlusion, transverse relationships, and overbite". Analysis by extraction pattern revealed that incisor extraction sites had a significantly greater percentage of closure than premolar extraction sites.^{16,117} However, Invisalign appliances are now manufactured using a material of intermediate stiffness.¹¹⁸

Djeu, Shelton and Maganzini compared the treatment outcomes of Invisalign cases and fixed appliance using the American Board of Orthodontics objective grading system.¹⁵ The overall passing rate for the Invisalign group was 27% lower than braces. Invisalign treatment finished 4 months sooner than fixed appliances. Invisalign was considered to be "especially deficient in its ability to correct large anterioposterior discrepancies and occlusal contacts". The Invisalign system compared well to fixed appliances in regard to its ability to close spaces and correct anterior rotations and marginal ridge heights. A limitation of the study was the difference in the clinician's experience with the two treatment modalities.¹³² The provider had less experience with the Invisalign system and refinements have been made to the technique since the cases were completed.¹⁵ The same sample from the Djeu *et al.* outcome study was used by Kuncio *et al.* to compare the post-retention dental

changes of patients using the ABO objective grading system. The authors found that the patients treated with Invisalign had more relapse, particularly in the maxillary anterior teeth.¹³³

There is considered to be a “lack of substantive controlled clinical trials” in regard to this treatment modality.¹¹² Further clinical trials are required to evaluate the strengths and limitations of Invisalign treatment.^{16,112} Until better quality evidence is available, clinicians will have to rely on their clinical experience, the opinions of experts and the limited published evidence when using Invisalign appliances.¹³⁰

3.6.2.3 Tooth movements

There is limited published information about the force levels produced for tooth movement by the Invisalign system and other systems of this kind.¹³⁴ Duong and Kuo compared the force-strain characteristics of orthodontic wires (0.017x0.017 stainless steel and nitinol) to aligners and reported a lower level of strain for aligners, 1-2% strain, compared to stainless steel wires, which deliver an average strain of 4% when activated. No information was provided regarding how this data was obtained.¹³⁵ Barbaggio and co-workers used a novel pressure film approach to determine the force generated by clear thermoplastic aligners made from 0.8mm Erkudor thermoplastic blanks that had 0.5mm of buccal movement programmed in each appliance. Digital imaging and spectrophotometry analysis were used to quantify the strain intensity mounted by the pressure on the films. The results indicated that high force levels (5.12N) were applied to the tooth initially but diminished rapidly over the 2 week period of wear (-2.67N).

Tooth movements that are performed well with clear aligner therapy.⁷¹

- Tipping
- Rotation of incisors¹¹⁶
- Intrusion (1-2 teeth)^{71,136}

- Expansion
- Constriction

Tooth movements that are not performed well with clear aligner therapy.⁷¹

- Extrusion¹⁸: This is considered to be one of the most difficult movements to achieve. Attachments are required to facilitate movement by creating an undercut area.¹²³
- Bodily movement during extraction space closure: this is primarily because the system has a limited ability to keep teeth upright during space closure.¹⁸
- Torque (labiolingual tip)
- Severe rotations (more than 20 degrees), especially premolars and canines. A survey by Sheridan revealed that “uncorrected rotations” were one of the most prevalent problems encountered by orthodontists using Invisalign, often resulting in the need for refinement or fixed appliance.¹³⁷
- Mesiodistal Tip – (Tipping) more than 45 degrees^{18,123}

Certain movements are possible using attachments:

- Closure of premolar extraction space
- Translation of molars
- Extrusion of incisors

Efficacy of tooth movements with clear aligner therapy can be evaluated by comparing the planned virtual treatment with the actual treatment outcome. This information can help improve the appliance, guide future treatment decisions and clarify treatment indications. Align Technology has a software tool that can be used to superimpose digital models to evaluate treatment outcomes in three dimensions.¹⁰⁵ Miller, Kuo and Choi showed that superimposition of digital models on the palatal rugae were reproducible and had a level of error similar or less than 2D cephalometric analyses. A single bicuspid extraction case was evaluated which showed that not all planned movements occurred. Most notably the treatment outcome showed that multiple teeth tipped into the extraction site.¹²⁷

Kravitz *et al.* evaluated the efficacy of different tooth movements with Invisalign.¹⁶ The amount of tooth movement predicted was compared with the amount achieved, using ToothMeasure, Invisalign's proprietary superimposition software. The types of movements studied were expansion, constriction, intrusion, extrusion, mesiodistal tip, labiolingual tip and rotation. The mean accuracy of tooth movement with Invisalign was 41%. The most accurate movement was lingual constriction (47.1%) and the least accurate movement was extrusion (29.6%), especially for maxillary and mandibular central incisors. The findings of this study are likely to vary from clinical setting as the research protocol prevented the use of auxiliaries and did not account for overcorrection.¹⁶ These results were less than the internal test results of Nguyen and Cheng who found a mean accuracy of 56% for anterior tooth movement.¹³⁸ In addition, the internal study by Nguyen and Cheng revealed that the overall accuracy of canine and premolar rotation was only 39%.

To overcome some of the limitations of the appliance resin attachments are placed on the teeth.^{17,123} In most circumstances the attachments increase the undercuts and retention of the appliance to facilitate the desired tooth movement. There are three fundamental types of attachments: those that assist tooth movement, those that augment retention of the appliance and those that assist auxiliary functions. All three categories of attachments act as force transmitters.¹⁷

Attachments vary in size and shape. The standard Invisalign attachment shapes are ellipsoid and rectangular. The dimensions of the ellipsoid attachments are height 3mm; width 2mm; and prominence of 0.75mm. The dimensions of the rectangular attachments can vary with heights of 3, 4 and 5mm; width 2mm and prominence of 0.5 or 1mm. They can be requested in horizontal or vertical orientations and with bevelled edges.¹⁷

Invisalign has introduced new optimised attachments for extrusion, rotations and torque (power ridges). These attachments are automated and pre-activated. According to Align Technology the optimised attachments cannot be moved, lengthened or repositioned as they are customised for each

tooth and are based on biomechanical studies.¹⁰⁹ There is limited clinical information about the effectiveness of the new attachments at present.

The attachments are used for increasing aligner retention and tooth control. Attachments are formed by bonding tooth coloured restorative material to the buccal surfaces of the teeth and give the aligners' greater rotation and angulation control.¹⁸ According to the experiences of Joffe, although attachments give the aligners greater rotation and angulation control it is only partially effective. He also acknowledges that as materials improve attachments will allow much greater control over tooth movement.¹⁸

Kravitz *et al.* performed a prospective clinical study to evaluate the influence of attachments and interproximal reduction (IPR) on the accuracy of canine rotation with Invisalign.¹⁹ 53 canines were examined and the mean accuracy of rotation with Invisalign was found to be 35.8%. These results agreed with findings of Nguyen and Cheng regarding the difficulty derotation canines and premolars.¹⁷ There was no statistical difference in rotational accuracy among the groups – attachment only, IPR only or neither. The highest accuracy was achieved when IPR was performed. The author's acknowledged the limitations of the study which included small sample size, lack of evaluation of IPR and failure to consider overcorrection. Further clinical tests were recommended regarding the placement and shape of Invisalign attachments, staging and amount of IPR, amount of overcorrection, and speed of tooth movement to improve the accuracy of rotating teeth.¹⁹

Other authors have also commented that auxiliaries such as elastic and detailing pliers are required to facilitate tooth movement with clear aligners. Align Technology recommends interproximal reduction, thermopliers, overcorrection and auxiliaries in addition to attachments to aid rotational movements.¹⁰⁷ Boyd recommends 10% overcorrection whereas Kuo suggests 5% beyond the ideal and use of thermopliers when needed.^{17,19} Kravitz *et al.* recommended far greater overcorrection.¹⁹

There are several factors that can affect treatment outcome with Invisalign. According to Duong and Kuo variation in biological response and tooth shape, such as irregular facial surfaces, unusual crown shapes and unfavourable crown shapes such as round teeth, reportedly affect the ability to achieve the desired outcome.¹³⁵ Compliance is a considerable factor given this system is removable and compliance indicators have been recently added to Invisalign products.¹⁰⁹ Different procedures have been recommended to improve treatment outcomes such as case refinements and detailing pliers.

3.6.2.4 Advantages

Numerous authors have given mention to the advantages and disadvantages of clear aligner therapy.^{18,114} Reported advantages of clear sequential aligner therapy over conventional appliances are:

- Excellent aesthetics¹⁸
- Facilitate good oral hygiene¹¹⁷
- Ease of use for patients^{18,139}
- More comfortable than fixed appliances^{15,139}
- Ability to remove aligners to eat¹³³
- Minimal need for adjustment
- Reduced chair time¹¹⁴
- Minimal impact on speech¹³⁹
- Potentially less root resorption^{116,134}

Miller *et al.* conducted a prospective, longitudinal cohort study to compare the treatment impacts between Invisalign aligner and fixed appliance therapy during the first week of treatment in adult patients (33 with aligners, 27 with fixed appliances).¹³⁹ The Invisalign group experienced fewer negative impacts on their lives in relation to function, psychosocial impact and pain-related criteria. The visual analog scale pain reports demonstrated that adults treated with Invisalign experienced less pain and they also took less pain medication. The results of this study support the claims that

Invisalign therapy is more comfortable and has a more favourable impact on patient quality of life compared to fixed appliances in the first week of treatment.¹³⁹

Periodontal health benefits and improved oral hygiene have been cited as advantages of aligner therapy.¹²³ Case reports of successful treatment in periodontally compromised patients have been documented in the literature to support such claims.¹²³ Miethke and Vogt compared the periodontal health of patients during treatment with Invisalign and fixed appliances.¹⁴⁰ Thirty consecutive patients for each treatment modality were enrolled and the study evaluated the modified gingival index, modified plaque index, modified Papillary bleeding index and sulcus probing depth. The plaque index was found to be lower for the Invisalign group overall but the periodontal condition of the two groups was nearly identical.¹⁴⁰ A similar comparison was performed for fixed lingual appliances and Invisalign.¹⁴¹ Clements *et al* reported a statistically significant decrease in average papillary bleeding score during treatment with aligners. They concluded that “unlike treatment with fixed appliances treatment with clear, removable aligners appears to have no adverse effects on gingival health during treatment”.¹¹⁷

A longitudinal study by Boyd suggested that patients with short roots may be “better candidates” for clear aligners than for fixed appliances.¹¹⁸ Barbagallo *et al* investigated the amount of OIIR generated by invisible removable thermoplastic appliances (ClearSmile) with a rate of tooth movement of 0.5mm every 2 weeks and light (25g) and heavy (225g) orthodontic forces. Over a treatment duration of 8 weeks it was found that thermoplastic appliances have similar effect on root cementum as light orthodontic forces with fixed appliances.¹⁴² These results agree with the few studies that show that removable appliances induce less OIIR than fixed appliances.

Brezniak and Wasserstein documented a case which had experienced orthodontically induced inflammatory root resorption of the four maxillary central incisors following Invisalign treatment. The authors’ intention was to demonstrate that this phenomenon can unpredictably appear with the Invisalign system, just as it does with all other orthodontic treatment modalities. “Force application,

even by the Invisalign technique, initiates sequential cellular processes, as do all other orthodontic appliances that might lead to root resorption". The author's hoped the preference of the Invisalign system versus another treatment modality will not be related to the OIIRR phenomenon, because it can result from all treatment procedures.¹³⁴

Computer-assisted processes, such as the Invisalign System, have additional benefits. Clinicians can evaluate multiple treatment options before finalising a treatment plan. The virtual treatment model can assist with patient communication and can serve as a motivational tool.¹⁰⁵

3.6.2.5 Disadvantages

- Short range of action
- Poor three dimensional control of tooth movement
- Limited effectiveness with other types of movements such as bodily movements, rotations, extrusions and severe intrusion of teeth
- Cannot control the angulation of a tooth when they are being moved
- Compliance dependent¹¹⁴
- Possible loss of appliance¹¹⁴

According to Djeu *et al.* the major advantages of Invisalign compared to fixed appliances are that they are aesthetic, removable and comfortable but there are no biomechanical advantages.¹⁵

The current virtual dental models used in computer-assisted treatment planning and manufacturing are still considered to be incomplete.¹⁰⁵ The addition of root geometry could enhance the model. This information could be added by measuring root dimensions from radiographs or CT scans. The current gingival model is also incomplete. Shape changes are only approximations and the model does not account for extreme movements that can have detrimental effects, such as recession.¹⁰⁵

Conclusion

Flexible removable appliances are evolving rapidly. At present, the use of aesthetic removable appliances have not been shown to be as efficient as fixed appliances in the treatment of malocclusions, especially more complex cases. The appliance is dependent on patient compliance being a removable appliance. New compliance detectors are intended to overcome this disadvantage. In the future these appliances may become as efficient as fixed appliances as technology evolves.

3.7 ORTHOPAEDIC TREATMENT WITH MAGNETIC FORCES

Magnetic forces have also been used to achieve orthopaedic corrections. A summary of the use of magnetic forces for orthopaedic correction of skeletal problems in orthodontics will follow.

3.7.1 Expansion

Vardimon et al was the first to investigate the use of magnets to provide the force for maxillary expansion.¹⁰ The study compared the effects of magnetic versus mechanical expansion with different force thresholds and points of force application. The animal experiment involved four juvenile monkeys - one control and three experimental receiving the following appliances: conventional jackscrew exerting a force of 2033 grams; tooth borne appliance with repelling magnets and endosseously pinned appliance with repelling magnets, both exerting 258 grams of force. Spatial changes of dental markers and facial implants were studied radiographically. The authors demonstrated orthopaedic changes with magnetic palatal expansion. The palatally pinned magnetic appliance induced bodily tooth movement, the greatest increase in intermolar distance and a superior repositioning of the maxillopalatine region.¹⁰

Darendeliler et al examined the effect of magnetic forces for maxillary expansion in human patients of different ages.¹⁴³ Two types of magnetic expansion device (MED) were used, bonded in two patients and banded in four other patients. Two repelling samarium-cobalt magnets (4x5x16mm) were used to generate forces between 250 and 500 grams. Following active treatment the patients were retained with a Hawley appliance for 6 months. More pronounced skeletal versus overall expansion was obtained with the banded appliance – between 16 and 77 per cent with the banded MED versus 0 and 25 per cent with the bonded MED. The degree of skeletal movement varied depending on the patient's growth status. The authors concluded that “it seems that 250-500g of continuous magnetic forces can produce dental and skeletal movement in a light force expansion concept, but further studies with larger samples are need to make firm conclusions”.¹⁴³ Darendeliler also commented that although a

skeletal effect is always present, the dental movements were greater. Tentatively, he stated that skeletal expansion with magnets is less effective than conventional methods.⁷²

Theoretically, magnetic expansion appliances may be useful because of the predictable, constant low force they deliver. However, the appliances are likely to be quite bulky as they must be adequately stabilised and contain guide rods to prevent the magnet coming out of alignment and causing unwanted rotational movements.¹³ Darendeliler commented that neodymium magnets which are more powerful than SmCo magnets could generate the same amount of force with a smaller and less bulky appliance.¹⁴³

3.7.2 Openbite

Magnetic forces have been used for the management of openbite cases. Removable or fixed appliances with acrylic bite blocks incorporating magnets to intrude the molars have been used.¹³ Dellinger introduced the first clinical appliance in this field the Active Vertical Corrector (AVC) in 1986.¹² This appliance used four pairs of repelling samarium-cobalt magnets to produce a posterior intrusive force of 700 grams per magnetic unit. The current generation of the AVC uses four NdFeB magnets that produce 675 grams of force in opposition and are only 0.151 inches high. At a gap of 3.5mm, this force falls to 110 grams. Thus actual forces applied to the teeth fall into 60 to 180 gm range with normal freeway space considerations.¹⁴⁴

This appliance was considered an 'energised' bite block intended to intrude the maxillary and mandibular molars leading to autorotation of the mandible. The author also attributed the effects of the appliance to the increased cellular activity that occurs when the tissues are subjected to magnetic fields.¹² The results of three cases treated with the appliance were presented to demonstrate the effectiveness of the technique. All achieved a positive overbite within 4-9 months but some labial or lingual tipping of the maxillary incisors was observed.¹² In 1996, Dellinger and Dellinger published the results of a long-term follow-up of the patients presented in the initial article. All the cases still

had normal facial heights and stability of overbite.¹⁴⁴ Woodside and Linder-Aronson also demonstrated the effective use of this appliance in a case report.¹⁴⁵

Barbre and Sinclair reported a case-control study of 25 growing openbite patients with the AVC for an average of 8 months. They reported an average of 3mm bite closure associated with molar intrusion and a small amount of autorotation of the mandible. Additional contributions to the correction of the openbite were maxillary incisor eruption and retroclination and mandibular incisor lingual movement. Only minimal changes were noted in the sagittal direction.¹⁴⁶ Bazzucchi *et al* evaluated retrospectively the changes that occurred in overbite during two-phase treatment with the AVC and fixed appliances. The overbite was significantly improved in the 29 treated cases compared with matched normal controls. The increase in overbite was attributed to small changes in relative mandibular vertical growth, bodily incisor movement towards the occlusal plane and lingual tipping of the lower incisors.¹⁴⁷

Other magnetic appliances for openbite correction have been documented in the literature.¹⁴⁸⁻¹⁵⁰ The MAD IV, designed in 1989, uses anterior attracting NdFeB magnets as well as posterior repelling magnets.^{14,148} The anterior magnets help to guide the mandible into a centred position and facilitate anterior rotation of the mandible. The posterior repelling magnets generate an intrusive force of 300 grams each. Three types of MAD IV have been described for different openbite cases.

Darendeliler *et al* presented three cases to demonstrate the effects of the appliance. All patients treated with the appliance achieved openbite closure. The authors attributed the mode of action of the appliance to a reduction in the anterior vertical dimension, a slight increase in the incisor inclination and eruption of the incisors, or both. A sagittal growth modification was also observed as reflected by a decrease in the ANB angle.¹⁴⁸ Following this the skeletal and dental effects of 16 growing patients treated with the MAD IV were evaluated by Meral and Yuksel. The patients were initially observed for 9 months, during which a downward and backward rotation of the mandible was observed resulting in an increase in lower face height and openbite. During the treatment period with the MAD

IV the patients showed an anterior mandibular rotation with a significant decrease in lower face height and openbite. No information was given about the long-term stability of the cases.¹⁵¹

Animal and clinical studies have been performed to differentiate the effect of opening the bite vertically with posterior bite blocks from the effects with repelling magnets.¹⁵²⁻¹⁵⁴ According to Kuster and Ingervall, theoretically there are several beneficial therapeutic effects of bite blocks.¹⁵⁵ They could intrude the posterior teeth leading to autorotation of the mandible and bite closure. In growing patients inhibition of the eruption of posterior teeth leads to relative intrusion and would have the same effect. Another possibility is that the bite block would increase the condylar growth. Unloading of the temporomandibular joints and/or protrusion of the condyles with the bite blocks may create a functional appliance effect. Increased vertical condylar growth would rotate the mandible anteriorly and tend to close the bite. A maximal effect would be achieved with bite blocks by simultaneous posterior intrusion and an increased posterior vertical growth.¹⁵⁵

A series of experiments in primates considered the effects of opening the bite vertically with posterior bite blocks.^{152-153,156-158} The experimental animals adapted to the appliances by a temporary lengthening of the masseter and other elevator muscles. In juvenile animals, the most consistent finding was a marked reorientation of the growth of the maxilla.¹⁵⁹ The normal downward displacement of the maxilla was decreased. Instead, the growth of this region was directed anteriorly and markedly superiorly. The maxillary displacement was shown to have a rotational component, with the anterior portion displaced more than the posterior.^{158,160} The extent of the expression depended on the amount of bite opening.^{158,160} The juvenile animals in which the bite had been opened to a greater degree showed 2 to 3 times the maxillary displacement of the control period, and 2 to 4 times more for an adolescent group.^{158,160} However, in the post-treatment periods downward and forward growth resumed and was greater than the control period in the vertical dimension. The maxillary translations which occurred during the experimental period were not reversed.^{158,160}

Adaptations were also reported in the growth of the mandible. Carlson *et al.* demonstrated that an increase in the vertical dimension stimulated progressive remodelling in the condyle. McNamara reported that adaptation was less evident in the mandible, except when a severe opening was created, resorption in the gonial angle region was evident.¹⁵⁸

Varied results have been reported regarding the relative intrusion of the posterior teeth in the experimental animals.¹⁵⁹ McNamara reported no actual intrusion of the maxillary or mandibular teeth in juvenile monkeys, although the eruption of these teeth was inhibited by the appliance. Altuna and Woodside reported a marked difference in the amount of buccal tooth intrusion between the juvenile and adolescent animals.¹⁶⁰ It has been demonstrated that intrusion of the buccal teeth occurs more readily in mature monkeys.^{156,160} Whereas inhibition of eruption with relative intrusion occurred in growing monkeys.¹⁶⁰

Woods and Nanda investigated the effects of repelling magnetic bite-blocks in growing baboons compared to acrylic bite-blocks to differentiate the effects of increasing the vertical dimension with bite blocks and the effect of the repelling magnets.¹⁵² The magnetic appliances altered the amount and direction of maxillary displacement occurring during growth, caused changes in mandibular shape and depression of the underlying teeth. However, similar responses were noted in the controls with bite block used alone. The authors reasoned these effects could be attributed as much to the muscular response to the artificially increased vertical dimension as to the presence of repelling magnets. The same authors later examined the effects of the appliances in four non-growing baboons.¹⁵³ The magnetic appliances caused depression of the posterior teeth but the effects were reduced compared to the growing animals, however no effect was seen in the controls. There was also no apparent maxillary skeletal displacement or mandibular remodelling in any of the animals in this study.

Comparative clinical studies have also been performed to evaluate the effects of magnetic bite-blocks.

¹⁵⁴⁻¹⁵⁵ Kiliaridis *et al.* ¹⁵⁴ compared the effect of the AVC to acrylic posterior bite blocks in 20 openbite patients, whereas Kuster and Ingervall compared cemented magnetic bite blocks to a

removable spring-loaded bite-block.¹⁵⁵ These studies reported that the magnetic appliances produced a faster and more marked response in the vertical dental and skeletal relationships, especially in younger patients.¹⁵⁴⁻¹⁵⁵ A one year post-treatment follow-up by Kuster and Ingervall of the magnetic bite blocks cases revealed that 50% of the beneficial effects of the treatment relapsed. The authors suggested that this could possibly be counteracted by a long phase of active retention.¹⁵⁵

Kilaridis *et al.* noted transverse problems i.e. unilateral crossbite in the patients treated with magnetic appliances, which necessitated the interruption of treatment.¹⁵⁴ Similar side-effects were reported by Karla *et al.* when a fixed appliance with repelling magnets was used to treat mandibular retrusion.¹⁴⁹ Conversely, transverse problems were not reported by other authors.^{12,144,146}

In an attempt to overcome this problem vertical flanges have been incorporated to help guide the mandibular closure so that more vertical forces can be produced. Lower force thresholds and use of a vertical chin cup have also been proposed to avoid the adverse lateral vectors. Dellinger eliminated the lateral shearing effect of the repelling magnets by redesigning the acrylic bases to restrict such movements.¹⁴⁴ Darendeliler *et al.* incorporate an anterior attracting magnet to overcome these effects.¹⁴⁸

Theoretically the bite blocks with repelling magnets transfer continuous forces to the posterior teeth, although the level varies according to the amount of separation between the magnets. Conversely, conventional bite-block appliances transfer intermittent forces to the teeth only when they are in contact.¹⁵⁴ Vardimon and co-workers investigated the 3-D force and moment/displacement behaviour of the AVC using the OMSS to define the optimum magnet arrangement.¹⁶¹ The criteria for the optimal force system were a constant intruding force and minimal shearing forces over a broad range of jaw movements and negligible moments. Four magnetic arrangements of disc-shaped SmCo magnets (8mm diameter x 2mm) were tested but none met all these criteria. The force analysis was in favour of the medial eccentric arrangements but the moment analysis preferred a centric arrangement. At a gap distance of 3 to 6mm the intrusive force was constant however there was a rapid decrease in

the force level with mouth opening. All arrangements generated lateral and sagittal shearing forces, which supports clinical findings of unilateral posterior crossbite with magnetic intrusive treatment.¹⁵⁴ The authors concluded that the centric arrangement is appropriate clinically when the separation is small and Muller prongs are used to prevent lateral shearing.¹⁶¹

3.7.3 Class III Magnetic Functional Appliances

The Functional Orthopaedic Magnetic Appliance (FOMA) III was developed by Vardimon and co-workers for the treatment of Class III malocclusions with midface sagittal deficiency with or without mandibular excess.⁷ The FOMA III consists of upper and lower plates with two disc shaped neodymium-iron-boron magnets (6mm diameter x 3mm) in an attractive configuration. The optimal orientation of the magnetic components was studied in vitro on a Zwick 1435 material testing machine. The ratio of horizontal to vertical forces was dictated by the inclination of the magnetic interface in the sagittal plane and the extent of the overlap. A maximum sagittal shearing force of 116g was generated at 50% overlap. A class III horizontal force develops when the upper magnet assumes a posterior relationship to the lower magnet. Therefore, reactivation of the upper magnet to a 50% overlapped position was required whenever 66% overlap was accomplished. Reactivation was achieved by periodic (3 to 4 weeks) repositioning of the upper magnet with a retraction screw.⁷

The effects of the appliance were examined in a primate study. Six female *Macaca fascicularis* monkeys were treated with the appliance and three controls received a sham appliance. Over a 4 month treatment period midface protraction occurred and significant forward movement of the maxillary incisors and molars. Inhibition of mandibular length was minimal but a tendency toward a vertical growth pattern of the condyle was noted. The author's recommended long term animal and clinical studies be performed.⁷

Clinical application of a magnetic functional appliance for Class III treatment has been demonstrated by Darendeliler *et al.* and Luthy-Burhop *et al.*^{11,14} Both case reports document successful treatment

with the MAD III, one in combination with a magnetic expansion device and the other with a Delaire facemask.^{11,14} The magnetic activator device (MAD) III consists of an upper and lower plate with two buccal pairs of attracting samarium cobalt magnets (6mm x 4mm x 5mm) placed eccentrically in the sagittal direction, so the mandible is pulled distally and the maxilla mesially. The total sagittal force between the upper and lower plates was 300g initially and increased to 600g as the condition was corrected.¹¹

3.7.4 Class II Magnetic Functional Appliances

A range of magnetic functional appliances have been developed for this purpose.^{8-9,20,149} With such appliances the mandible is kept in a more forward position with the help of magnetic forces. The patients rest position is altered by the presence of magnetic forces to a “magnetic rest position” which is dictated directly by the placement of the magnets.¹⁶² It has been suggested by Darendeliler¹⁶² and Vardimon *et al*⁹ that by using magnetic forces a full time influence on mandibular position and function can be achieved.

Inadequate treatment results with functional appliances have been attributed to incompetency of some appliances to securing the lower jaw in a forward posture. Normal interjaw tooth contact totals between 8 minutes and 20 minutes during a 24 hour period and is only 1 to 2 minutes during the night. In addition, according to Manns and co-workers the clinical rest position with a 1-3mm occlusal space does not coincide with the electromyographic (EMG) relaxed position, with a larger 5 to 12mm occlusal clearance. This means that the patient can wear a conventional orthopaedic appliance in an unproductive position, especially at night when the muscles are relaxed and the chin drops back.¹⁶² The proposed advantages of magnetic forces are that they keep the mandible in a forward magnetic rest position and allow the patient to function continuously in a class I posture.^{9,162}

Vardimon et al developed the functional orthopaedic magnetic appliance (FOMA) II, a functional appliance that uses anteriorly positioned attractive magnetic means to constrain the lower jaw in an

advanced sagittal posture.⁹ An *in vivo* study was performed on 13 prepubertal *Macaca fascicularis* primates to analyse the response of the craniofacial system, over a 4 month treatment period, to 4 appliances – conventional functional (FA), FOMA II, combined FOMA II and FA and control appliance. The mandibular length increased significantly in the treated animals over the controls. The functional performance of the FOMA II and the FOMA II & FA was greater in comparison to the FA alone, as evaluated by Pg-Co length (22 and 28% more respectively). There was less incisor proclination in the animals treated with the magnetic appliances (4.57 +/- 1.76) compared to those treated with conventional functional appliance (8.75 +/- 1.85). The authors suggested that supplemental condylar cartilage growth with the FOMA II was related to the lack of interference with normal oral activity and its effects on mandibular posture during hypotonic muscle activity, like sleep periods.⁹

An *in vitro* component of the study measured the magnetic attractive path and forces generated by the two rectangular (13x6x4mm) NdFeB magnets that are incorporated in the FOMA II. The results showed that 570 grams of force was generated in the protrusive position, 219 grams when the jaws are in a habitual rest position (3mm) and 45 grams at a relaxed position (8.5mm). The functional performance was further improved when the magnetic interface acted as a magnetic inclined plane, with the interface descending anteroposteriorly to the occlusal plane. The authors suggested that the tendency for the lower jaw to drop during sleep due to physiological muscle relaxation, rendering a conventional functional appliance ineffective, is resisted by the effective continuous attractive force between the magnets.⁹

Vardimon *et al.* also conducted a retrospective clinical study to determine the skeletal and dental response to the functional magnetic system (FMS).²⁰ The FMS is a removable functional appliance which induces mandibular advancement by means of attracting mandibular and maxillary magnets and a guiding prong on the lingual side of the incisors. Darendeliler commented that the design of the FMS reduces the tongue space and may be a disadvantage which compromises patient cooperation.¹⁶²

The study compared 20 Class II patients treated with the FMS to matched Class II patients and Class I controls. A large increase in articulare-gnathion distance (3.07mm) was reported and this was attributed to the attractive magnetic component of the FMS which dictated prolonged propulsion of the mandible according to the authors. The skeletal:dental response ratio was 1:2 for the anterior region and 1:1 for the posterior region. Furthermore, the dental and skeletal parameters demonstrated a synergistic response in the maxilla and a competitive response in the mandible. As the restraint on maxillary growth is increased a greater amount of upper molar distalisation is achieved. In contrast, increasing the mandibular molar mesial movement and incisor proclination accompanied less advancement of the mandible.²⁰

The force system generated by the FMS was analysed using the Orthodontic Measurement Simulation System (OMSS). The mandibular and maxillary plates contain two cylindrically shaped SmCo magnets 4mm in diameter and 3mm in height, which are welded into stainless steel housings in association with a guiding prong.¹⁶³ The OMSS simulated the mandibular jaw movements by separating the installed magnets vertically, sagittally and transversely 10mm. The maximum force reached in the vertical plane was 0.65N, the maximum medial shearing force at a partial transverse overlap was 0.65N and the maximum sagittal shearing force was 1.2N. The range of active magnetic forces were found to be a mouth opening of 6mm, a transverse shift of 10mm and an overjet of 6mm. Outside of this range the attractive forces reached almost zero and converted into a repulsive force. An additional mechanical aid to counteract the repulsive force and increase the mandibular guidance was recommended.¹⁶³

Moss *et al.* incorporated magnets in the twin block appliance in the treatment of Class II division I malocclusions.¹⁵⁰ The authors commented that the incorporation of magnets into the appliance decreased the time taken to produce the sagittal change and increased the soft tissue change compared to the conventional appliance. Chate described the use of the propellant unilateral magnetic appliance in the treatment of hemifacial microsomia. Samarium-cobalt magnets embedded in unilateral blocks of acrylic were used to stimulate growth following an autogenous costochondral graft.¹³

Kalra and co-workers¹⁴⁹ reported on the use of a fixed magnetic appliance with repelling magnets for Class II division I cases with mandibular retrusion and increased lower face height. The effects of the appliance were evaluated in 10 such cases compared to matched controls. After 4 months of treatment with an intrusive force of 90 grams per tooth the authors reported an average of 3.2mm (+/- 0.5mm) increase in the length of the mandible in comparison to an average of 0.8mm (+/- 0.2mm) in the controls. A decrease in the mandibular plane angle (1.3+/-0.8) was also noted for the group receiving active treatment.¹⁴⁹ The results of this study were questioned given the significant increase in mandibular length in a 4 month period.¹⁶⁴ This increase was confirmed to be accurate, however the long-term stability of such a rapid response has not been reported.^{162,165}

Another functional magnetic appliance, called the Magnetic Activator Device (MAD), was introduced by Darendeliler and Joho.^{8,77} Several types have been designed to manage different clinical problems e.g. MAD 1 – lateral displacement,⁸ MAD II – class II malocclusions,^{8,77} MAD III – class III malocclusions¹¹ and MAD IV – open bite.¹⁴⁸ The MAD can be worn full time, except during meals since phonation and deglutination are not as limited. It has also been suggested by Darendeliler that bonded magnetic appliances could be used as fixed functional appliances.¹⁶²

The design of the MAD II developed progressively using smaller magnets and reduced force levels.¹⁴ The magnet shape and dimensions changed from a rectangular bar,⁷⁷ to a triangular prism⁸ and then to a cylindrical form.¹⁴ From the results of a limited number of patients treated with the MAD II Darendeliler and Joho commented that the skeletal versus dental response depended on the intensity of the magnetic force.⁸ The use of attracting magnetic forces, ranging from 150 to 600 grams per side, revealed that a force of more than 500 grams appeared to produce unwanted or exaggerated dental movements. With forces above 500grams it was stated that the muscle force necessary to disengage the magnets is transmitted through the appliances to the dentition generating exaggerated tooth movement. Forces below 200 grams were insufficient to obtain protrusion of the mandible. A force of

300 grams per side was found to be appropriate in patients age 7 to 12 for correcting Class II malocclusion by growth modification with only minimal tooth movement.⁸

The skeletal and dental effects of the MAD II was evaluated in 19 patients age 8-13 with deep bite Class II malocclusions compared to a sample of 19 non-treated Class II controls matched for age, sex, ANB angle, cranial base mandibular plane angle and observation period.¹⁶⁶ The retention of the appliances was achieved by Smart clasps on the first molars and torquing springs on the upper incisors.¹⁶² The results showed statistically significant changes in the lower facial height (2.02mm) as demonstrated by an increase in the cranial base/palatal plane angle, palatal plane/mandibular plane angle, lower face height and decrease of the Jarabak percentage. Correction of deep overbite and class II molar relationship was reported in all patients by a combination of dental and skeletal effects.¹⁶⁶ There was a maxillary restraining effect (SNA reduced by 1.4), retroclination of the upper incisors (3.6 to SN), proclination of the lower incisors (2.2) and anterior repositioning of the mandible (SNB increased 0.94) The authors concluded that the MAD II was effect for the treatment of Class II deep bite malocclusion.¹⁴

The design of the MAD II has evolved to improve efficiency, patient compliance and reduce bulk. This resulted in the new magnetic functional appliance examined in this thesis, the Sydney Magnoglide (SM).

3.8 NEW MAGNETIC FUNCTIONAL APPLIANCE FOR ORTHOPAEDIC CORRECTION

The aim of this thesis is to investigate the application of magnet force delivery in two situations – facilitating tooth movement in combination with clear sequential aligners and orthopaedic correction with a new magnetic functional appliance, the Sydney Magnoglide.

The Sydney Magnoglide has evolved to improve efficiency and patient comfort. The SM is a fixed functional appliance consisting of maxillary and mandibular right and left bonded acrylic resin blocks. Each block has embedded magnets arranged in a manner that postures the mandible into a Class I occlusion.

A prospective clinical study of the effects of the new magnetic functional appliance, the Sydney Magnoglide, was performed. The study was performed to determine the skeletal and dental effects of the magnetic functional appliance compared to a group of untreated Class II controls utilising cephalometrics. Therefore, the following section of this literature review will examine the use of functional appliances in the treatment of Class II malocclusions.

3.9 FUNCTIONAL APPLIANCES IN THE TREATMENT OF CLASS II

MALOCCLUSION

Class II malocclusions are a common orthodontic problem, occurring in about one third of the population.¹⁶⁷⁻¹⁶⁸ A Class II malocclusion occurs in a variety of dental and skeletal configurations.¹⁶⁹ Consequently, many treatment approaches are utilised for the alteration of the occlusal relationships of a Class II malocclusion.¹⁷⁰ Treatment modalities that have been employed include a variety of extra-oral traction appliances, fixed appliances, arch expansion, extraction protocols, functional jaw orthopaedic appliances and surgery.^{71,170} The treatment approach employed in the correction of a class II malocclusion is influenced by the diagnosis of the Class II problem, tooth movements which can be achieved and the growth potential of the patient.¹⁶⁹

Functional jaw orthopaedic appliances are a treatment modality for the correction of Class II malocclusions due to mandibular retrusion. A wide range of functional appliances which aim to stimulate mandibular growth by holding the mandible forward are available to correct this type of skeletal and occlusal disharmony.¹⁷¹ However, the effects of functional appliances are still controversial. Numerous animal experiments and clinical studies have been performed to help ascertain the mechanisms underlying the effects of functional appliances and the optimal timing of treatment. This literature review will be restricted to a discussion of the role of functional appliance therapy in the treatment of class II malocclusions.

3.9.1 Class II malocclusion

Edward Angle classified a Class II malocclusion as having a distal relationship of the mandibular teeth to the maxillary teeth of more than one-half the width of the cusp.¹⁷² The molar relationship can be bilateral or unilateral. Unilateral cases are classified as a “subdivision”.¹⁷² He further categorised two types of Class II malocclusions based on the inclination of the maxillary central incisors. Class II

Division I malocclusions have labially inclined maxillary incisors, an increased overjet with or without a relatively narrow maxillary arch. Class II Division II malocclusions are depicted as having excessive lingual inclination of the maxillary central incisors overlapped on the labial by the maxillary lateral incisors. It is often accompanied by a deep overbite and minimal overjet.¹⁷²⁻¹⁷³ According to a study comparing Class II Division I and Class II Division II subjects, the only clinically significant difference clinically, morphologically and radiographically between the two groups was the inclination of the upper incisors.¹⁷⁴

The validity of Angle's classification, which uses the first molar as the main criteria for classification, has been questioned.^{71,172-173,175} Each class of malocclusion incorporates variations that affect the diagnosis and treatment.¹⁷³ Angle assumed the position of the first permanent molars was constant relative to the jaws and therefore reflected the sagittal position of the maxilla and mandible.¹⁷⁶ However, many investigations have demonstrated that a variety of skeletal and dental configurations occur with a class II molar relationship. The aetiology of Class II malocclusions is believed to be multifactorial with causative factors including genetic, racial and functional characteristics.¹⁷³

Cross-sectional and longitudinal studies have been performed to determine the nature and frequency of the specific components that can contribute to a Class II occlusal relationship. Cross sectional studies in the literature have usually compared Class II individuals to either a group of Class I or normal subjects.¹⁷⁰ Ngan, Byczek and Scheick summarised a large number of the cross-sectional studies on this topic.¹⁶⁹ (Table 1) Based on their review of the cross-sectional studies the components of Class II malocclusion were categorised into four groups: anteriorly positioned maxilla; anterior positioning of the maxillary dentition; mandibular skeletal retrusion in absolute size or relative position; and excessive or deficient vertical development.¹⁶⁹

McNamara also reviewed the literature on this topic and concluded that the majority of authors agreed that mandibular skeletal retrusion, in either absolute size or relative position, and maxillary dental protrusion were important components of a Class II malocclusion. There was conflict about the

maxillary skeletal component with some authors reporting maxillary skeletal protrusion, some retrusion and others no difference in maxillary position.¹⁷⁰ The variation in findings was related to differences in cephalometric measurements, selection criteria and standards to which samples were compared.¹⁷⁰

The same author investigated the frequency of specific dental and skeletal components in 277 children age 8 to 10 with at least an end-on molar and cuspid Class II relationship from lateral cephalograms. The study confirmed that a Class II malocclusion is not a single entity but can result from numerous combinations of skeletal and dental components. The results indicated that retrusion of the mandible was the most common single characteristic of the Class II sample. Maxillary skeletal protrusion was not a common finding.¹⁷⁰

Longitudinal studies have also been performed to describe the growth changes in the dentofacial region of Class II subjects over time.^{169,176-180} The results of longitudinal studies demonstrate that the dentoskeletal characteristics of Class II malocclusions are established early and are maintained without orthodontic intervention.^{169,176-179,181-182} Bishara *et al.* studied the changes in molar relationship from the deciduous to the permanent dentition in 121 individuals.¹⁸¹ They found that all cases with a distal step relationship in the deciduous dentition proceeded to have a Class II molar relationship in the permanent dentition. 45% of the cases with an end-to-end deciduous molar position remained that way, the rest assumed a full Class II occlusion. The findings also indicated that once a Class II molar relationship is established it does not self-correct despite differential mandibular growth.¹⁸¹ Likewise, growth studies emphasise that there is no tendency for self-correction of the dentoskeletal disharmony in subjects with Class II malocclusions.^{169,176-177,183}

Bishara and co-workers compared the growth trends of Class II Division I patients from the deciduous to the permanent dentition with normal subjects. According to this study few consistent differences were found between the groups, except in regard to upper lip protrusion.¹⁷⁷ On the contrary, longitudinal studies performed by Kerr and Hirst and Ngan *et al.* reported significant differences

between Class II and Class I subjects.^{169,178} Kerr and Hirst found that mandibular growth was deficient in Class II subjects, with the largest difference, of 2mm (Ar-Pg), occurring between 10 and 15 years of age.¹⁷⁸ Ngan *et al.* also found the mandibular length and corpus length to be shorter in Class II subjects.¹⁶⁹ Stahl suggested that Bishara *et al.* reached a different conclusion to other authors because the sample consisted of mild class II malocclusions and ended on average at 12.2 years when active growth was incomplete.¹⁷⁶⁻¹⁷⁷

Stahl *et al.* also performed a longitudinal study of growth in Class II Division I patients but used a biological indicator of skeletal growth, the cervical vertebral maturation method, to determine the developmental status of the subjects.¹⁷⁶ No prior investigation utilised a biological indicator of skeletal maturity to evaluate growth changes. Other studies have been based on the subjects' chronological age or dentition stage, which are not reliable indicators of skeletal maturation.^{108,176-178} Craniofacial growth in class II malocclusions was found to be similar to untreated subjects with normal occlusion at all developmental stages except for the growth spurt, where Class II subjects had a significantly smaller increase in mandibular length.¹⁷⁶ In view of their findings the authors' suggested that treatment should aim to enhance mandibular growth as a component of class II correction during the pubertal phase.¹⁷⁶

3.9.2 History of functional appliances

The history of the functional appliance dates back to 1879, when Norman Kingsley introduced his “bite-jumping” appliance.¹⁸⁴ His removable plate might be considered the prototype of functional appliances as his objective “was not to protrude the lower teeth, but to change or jump the bite in the case of an excessively retreating lower jaw”. Subsequently, the work of Wilhelm Roux provided the foundation for general orthopaedic and dental functional orthopaedic principles. He was the first to study the influence of natural forces and functional stimulation on form (1883) (Wolff's law, Chapter 4).¹⁸⁴

In the early part of the twentieth century functional appliances were predominantly used in Europe. In the United States fixed appliances and headgear were predominantly utilised due to the dominating influence of Edward Angle.¹⁸⁵ Geographic barriers restricted the sharing of knowledge and experience in these philosophies.¹⁸⁴

In 1902 Pierre Robin developed the monobloc appliance to treat glossoptosis syndrome, which has since been termed Pierre Robin's syndrome. He was the first practitioner to use functional jaw orthopaedics to treat a malocclusion. His appliance normalised the occlusion by influencing muscle activity through a change in the spatial relationship of the jaws. Viggo Andersen developed a similar appliance in 1909, the Activator, although he claimed he had no knowledge of Robin's appliance. It was intended as a retainer for his daughter but it unexpectedly eliminated her Class II malocclusion. The original Andresen activator was loosely fitting and had a lingual horseshoe flange which guided the mandible forward 3 to 4mm. Although Andresen designed the activator, Karl Haupl was instrumental in promoting the device.^{184,186}

Around the same time, Emil Herbst developed the Herbst appliance, a fixed tooth borne functional appliance for potentially uncooperative children. He first introduced the appliance in 1905 at the 5th International Dental Congress but his full findings were not published until 1935.¹⁸⁷ It was not until the late 1970s when Hans Pancherz reintroduced the appliance that the Herbst appliance became a widely used functional appliance for the treatment of skeletal Class II malocclusions.¹⁸⁸ Several designs have been proposed but the typical Herbst consists of a telescoping mechanism connected to the maxillary first molars and a cantilever arm attached to the mandibular first molar, which forces the mandible forward.¹⁸⁷

Later, Rolf Frankel developed the only tissue-borne functional appliance, the functional regulator (FR).^{184,189} The FR-1, FR-2 and FR-3 were designed to treat Class I, Class II and Class III malocclusions. The FR-2 stimulates mandibular repositioning via a pad against the lingual mucosa

beneath the lower incisors. Large buccal shields and lip pads eliminate the soft tissue pressures of the lips and cheeks creating arch expansion in additions to the effects on jaw growth.¹⁹⁰

Around the time of World War II the use of functional appliances increased in Europe because precious metals were no longer available for fixed appliances.¹⁸⁴ Although functional appliances continued to be used throughout the twentieth century in Europe, orthodontics in America took a different path. The use of headgear was abandoned by the 1920s due to Angle's belief that fixed appliances with elastics were as effective as extra-oral force and a decline in enthusiasm for the possibility of altering facial morphology with orthopaedic forces. Kloehn reintroduced extra-oral force around the same time cephalometrics was used as evidence to refute the assumption Class II elastics produced a skeletal correction.^{185,191} It was not until the 1960s that the separate philosophies of American and European orthodontists converged as communication improved.¹⁸⁵

3.9.3 Types of functional appliances

A functional appliance refers to an oral appliance that is used to produce orthopaedic changes by altering the influence of the muscle groups that affect the functional and sagittal and or vertical position of the mandible.¹⁹² A wide range of functional / orthopaedic appliances have been developed for the correction of Class II skeletal and occlusal disharmonies.¹⁹³

Functional appliances have been classified as fixed – for example the Herbst appliance, Jasper Jumper and removable – the majority of functional appliances.¹⁸⁴ Removable functional appliances are dependent on patient co-operation for success.¹⁹² The significance of this is indicated by a recent randomised clinical trial that found that treatment with a fixed Herbst appliance resulted in a lower failure to complete rate of 12.9% compared to the removable twin-block which was 33.6%.¹⁹⁴ However, the downside was more appointments were required for repair of the Herbst appliance and relatively high complication rates have been reported for banded and cast Herbst appliances by Sanden, Pancherz and Hansen.¹⁹⁴⁻¹⁹⁵

Proffit et al further categories functional appliances into three groups: passive tooth-borne, active tooth-borne and tissue-borne.⁷¹ The largest category is the passive tooth-borne appliances. The monobloc, activator, bionator, Bimler, and Twin-block fit this classification. Active tooth borne appliances incorporate an active component to move teeth, such as a spring or screw, and are generally modifications of activator and bionator appliances. A tissue-borne appliance for class II treatment is the FR-2.^{71,184}

A recent systematic review by Cozza et al appraised the efficiency of different types of functional appliances in enhancing mandibular growth in Class II subjects. The Herbst appliance was reported to have the highest coefficient of efficiency (0.28mm per month), followed by the Twin-block (0.23mm/month). Intermediate scores of efficiency were found for the bionator and activator (0.17 and 0.12 per month, respectively). The Frankel appliance had the lowest efficiency (0.09mm per month).¹⁷¹

3.9.4 Indications

Functional appliances have been used to treat dental and skeletal Class II malocclusions, specifically cases with mandibular deficiency. Bishara and Ziaja identified the following characteristics as indications for functional appliance therapy: normal or slightly excessive maxilla; normal or slightly short face; class II division I; slightly protrusive maxillary teeth; normal or slightly retrusive lower incisors; well aligned arches; active growth. Relative contra-indications included: proclined lower incisors; backward mandibular rotations; minimal overbite and crowded cases.¹⁹²

3.9.5 Advantages and Limitations

Reported advantages of functional appliances include: minimal chair side time; less frequent adjustments; better improvement in profile; effective at improving overbite; and utilisation of the maximum growth potential of the dental arches.¹⁹² Fixed functional appliances have several

advantages: they are active 24 hours a day; active treatment time can be shorter; and no cooperation is required by the patient.¹⁹⁶

Limitations identified for functional appliances include: difficulties achieving individual tooth movements; the need for a final phase of fixed appliance therapy to ensure ideal alignment; molar extrusion typically associated with functional appliances can be unfavourable as additional mandibular growth may be expressed vertically and not horizontally; removable functional appliances are dependent on patient cooperation for success; and limited use in non-growing patients.¹⁹²

3.9.6 Mode of action

The foundation for jaw orthopedics was provided by Wilhelm Roux following his study of the influence of natural forces and functional stimulation on form. Consequently, the fundamental principle of functional appliance treatment is centered on the notion that a “new pattern of function” dictated by an appliance leads to the development of a corresponding “new morphological pattern”.¹⁹⁷ As noted above, a large number of functional appliances have been developed with the aim of stimulating mandibular growth by posturing the mandible forward.¹⁷¹ Each proponent of the different functional appliances has developed and promoted their own rationale for the effects of their device.^{186,188-189,198-199}

Despite the long history of functional appliance usage there is still controversy regarding their mode of action.^{192,200} The literature suggests that the affects of functional appliances are multifactorial, with several mechanisms contributing to the correction of Class II malocclusion.^{192,200-202} Bishara and Ziaja suggested that regardless of the type of functional appliance the improvement is achieved in a similar way and includes:

1. Restraint or redirection of maxillary growth
2. Optimising mandibular growth
3. Retardation of the mesial and vertical maxillary dentoalveolar growth

4. Mesial and vertical mandibular dentoalveolar growth
5. Lingual tipping of the maxillary incisors and labial tipping of the mandibular incisors
6. Remodeling changes in the temporomandibular joint.¹⁹²

Therefore, a combination of orthodontic and orthopedic effects are considered to be responsible for the outcomes of functional appliances.^{192,203}

Woodside, Metaxis and Altuna also emphasized that the correction of a Class II malocclusion is the result of a combination of different effects.²⁰⁰ Following a review of the literature they summarized the many theories offered to explain the action of functional appliances as one or a combination of the following: dentoalveolar changes, condylar growth, restriction of midface growth, mandibular growth induction and reorientation, mandibular gonial angle changes, glenoid fossa remodeling and changes in neuromuscular anatomy and function.²⁰⁰

Much of the debate about the mode of action of functional appliances centers on their ability to permanently increase mandibular length. There is controversy about whether the therapy results in an absolute stimulation of growth creating a larger mandible or a temporal acceleration of growth during treatment.⁷¹ Johnston proposes that functional appliances create a rapid forward shift of the mandible, which “locks” further mandibular growth to the growth of the maxilla.²⁰⁴ This theory is supported by the work of Pancherz and Hansen who reported the same amount of maxillary and mandibular growth in the post-functional phase following Herbst treatment.²⁰⁵

3.9.7 Effects of functional appliances

Numerous animal experiments and clinical studies have been performed to evaluate the mechanism of action and efficiency of functional appliance therapy. However, the results have generally been a subject of debate.²⁰⁶

3.9.7.1 Animal studies

Numerous animal studies have been performed to investigate the craniofacial effects of functional appliances. Primate^{200,207-209} and rodent²¹⁰⁻²¹² models have been used most commonly and the effects have been studied cephalometrically and histologically.²⁰⁶ Several investigators have reported an increase in effective length of the mandible after protrusion of the mandible in animals.^{200,207,210-212} McNamara showed that after 144 weeks mandibular growth was 5 to 6mm greater in experimental monkeys fitted with the protrusive appliance compared to control animals.²⁰⁷

Similarly, Petrovic, Stutzmann and co-workers have demonstrated that anterior displacement of the mandible with a hyperpropulsion device in rats increases the growth of the condylar cartilage by stimulating prechondroblastic zone cells.²¹⁰⁻²¹² They concluded that “no genetically predetermined final length of the mandible could be detected in these experiments”.²¹¹ Other animal studies have demonstrated remodelling of the glenoid fossa as a therapeutic effect of mandibular protrusion.^{200,208,213} Woodside *et al.* found extensive remodelling in the condyle and anterior relocation of the glenoid fossa of monkeys treated with 7 to 10mm advancement with the Herbst appliance.²⁰⁰ Therefore, based on the early animal studies the potential for change as a result of actual increased mandibular length and effective mandibular position though temporomandibular joint remodelling was proposed.²¹⁴

However, several authors have questioned the validity of correlating findings from animal studies to humans.²⁰⁶ Problems with animal studies include:

- The difference in masticatory and craniofacial systems between animals, especially rodents, and humans
- The lack of skeletal malocclusion in laboratory animals
- Short duration of animal experiments²⁰⁶
- Appliances are worn full time in experiments involving animals²⁰⁶
- Small sample size in primate studies²⁰⁶

- Flaws in experimental designs.

Animal studies have also facilitated the investigation of the molecular mechanisms responsible for the adaptive changes seen with functional appliance therapy. The literature indicates there is an association between forward mandibular posture with appliances and the alteration of growth factor gene expression such as insulin growth factor I and II and fibroblast growth factor in the mandibular condylar cartilage (MCC).²¹⁵⁻²¹⁶ Also changes in the level of expression of type II and type X collagen, important components of the condylar cartilage matrix, have been shown.²¹⁷⁻²¹⁸

Indian Hedgehog (Ihh), a morphogenic protein involved with skeletal development, has been shown to increase in expression during FA therapy, corresponding with an increase in cellular proliferation in the MCC.²¹⁹ Furthermore, stepwise advancement has been found to result in an increase in tissue reaction over a single advancement. The authors suggested that stepwise advancement induced repeated cycles of mechanotransduction and cellular activity resulting in increased vascularity and therefore bone formation.²²⁰ Increased expression of the transcription factor, Sox 9, has been demonstrated in animal models with mandibular protrusion. This is thought to accelerate the differentiation of mesenchymal cells into chondrocytes, leading to earlier formation and increase in the amount of cartilage matrix.²¹⁸

3.9.7.2 Human studies

Although the results from animal models are positive in relation to the orthopaedic effects of functional appliances, the topic is still an area of contention in humans. A vast number of investigations have been performed to evaluate the effects of functional appliances in humans.²²¹ However, the interpretation of results from clinical studies are limited due to inconsistencies in study design, lack of appropriate control groups, the range of appliances used, wide variation in ages studied, the difficulty measuring changes in vivo with cephalometrics, the relatively small size of treatment effects and the wide variation in patient responsive.^{214,221} Retrospective studies have the potential for bias and may overestimate the effectiveness of an appliance as they can include patients

who responded well to treatment and not include patients that did not respond well or discontinued treatment.²¹⁴

A number of systematic reviews have been performed in an attempt to summarise the literature on this topic.^{171,206,221-224} Aelbers and Dermaut reviewed 52 studies that investigated the orthopaedic effects of activators, Herbst appliances and headgears and concluded that only the Herbst modified mandibular growth to a significant degree.²²¹ However, when they reviewed articles with a long term follow-up period, that varied from a few months to 5-10 years, they concluded there was little scientific evidence that the craniofacial complex could be permanently modified.²⁰⁶ The reviews by Tulloch et al and Chen et al emphasised that it is difficult to obtain definitive answers given the inconsistencies in methodologies.^{222,224}

On the contrary, a recent systematic review by Cozza et al which included RCTs, and prospective and retrospective longitudinal clinical trials with untreated class II controls reported that two thirds of the 22 studies included reported a clinically significant supplemental elongation in total mandibular length, a change greater than 2 mm. The authors commented that the amount of supplemental mandibular growth appeared to be significantly larger if the functional treatment was performed at the pubertal peak in skeletal maturation. None of the studies where treatment was performed in the pre-peak period had a clinically significant amount of supplementary mandibular growth.¹⁷¹

Many comparative studies have been performed to evaluate the effects of different functional appliances^{225-226 227} and other treatment modalities for Class II correction, such as fixed appliances with elastics²²⁸ and headgear. Nelsen et al performed a prospective study to determine the skeletal and dental contributions to Class II correction in 36 subjects treated with Class II elastics (Begg technique) and Herbst appliance. The skeletal changes were found to be larger in the Herbst-treated group, 51% compared to 4% in the Begg group for overjet reduction.²²⁸ Other studies have supported such findings.

Schaefer et al compared the effects of two of the most commonly used functional appliances, the Twin Block and the Herbst appliance. Both appliances were shown to be effective but Twin block therapy induced approximately 2mm greater correction of the sagittal intermaxillary relationships than the crown Herbst group. This was related to better control of sagittal midface growth by the Twin block and the slightly greater increase in total mandibular length with the Twin block was attributed to the larger increase in the height of the mandibular ramus.²²⁷ Similar findings were confirmed by a comparison of the two appliances by O'Brien.¹⁹⁴

Randomised clinical trials are advocated as the gold standard for comparing alternate treatment approaches. To date a limited number of RCT's have been performed to examine the outcomes of functional jaw orthopaedics.¹⁷¹ The first RCT on the treatment of Class II treatment was conducted at the University of Otago.²²⁹ Around the same time The National Institute of Dental Research funded three randomised controlled trials in America to investigate Class II treatment.²³⁰⁻²³⁴ More recently the University of Manchester reported on a large multicentre RCT.¹⁹⁴ The selection criteria, age at commencement, appliances used, duration, outcomes and conclusions are summarised in Table 2.

Several authors have criticised the study design and selection criteria of the RCTs.^{171,235-236} Not all patients with an increased overjet, Class II molar relationship or increased ANB angle have the same malocclusion²³⁵. Therefore a major weakness of these RCTs is their disregard of the various phenotypes of a Class II malocclusion²³⁵. Furthermore, direct comparisons of the results are difficult due to the differences in appliances used, treatment duration and timing and data analysis.

Darendeliler highlighted that although the reported differences of the RCTs are small, profile studies indicate that a few millimetres of change in one feature is enough to alter the appeal of the face.^{235,237-}

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Data from the clinical trials demonstrated that on average children treated with headgear or a functional appliance had a small but statistically significant improvement in their jaw relationships. Headgear treatment showed greater restraint of maxillary growth and functional appliances had

greater mandibular effects.^{71 232,234} The results of one clinical trial did not support this finding as correction with either headgear or functional appliances occurred primarily through changes in mandibular position.^{233,239}

3.9.7.3 Variability in treatment responses

The literature indicates that there is large individual variation in patient responses to functional appliances.^{202,240-241} This concept was supported by the results of the randomised clinical trials. Despite statistically significant mean changes in these studies large variation was noted, both with and without early treatment.^{233,242-243} Approximately 20% of children treated with headgear or a modified bionator had no change or an increase in the class II discrepancy.²³² Overall, it was concluded that 75% of patients treated with growth modification stood to have a clinical improvement.²³⁵ The University of North Carolina's trial could not identify any patient characteristics that could serve as predictors of treatment response, but the University of Florida's clinical trial found that the success of treatment was associated with the severity of the malocclusion.^{232,239,242}

Studies have been performed to identify indicators of treatment success with functional appliances. Petrovic and co-workers²⁴⁴ demonstrated a parallelism between alveolar bone turnover rate, subperiosteal ossification rate and condylar cartilage growth and responsive rate in humans. With successful treatment occurring in those with a high tissue-level growth potential²⁴⁴. Mamandras and Allen compared 20 subjects who underwent successful Bionator treatment to those who were less successful and concluded that persons who have a small mandible benefited more from functional appliance therapy.²⁴⁰

Caldwell and Cook conducted a prospective study to identify if any pre-treatment parameters could predict the outcome of Twin-block treatment. The overbite and SNB angle were most strongly related to percentage reduction in overjet.²⁴¹ Franchi and Baccetti studied 51 subjects with a Class II malocclusion that had been treated with functional jaw orthopaedics to identify pre-treatment cephalometric variables that could predict individual mandibular outcomes. Discriminate analysis

identified a single predictive parameter, the Co-Go-Me degrees, with a classification power of 80%. A Class II patient at the peak in skeletal maturation (CS 3) with a pre-treatment mandibular angle smaller than 125.5 degrees is expected to respond favourably to functional jaw orthopaedics, while a patient with an angle greater than 125.5 degrees is expected to respond poorly.²⁴⁵

3.9.7.4 Timing of functional appliance treatment

Another contentious issue related to the use of functional appliance therapy is the optimal timing of treatment and the value of early treatment in patients with Class II malocclusion.²³⁶ A popular strategy for treatment has been to initiate a first/initial/early phase of functional appliance therapy for growth modification, followed by a second/subsequent/final phase of fixed appliance therapy. Ideally, the second phase of treatment is simpler, shorter in duration and prevents the need for extractions.^{71,236}

Randomised clinical trials were extended into a second phase of treatment for all participants to compare early two-stage treatment with later one-stage treatment.^{230-231,239,246} The results of the randomized clinical trials indicated that early treatment had limited benefits. There were no significant differences for those that received early treatment and those that did not in regard to skeletal or dental measurements, PAR score, length of fixed appliance treatment, need for extraction or orthognathic surgery. Treatment time was considerably longer if the early phase of treatment was included. It was concluded that two-phase treatment commencing in the mixed dentition may be no more clinically efficient than one-phase treatment in the early permanent dentition.^{71,247} However, early treatment is still indicated for a child with psychosocial problems related to dental and facial appearance and has been advocated to reduce the risk of trauma.^{194,246}

Treatment timing has been acknowledged as one of the critical factors for success in Class II correction^{193,248} and it is now generally agreed that treatment should be initiated during the peak adolescent growth spurt.^{247,249-250} The inclusion of the pubertal growth spurt in the treatment period is

regarded as a key factor in the attainment of clinically significant supplemental mandibular growth with functional appliances.¹⁷¹

It has been demonstrated that the effectiveness of functional appliance treatment in patients with mandibular deficiency depends heavily on the biological responsiveness of the condylar cartilage, which depends on the growth rate of the mandible.²⁵¹⁻²⁵³ Malmgren et al showed significantly greater skeletal effects with the Bass appliance in boys treated during the peak growth period compared to those in the pre-peak period.²⁵² Hagg and Pancherz demonstrated that patients treated during the peak in pubertal growth had twice the amount of condylar growth than patients treated 3 years before or after the peak.²⁵¹

Therefore, the issue of treatment timing is linked to the identification and prediction of growth. It is well known that neither chronological age nor dental development are reliable for identifying the stage of development.²⁵⁴⁻²⁵⁵ However, it has been demonstrated that skeletal maturity is closely related to sexual and somatic maturity.²⁵⁵ Skeletal maturity can be assessed by several biological indicators including: increase in body height, hand wrist radiographs, cervical vertebral maturation, menarche and secondary sexual characteristics such as breast and voice changes.²⁵⁰ It has been acknowledged that the future of craniofacial growth assessment lies in the area of measurement of physiological parameters.²⁵⁴

The existence of a pubertal peak in mandibular growth has been described in cephalometric studies. The onset, duration and intensity of the pubertal spurt in mandibular growth vary on an individual basis. The cervical vertebrae method is reliable for detecting a subject's skeletal maturity and for identifying the pubertal growth spurt in the mandible. This method has been validated as a biological indicator of mandibular and somatic skeletal maturity.²⁵⁶⁻²⁵⁷ The peak in mandibular growth occurs between CS3 and CS4 in males and females.^{250,258-259} Treatment with functional appliances during the peak mandibular growth period, as measured by the cervical vertebrae maturation stage 3 or 4, has been shown to improve the long term treatment results and gains in mandibular length.²⁵⁰

Baccetti, Franchi and McNamara²⁵⁰ summarised the effects of treatment timing on supplemental elongation of the mandible from the results of a series of short-term studies.^{193-194,232-233,260-262} (Table 3) When Class II treatment commenced before the pubertal peak in mandibular growth the net difference in supplemental growth of the mandible compared to the controls ranged between 0.4 and 1.8mm. When treatment timing included the pubertal peak in mandibular growth the net supplemental growth ranged from 2.4 to 4.7mm. The authors concluded that the timing of treatment has a greater impact on supplementary elongation of the mandible than does the type of appliance used.²⁵⁰ The recent systematic review by Cozza et al supports such conclusions.¹⁷¹

Konik, Pancherz and Hansen examined the mechanism of Class II correction in Herbst treatment after the maximum pubertal growth compared to treatment during the maximum pubertal growth spurt. Differences were found for the dental changes - the anterior teeth were retroclined and the lower anterior teeth were more proclined in the late cases.²⁶³ Likewise improvements in incisor and molar relationships in young adults with Herbst treatment were achieved by more dental changes. The amount of skeletal change contributing to the incisor and molar correction was smaller in the adult group (22 and 25% respectively) compared to the early adolescent group (39 and 41%).²⁶⁴ These findings contradicted those of McNamara who demonstrated little if any change in skeletal and molar relationships with the Frankel appliance. The lack of response was attributed to the removable nature of the appliance although good compliance was reported and avoidance of the protruded position.²⁶⁴

3.9.7.5 Retention and stability

Several studies have reported anteroposterior relapse following functional appliance treatment, predominately from dentoalveolar rebound.^{196,233,236,265-266} Pancherz investigated the nature of relapse at least 5 years after Herbst appliance treatment and found that relapse resulted mainly from dental changes. The main causes of relapse were a persisting lip-tongue dysfunction habit and an unstable cuspal interdigitation after treatment.²⁶⁷

Furthermore it has been suggested that later treatment is more efficient and more stable than early treatment. Ruf and Pancherz reported that relapse occurred more in cases treated before the pubertal growth spurt. Relapse of the overjet or molar relationship occurred in 30% of the patients treated before the peak, whereas relapse only occurred in 8% of post-peak Herbst patients. It has been proposed that early treatment in the deciduous or mixed dentition is undesirable as a stable cuspal interdigitation after treatment is difficult to achieve.¹⁹⁶ Pancherz also emphasised that treatment in the permanent dentition has the advantage of promoting good cuspal interdigitation of the teeth which is important dental as well as a skeletal post-treatment relapse.¹⁹⁶

It has also been recommended that treatment at the pubertal growth spurt will limit the potential for relapse as a result of limited remaining Class II growth.²³⁶ Long-term evaluation of growth after appliance therapy indicates that the inherited growth patterns of the jaws reappear and growth returns to what would have occurred without intervention.^{206,268} The long term Herbst studies show that the existing skeletofacial growth pattern is only temporarily affected by the treatment.¹⁹⁶

The randomised clinical trial by Wheeler and co-workers examined the influence of a 6 month retention protocol on the treatment outcomes. A greater proportion of the subjects without retention experience relapse compared to the group that was retained with appliance wear on alternate nights for 6 months (42% vs 32%). Relapse after an additional 6 months observation was primarily dental in origin.²³³ Tulloch et al found the gains from early treatment were lost but their study did not include a retention period.²³² Wheeler et al suggested that an improved retention scheme may be more effective in retaining the dental correction.²³³ It has been suggested that orthopaedic retention may be instituted at night for as long as 2 to 5 years but further study is required.^{236,269}

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Table 1	Cross-sectional studies on the aetiologies and components of Class II malocclusion
Table 2	Modified table from Darendeliler 2006 – Randomised clinical trials on Class II malocclusion treatment
Table 3	Analysis of the literature regarding treatment timing for Class II malocclusion

Table 1 - Cross-sectional studies on the aetiologies and components of Class II malocclusion ¹⁶⁹

Source				
	Size	Age	Sex	
Drelich, 1948	48	9-24	M-F	Max skeletal protrusion Max dentoalveolar protrusion Mand skeletal retrusion Decreased PFH/AFH
Nelson and Higley 1948 Renfroe, 1948	250 95	10 – 14	M-F	Mand skeletal retrusion Max skeletal retrusion Max dentoalveolar protrusion Mand skeletal retrusion
Gilmore, 1950 Craig, 1951	128 70	16-42 12	M-F M-F	Mand skeletal retrusion Max skeletal retrusion Max dentoalveolar protrusion Mand skeletal retrusion
Riedel, 1952	114	7-36	M-F	Max dentoalveolar protrusion Mand skeletal retrusion
Blair, 1954 Altemus, 1955	100 40	10-14 Avg 12	M-F F	Mand skeletal retrusion Max skeletal protrusion Max dentoalveolar protrusion Mand dentoalveolar retrusion
Henry 1957	130			Max skeletal retrusion Mand skeletal retrusion Increased AFH
Hunter, 1967	75	10-11	M-F	Max dentoalveolar protrusion Mand skeletal retrusion Mand dentoalveolar retrusion Increased AFH
Rothstein, 1971	608	8-15	M-F	Max skeletal protrusion Max dentoalveolar protrusion
Hitchcock, 1973	149	7-28	M-F	Max dentoalveolar protrusion Mand skeletal retrusion Mand dentoalveolar retrusion
McNamara, 1981	277	8-10	M-F	Various combination of skeletal and dental components
Carter, 1987	30	12-17	M-F	Mandibular skeletal retrusion

Table 2 - Modified table from Darendeliler 2006 – Randomised clinical trials on Class II malocclusion treatment ²³⁵

	UF	UP	UNC	UO	UM
Selection criteria	Class II molars incl. subdivisions	Bilat. Class II molars, ANB $\leq 4.5^\circ$	OJ > 7mm Class II molar & Skel.	Consecutive Class II/1	Class II/1
Age	9.6 \pm 0.8yrs	7 ys 4mo - 13 yrs 4 mo	7.7yrs - 12.4yrs mean 9.9yrs	Control 11.70 (\pm 0.89) Harvold 11.70 (\pm 0.84) FR II 11.53 (\pm 0.93)	8 – 10 yrs 9.7 yrs (\pm 0.98)
Sample Size	249	63	166	42	174
Appliance	Bionator HG & plate	HG-straightpull Fränkel II	HG-combi pull Bionator	Harvold Activator & Fränkel II	Twin Block
Control grp	Yes	No	Yes	Yes	Yes
Duration of treatment	Until Class I achieved or 2yrs	Neutroclusion by 2 orthos for 3 months	15 months	18 months	15 months
Effect on Mx (SNA)	No difference	HG -3.14° FR II 0.15°	Cont 0.26mm HG 0.92mm Bio 0.11mm		Cont 1.45mm TB 0.57mm
Effect on Md (SNB)	Bionator and Headgear significantly affected anterior mandibular growth over controls	HG -0.55° FR II 1.44°	Cont 0.43mm HG 0.15mm Bio 1.07mm	Control 0.66° Harvold 0.75° FR II 0.44°	Cont 2.52mm TB 3.52mm
Conclusion of the authors	Similar skeletal response between HG and bionator, neither affected maxillary growth but both enhanced mandibular growth More dental response with headgear. More relapse in dental with headgear.	HG: distal effect on maxilla and molars FR: Forward movement of mandible and proclination of lower incisors	HG: greater change on mx Bionator: greater change on mandible Differences between tx and control groups are small	No evidence of an increase in on mandibular length when compared to controls Mostly vertical dimension increase	Functional appliance treatment does not influence Class II pattern to a clinically significant degree

UF = University of Florida

UNC =University of North Carolina

UO = University of Otago

UP = University of Pennsylvania

Table 3 - Analysis of the literature regarding treatment timing for Class II malocclusion ²⁵⁰

Pre-Pubertal Class II Treatment (treatment ends before the pubertal peak in mandibular growth)		
Study	Appliance	Net increase in mandibular length over untreated controls
McNamara et al., 1985	FR-2	+1.2 mm
Petrovic et al., 1994	Class II elastics	+1.0 mm
Tulloch et al., 1997	Bionator	+1.4 mm
Keeling et al., 1998	Bionator	+0.4 mm
Baccetti et al., 2000	Twin-Block	+1.8 mm
Baccetti and Franchi., 2001	FR-2	+1.0 mm
De Almeida et al., 2002	FR-2	+0.9 mm
Janson et al., 2003	FR-2	+0.5 mm
O'Brien et al., 2003	Twin-block	+1.6 mm
Faltin et al., 2003	Bionator	+0.8 mm
Pubertal Class II Treatment (treatment includes the pubertal peak in mandibular growth)		
Study	Appliance	Net increase in mandibular length over untreated controls
McNamara et al., 1985	FR-2	+3.6 mm
Petrovic et al., 1994	Class II elastics	+3.0 mm
Lund and Sandler, 1998	Twin-block	+2.4 mm
Franchi et al., 1999	Acrylic Herbst	+2.7 mm
Baccetti et al., 2000	Twin-block	+4.7 mm
Baccetti and Franchi, 2001	FR-2	+3.9 mm
Faltin et al., 2003	Bionator	+4.3 mm
*The appraisal of treatment timing in individual studies was based upon chronologic age, hand and wrist, or CVM method. All data are short-term and refer to controlled studies.		

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Figure 1	Magnet and magnetic field
Figure 2	Hysteresis loop for a ferromagnetic material
Figure 3	Schematic diagrammatic of the use of neodymium iron boron magnetic attachments for tooth movement in combination with clear sequential aligners

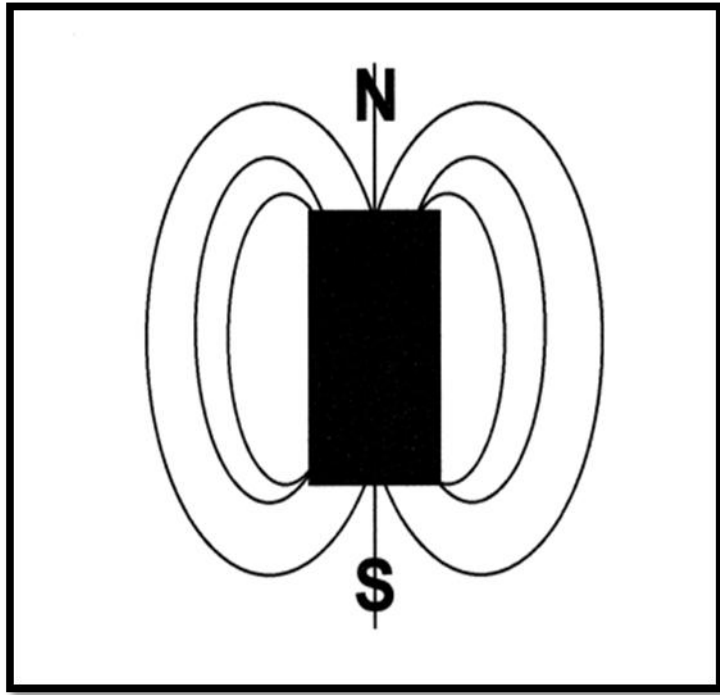


Figure 1 – Magnet and magnetic field. ¹³

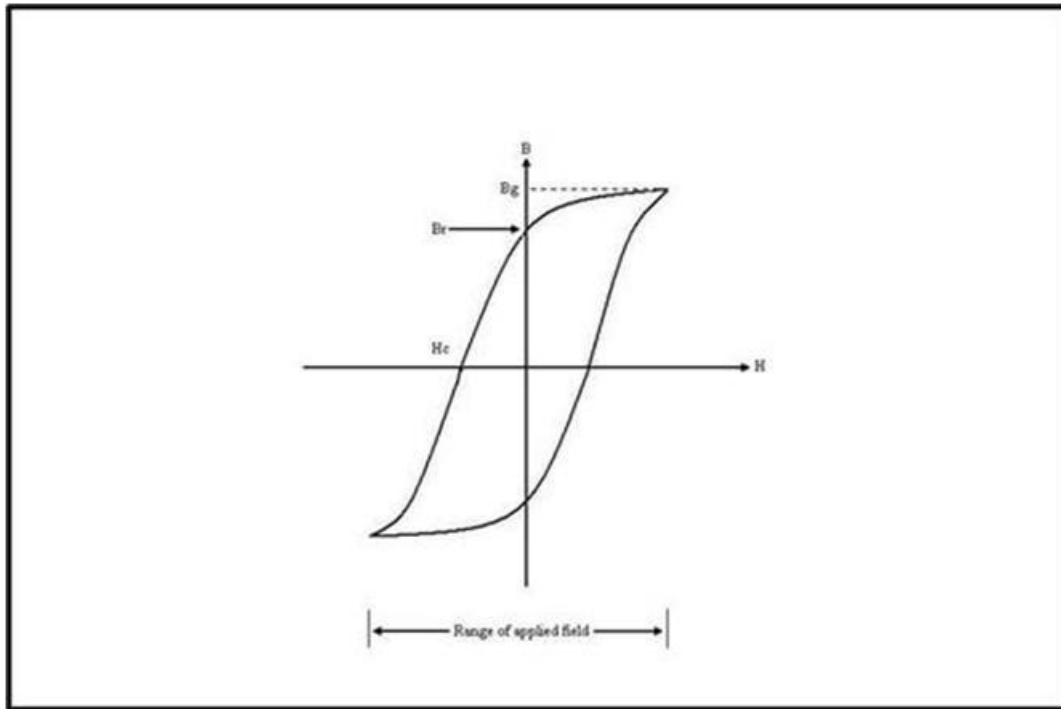


Figure 2 – Hysteresis loop for a ferromagnetic material. The B-H plot depicts the induction as a function of magnetic field strength (H). Initially the sample was demagnetised. The induction reaches saturation at (B_s). Much of the induction is retained upon removal of the field (B_r = remnant induction). A coercive field (H_c) is required to reduce the induction to zero. By cycling the field strength through the range indicated a hysteresis loop is generated. ²³

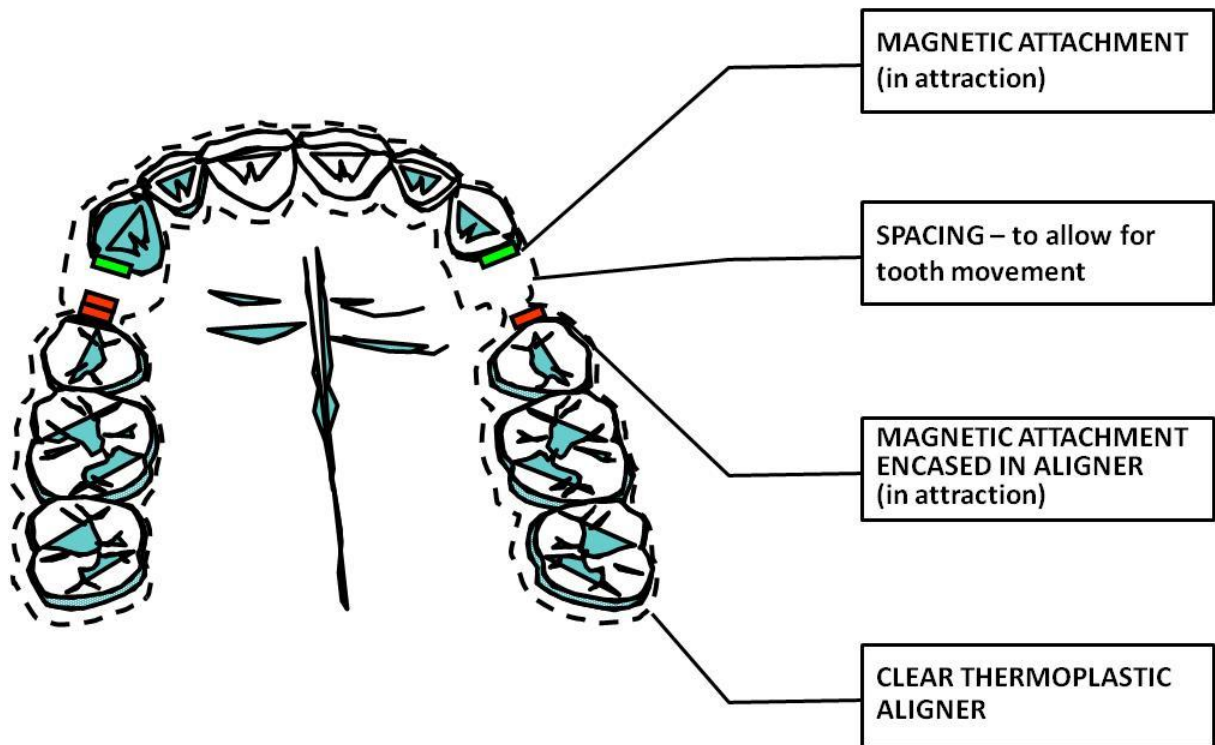


Figure 3 - Schematic diagrammatic of the use of neodymium iron boron magnetic attachments for tooth movement in combination with clear sequential aligners.

7 MANUSCRIPT ONE



**The force-distance properties of attracting neodymium
iron boron magnetic attachments for tooth movement in
combination with clear sequential aligners**

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Orthopedics

The force-distance properties of attracting neodymium iron boron magnetic attachments for tooth movement in combination with clear sequential aligners

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7.1. Abstract

Title

The force-distance properties of attracting neodymium iron boron magnetic attachments for tooth movement in combination with clear sequential aligners.

Abstract

Introduction: Clear sequential aligner therapy is a popular treatment modality but is less effective than fixed appliances. An improved system utilising small neodymium iron boron (NdFeB) magnetic attachments has been proposed to enhance the capabilities of this appliance. Using magnetic attachments would create a magnetic force interaction that can theoretically make the movement of teeth in any direction possible and easier.

Aim: This paper reports a laboratory-based study conducted to examine the physical properties of attracting neodymium iron boron (NdFeB) magnets that can be used as attachments to facilitate tooth movement in combination with clear sequential aligners. The aim of the investigation was to analyse the force system diagrams produced by small attracting NdFeB magnets to determine: if the force levels are sufficient to induce tooth movement; the effect of different magnet morphologies on the force characteristics; and the most appropriate dimensions of magnets that could be utilised in this application.

Materials and Methods: A total of 29 NdFeB rectangular magnets of varying dimensions were tested in this investigation. The dimensions were chosen with regard to the average crown dimensions and the size of resin attachments used by the Invisalign® system (Align Technology Inc, Santa Clara, California) when the study was designed. The Mach-1universal testing machine (Biosyntech Inc, Quebec, Canada) was used to measure the attractive force of pairs of magnets. Measurement commenced with the magnetic pair in contact and the magnets were vertically separated 10mm at a

speed of 12mm/min. For all magnetic configurations four repeat measurements were performed on five magnetic pairs of the same size.

Results: The force-distance diagrams for all magnet configurations demonstrated a dramatic decrease in force with increasing vertical separation. The highest peak force of 555.16g was produced by the 4x4x2mm magnet, followed by the 3x3x2mm magnet which produced a peak force of 312.71g. The lowest peak force of 44.1g was generated by the 2x2x0.5mm magnet. The data suggests that magnets with large pole face areas and longer magnetic axes provide the greatest force. For the majority of magnets insignificant forces were attained above a 2mm separation. The experimental data did not follow an inverse square law, although an inverse fourth law was found to apply when an offset was applied to the distance. The variation of magnetic force between different NdFeB magnets was 2.32 – 9.37%.

Conclusions: The tested attractive NdFeB magnet configurations displayed varying levels of clinical usefulness. Magnet morphology affected the clinical properties and performance of the magnets. A select range of magnet configurations exhibited suitable and reliable attractive forces and therefore could be advocated for the intended clinical application as magnetic attachments in combination with clear sequential aligners.

Keywords: Attachments, Clear Sequential Aligner Therapy, Neodymium Iron Boron Magnets.

7.2. Manuscript One

Introduction:

The demand for aesthetic orthodontic appliances has increased dramatically in recent years. Consequently, clear sequential aligner therapy has become a popular alternative to fixed appliances. Clear aligner therapy or clear sequential aligner treatment refers to a sequence of clear thermoplastic appliances made on a series of casts with reset teeth, each incorporating another small amount of tooth movement.¹

These appliances, which are marketed as practically ‘invisible’, are considered to be more aesthetically appealing and facilitate good oral hygiene as they can be removed for brushing.²⁻³ Despite their superior aesthetics this appliance is less effective than fixed appliance therapy.⁴ They are quite effective in achieving tipping movements but have limited effectiveness with other types of movements such as bodily movements, rotations, extrusions and severe intrusion of teeth.^{1,5-6}

To overcome some of the limitations of the appliance resin attachments are placed on the teeth.⁷⁻⁹ Attachments are generally placed on the teeth to increase the undercuts and retention of the appliance to facilitate the desired tooth movements.⁸ The selection of the appropriate attachment size and shape is influenced by several factors such as dental morphology, the role of the attachment and the desired tooth movement.⁸ Unfortunately, the use of attachments has been shown to be only partially effective.^{6,9} Given the inherent limitations of the appliance it cannot be used routinely in severely crowded cases or as effectively in extraction cases.¹⁰⁻¹²

An improved system utilising small neodymium iron boron (NdFeB) magnetic attachments has been proposed to enhance the capabilities of this appliance (Patent number: PCTAU2008000294). In this system a sequential orthodontic appliance is combined with at least one magnetic attachment positioned in an attractive or repulsive configuration bonded to the surface of a tooth and a magnet

encased in the body of the thermoplastic material (Figure 1). NdFeB rare earth magnets provide the highest energy per unit volume of any commercially available magnetic material.¹³⁻¹⁴ Using magnetic attachments would create a magnetic force interaction that can theoretically make the movement of teeth in any direction possible and easier.

Magnetic forces have been used in orthodontics for both tooth movement¹⁵⁻¹⁹ and orthopaedic correction²⁰⁻²⁵ with varying degrees of success. The magnets initially used were bulky and there were concerns raised about possible toxic effects.²⁶ With improved safety due to better coating materials and the introduction of rare earth magnets which led to a dramatic reduction in magnet size further interest in the field of orthodontics has been stimulated.^{13,26}

The physical properties of permanent magnets have to be taken into consideration when utilising magnetic devices.¹⁵ Magnets have several advantages over traditional force delivery systems including no friction, no material fatigue and the ability to produce predictable force levels over long periods of time.^{13,26} There is no need for direct contact as spatially displaced attractive magnets will converge as magnetic fields prevail between any organic medium.¹⁵ However, magnetic forces are dependent on the distance separating a pair of magnets. This is because the attractive force of the magnets drops dramatically as the distance between the magnets increases. In the dental literature, the inverse square law ($F \propto 1/d^2$) has been said to apply for both denture retention and orthodontic magnets.^{15,16,27-29} However, other relationships have been suggested including an inverse fourth power law.²⁹⁻³²

This paper reports a laboratory-based study conducted to examine the physical properties of attracting NdFeB magnets that can be used as attachments to facilitate tooth movement in combination with clear sequential aligners. The aim of the investigation was to analyse the force system diagrams produced by small attracting NdFeB magnets to determine:

1. If the force levels are sufficient to induce tooth movement
2. The effect of different magnet morphologies on the force characteristics

3. The most appropriate dimensions of magnets that could be utilised in this application.

Materials and Method

NdFeB Magnets

The magnets used in this experiment were fabricated from the alloy neodymium iron boron and were coated with Nickel and Copper (AMF Magnetics, Sydney, Australia). All magnets were magnetised through the thickness and are commercially available for dental applications (Figure 2). The NdFeB permanent magnets are produced by a powder metallurgy process.

A range of rectangular magnets of varying dimensions were utilised in this investigation. The dimensions were chosen with regard to the average crown dimensions and the size of resin attachments used by the Invisalign® system (Align Technology Inc, Santa Clara, California) when the study was designed.^{8,33} The dimensions of rectangular Invisalign® attachments varied with heights of 3, 4 and 5mm; width of 2mm; and prominence of 0.5 or 1mm.⁸ A total of 29 different rectangular magnet dimensions were selected for testing. (Table 1)

Apparatus

The Mach-1universal testing machine (Biosyntech Inc, Quebec, Canada) was used to measure the attractive force of pairs of magnets. The lower component was immobile, while the upper component was attached to an electric motor that moved vertically. A customised mounting jig was constructed using aluminium which is a non-magnetic material. A 10kg load cell was used. The base magnet was fixed with adhesive to an aluminium tab that screwed into position on the inferior component of the jig. The opposing magnet was placed above the base magnet in a parallel position with no vertical displacement. A small amount of adhesive (Loctite® Super Glue Gel Control™, Henkel, Düsseldorf, Germany) was placed on the superior magnet and the mobile upper component with the aluminium tab attached was lowered until it came into contact with the magnet. After five minutes the upper component was raised, separating the magnetic pair. The load cell was calibrated at this position. (Figure 3)

Measurement commenced with the magnetic pair in contact and the magnets were vertically separated 10mm at a speed of 12mm/min. There are no generally valid instructions available for fixing the characteristic curves of magnetic attachments (e.g. International Organisation for Standardisation (ISO) norms); consequently the measurement parameters were chosen with reference to previous studies.^{27,30,32,34} The start position (0 μ m) was determined as the position corresponding to the peak tensile force (the “breakaway” load).³⁰ Force measurements were recorded in grams and the results were recorded electronically. Each measurement was repeated 4 times for every magnetic pair and 5 magnetic pairs were tested for every size. Therefore a total of 20 measurements were generated for each magnet size tested.

Measurement Error

The presented force-displacement diagrams were constructed from the average of 20 measurements. One-way analysis of variance (ANOVA) for repeated measurements was performed on seven randomly selected magnet sizes. Both intra-magnet and inter-magnet measurement errors were analysed using the Statistical Package for Social Sciences (SPSS for Windows, version 16.0, Chicago, Illinois, USA).

Results

The force-displacement characteristics of 29 magnets with differing dimensions were assessed in this investigation. The average force-displacement diagrams of all magnet configurations measured in this investigation are depicted in Figure 4. For all magnets the force decreased with increasing vertical separation. High forces were generated at small separations. The highest peak force of 555.16g was produced by the 4x4x2mm magnet, followed by the 3x3x2mm magnet which produced a peak force of 312.71g. The lowest peak force of 44.1g was generated by the 2x2x0.5mm magnet. (Table 2)

Figure 5 demonstrates the typical force-distance diagrams generated for repeat measurements of one particular magnet configuration (3x3x2mm). For all magnetic configurations four repeat measurements were performed on five magnetic pairs of the same size. The variance of repeat

measurements of an individual magnetic pair ranged from 0.67 - 3.1% of the mean value. While the variance between different magnetic pairs of the same size ranged from 2.32 – 9.37% of the mean value. (Table 3)

A range of 15-200 grams was chosen to represent the clinically relevant force levels for tooth movement in this investigation.²⁸ Figure 6 depicts the force-displacement curves of all magnet configurations with respect to this clinically relevant force range. All the magnet configurations tested in this investigation generated forces within this range. For all magnet configurations, except the three largest magnets, the peak force occurred within this range. With the larger magnet configurations 4x4x2mm, 3x3x2mm and 4x3x1mm the maximum clinical force of 200g was generated at a vertical separation of 990 μ m, 328 μ m and 83 μ m respectively.

For all magnet configurations the force decreased dramatically with vertical separation. For the majority of magnets the minimum clinically significant force of 15g was attained at approximately a 2mm separation or less. (Table 2) The three largest magnet configurations 4x4x2mm, 3x3x2mm and 4x3x1mm reached the minimum clinical force of 15g at a vertical separation of 5171 μ m, 3252 μ m and 2625 μ m respectively. Three magnet configuration, 3x0.75x1.25mm, 4x1x0.5mm and 2x2x0.5mm, reached the minimum force of 15g before a 0.5mm separation.

The range of vertical displacement over which clinically relevant forces were generated varied for all magnet configurations. The vertical displacement in microns through which clinically relevant forces were generated was deemed to be the activation range for each tested magnet. (Table 2) Comparison was conducted between the magnet configurations by noting the range of vertical displacement where desired force levels were obtained. (15-200g; Figure 7) The 4x4x2mm magnet had the greatest range of activation and the 2x2x0.5mm magnet had the poorest range.

The relationship between force and magnet separation was evaluated by plotting the logarithm of magnetic force against the logarithm of distance. A typical log-log plot is shown in Figure 8A. A

distinct curvature was evident in the log (force)-log (distance) plot suggesting that the data did not obey the classic inverse square law. By applying a systematic data transformation approach the inverse fourth root of the force ($fm^{-0.25}$) against distance was found to approximate a linear relationship (Figure 8B). Addition of an offset (A/B) to the distance, obtained by fitting a linear regression of the transformed force variable ($fm^{-0.25}$) against distance, suggests that force versus distance plus offset follows an inverse fourth power law. Figure 8C demonstrates that the relationship for the log (force) against the log D (distance plus offset) follows a power law with coefficient -4. Figure 8D indicates that the relationship is consistent for repeat measurements of individual magnet configurations. The results of the 3x3x2mm magnet are presented as an example of the typical outcomes.

Table 4 summaries the offset values from the regression analysis for all magnetic configurations and the slope of the resulting plot of log force against log distance plus offset (D). The results were generally consistent with the finding of an inverse fourth power law at small separations of 2mm or less. Correlation between the offset and magnet dimensions – length (l), width (w), height (h), lw, lh or wh were analysed. The combination of height and cross-sectional area, lw, was highly significant ($p<0.001$) with a correlation coefficient of 0.91. The regression on height alone was insignificant with a correlation coefficient of 0.44.

Discussion

This laboratory based study examined the force-displacement characteristics of attracting NdFeB magnets to assess if the force levels generated were sufficient to induce tooth movement. Most clinical strategies are based on the assumption that a force magnitude or a range of forces exist that when applied to the periodontium will yield an optimal rate of tooth movement.^{1,35} The major factor that affects the movement of teeth is not really the force magnitude but rather the distribution of stress generated in the periodontium.³⁵⁻⁴⁰ However, it is very difficult to measure stresses and strains within the periodontal ligament and therefore force magnitudes have received significant attention in orthodontics.³⁷

In this investigation a range of 15-200grams was chosen to represent a clinically relevant force range. This force range was selected with regard to previous investigations of the physical characteristics of magnets for orthodontic tooth movement.^{28,32} Mancini *et al*²⁸ applied a clinically relevant force range of 15-200g in an investigation of the physical characteristics NdFeB magnets, whereas von Fraunhofer³² and co-workers analysed the force generation by orthodontic samarium-cobalt magnets in relation to an optimal orthodontic force range of 75-150g. The larger force range of Mancini *et al* was selected for this project.²⁸

A range of magnets of varying dimensions were examined in this investigation. According to Vardimon *et al*¹⁵ the performance of the magnetic system can be enhanced by increasing the length, which extends the magnetic axis, or the width, which extends the pole surface. The paramount factor in determining the maximum attractive force is the length of the magnetic axis, i.e. the distance between the two poles of a magnet. While increasing the width affects the slope of the force-distance curve.¹⁵ The results of this experiment support these conclusions as the magnet configurations with the largest pole face area and magnetic axis length generated the highest forces.

The larger magnet configurations 4x4x2mm, 3x3x2mm and 4x3x1mm generated forces above the clinically relevant force range. In orthodontics high forces are considered to be harmful due to the risk of high stress resulting in root resorption, soft tissue dehiscences or loss of supporting bone.^{27,41-43} Therefore, to avoid potential complications the pole distance of these magnets would need to be monitored.

The force-distance diagrams for all magnet configurations demonstrated a dramatic decrease in force with increasing vertical separation. This could equally be stated as an increasing force gradient as the vertical separation decreased, which is the case clinically with attractive magnets. Burstone⁴⁰ suggested that it might be better biologically to have an increasing gradient appliance. His rationale was that as the periodontal ligament widens following orthodontic tooth movement, increasing forces might be used, since mobilisation and vascularity have increased.

In this investigation the anticipated inverse square law was found not to apply to the experimental data. According to Coulomb's law the force produced by any two magnets is inversely proportional to the square of the distance between them.^{15-16,27-29} An inverse fourth law was found to apply when an offset was applied to the distance. Although mention is given to the application of the inverse square law in the dental literature^{15-16,27-29} many authors present curves without comment on the functional relationship^{34,44-45} or have reported that it applies only "approximately".^{16,27} Alternate relationships have been documented previously with reports that the force "decreases as the square of the distance initially and then as the cube"²⁹ and an "inverse square-root" relationship applying at small distances.³²

The finding of a non-inverse square force-distance law in this investigation is consistent with the work of Darvell and Dias.³⁰⁻³¹ They also found that an inverse square law did not apply for long thin magnets and have presented data that demonstrated that the expected force-distance relationship approaches an inverse fourth power law.³⁰⁻³¹ Their rationale was that the commonly used elementary view of a simple dipole magnet is of little value for understanding the force-distance relationship at small distances.³⁰

It has previously been assumed that the surface of a magnet provides the reference plane for measuring distance and the variation in force is a simple function of this distance.^{13,30} However, there is no known justification that the functional pole resides at the magnet face.^{30,46} In this investigation an individual offset was added to the distance in order for the inverse fourth law relationship to apply. The offset adjusts the distance for the physical size of the magnets, and increases with greater height and greater cross-sectional area of the magnets ($p < 0.001$; correlation coefficient 0.91). Considering the offset is dependent on the physical characteristics of the magnet, as Darvell and Dias³⁰ suggested it may represent the deviation of the apparent pole position from the end of the magnets.

For the majority of magnets the minimum clinically significant force of 15g was attained at approximately a 2mm separation or less. This finding is clinically significant as the threshold force

capable of producing orthodontic tooth movement may not be attained even at small separations.²⁸ The work of Bondemark and Kurol,²⁷ Vardimon *et al*¹⁵ and several other authors have demonstrated this previously.²⁸ Therefore, another important consideration is the range of action of the different magnetic attachments. The vertical displacement through which clinically relevant forces were generated was deemed to be the activation range for each tested magnet. (Figure 7)

Considering that thermoplastic appliances can store 0.25-0.5mm of tooth movement per aligner the magnetic attachments must deliver clinically useful forces over this range to be of additional benefit.^{1,8,47,48} The three weakest magnet configurations, 3x0.75x1.25mm, 4x1x0.5mm and 2x2x0.5mm, which reached the minimum force of 15g before a 0.5mm separation, are therefore not considered to be clinically useful.

When magnetic attachments are utilised clinically a coating material will need to be applied to bond the magnet to the tooth surface and also to prevent corrosion.⁴⁹⁻⁵² A range of coating materials have been documented in the literature, for example biocompatible epoxy resin¹⁶, stainless steel⁵³ or a thin layer of parylene¹⁵ The NdFeB magnets used in this investigation are plated with nickel and copper and should be covered with resin when used clinically to prevent corrosion.⁵⁴

The thickness of the superficial coating material effectively increases the separation of the magnetic surfaces. The range of action of the magnets must be double the thickness of the coating material as both surfaces of a pair of magnets will be covered. Considering this, the minimum active range of a magnetic attachment would need to be above 1000µm to also account for the thickness of the coating material, which has been estimated to be approximately 500µm. Based on these criteria approximately half the magnet configurations tested (14 out of 29) are not clinically useful. (Figure 7) As advances are made in material sciences and the thickness of coating materials reduce the application of this technique is likely to be enhanced.

The dimensions of the magnets were chosen with regard to the average crown dimensions and the size of resin attachments used by the Invisalign® system when the study was designed.^{8,33} The intention

was that the new magnetic attachments would be no larger than conventional resin attachments. Therefore, the most ideal magnetic configurations were considered to be those with a range of action above 1000µm and a prominence no larger than standard resin attachments.

The magnet configurations with a thickness of 2mm, demonstrated clinically useful force characteristics over a broad range but the relatively large size limits their application. Although they would not be ideal for bonding to the surfaces of the teeth they could be incorporated into the aligners to facilitate space closure. Approximately half the tested magnet configurations (14 out of 29) were not considered to be clinically useful as they had a limited range of action. Based on the criteria defined above eleven magnet configurations were deemed to be suitable for use as magnetic attachments in combination with clear sequential aligners. (Table 5)

The difference in force between individual magnet pairs was found to range from 2.32 – 9.37% in this investigation. This compares favourably with the work of Bondmark and Kuroi²⁷ who reported a similar level of variation for repelling samarium cobalt magnets. They considered a variation of 6-9% to be low and concluded that the magnets could be used routinely without measuring the force of an individual pair in each case.²⁷ Given that an equivalent variation was found in this investigation a similar conclusion is justifiable for this application.

In this study the force-displacement characteristics of a range of magnets were measured in one dimension, the vertical dimension, with the surfaces parallel to each other. If the magnets were applied clinically as attachments in combination with clear sequential aligners it is unlikely that such conditions would be replicated and it is possible that the magnets could be offset in all three planes of space. Mancini *et al*²⁸ found that offsets and angulations significantly reduced the pole face overlap, directly affecting the magnetic flux density and direction and therefore the force of attraction between magnets.

Since both forces and moments work in all three planes, the effective force system acting on a tooth should be represented in three-dimensions.⁵⁵ 3-D forces and moments generated by magnetic devices

have been measured in previous investigations.^{15,55-58} Therefore, a recommendation for future research is the characterisation of the three-dimensional force-displacement and moment-displacement diagrams of the most ideal magnetic attachments identified in this investigation.

The use of small magnetic attachments was proposed to enhance the capabilities of clear aligner therapy. Given that appropriate force levels have been verified, clinical investigation of this technique is now warranted. Future research is also needed to identify an ideal coating material that effectively seals the magnets, has minimal thickness and is aesthetically acceptable.

Conclusion

Based on the results of this study the following conclusions can be drawn:

1. Neodymium iron boron magnet configurations display varying levels of clinical usefulness.
2. Magnet morphology affected the clinical properties and performance of the magnets.
3. A select range of magnet configurations exhibited suitable and reliable attractive forces and therefore could be advocated for the intended clinical application as magnetic attachments in combination with clear sequential aligners.

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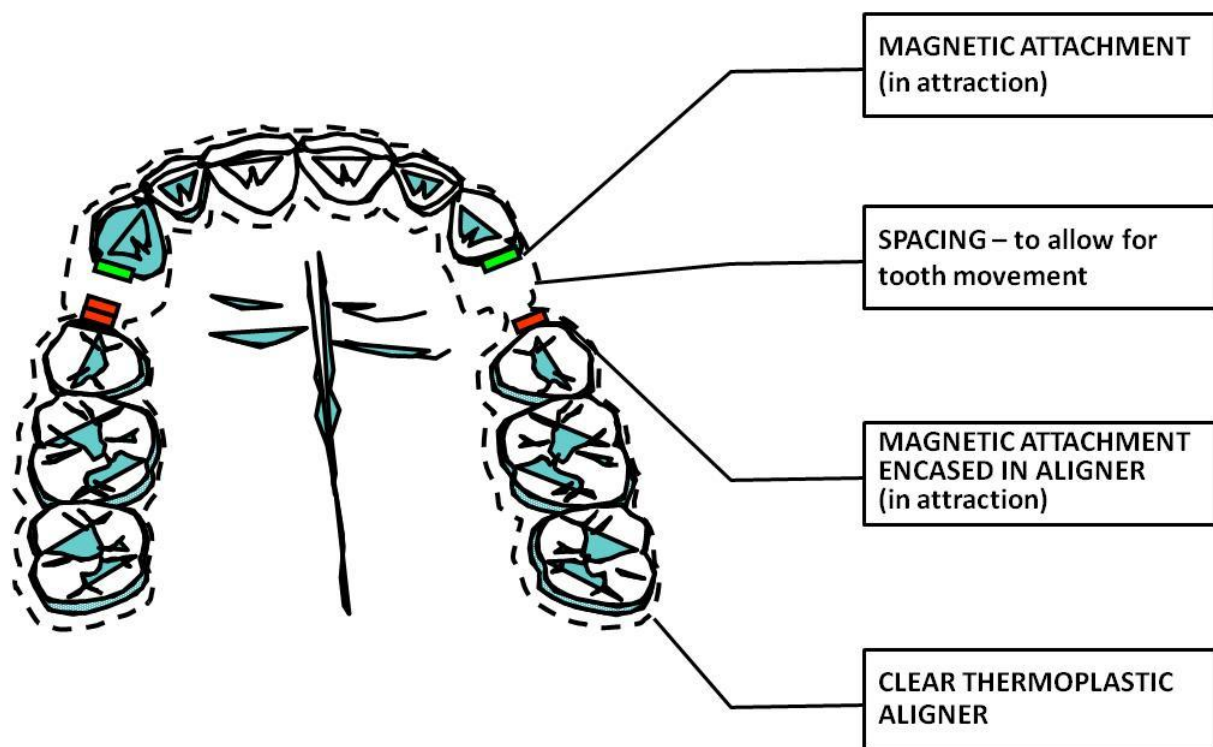


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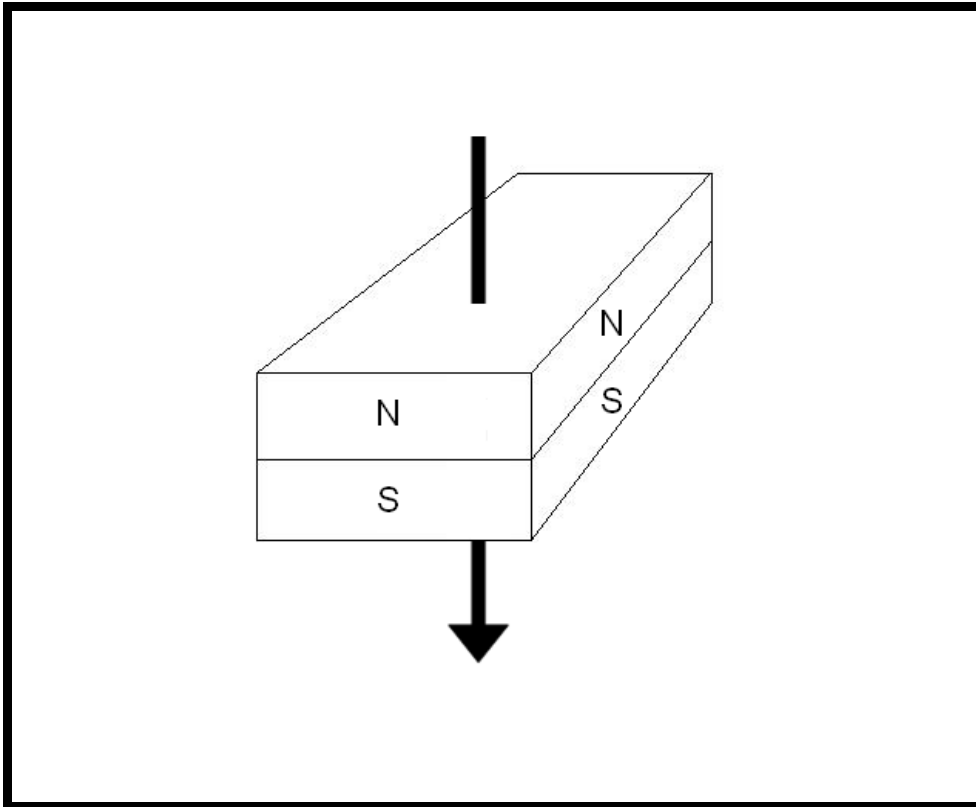


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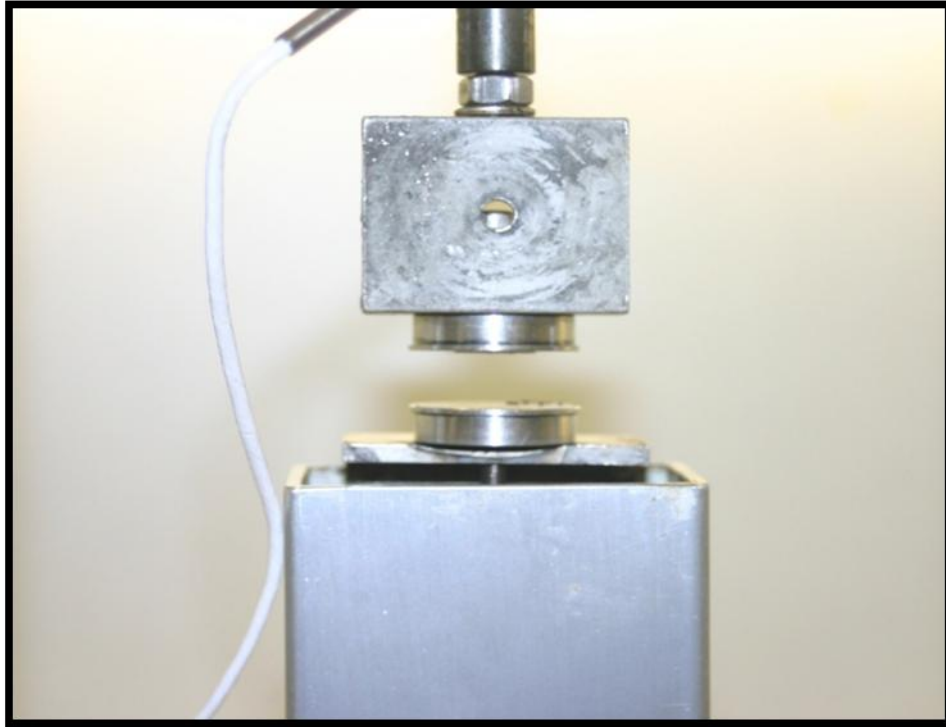


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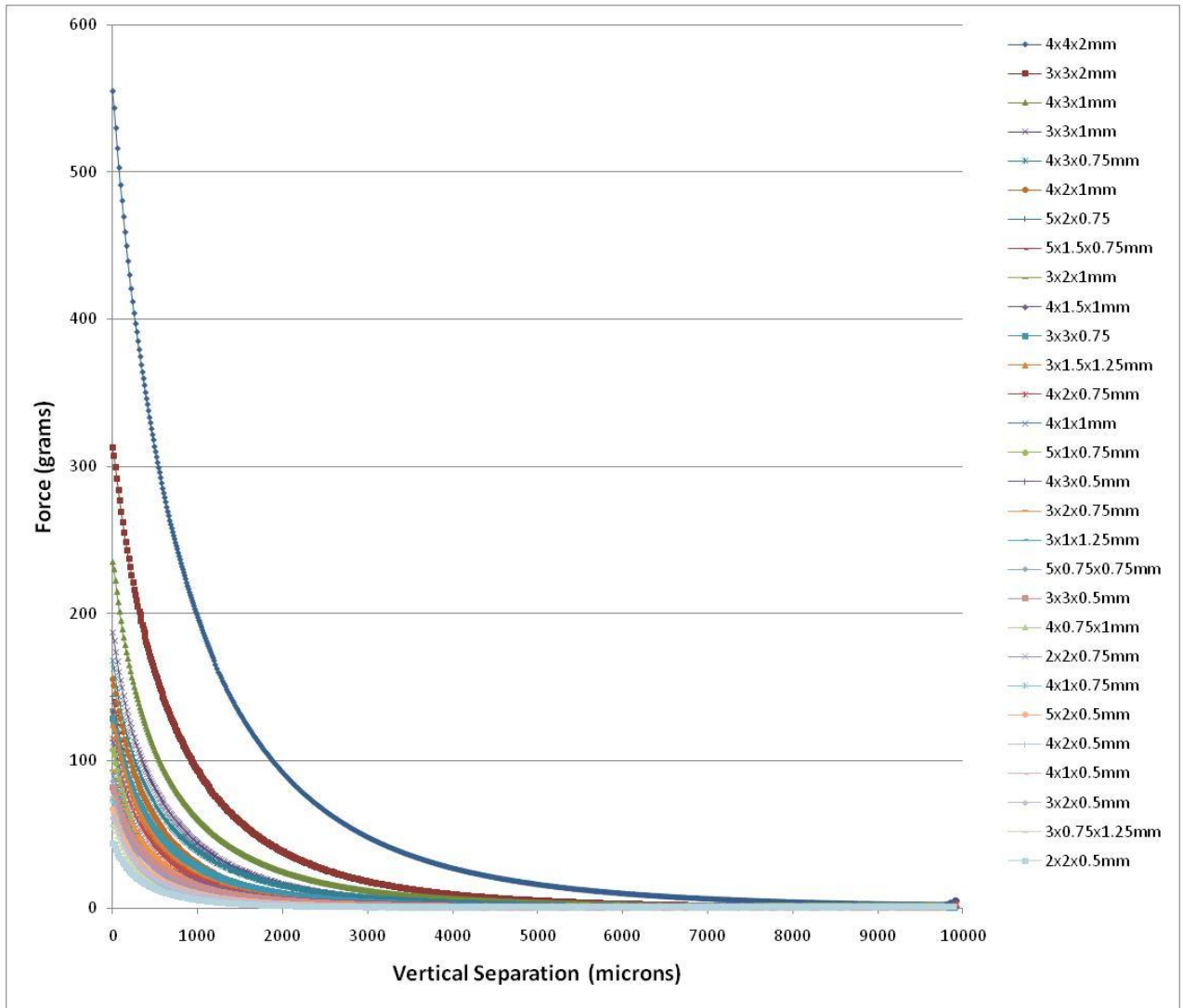


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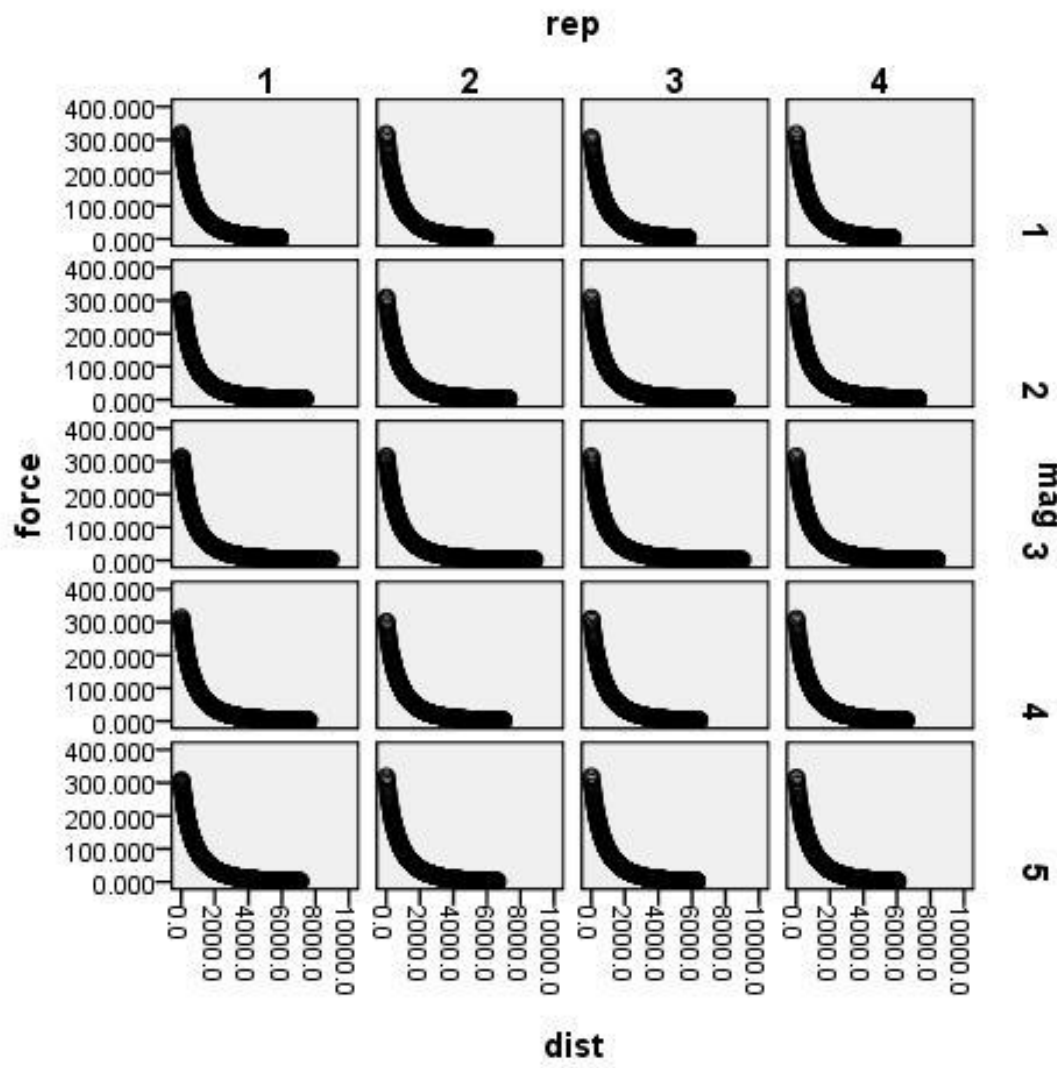


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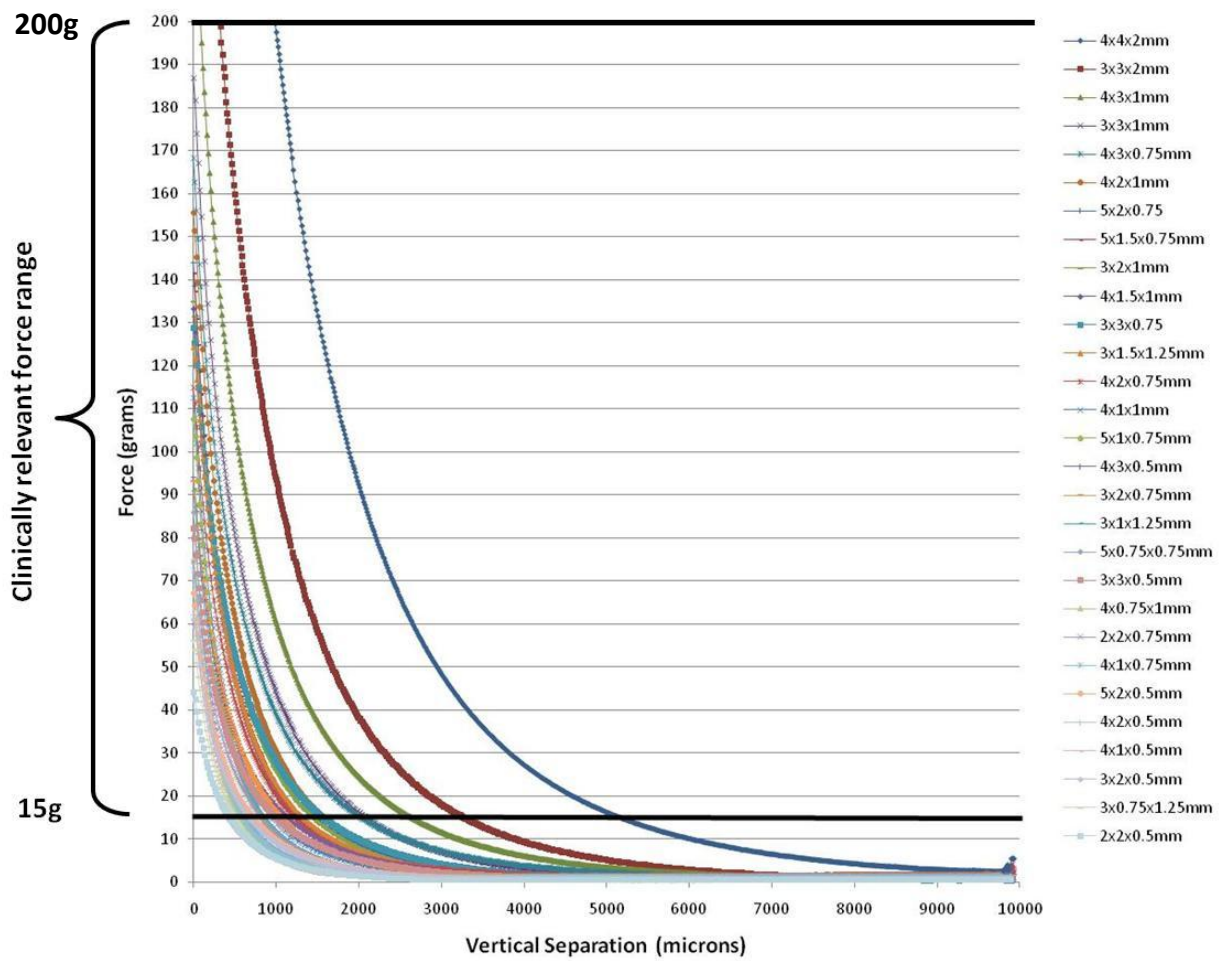


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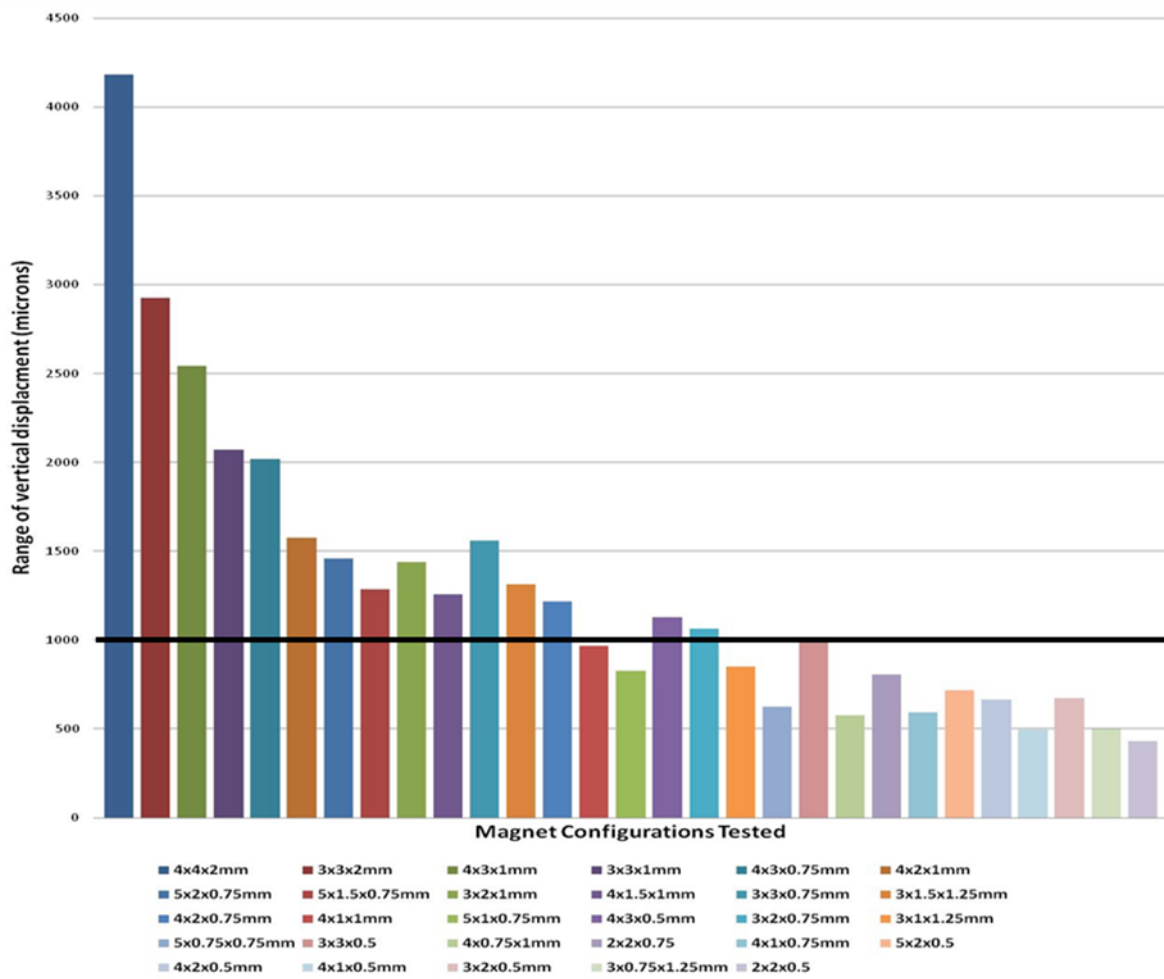


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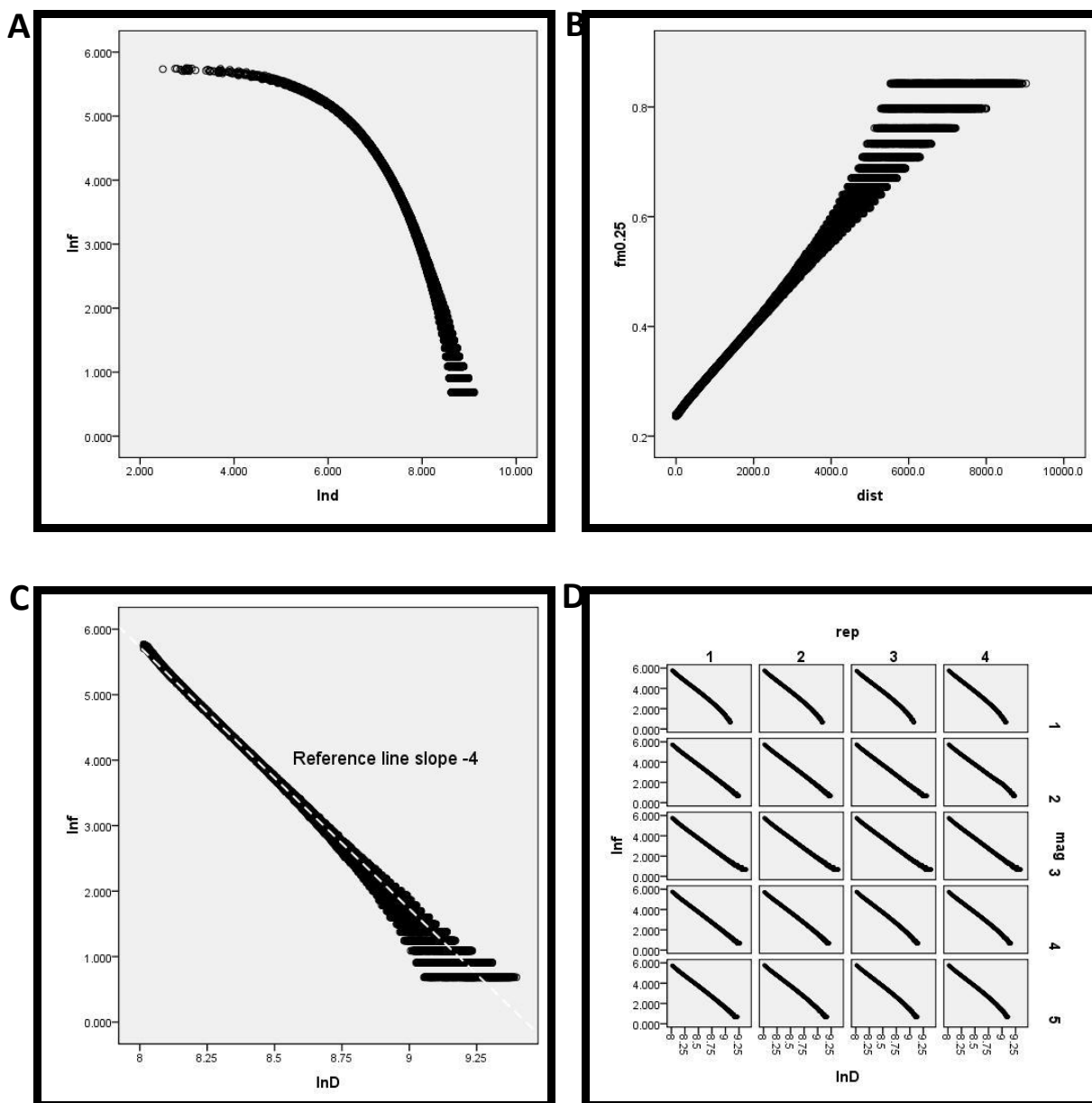


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Table 1- The morphology of magnets used in this investigation

Dimensions (mm)	THICKNESS				
	<u>0.5</u>	<u>0.75</u>	<u>1</u>	<u>1.25</u>	<u>2</u>
WIDTH X LENGTH	1 x 4	0.75 x 5	0.75 x 4	0.75 x 3	3 x 3
	2 x 2	1 x 4	1 x 4	1 x 3	4 x 4
	2 x 3	1 x 5	1.5 x 4	1.5 x 3	
	2 x 4	1.5 x 5	2 x 3		
	2 x 5	2 x 2	2 x 4		
	3 x 3	2 x 3	3 x 3		
	3 x 4	2 x 4	3 x 4		
		2 x 5			
		3 x 3			
		3 x 4			

Table 2 - Results for the tested magnets with varying morphology

Dimensions (l x w x h)	Maximum force (grams)	Activation Range (microns)	<u>Clinically Relevant Force Range</u>	
			Separation at MINIMUM force 15g (microns)	Separation at MAXIMUM force 200g (microns)
4x4x2	555.16	4181	5171	990
3x3x2	312.71	2924	3252	328
4x3x1	235.14	2542	2625	83
3x3x1	186.92	2072	2072	-
4x3x0.75	168.14	2020	2020	-
4x2x1	155.65	1575	1575	-
5x2x0.75	143.86	1458	1458	-
5x1.5x0.75	141.45	1285	1285	-
3x2x1	134.81	1440	1440	-
4x1.5x1	133.25	1257	1257	-
3x3x0.75	128.67	1558	1558	-
3x1.5x1.25	124.14	1315	1315	-
4x2x0.75	114.82	1218	1218	-
4x1x1	112.54	969	969	-
5x1x0.75	107.44	826	826	-
4x3x0.5	93.96	1127	1127	-
3x2x0.75	93.19	1066	1066	-
3x1x1.25	91.26	852	852	-
5x0.75x0.75	85.90	623	623	-
3x3x0.5	82.11	988	988	-
4x0.75x1	74.95	575	575	-
2x2x0.75	74.43	806	806	-
4x1x0.75	72.60	594	594	-
5x2x0.5	67.10	719	719	-
4x2x0.5	61.99	667	667	-
4x1x0.5	63.41	497	497	-
3x2x0.5	60.98	673	673	-
3x0.75x1.25	56.02	498	498	-
2x2x0.5	44.10	433	433	-

Table 3 - One-way analysis of variance (ANOVA) of repeat measurements – within an individual magnetic pair and between different magnetic pairs of the same size

One-way analysis of variance							
	<u>INTRA - MAGNET ERROR</u>				<u>INTER – MAGNET ERROR</u>		
MAGNET DIMENSIONS (mm)	Mean	Mean Square Error	Standard Deviation	% Error	Mean Square Error	Standard Deviation	% Error
3x3x2	312.72	23.53	4.851	1.55	52.41	7.24	2.32
3x3x1	186.92	12.51	3.54	1.89	307.04	17.52	9.37
2x2x0.5	44.10	1.875	1.37	3.1	6.354	2.52	5.72
5x1x0.75	107.44	1.86	1.36	1.27	63.95	7.99	7.44
4x2x1	155.65	7.42	2.73	1.75	16.84	4.10	2.64
4x1.5x1	133.25	5.66	2.38	1.79	16.93	4.12	3.09
4x4x2	555.16	13.67	3.70	0.67	377.76	19.44	3.50

Table 4 - Summary of offset values from linear regression analysis and the gradient of the slope for log (force) against log (distance plus offset) for all magnetic configurations tested

Magnet Dimensions	A	B	OFFSET (A/B)	Slope	Standard Error	Power value
4x4x2	0.21	0.000057	3667	-4.00	0.002	2.0
3x3x2	0.24	0.000083	2871	-3.98	0.002	2.0
4x3x1	0.26	0.000096	2719	-3.94	0.004	2.0
3x3x1	0.27	0.000116	2353	-4.01	0.003	2.0
4x3x0.75	0.29	0.000111	2568	-3.90	0.005	2.0
4x2x1	0.28	0.000157	1796	-4.24	0.014	2.0
5x2x0.75	0.29	0.000156	1853	-3.98	0.011	2.0
5x1.5x0.75	0.29	0.000179	1615	-4.08	0.010	2.0
3x2x1	0.29	0.000150	1960	-3.95	0.008	2.0
4x1.5x1	0.29	0.000173	1702	-4.04	0.010	2.0
3x3x0.75	0.30	0.000136	2197	-3.97	0.005	2.0
3x1.5x1.25	0.30	0.000162	1846	-3.97	0.008	2.0
4x2x0.75	0.31	0.000173	1763	-3.93	0.026	2.0
4x1x1	0.31	0.000207	1488	-3.83	0.013	2.0
5x1x0.75	0.31	0.000252	1224	-4.11	0.018	2.0
4x3x0.5	0.32	0.000169	1905	-3.94	0.013	2.0
3x2x0.75	0.32	0.000180	1783	-3.96	0.013	2.0
3x1x1.25	0.32	0.00022	1473	-3.93	0.007	2.0
5x0.75x0.75	0.33	0.000287	1143	-3.82	0.020	2.0
3x3x0.5	0.33	0.000171	1953	-3.82	0.011	2.0
4x0.75x1	0.34	0.000289	1176	-3.78	0.022	2.0
2x2x0.75	0.34	0.000222	1529	-4.02	0.016	2.0
4x1x0.75	0.34	0.000266	1179	-4.02	0.017	2.0
5x2x0.5	0.35	0.000218	1610	-3.88	0.011	2.0
4x2x0.5	0.36	0.000230	1552	-3.94	0.017	2.0
4x1x0.5	0.35	0.000334	1054	-4.13	0.017	2.0
3x2x0.5	0.36	0.000219	1642	-3.88	0.014	2.0
3x0.75x1.25	0.36	0.000288	1264	-3.93	0.014	2.0
2x2x0.5	0.39	0.000273	1422	-3.95	0.012	2.0

Table 5 - Dimensions of the magnets with the most clinically useful force characteristics and range

Dimensions (mm)	<u>THICKNESS</u>		
	<u>0.5</u>	<u>0.75</u>	<u>1</u>
WIDTH X LENGTH	3 x 4	1.5 x 5	1.5 x 4
		2 x 3	2 x 3
		2 x 5	2 x 4
		2 x 4	3 x 3
		3 x 3	
		3 x 4	

8 MANUSCRIPT TWO



The skeletal and dental outcomes of a new magnetic functional appliance, the Sydney Magnoglide, in Class II correction

This manuscript is to be submitted to the American Journal of Orthodontics and Dentofacial Orthopedics

The skeletal and dental outcomes of a new magnetic functional appliance, the Sydney Magnoglide, in Class II correction

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8.1. Abstract

Title:

The skeletal and dental outcomes of a new magnetic functional appliance, the Sydney Magnoglide, in Class II correction

Abstract:

Aim: The purpose of this prospective study was to evaluate the dentoskeletal effects of a new magnetic functional appliance, the Sydney Magnoglide, both at the end of active treatment with the appliance and after completion of comprehensive fixed appliance therapy, compared to a group of untreated Class II controls.

Subjects and Methods: 34 consecutively treated Class II division 1 cases treated with the Sydney Magnoglide followed by fixed appliances were compared to 30 untreated Class II controls with the same initial dentoskeletal Class II features and matched for age and sex. Subjects were assessed according to the cervical vertebral maturation method. Lateral cephalograms were taken pre-treatment (T1), immediately after functional appliance therapy (T2) and after comprehensive fixed appliance therapy was completed (T3). The mean age of patients at the start of treatment was 13.5 years \pm 1.2 years. The average age after functional appliance treatment was 14.5 years \pm 1.1 years and the average age at the completion of treatment was 15.4 years \pm 1.2 years. Cephalometric analysis included Pancherz analysis and linear and angular measurements were performed. The comparisons were carried out by means of Student's t tests ($p < .05$).

Results: There was no statistical difference between the treated and control group at T1. Treatment with the Sydney Magnoglide and comprehensive fixed appliance therapy normalised the overjet and corrected the Class II relationship in all treated subjects. According to the Pancherz analysis treatment induced a statistically significant overjet correction of 5.3mm ($p < 0.001$) and a correction in molar relation of 2.9mm ($p < 0.001$) when compared with growth changes in the control group. Skeletal

contributions to the molar relationship were predominant (62%), and it was mainly due to significantly greater increments in mandibular base (55%). The dentoalveolar contribution to molar correction was due to a predominantly greater mesial movement of the mandibular molar (1.5mm) compared to the upper molar (0.4mm). The skeletal contribution to the overjet correction was predominately due to mandibular changes (30.2%). The dentoalveolar component of the overjet correction was due to a combination of 2.4mm maxillary incisor lingual movement and 1.1mm labial movement of the mandibular incisors.

There was a significant gain in mandibular length as measured by the change in Co-Gn, with the treatment group showing 2.3mm ($p < 0.01$) more increase in mandibular length compared to the controls. The ANB angle showed a reduction in the treated group of 1.0 degrees as opposed to an increase of 0.3 degrees in the untreated controls. The comparison was statistically significant ($p < 0.01$), with statistically significant improvement in the SNB angle ($p < 0.05$). Changes in the lower incisor angulation were statistically insignificant following functional appliance therapy but a 5.1 degree LI to GoMe change in the treated group compared to the controls at the completion of fixed appliance therapy was statistically significant ($p < 0.001$).

Conclusion: The outcomes of this prospective study demonstrate that the compliance-free Sydney Magnoglide, is an effective functional appliance for Class II correction, both in the short term and at the completion of fixed appliance therapy. The correction of the overjet and molar relation that was achieved in all patients treated with the SM was mainly associated with favourable skeletal mandibular changes. The appliance is comfortable for the patient and the very limited breakages and easy, chair-side repair confers benefits to the clinician as well.

Key Words: Cephalometrics, Magnets, Functional Appliance

8.2. Manuscript Two

Introduction:

Class II malocclusion is a common orthodontic problem, occurring in about one third of the population.¹⁻² A variety of skeletal and dental configurations arise in combination with a Class II relationship, with mandibular skeletal retrusion the most consistent finding.³ Therefore, functional appliance therapy, which aims to stimulate mandibular growth by forward posturing of the mandible, has been a popular approach for Class II treatment.

A wide range of functional appliances have been developed for this purpose. Functional appliances can be classified as fixed, such as the Herbst appliance, and removable, such as the Twin-block and Activator appliance.⁴ A recent systematic review found the Herbst appliance had the highest efficiency for enhancing mandibular growth, followed by the Twin-block.⁵ However, there are shortcomings associated with both of these appliances. A multicentre, randomised clinical trial reported a 33% failure-to-complete rate for the Twin-block indicating compliance is an issue and high breakages with the Herbst appliance, necessitating more appointments for repair.⁶

A new magnetic functional appliance has been developed with the intention of addressing these shortcomings. The Sydney Magnoglide is a fixed functional appliance consisting of maxillary and mandibular right and left bonded acrylic resin blocks. Each block has embedded magnets arranged in a manner that postures the mandible into a Class I occlusion. Bonding the appliance addresses the issue of compliance and the lack of moving parts reduce the likelihood of breakages and improves patient comfort.

Magnetic forces have been used in orthodontics for both tooth movement⁷⁻¹¹ and orthopaedic correction¹²⁻¹⁷ with varying degrees of success. The magnets initially used were bulky and there were concerns raised about possible toxic effects. Improved safety with better coating and the introduction of rare earth magnets, which led to a dramatic reduction in magnet size, stimulated further interest in

orthodontic applications.¹⁸⁻¹⁹ The advantages of magnets over traditional force delivery systems include: no friction; no material fatigue; the ability to produce predictable force levels over long periods of time and no need for direct contact.¹⁸⁻¹⁹

A variety of magnetic functional appliances have been introduced in the literature.^{13-14,20-21} With such appliances the mandible is held in a forward position with the help of magnetic forces.²² Darendeliler and Joho introduced the Magnetic Activator Device II (MAD II) for this purpose and have demonstrated successful correction of Class II malocclusion with the appliance.^{13,23} The design of the appliance has evolved to improve efficiency, patient compliance and reduce bulk. This resulted in the new magnetic functional appliance used in this study, the Sydney Magnoglide (SM).

Treatment timing has also been acknowledged as one of the critical factors for success in Class II correction and it is now generally accepted that treatment should be undertaken during the peak mandibular growth.²⁴⁻²⁷ The rate, onset, duration and intensity of the pubertal spurt in mandibular growth varies for each individual.²⁴ Thus, optimal timing of dentofacial orthopaedics is intimately linked to the identification of periods of accelerated growth.²⁵ Numerous maturational indices have been suggested to evaluate skeletal maturity in growing patients. Among these indices, the Cervical Vertebral Maturation (CVM) method has been validated as a biological indicator of mandibular and somatic skeletal maturity.²⁸⁻³⁰ The growth interval between CVM stage 3 and 4 has been shown to coincide with the pubertal peak in mandibular growth and is advocated as the optimal time for Class II treatment.^{25,28-29}

The purpose of this prospective study was to evaluate the dentoskeletal effects of a new magnetic functional appliance, the Sydney Magnoglide, both at the end of active treatment with the appliance and after completion of comprehensive fixed appliance therapy, compared to a group of untreated Class II controls. Both treated and control subjects were evaluated with reference to the CVM method given the impact of timing on treatment outcomes.

Subjects and Methods:

This prospective clinical study was based on the records of 34 consecutively treated cases from the private practice of the fourth author. The sample comprised 20 males and 14 females. The criteria for case enrolment were as follows:

1. Class II division 1 malocclusion of half or full cusp
2. Overjet of 6mm or greater
3. ANB angle greater than 3.5 degrees
4. Non-extraction treatment plan

Of the original sample, 2 patients moved location during the course of treatment, while one terminated treatment early due to poor oral hygiene. The number of dropouts was then 3, which led to a final sample for statistical analysis of 31 subjects.

Lateral cephalograms were taken pre-treatment (T1), immediately after functional appliance therapy (T2) and after comprehensive fixed appliance therapy was completed (T3). Clinical photographs and study models were obtained for all the subjects at the start and conclusion of treatment. The duration of time between the pre-treatment records and the end of functional appliance therapy (T2-T1) was approximately 1.0 year (SD 0.4 years). Fixed appliance therapy immediately followed the functional jaw orthopaedics (T3-T2), with a mean duration of 1.0 year (SD 0.4 years). As shown in (Table 1), the mean age of the patients at the start of treatment was 13.5 years (SD 1.2 years). The average age at T2 was 14.5 years (SD 1.1 years) and the average age at the completion of treatment (T3) was 15.4 years (SD 1.2 years).

The treated group was compared to an untreated control group that was comprised of 30 subjects (15 males and 15 females) with the same initial dentoskeletal Class II features as the treated subjects (Table 2). The control subjects were derived from the University of Michigan Elementary and Secondary School Study and from the University of Florence, Italy. The control group was matched as closely as possible to the treatment group for age, sex, and CVM stage. The control group was followed on a parallel basis with the treated subjects. As shown in (Table 1), the mean age of the

controls at T1 was 13.0 years (SD 1.6 years). The average age at T2 was 14.5 years (SD 1.1 years) and the average age at the end of the review (T3) was 15.4 years (SD 1.2 years).

Patients were categorized according to the CVM stage as described by Baccetti *et al.*²⁹ As shown in (Table 1), 77.4% of the treated subjects were at CS 3 or CS 4 at T1, 12.9 % at CS 2 and 9.7% at CS 5. 90% of the untreated Class II control subjects were at CS 3 or CS 4 at T1, 6.7% at CS 2 and 3.3% at CS 5. Thus, the majority of subjects were between CS stage 3 and 4 at the start of treatment, indicating they were treated/observed during a period of intense mandibular growth rate.^{25,28} At T2 and T3 all subjects in both groups were at a postpubertal stage of skeletal maturation (CS 4 to CS 6).

Appliance Design

The SM is a fixed functional appliance composed of 4 acrylic resin blocks. Two blocks are bonded to the maxillary right and left buccal segments and 2 to the mandibular right and left buccal segments. Each block contains 2 embedded (7mm x 4mm x 3mm) neodymium iron boron (NdFeB) magnets, which are arranged to be in attraction with the 2 magnets in the opposing jaw when the casts are positioned in a Class I occlusion through the construction bite registration (Figure 1). The appliance thus postures the mandible forward into Class I occlusion with the magnets in attraction, while repulsive forces deflect the occlusion away from a retrusive position (Figure 2). A small step in the occlusal surface of the acrylic resin blocks is also designed to mechanically interlock the occlusion in a Class I relationship. This configuration provides both mechanical and magnetic forces to maintain protrusion of the mandible. The magnets are positioned buccally in order to minimize the vertical dimension of the appliance and improve patient comfort.

The NdFeB magnets are encased in a Nickel and Copper casing and then coated with Signum metal bond (Heraeus, Hanau, Germany) to improve the retention with the acrylic resin. The blocks also include a cobalt-chromium alloy framework, which is essential to facilitate removal of the blocks in a single piece when treatment is completed. The internal surface of the blocks is sandblasted to improve

the interlocking with the bonding cement. The appliance is cemented using glass ionomer cement after the enamel surface is cleaned and polished. (Figure 1)

The Robotic-Measurement System (RMS) was used to measure the force-displacement characteristics of the Sydney Magnoglide by simulating mandibular jaw movements vertically, transversally and sagittally $\pm 5\text{mm}$. The RMS consists of a precision industrial robot RX 60 (Stäubli, Bayreuth, Germany) with six degrees of freedom and a FTS nano 12-0.12 3-D force-moment sensor (Schunk, Lauffen/Neckar, Germany).³¹ The starting position ($X=Y=Z=0$) corresponds to the constructed protruded position with a vertical separation of 0.5mm. Figure 3 depicts a three-dimensional force displacement curve of the Sydney Magnoglide with changes in vertical and sagittal displacement. Because of the overall thickness of the acrylic resin coating (0.5 to 0.6 mm), the intermagnet distance produced by a gap between the magnets of 1 to 1.5 mm, reduced the force magnitude 325 to 442 grams on each side.

The magnetic appliances were cemented for a period of 7-8 months, and no other fixed appliance treatment rendered during the functional appliance stage. One week after the removal of the functional appliance all patients underwent non-extraction fixed appliance therapy with a straight wire appliance. Three bracket systems were utilised – SPEED (Strite Industries), Inspire Ice (Ormco) and In-Ovation (Dentsply GAC). Class II elastics (1/4 inch 3.5oz) were worn during fixed appliance therapy for an average of 17 weeks (SD 16 weeks). The average treatment time with fixed appliances was 1.0 year (SD 0.4 years).

Cephalometric analysis

Radiographs were traced by the same operator. The lateral cephalograms were analysed manually using the method described by Pancherz³² and several classical linear and angular measurements from the analyses of Steiner³³, Ricketts³⁴, and McNamara³⁵ were measured using a customised digitisation regimen (Dolphin Imaging Version 11, Chatsworth, California). The magnification factor of all lateral cephalograms was 8%.

Statistical Analysis

The power of the study as calculated on the number of subjects enrolled in the prospective trial and the standard deviations of the chosen cephalometric variables at an alpha of 0.05 exceeded 0.90. An exploratory Shapiro-Wilks test revealed normal distribution of the data in both treated and control groups. Therefore, Student *t* tests were applied to compare initial starting forms in the 2 groups at T1, and then the T1-T2, T3-T2 and T3-T1 changes for all the cephalometric variables.

Error measurement

Lateral cephalograms were randomly chosen and re-traced and re-digitized to calculate the method error by means of Dahlberg's formula.³⁶ Both intra-operator and inter-operator measurement errors were analysed. The intra-operator error was assessed by comparing 30 cephalograms measured by the operator (A.P.) at two time points (t-test for paired observations, $P < 0.5$). The error for linear measurements ranged from zero (molar relation) to 0.3mm (Co-Pg), while the error for angular measurements varied from zero (Y-axis) to 1.2 degrees (LI-toGoMe). No differences between repeated measurements were significant. The inter-operator error was assessed by comparing 20 cephalograms measured by the operator (A.P.) and by another expert operator (N. T.) (t-test for independent observations, $P < 0.05$). The error ranged from 0.1 mm for Ar-Gn to 0.7 degrees for U1-to SN. No differences in the measurements between the two operators were significant.

Results:

The comparison between the treatment and control at T1 showed that there were no statistically significant differences between the groups at the start of the treatment period. (Table 2) Changes in the subjects in the treatment and control groups from T2-T1, T3-T2 and T3-T1 are compared in Tables 3-5. The results in the treated group are subdivided according to gender, although they were not used separately for statistical comparison.

Treatment Effects of SM (Table 3 and Figure 4A)

The new magnetic functional appliance treatment resulted in correction of the Class II relationship in all 31 treated subjects. According to the Pancherz analysis treatment with the Sydney Magnoglide induced a statistically significant overjet correction of 3.5mm ($p<0.001$) and a correction in molar relation of 4.7mm ($p<0.001$) when compared with growth changes in the control group. (Figure 4A) The skeletal contribution to the overjet correction (51.5%) was exclusively due to mandibular changes, while there was a statistically insignificant increase in the maxillary base of 0.1mm. The dentoalveolar component of the overjet correction was mainly due to maxillary changes. The maxillary incisors were retracted (1.8mm), as were the mandibular incisors (0.1mm). Skeletal contributions to the molar relationship were almost equivalent, with increments in mandibular base measurements (1.9mm) accounting for the improvement. The dentoalveolar contributions to molar correction were due to distal movement of the maxillary molars (1.7mm) and mesial movement of the mandibular molars (1.2mm).

Table 3 illustrates the results of cephalometric changes from T1 to T2 in treated and control subjects. There was a statistically significant difference in ANB angle between the groups with the treated subjects showing a reduction of 1.2 degrees as opposed to an increase of 0.4 degrees in the controls. There was a significant gain in mandibular length as measured by the change in Co-Gn, with the treatment group showing a 5.2mm increase in mandibular length compared to 2.7mm in the controls. The 2.5mm greater increase in mandibular length in the treated group was highly significant ($p<0.001$). The Ar-Gn measurements replicated these significant findings. The vertical changes in the treatment group, reflected in the Y axis, were statistically insignificant when compared to the control group. A comparison of the dental changes showed that the upper and lower incisor angulations did not change significantly in the treated group.

The need for repair of the appliance was also examined. In 38.7% of the patients some repairs had to be done to the appliances. In the 31 patients, a total of 124 blocks were cemented (1 block for each quadrant): of these, only 15.3% needed repair. The majority of these problems were due to debonding

of the blocks (13.7%), with very few exposed magnets (1.6%). It should be noted that 100% of the debonds occurred in the mandibular blocks.

Treatment Effects of fixed appliance therapy (Table 4 and Figure 4B)

There was a statistically significant further reduction in the overjet during fixed appliance therapy compared to the control group ($p < 0.05$). Lower incisor proclination was predominately accountable for the change, as the LI to GoMe angle increased 4.3 degrees more in the treated group than the controls ($p < 0.05$). Upper incisor retraction also contributed to the overjet reduction but was not statistically significant. In contrast to the overjet, there was a statistically significant relapse in the molar relationship ($p < 0.05$). According to the Pancherz analysis molar relapse was a result of dental changes with almost equivalent mesial movement of the maxillary (1.0mm) and mandibular molars (0.9mm). There was statistically insignificant skeletal change in the treated group compared to the controls during fixed appliance therapy and thus skeletal change made a limited contribution to the occlusal changes. No other statistically significant differences were found between the treated group and the untreated controls during the fixed appliance phase of therapy.

Overall Treatment Effect (Table 5 and Figure 4C)

Treatment with the Sydney Magnoglide and comprehensive fixed appliance therapy normalised the overjet and corrected the Class II relationship in all treated subjects. According to the Pancherz analysis treatment induced a statistically significant overjet correction of 5.3mm ($p < 0.001$) and a correction in molar relation of 2.9mm ($p < 0.001$) when compared with growth changes in the control group (Figure 4C). Skeletal contributions to the molar relationship were predominant (62%), and it was mainly due to significantly greater increments in mandibular base (55%). The dentoalveolar contribution to molar correction was due to a predominantly greater mesial movement of the mandibular molar (1.5mm) compared to the upper molar (0.4mm). The skeletal contribution to the overjet correction was predominately due to mandibular changes (30.2%). The dentoalveolar component of the overjet correction was due to a combination of 2.4mm maxillary incisor lingual movement and 1.1mm labial movement of the mandibular incisors.

The ANB angle showed a reduction in the treated group of 1.0 degrees as opposed to an increase of 0.3 degrees in the untreated controls. The comparison was statistically significant ($p < 0.01$), with statistically significant improvement in the SNB angle ($p < 0.05$). There was a significant gain in mandibular length as measured by the change in Co-Gn, with the treatment group showing a 6.9mm increase in mandibular length compared to 4.6mm in the controls. The 2.3mm greater increase in mandibular length in the treated group was statistically significant ($p < 0.01$). The Ar-Gn measurements replicated these significant findings. The vertical changes in the treatment group, as reflected in the Y axis, were statistically insignificant when compared to the control group. A comparison of the dental changes showed that the 5.1 degree LI to GoMe change in the treated group compared to the controls was statistically significantly ($p < 0.001$). The difference in upper incisor angulation was not statistically significant.

Discussion:

The present study analysed the skeletal and dental effects of a new magnetic functional appliance compared to a group of untreated Class II controls. The results of this prospective clinical study demonstrate that the Sydney Magnoglide is an effective appliance for functional Class II correction. The outcomes of the orthopaedic phase of treatment with the Sydney Magnoglide show that more than 50% of the overjet correction was due to skeletal changes, almost exclusively in the mandible. These results compare favourably with the Herbst appliance^{32,37-39} and the Twin-block.²⁴

The Sydney Magnoglide demonstrated a greater skeletal contribution to the overjet correction than previous reports with the Herbst appliance. Pancherz has demonstrated up to 40% skeletal contribution to overjet correction when treatment is started at the peak velocity of growth.^{27,40} The difference could be ascribed to the gradual nature of mandibular advancement that occurs with the magnetic functional appliance. The magnetic forces gradually advance the mandible over the first 6 to 8 weeks of treatment.²² In contrast, with the Herbst appliance a greater protrusion is achieved in a single step and the patient maintains a continually protruded position.^{38,41} Gradual advancement of the mandible has been shown to have more favourable effects on mandibular growth modification

than single stage advancement.⁴¹⁻⁴³ Stepwise advancement has been found to result in an increase in tissue reaction over a single advancement. Research by Leung *et al.* suggested that stepwise advancement induced repeated cycles of mechanotransduction and cellular activity resulting in increased vascularity and therefore bone formation.⁴⁴

The magnetic force is only active when the patient closes and therefore the forces acting on the dentition are not continuous. This is because the attractive force of the magnets drops dramatically as the distance between the magnets increases, according to Coulomb's law ($F \sim 1/d^2$).^{7,45-46} This may explain the smaller amount of dental movement or "anchorage loss" with the Sydney Magnoglide. Pancherz commented that the dental changes seen during Herbst appliance treatment were basically a result of anchorage loss in the two arches, resulting in distal tooth movement in the maxilla and mesial tooth movement in the mandible.³² With the Sydney Magnoglide the mandibular incisors moved distally 0.1mm compared to 1.8mm mesial movement with the Herbst appliance.³² Lower incisor proclination is a consistent finding with the Herbst appliance and a study comparing five different lower anchorage systems for this appliance demonstrated that anterior movement of the incisors and molars could not be prevented in any of the system.⁴⁷

The same rationale mentioned above may explain the smaller overjet and molar correction found in this study compared to previous studies on the Herbst appliance. The magnetic forces acting on the dentition are not continuous leading to less dental movement with the Sydney Magnoglide. The average overjet and molar correction at the end of the new magnetic functional appliance treatment was 3.5mm and 4.7mm respectively. With the Herbst appliance overjet corrections of 6–9mm and molar corrections of 5–8mm have been reported.³⁷ It may be that attempts to overcorrect the Class II relationship with the Herbst appliance leads to excessive anchorage loss. Furthermore, relapse has been shown with the Herbst appliance post treatment with approximately 30% of the overcorrected overjet and 25% of the overcorrected molar relationship recovering after occlusal settling in the first year.^{37,48-49} The molar correction with the Sydney Magnoglide compared favourably with a study on the Twin-block, which demonstrated molar corrections of about 4.8mm.²⁴

The Sydney Magnoglide had a limited effect on the growth of the maxilla. There was on average 0.1mm more forward maxillary growth in the treated subjects during the functional appliance phase of therapy compared to the controls. This may also be attributed to smaller forces transmitted to the dentition with a magnetic functional appliance and the lack of a rigid mechanical maxilla-mandibular connection. Investigations on Twin-block therapy also demonstrate a lack of an effect on the sagittal position of the maxilla.^{24,50-52} This is unlike the Herbst appliance which has been reported to have a restraining effect on maxillary growth.³⁷⁻³⁸

The skeletal changes with the Sydney Magnoglide were due to skeletal modifications occurring exclusively in the mandible. The chin point at pogonion showed an increase advancement of about 1.9mm/year in the treated group compared to the controls. Significant changes in mandibular dimensions consisting of greater increments in total mandibular length (Co-Pg) were also found. At the end of functional appliance therapy the treated group in this study showed an average gain of 5.2mm in mandibular length, which is an average of 2.5mm more than the control group, and therefore almost twice the effect. This outcome was less favourable than the Herbst appliance, which enhances mandibular growth on average three times as much as the untreated control cases.^{32,37} A recent systematic review by Cozza *et al* reported that the amount of supplemental growth of the mandible compared with untreated Class II controls varied widely.⁵

The inclusion of the pubertal growth peak in the treatment period can probably be regarded as a key factor in the attainment of clinically significant supplemental mandibular growth with functional jaw orthopaedics.⁵ Therefore, optimal timing of dentofacial orthopaedics is intimately linked to the identification of periods of accelerated growth.²⁵ The Cervical Vertebral Maturation (CVM) method has been validated as a biological indicator of mandibular and somatic skeletal maturity.²⁸⁻³⁰ The interval between CVM stage 3 and 4 has been shown to coincide with the pubertal peak in mandibular growth and is advocated as the optimal time for Class II treatment.^{25,28-29} In the present investigation 22.6% of the subjects treated with the Sydney Magnoglide, were not treated during the optimal time. This may explain why the skeletal response was less favourable than reports of the Herbst

appliance.^{32,37} Baccetti *et al* found that treatment with the Twin-block during or slightly after the pubertal peak resulted in more than twice the amount of supplemental growth of the mandible compared to early treatment (4.75mm versus 1.88mm/year).²⁴

Different functional appliances require different treatment durations to achieve the correction of a Class II malocclusion.⁵ The active treatment time with the Sydney Magnoglide of 7-8 months compares well to the short treatment time of the Herbst appliance which is 6-8months.³⁷ Longer treatment duration may have enhanced the treatment response. The work of Tumer and Gultan illustrate this concept.⁵³ Their study of the Twin-block and monoblock appliance in patients treated during the pubertal peak failed to show clinically significant (>2mm) supplemental mandibular growth when the average active treatment was about half that reported by other studies for the same type of appliance.^{5,53} Rabie and co-workers recommend that the duration of mandibular advancement should be double the commonly reported period of 5-7 months^{32,38,54} to allow newly formed bone to mature and improved clinical results with extended treatment times.⁵⁵⁻⁵⁶

The SM showed complications in 38.7% of the patients, mainly due to debonding of the blocks. This complication rate compares favourably with the banded and cast-splint Herbst appliances which have been reported to be 67% and 60% respectively.⁵⁷ It was noted that 100% of the de-bonds were in the mandible. This indicates that there may be a problem with moisture contamination during cementation and more rigorous moisture control may yield better results in the future. Only 1.6% of the resin blocks needed repair due to exposure of the magnets. Fortunately, most of the problems can be addressed chairside and quickly as the debonded blocks were simply re-cemented, and the exposed magnets covered with composite resin.

During the second phase of treatment with fixed appliances there was statistically insignificant skeletal change in the treated group compared to the controls, demonstrating that the favourable skeletal effects with the Sydney Magnoglide were predominately maintained. Skeletal change made a limited contribution to the occlusal changes seen during fixed appliances. The overcorrected molar

relationship relapsed during fixed appliance treatment due to mesial movement of the maxillary molars (1.0mm). This finding is analogous with the effects of the Herbst appliance post treatment with approximately 25% of the overcorrected molar relationship recovering after occlusal settling in the first year.^{37,48-49}

The overjet was reduced by lower incisor proclination and upper incisor retraction. The increased proclination of the lower incisor of 4.1 degrees compared to the controls was statistically significant ($p < 0.05$). These findings are consistent with the effects of Class II elastics.⁵⁸ On average the treated subjects wore Class II elastics for 17 weeks. However, the vertical changes were minimal as there was no significant change in the Y-axis during treatment. The use of the appliance tends to create a posterior openbite in the molar/premolar region as well as a slight increase in dental overbite that is apparent at the time of removal of the Magnoglide. These occlusal discrepancies are corrected during the fixed appliance treatment.

The skeletal contribution to the overjet correction with the SM was predominately due to mandibular changes (30.2%) but a significant dental component was introduced during the fixed appliance phase to achieve complete overjet correction. Consequently, at the end of treatment the degree of lower incisor proclination parallels the results of the Herbst appliances.³² Skeletal contributions to the molar relationship were predominant (62%), and it was mainly due to significantly greater increments in the mandibular base (55%). The significant gain in mandibular length achieved with the Sydney Magnoglide was maintained, with a 2.3mm greater increase in mandibular length present at the completion of treatment. There was a statistically significant increase in the SNB at the end of treatment. Very few studies on functional jaw orthopaedics demonstrate a significant impact on the SNB angle.⁵

The outcomes of this prospective study demonstrate that the Sydney Magnoglide, is an effective functional appliance for Class II correction. The appliance offers several advantages. It is relatively aesthetic and more comfortable for patients as there is minimal vertical opening due to the buccal

placement of the magnets. Construction of the appliance is less technically demanding than cast splints required for the Herbst appliance and less expensive. However, the correct configuration of the magnets makes it more technically demanding than conventional Twin-blocks. Because of the simple nature of the appliance, complications and emergency appointments are less frequent and addressed quickly in the surgery. There are disadvantages associated with the appliance. Reactivation of the appliance is not possible and a second appliance may be required with large overjet corrections, as the magnets may be too far apart to produce a significant force to posture the mandible forward. Lastly, expansion must be performed before or after the functional appliance therapy as it pushes the magnets out of alignment.

Conclusion:

The outcomes of this prospective study demonstrate that the compliance-free Sydney Magnoglide, is an effective functional appliance for Class II correction, both in the short term and at the completion of fixed appliance therapy. The correction of the overjet and molar relation that was achieved in all patients treated with the SM were mainly associated with favourable skeletal mandibular changes. The appliance is comfortable for the patient and the very limited breakages and easy, chair-side repair confers benefits to the clinician as well.

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8.4. List of Figures

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Figure 5	Pancherz analysis showing the skeletal and dental contribution to the overjet and molar correction
Figure 6	Illustration of the gradual nature of mandibular advancement with the Sydney Magnoglide

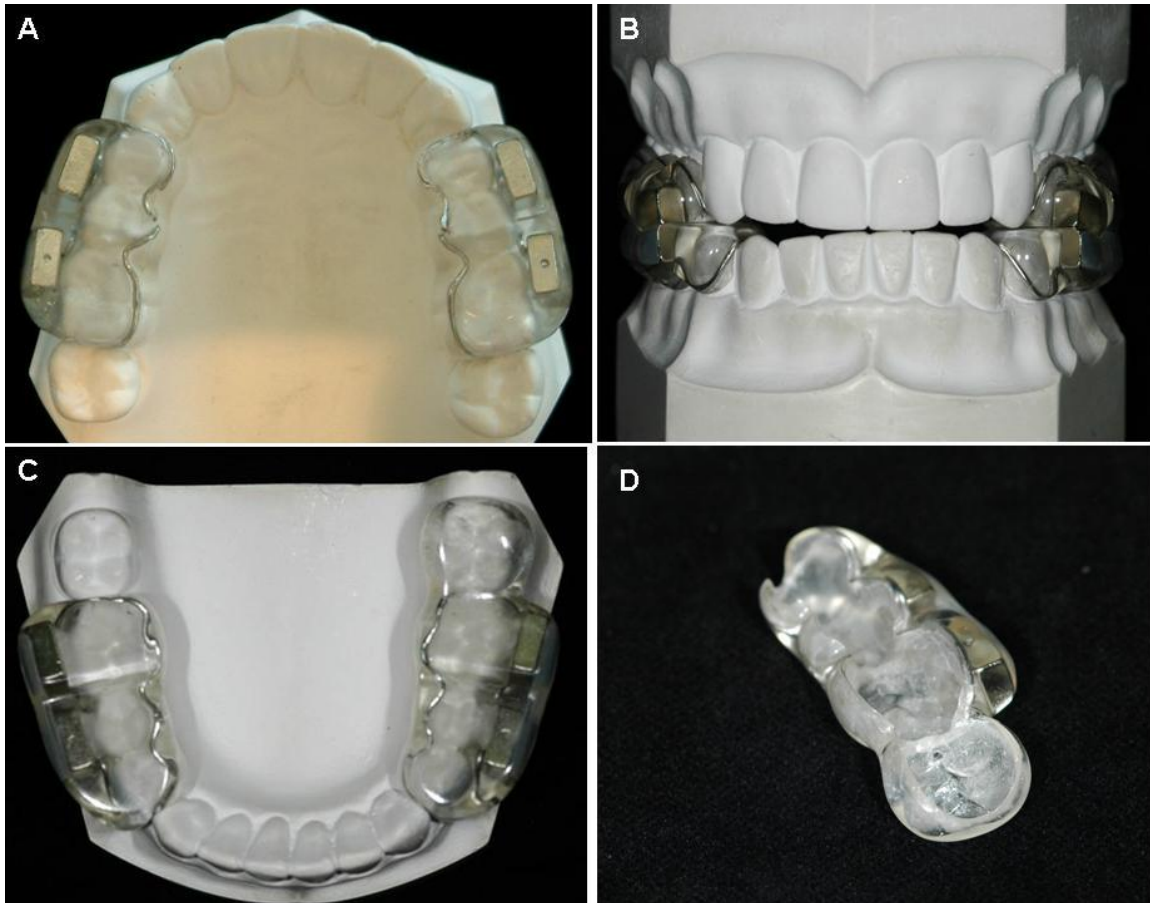


Figure 3 - Sydney Magnoglide. A, B and C demonstrates the Sydney Magnoglide's minimally obtrusive design with buccal placement of the magnets and minimal bite opening. C. The block may or may not cover the second molars depending on their stage of eruption and whether posterior eruption may be required to facilitate bite opening. D. Maxillary block with the bonding surface sandblasted for increased retention when bonding.

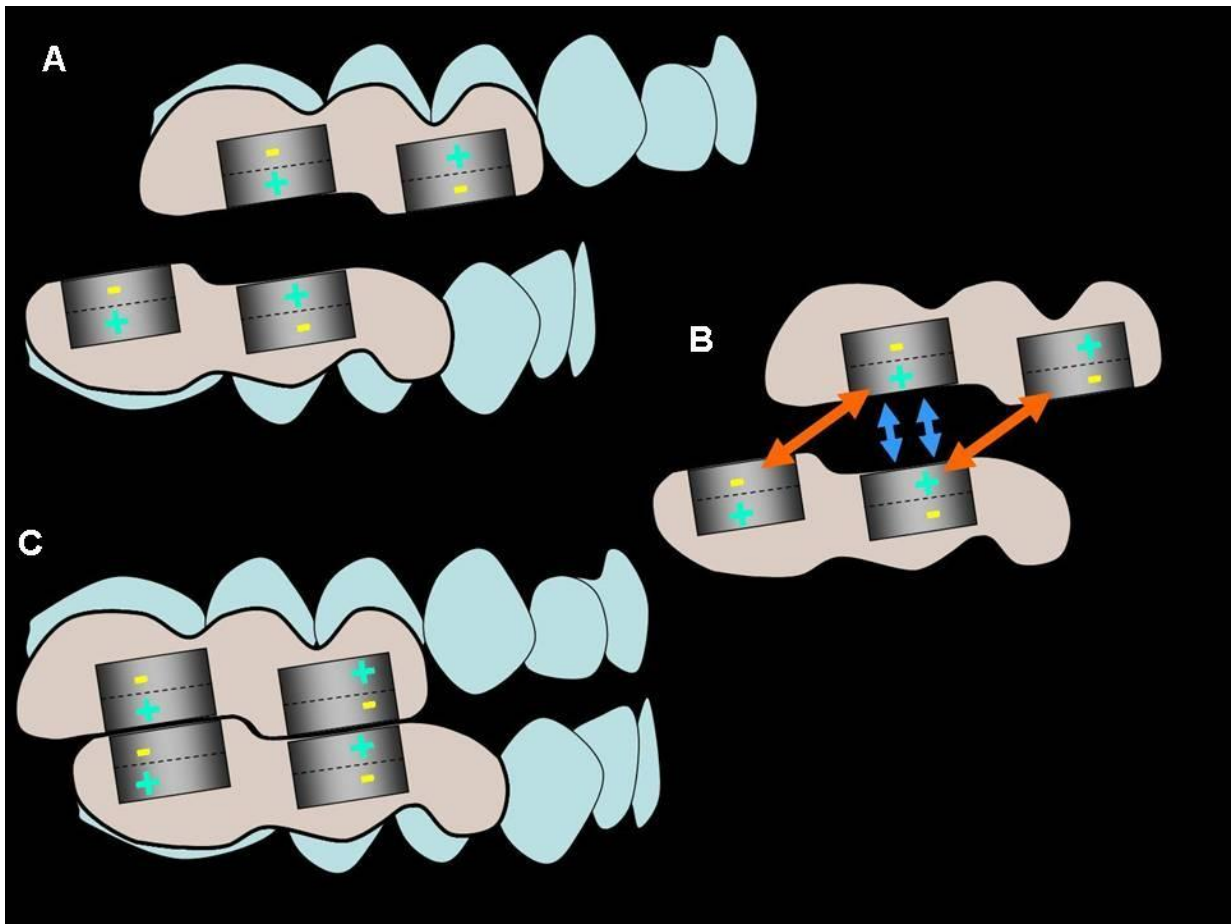


Figure 4 - A and B In centric relation (Class II) the distal magnets in the maxillary appliance will be in repulsion with the mesial magnets in the mandibular appliance (blue arrow) thus inhibiting closure in Class II relation. The distal magnets in maxillary appliance and the distal magnets in mandibular appliance will be attracted to each other, as will the maxillary and mandibular mesial magnets (red arrow), to pull the mandible forward into a Class I occlusion (C).

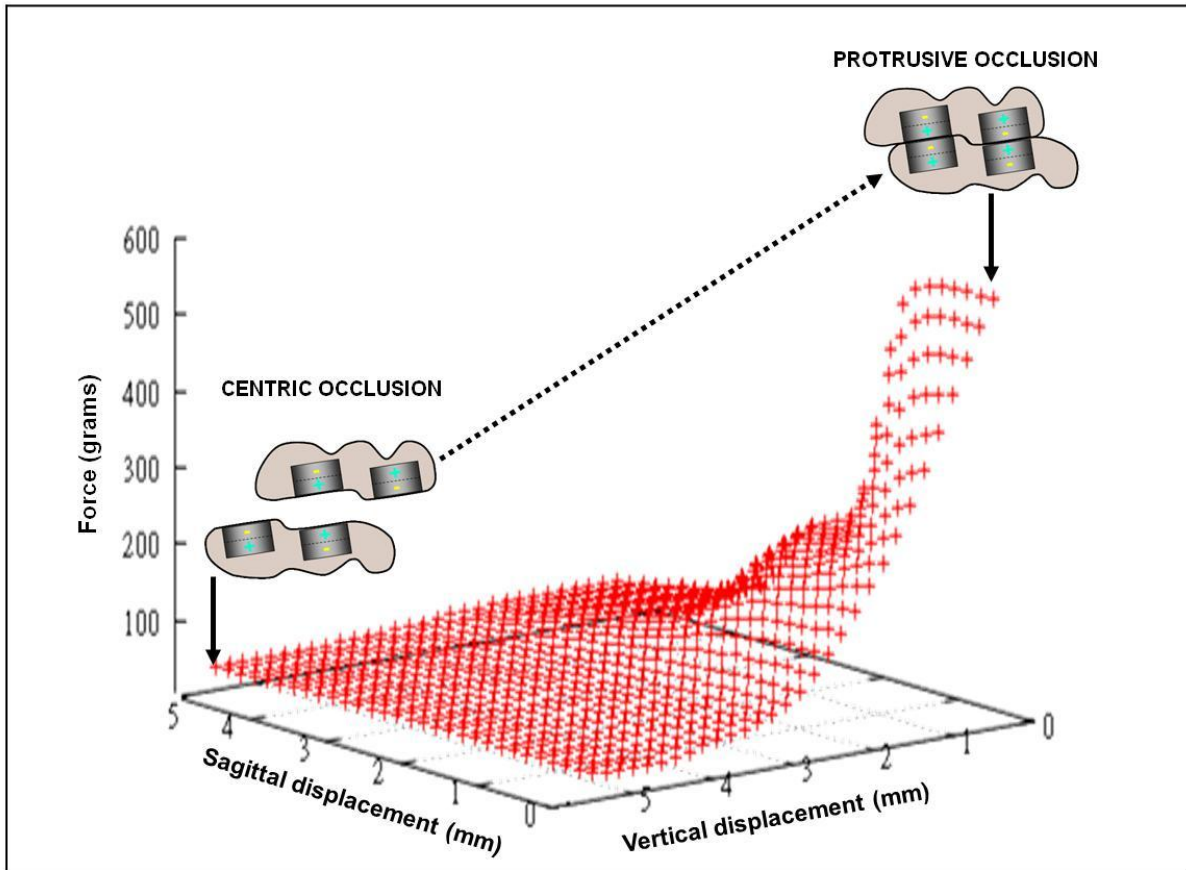


Figure 3 – Three-dimensional force-displacement curve depicting the magnetic attraction per side of the Sydney Magnoglide with sagittal and vertical displacement.

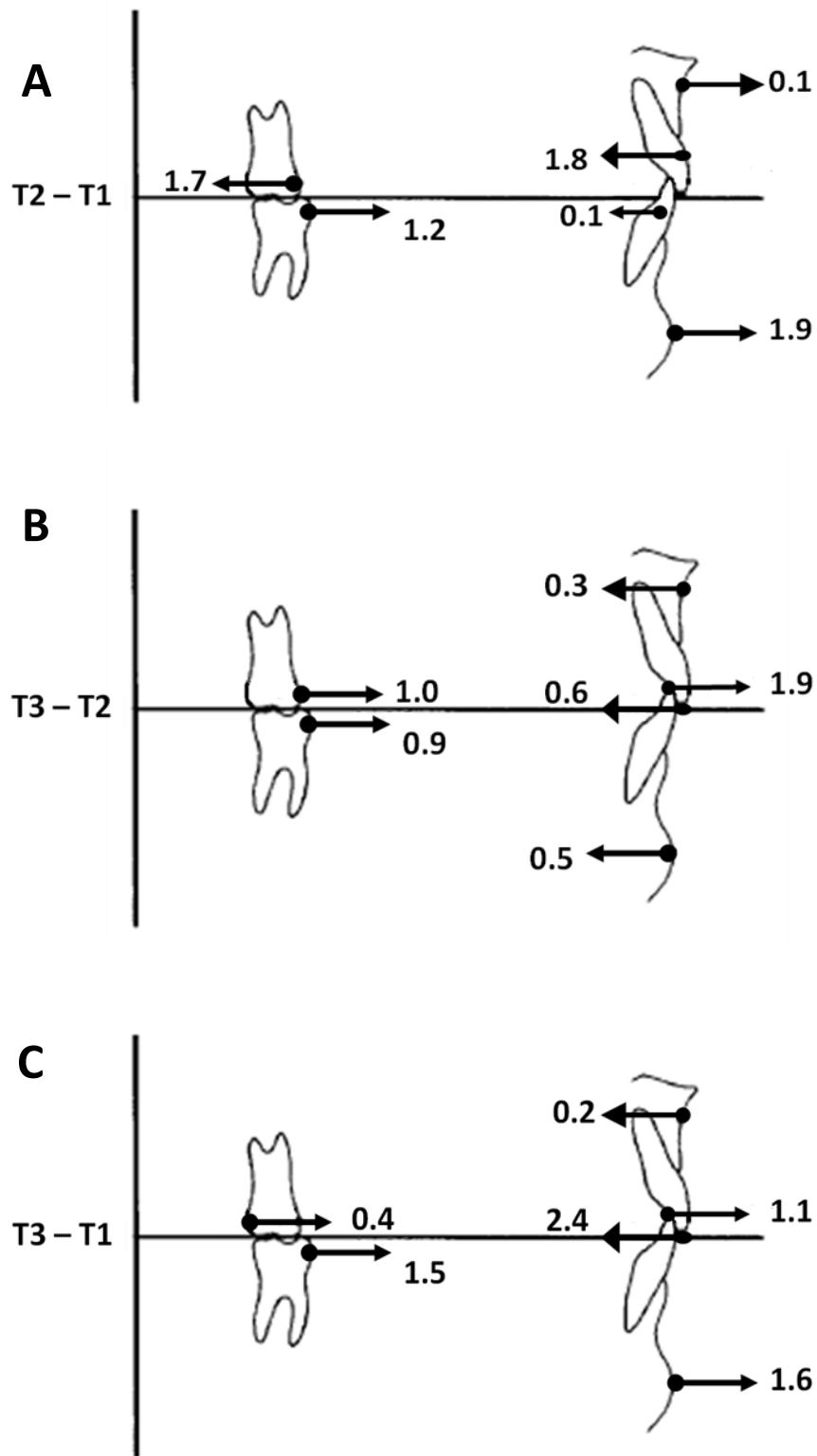
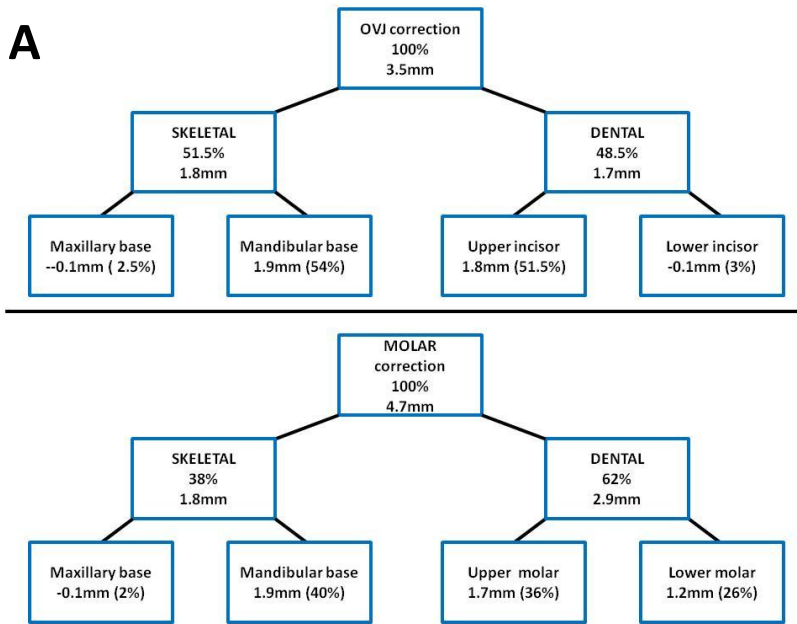


Figure 4 – Diagram of skeletal and dentoalveolar changes contributing to overjet and molar corrections: A, T2-T1 (treatment vs. control); B, T3-T2 (treatment vs. control); C, T3-T1 (treatment vs. control)

PANCHERZ ANALYSIS T2-T1 MANUSCRIPT

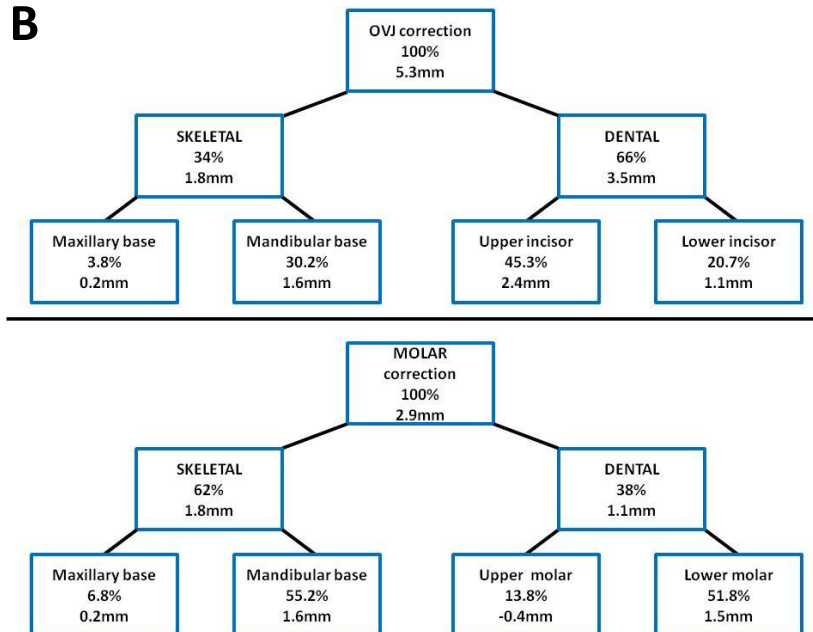
A



*Minus (-) sign indicates unfavourable change for the overjet and molar correction

PANCHERZ ANALYSIS T3-T1 MANUSCRIPT

B



*Minus (-) sign indicates unfavourable change for the overjet and molar correction

Figure 5 - Pancherz analysis showing the skeletal and dental contribution to the overjet and molar correction: A - effects of magnetic functional appliance; B - overall treatment effects.

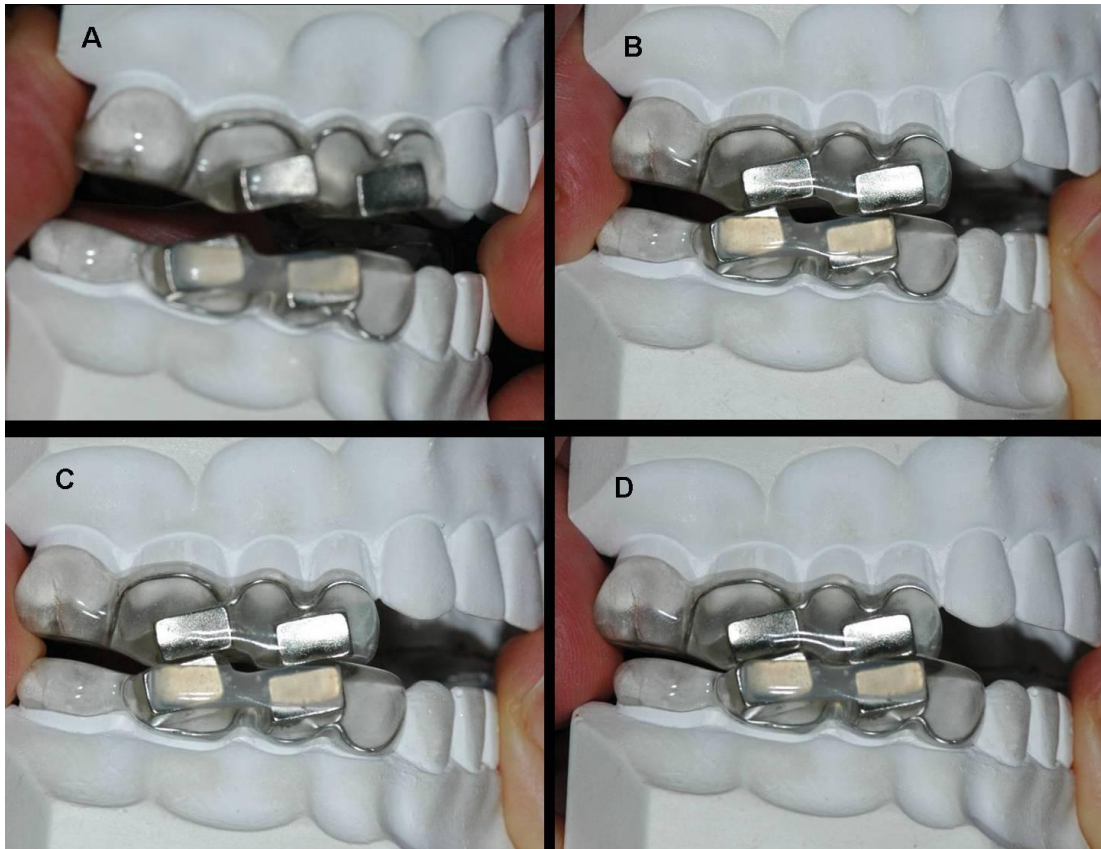


Figure 6 - This figure demonstrates the gradual movement of the mandible into Class I occlusion in the first months of treatment: A. on the day of insertion; B – C gradual sliding forward into the corrected position D the final position in Class I occlusion.

8.5. List of Tables

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Table 1- Descriptive statistics for age and CVM stage

	Magnoglide Group Class II subjects (n=31)		Control Group Untreated Class II subjects (n=30)	
At T1	Mean	SD	Mean	SD
Age (ys)	13.5	1.2	13.0	1.6
	N of subjects	%	N of subjects	%
CS1	0	0	0	0
CS2	4	12.9	2	6.7
CS3	8	25.8	13	43.3
CS4	16	51.6	14	46.7
CS5	3	9.7	1	3.3
CS6	0	0	0	6
At T2	Mean	SD	Mean	SD
Age (ys)	14.5	1.1	14.3	1.2
	N of subjects	%	N of subjects	%
CS1	0	0	0	0
CS2	0	0	0	0
CS3	0	0	0	0
CS4	20	64.5	13	43.3
CS5	10	32.3	14	46.7
CS6	1	3.2	3	10
At T3	Mean	SD	Mean	SD
Age (ys)	15.4	1.2	15.3	1.3
	N of subjects	%	N of subjects	%
CS1	0	0	0	0
CS2	0	0	0	0
CS3	0	0	0	0
CS4	2	6.5	0	0
CS5	26	83.9	15	50
CS6	3	9.6	15	50
T1-T2	Mean	SD	Mean	SD
Age (ys)	1.0	0.4	1.1	0.8
T2-T3	Mean	SD	Mean	SD
Age (ys)	1.0	0.4	1.1	0.8

Table 2- Cephalometric analysis at T1

Cephalometric Measures	Magnoglide Male (n=19) T1		Magnoglide Female (n=12) T1		Magnoglide Total (n=31) T1		Untreated Class II Controls (n=30) T1		Difference Magnoglide Total-Controls T1	Sig.†
	Mean	SD	Mean	SD	Mean	SD	Mean	SD		
SNA (°)	83.1	3.3	83.0	3.6	83.0	3.3	81.8	3.5	1.2	NS
SNB (°)	77.9	3.6	76.8	3.3	77.5	3.5	76.6	3.4	0.9	NS
ANB (°)	5.2	1.6	6.2	1.3	5.6	1.5	5.5	1.3	0.1	NS
SN-GoMe (°)	31.8	6.0	33.7	5.9	32.5	5.9	30.8	5.1	1.7	NS
Co-Gn (mm)	117.8	5.6	109.4	5.0	114.5	6.7	113.9	4.9	0.6	NS
Ar-Gn (mm)	110.6	5.9	102.8	5.1	107.6	6.7	108.1	4.8	-0.5	NS
Y axis (°)	67.1	4.5	68.0	3.8	67.5	4.2	66.7	3.8	0.8	NS
U1 to SN (°)	109.6	8.2	106.1	7.2	108.2	7.9	108.2	7.1	0.0	NS
L1 to GoMe (°)	98.5	4.3	96.0	12.8	97.5	8.5	98.7	6.2	-1.2	NS
Overjet (mm)	7.9	1.7	7.0	1.2	7.6	1.6	7.7	1.7	-0.1	NS
Molar relation (mm)	1.7	1.1	1.7	1.3	1.7	1.2	1.6	1.1	0.1	NS
Pancherz's Analysis										
Maxillary Base (mm)	81.9	3.8	79.1	3.1	80.8	3.8	80.9	4.1	-0.1	NS
Mandibular Base (mm)	82.9	5.0	78.5	6.0	81.2	5.7	79.8	5.1	1.4	NS
Maxillary Incisor (mm)	91.4	4.2	87.7	4.5	90.0	4.7	92.7	4.7	-2.7	NS
Mandibular Incisor (mm)	83.2	4.5	80.6	4.4	82.2	4.6	83.6	4.6	-1.4	NS
Maxillary Molar (mm)	57.7	4.3	55.4	3.5	56.8	4.1	55.8	4.4	1.0	NS
Mandibular Molar (mm)	56.6	4.9	54.1	4.2	55.6	4.7	54.9	4.7	0.7	NS
† Student's t-test for independent samples; NS= not significant at p<0.05; Magnification factor of cephalograms=8%										

Table 3 - Cephalometric analysis at T2-T1

Cephalometric Measures	Magnoglide Male (n=19) T2-T1		Magnoglide Female (n=12) T2-T1		Magnoglide Total (n=31) T2-T1		Untreated Class II Controls (n=30) T2-T1		Difference Magnoglide Total-Controls T2-T1	Sig.†
	Mean	SD	Mean	SD	Mean	SD	Mean	SD		
SNA (°)	-0.6	1.4	-1.2	1.9	-0.8	1.6	0.5	1.2	-1.3	*
SNB (°)	0.5	1.3	0.3	1.9	0.4	1.5	-0.2	1.5	0.6	NS
ANB (°)	-1.0	1.2	-1.5	0.9	-1.2	1.1	0.4	1.2	-1.6	***
SN-GoMe (°)	0.5	1.5	1.0	1.3	0.7	1.5	0.5	2.2	0.2	NS
Co-Gn (mm)	5.5	2.0	4.8	1.6	5.2	1.9	2.7	2.2	2.5	***
Ar-Gn (mm)	5.2	1.7	4.0	2.0	4.7	1.9	2.3	2.3	2.4	***
Y axis (°)	0.7	1.3	1.3	1.4	0.9	1.4	0.3	2.6	0.6	NS
U1 to SN (°)	-3.1	4.3	-4.5	4.9	-3.6	4.5	-1.4	3.6	-2.2	NS
L1 to GoMe (°)	-0.2	3.7	0.6	2.5	0.1	3.3	-0.3	2.4	0.4	NS
Overjet (mm)	-2.8	1.4	-3.3	0.9	-3.0	1.3	0.0	0.7	-3.0	***
Molar relation (mm)	-5.1	1.5	-5.3	1.3	-5.2	1.4	-0.1	0.8	-5.1	***
Pancherz's Analysis										
Maxillary Base (mm)	1.1	1.1	0.0	1.9	0.7	1.5	0.6	1.5	0.1	NS
Mandibular Base (mm)	3.0	2.3	2.0	3.0	2.6	2.6	0.7	2.2	1.9	**
Maxillary Incisor (mm)	0.3	1.9	-1.2	2.5	-0.3	2.2	1.4	0.8	-1.7	**
Mandibular Incisor (mm)	3.3	1.7	2.8	2.1	3.1	1.9	1.3	0.9	1.8	**
Maxillary Molar (mm)	0.0	1.4	-1.1	2.1	-0.5	1.8	1.1	1.6	-1.6	***
Mandibular Molar (mm)	4.6	2.3	3.6	2.4	4.2	2.3	1.1	1.8	3.1	***
† Student's t-test for independent samples; *p<0.05, **p<0.01, ***p<0.001, NS= not significant Magnification factor of cephalograms =8%										

Table 4 - Cephalometric analysis at T3-T2

Cephalometric Measures	Magnoglide Male (n=19) T3-T2		Magnoglide Female (n=12) T3-T2		Magnoglide Total (n=31) T3-T2		Untreated Class II Controls (n=30) T3-T2		Difference Magnoglide Total-Controls T3-T2	Sig.†
	Mean	SD	Mean	SD	Mean	SD	Mean	SD		
SNA (°)	0.5	1.1	0.2	1.6	0.4	1.3	0.0	1.4	0.4	NS
SNB (°)	0.2	1.4	0.2	1.7	0.2	1.5	-0.1	1.5	0.3	NS
ANB (°)	0.3	1.0	0.0	0.5	0.2	0.9	-0.1	0.8	0.3	NS
SN-GoMe (°)	0.3	2.0	-0.8	1.2	-0.1	1.8	-0.1	1.6	0.0	NS
Co-Gn (mm)	1.9	1.2	1.4	0.6	1.7	1.0	1.9	1.4	-0.2	NS
Ar-Gn (mm)	1.8	1.8	1.1	1.2	1.5	1.6	1.6	1.4	-0.1	NS
Y axis (°)	-0.2	1.7	-0.6	1.3	-0.4	1.6	0.1	1.7	-0.5	NS
U1 to SN (°)	-2.3	6.8	1.5	4.0	-0.8	6.1	0.6	5.4	-1.4	NS
L1 to GoMe (°)	5.7	5.8	3.4	3.7	4.8	5.2	0.5	6.2	4.3	*
Overjet (mm)	-2.7	1.7	-1.1	1.0	-2.1	1.7	-0.2	1.6	-1.9	**
Molar relation (mm)	1.9	1.7	1.9	1.5	1.9	1.6	0.2	1.7	1.7	**
Pancherz's Analysis										
Maxillary Base (mm)	0.4	1.3	-0.7	1.5	0.0	1.5	0.3	1.4	-0.3	NS
Mandibular Base (mm)	0.2	3.0	-1.3	1.8	-0.4	2.7	0.1	2.5	-0.5	NS
Maxillary Incisor (mm)	-0.8	2.7	-1.3	2.2	-1.0	2.5	-0.1	2.4	-0.9	NS
Mandibular Incisor (mm)	2.0	2.5	-0.5	2.3	1.0	2.7	-0.4	2.6	1.4	NS
Maxillary Molar (mm)	1.1	1.8	0.3	2.2	0.8	2.0	0.1	2.1	0.7	NS
Mandibular Molar (mm)	0.1	1.9	-0.8	2.3	-0.2	2.1	-0.6	2.2	0.4	NS
† Student's t-test for independent samples; *p<0.05, **p<0.01, ***p<0.001, NS= not significant Magnification factor of cephalograms =8%										

Table 5 - Cephalometric analysis at T3-T1

Cephalometric Measures	Magnoglide Male (n=19) T3-T1		Magnoglide Female (n=12) T3-T1		Magnoglide Total (n=31) T3-T1		Untreated Class II Controls (n=30) T3-T1		Difference Magnoglide Total-Controls T3-T1	Sig. †
	Mean	SD	Mean	SD	Mean	SD	Mean	SD		
SNA (°)	0.0	1.2	-1.0	1.4	-0.4	1.3	0.5	1.4	-0.9	NS
SNB (°)	0.7	1.5	0.5	1.1	0.6	1.4	-0.3	1.3	0.9	*
ANB (°)	-0.7	1.0	-1.5	0.8	-1.0	1.0	0.3	1.1	-1.3	**
SN-GoMe (°)	0.7	2.5	0.2	1.3	0.5	2.1	0.4	2.2	0.1	NS
Co-Gn (mm)	7.3	2.4	6.2	1.5	6.9	2.2	4.6	2.1	2.3	**
Ar-Gn (mm)	7.0	2.7	5.1	2.1	6.2	2.6	4.0	2.2	2.2	**
Y axis (°)	0.4	1.9	0.7	1.3	0.6	1.7	0.4	1.8	0.2	NS
U1 to SN (°)	-5.3	6.1	-3.0	5.9	-4.4	6.1	-0.8	5.7	-3.6	NS
L1 to GoMe (°)	5.5	4.5	4.0	4.1	4.9	4.4	-0.2	3.2	5.1	***
Overjet (mm)	-5.6	1.7	-4.4	1.5	-5.1	1.7	0.1	1.5	-5.2	***
Molar relation (mm)	-3.2	1.2	-3.3	1.3	-3.3	1.2	0.2	1.5	-3.1	***
Pancherz's Analysis										
Maxillary Base (mm)	1.6	1.8	-0.7	1.4	0.7	2.0	0.9	2.1	-0.2	NS
Mandibular Base (mm)	3.2	3.6	0.7	2.2	2.2	2.8	0.6	1.8	1.6	*
Maxillary Incisor (mm)	-0.5	2.8	-2.5	2.3	-1.3	2.7	1.3	2.6	-2.6	**
Mandibular Incisor (mm)	5.3	2.6	2.3	1.7	4.1	2.7	1.4	2.3	2.7	***
Maxillary Molar (mm)	1.1	2.2	-0.9	1.6	0.3	2.2	0.1	2.4	0.2	NS
Mandibular Molar (mm)	4.8	2.5	2.8	1.8	4.0	2.4	0.9	2.3	3.1	***
† Student's t-test for independent samples; *p<0.05, **p<0.01, ***p<0.001, NS= not significant Magnification factor of cephalograms =8%										

9 CASE REPORT



CASE REPORT

**Treatment utilising magnetic attachments in combination
with clear sequential aligners**

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9.1 CASE REPORT

Treatment utilising magnetic attachments in combination with clear sequential aligners

Introduction

Clear sequential aligner therapy has become a popular alternative to fixed appliances in recent years with the increased demand for aesthetic treatment options. Clear aligner therapy or clear sequential aligner treatment refers to a sequence of clear thermoplastic appliances made on a series of casts with reset teeth, each incorporating another small amount of tooth movement.¹ These appliances, which are marketed as practically ‘invisible’, are considered to be more aesthetically appealing and facilitate good oral hygiene as they can be removed for brushing.²⁻³

However, the concept of aligning teeth with thermoplastic appliances is not new. Kesling introduced the use of a flexible removable orthodontic appliance for minor tooth movement, the tooth positioner, in 1945.⁴ Nahoum later described his “vacuum formed dental contour appliance” in 1964 which utilised elastics and attachments.⁵ In the 1990s, Sheridan popularised the Essix appliance, a technique whereby clear pressure-formed thermoplastic appliances are used to perform minor tooth movements by placing divots which apply pressure to the teeth.⁶⁻⁷

Such techniques have traditionally only been used to treat minor malocclusions as only small amounts of tooth movement can be achieved with each thermoplastic appliance and the process is labour intensive.^{1,8} With the advent of three-dimensional graphical imaging and computer aided modelling techniques the process has been revolutionised.⁸ In 1999, Align Technology (Santa Clara, California, USA) introduced the Invisalign® system which computerised the process of producing sequential aligners.⁸⁻¹⁰ As a result, the ability to treat more difficult malocclusions with the technique has expanded and more recent case reports have demonstrated successful treatment of moderate to difficult orthodontic malocclusions with the Invisalign® system.¹⁰⁻¹⁹

Despite their superior aesthetics, clear aligner therapy is less effective than fixed appliance therapy.²⁰ Clear sequential aligners are quite effective in achieving tipping movements but have limited effectiveness with other types of movements such as bodily movements, rotations, extrusions and severe intrusion of teeth.^{1,21} Djeu, Shelton and Maganzini compared the treatment outcomes of Invisalign® cases and fixed appliances using the American Board of Orthodontics objective grading system and reported that the overall passing rate for the Invisalign group was 27% lower than braces.²⁰

To overcome some of the limitations of the appliance resin attachments are placed on the teeth.^{9,18,22} Attachments are generally placed on the teeth to increase the undercuts and retention of the appliance to facilitate the desired tooth movements.¹¹ However, the use of attachments has been shown to be only partially effective.^{11,22} Given the inherent limitations of the appliance they are not used routinely in severely crowded cases and are not as effective in extraction cases.^{10,23-24}

An improved system utilising small magnetic attachments has been proposed to enhance the capabilities of this appliance. In this system a sequential orthodontic appliance is combined with magnetic attachments that are positioned in an attractive or repulsive configuration on the teeth with or without magnets incorporated in the body of the thermoplastic material. The magnets used in this system are neodymium iron boron (NdFeB) rare earth magnets which have the highest energy per unit volume of any commercially available magnetic material.²⁵

Magnetic forces have been used in orthodontics for both tooth movement²⁶⁻³⁰ and orthopaedic correction³¹⁻³⁶ with varying degrees of success. The use of magnetic attachments in this application will create a magnetic force interaction that can theoretically make the movement of teeth in any direction possible and easier. The magnets initially used in orthodontics were bulky and there were concerns raised about possible toxic effects. Improved safety with better coating and the introduction of small, high energy rare earth magnets has enhanced the application of magnets in orthodontics.^{25,37}

Two cases are presented to demonstrate the ability of this system to enhance the capabilities of clear sequential aligner therapy. The initial phase of treatment was conducted using laboratory fabricated clear thermoplastic appliances in combination with magnetic attachments. After the treatment objectives of this initial phase were fulfilled conventional sequential aligner therapy was completed using the Invisalign® appliance. Clinical photographs, study models and panoramic radiographs were obtained at the start of treatment and at the conclusion of phase one of treatment. Lateral cephalograms were taken pre-treatment.

Protocol

All NdFeB magnets used in this case report were arranged in an attractive configuration. The dimension, structure, number and composition of the magnetic attachments depended on the space available, force level and type of tooth movement needed. The NdFeB magnets were plated with nickel and copper and coated with composite resin to provide an impermeable barrier, preventing ionic diffusion that would lead to corrosion, as well as facilitating the attachment of the magnet to the teeth.³⁸

The magnets were attached to the teeth using the acid-etch technique directly or with the aid of laboratory fabricated customised positioning jigs. Depending on the case requirements the magnetic attachments on the teeth were interchanged at appointments or maintained as magnets encased in the appliance were changed.

The magnetic attachments were positioned on the teeth before or after the impression for the clear sequential appliance. The impressions were poured in dental stone and clear thermoplastic appliances were prepared. A space for tooth movement was created in the thermoplastic appliance by blocking out an area of the model with plaster or heat tolerant wax. The appliances were generated using a 0.80mm thermoplastic material (Erkodur, Erkodent®, Pfalzgrafeweiler, Germany). The magnetic attachments encased in the thermoplastic appliance were incorporated during production in the laboratory using clear acrylic. Care was needed to ensure the magnets were positioned with the

correct polarity. A new impression was taken when additional appliances were required. Patients were advised to wear the appliance full time except when cleaning their teeth.

Case Presentations

The two cases presented here had non-contributory medical histories, no symptoms of temporomandibular dysfunction and expressed a desire not to have fixed appliances. Both patients had well balanced soft tissue profiles and treatment was therefore restricted to dental correction.

The first stage of treatment was conducted using laboratory fabricated clear thermoplastic appliances in combination with magnetic attachments. Limited treatment objectives were established for the first stage of treatment using the thermoplastic aligners with magnetic attachments. These treatment objectives included the completion of complex tooth movements which may be considered beyond the boundaries of conventional sequential aligner therapy. Following the achievement of these initial objectives conventional sequential aligner therapy was completed using the Invisalign® appliance.

Patient 1

The first patient is a twenty-year-old female who completed fixed appliance therapy four years prior at the Department of Orthodontics, University of Sydney. She presented for a retention review with the chief complaint that her “retainer had broken” and there was a “big gap between the front teeth now”. She had a fixed retainer which had debonded from the 22 creating a 5mm diastema between the central incisors and tipped the 22. This was not a feature of her original malocclusion. The canine and molar relationship was class I.

Appendix 1 shows pre-treatment intraoral and facial photos, panoramic radiograph (OPG) and lateral cephalometric radiograph and analysis. The OPG revealed the presence of a supernumerary above the unerupted 27. The original treatment plan included a referral to have the supernumerary and the 27 extracted to facilitate eruption of the 28. The patient failed to attend appointments for this procedure. This will be re-addressed during the current course of treatment as a new referral has been issued.

Given the patient's concerns about aesthetics, treatment was initiated prior to the extractions being performed. Furthermore, the presence of the supernumerary and unerupted 27 would not impact on the movement of the anterior teeth.

The objective of the initial phase of treatment using clear thermoplastic appliances in combination with magnetic attachments was confined to reduction of the diastema. Following this conventional sequential aligner therapy was completed using the Invisalign® appliance with the objectives of closing the small residual spaces and achieving ideal alignment of the anterior teeth.

A stainless steel wire (016) was bonded to the lingual surfaces of the 13, 12, and 11 to prevent movement of these teeth, as the facial midline was coincident with the mesial surface of the 11. Magnetic attachments were initially placed on the interproximal surfaces of the central incisors and then on the buccal surface as the space reduced. The patient was provided with clear thermoplastic appliances that incorporated space for the desired tooth movement. The dimensions of the magnetic attachments were 5x1.5x0.75mm. Magnetic forces were generated over a 3.72 mm range, reaching a maximum of 141grams. The maximum force was not reached as the resin coating material prevented full contact of the magnets. Appendix 1 shows progress intraoral and facial photographs.

The objectives of phase one of treatment were achieved within 15 weeks. Appendix 1 shows the intraoral photos, facial photos and panoramic radiograph taken at the end of this phase of treatment. The OPG demonstrates that there was minimal tipping of the incisors with the space closure. PVS impressions were then taken for construction of the Invisalign® appliance. The patient was issued with a passive thermoplastic appliance that was worn prior to receiving the Invisalign® aligners.

A total of 15 aligners were planned in the upper arch and 20 in the lower to achieve the objectives of the final phase of treatment. The pre and post-treatment ClinCheck images are included in Appendix 1 to demonstrate the intended outcome at the end of treatment.

Patient 2

The second patient is a sixteen-year-old female who began treatment with a chief complaint of “crowded teeth”. She had a Class I malocclusion with anterior crossbite of the 12 and 22, mild lower crowding and moderate upper crowding.

Appendix 2 shows pre-treatment facial and intraoral photos, panoramic radiograph and lateral cephalometric radiograph and analysis. The OPG revealed the presence of caries on the 17, 27, 37, 46 and 47. The 16 and 26 were heavily restored with breakdown of the margins evident clinically. All third molars were present and unerupted. The patient was referred to the Paediatric Department for restorative treatment. Large restorations with pulpal involvement were required on the 16, 26 and 17. Extraction of 16 and 26 was recommended. Extraction of the 16 was chosen in preference to the 17, as a better restorative seal could be achieved as the margins of the cavity were smaller. Root canal treatment is planned for the 17 in the future. The orthodontic treatment objective was to mesialise the 17 and 27 to facilitate the eruption of the 18 and 28 into a functional position.

The objective of the initial phase of treatment using clear thermoplastic appliances in combination with magnetic attachments was confined to mesialising the 17 and 27 to a point where the space is within the realm of conventional sequential aligner therapy, approximately 3 to 6mm of space closure.

Magnetic attachments were placed on the interproximal surfaces of the upper second premolars and upper second molars. The dimensions of the magnetic attachments varied during treatment. The patient was provided with clear thermoplastic appliances that incorporated a larger magnet (4x4x2mm) and space for the desired tooth movement. As the extraction space decreased the magnetic force generated between the attachments was sufficient to provide the force for space closure. 4x3x0.75mm and 4x2x0.75mm magnetic attachments were used in quadrant 1 and 2 respectively at this stage. The appliance was used as anchorage to prevent the distalisation of the second premolars as the 17 and 27 were mesialised. The 4x3x0.75mm magnets generated magnetic forces over a 5.2 mm range, reaching a maximum of 168grams. The 4x2x0.75mm magnets generated magnetic forces over a 3.7 mm range, reaching a maximum of 115grams. The maximum force was

not reached as the resin coating material prevented full contact of the magnets. Appendix 2 shows progress intraoral and facial photographs.

The objectives of phase one of treatment were achieved within 10 months and 2 weeks. The 17 and 27 had been mesialised sufficiently to allow partial eruption of the 18 and 28. Appendix 2 shows the intraoral photos, facial photos and panoramic radiograph taken at the end of this stage of treatment. PVS impressions were then taken for construction of the Invisalign® appliance. The patient was issued with a passive thermoplastic appliance prior to receiving the Invisalign® aligners.

A total of 44 aligners were planned in the upper arch and 38 in the lower to achieve the objectives of the final phase of treatment. The pre and post-treatment ClinCheck images are included in Appendix 2 to demonstrate the intended outcome at the end of treatment.

Discussion

This case report demonstrates the potential for magnetic attachments to expand the scope of clear sequential aligner therapy. The initial phase of treatment with the magnetic attachments was confined to specific treatment objectives, as the appliances were manually fabricated in the laboratory. Manual methods generally do not allow the treatment of more serious malocclusions as they require laborious and detailed setups to be done by the technician.⁸ The application of a three-dimensional graphical imaging and computer aided modelling technique would expand the capabilities of this technique. The Invisalign® system is generated using a computer-based manufacturing process.⁸ The proposed use of magnetic attachments could easily be integrated into such a system.

Patient compliance is a critical factor for successful treatment with clear sequential aligners¹³.

Treatment success is dependent on how compliant the patient is with wearing the aligners. The same applies to this system using magnetic attachments. Treatment efficiency was achieved in the first case as the magnetic attachments were bonded to the teeth and the appliance was used for anchorage and to guide the tooth movement. When the magnetic attachments are incorporated in the aligner the

appliance is only active when it is being worn. This may explain why the treatment of the second case was longer than anticipated.

Limitations were identified during treatment. The aesthetics of the magnetic attachments were not ideal with a tooth coloured resin coating. Problems were encountered with breakage of the appliances and attachments during treatment. Full-time wear of the appliance, especially during eating, was necessary to avoid complications with the magnets. Therefore, further research is necessary to identify an ideal coating material that effectively seals the magnets, has minimal thickness, facilitates bonding to the tooth surface and is aesthetically acceptable.

Conclusion

This case report demonstrates the potential for magnetic attachments to expand the scope of clear sequential aligner therapy, but future research is necessary to identify an ideal coating material.

References

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9.3. Appendix 1

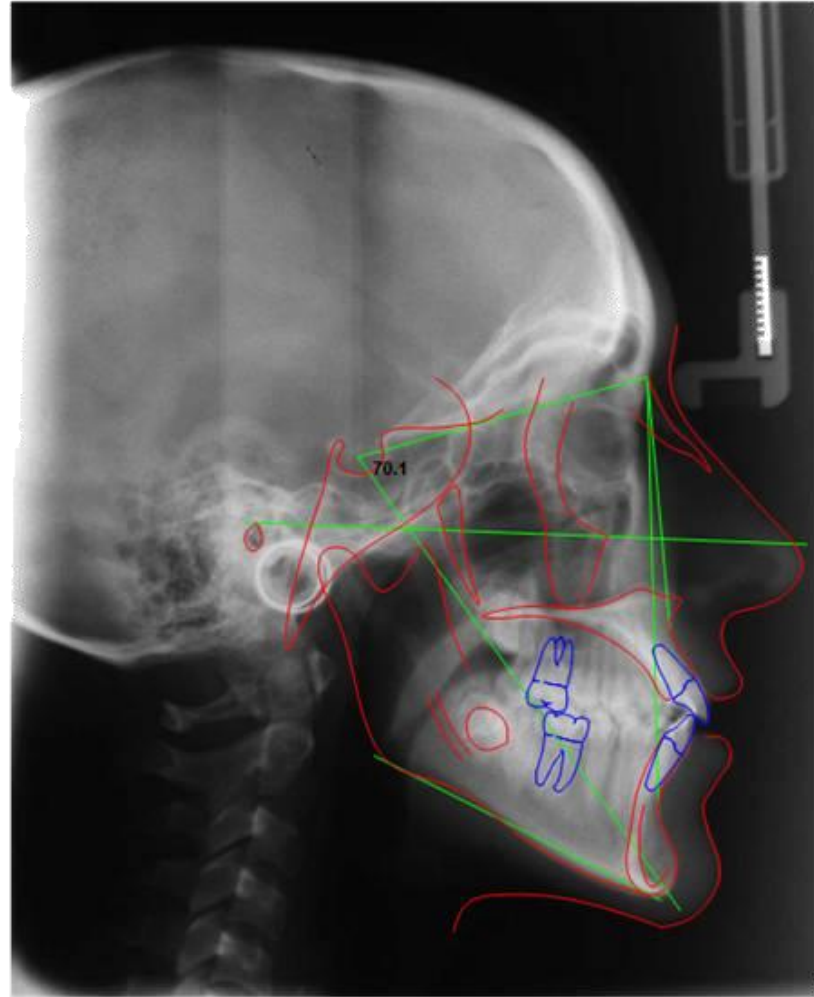
List of Images

Image 1	Pre-treatment intraoral and facial photographs, panoramic radiograph and lateral cephalometric radiograph and analysis
Image 2	Pre-treatment lateral cephalometric radiograph and analysis
Image 3	Pre-treatment panoramic radiograph
Image 4	Progress intraoral and facial photographs - first day appliance was issued
Image 5	Progress intraoral photographs
Image 6	End of Phase 1 – intraoral and facial photographs
Image 7	End of Phase 1 - panoramic radiograph
Image 8	Phase 2 pre-treatment ClinCheck images
Image 9	Phase 2 post-treatment ClinCheck images



APPENDIX 1

Image 1: Pre-treatment intraoral and facial photographs, panoramic radiograph and lateral cephalometric radiograph and analysis



APPENDIX 1

Image 2: Pre-treatment lateral cephalometric radiograph and analysis



APPENDIX 1

Image 3: Pre-treatment panoramic radiograph



APPENDIX 1

Image 4: Progress intraoral and facial photographs - first day appliance was issued



T = 0



T = 8 weeks



T = 12 weeks



T = 15 weeks
Completion Phase 1

APPENDIX 1

Image 5: Progress intraoral photographs



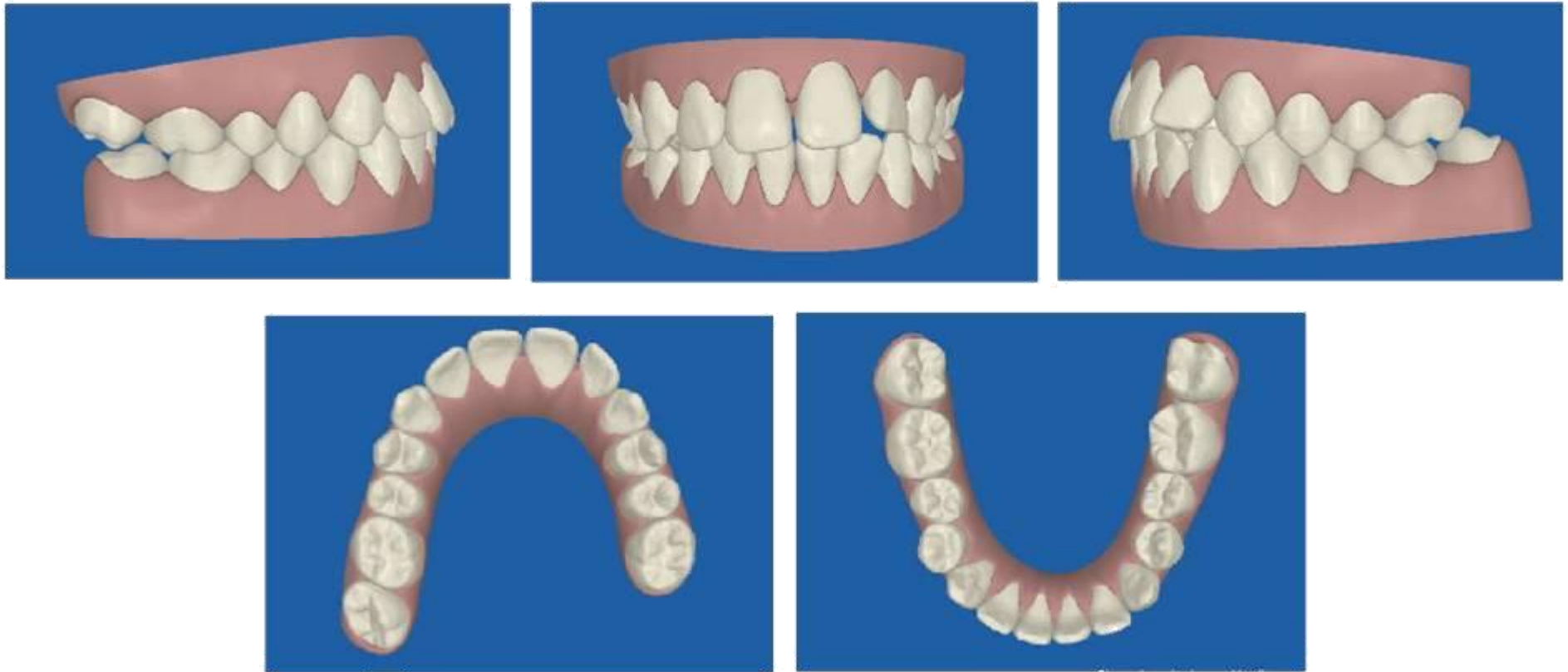
APPENDIX 1

Image 6: End of Phase 1 – intraoral and facial photographs



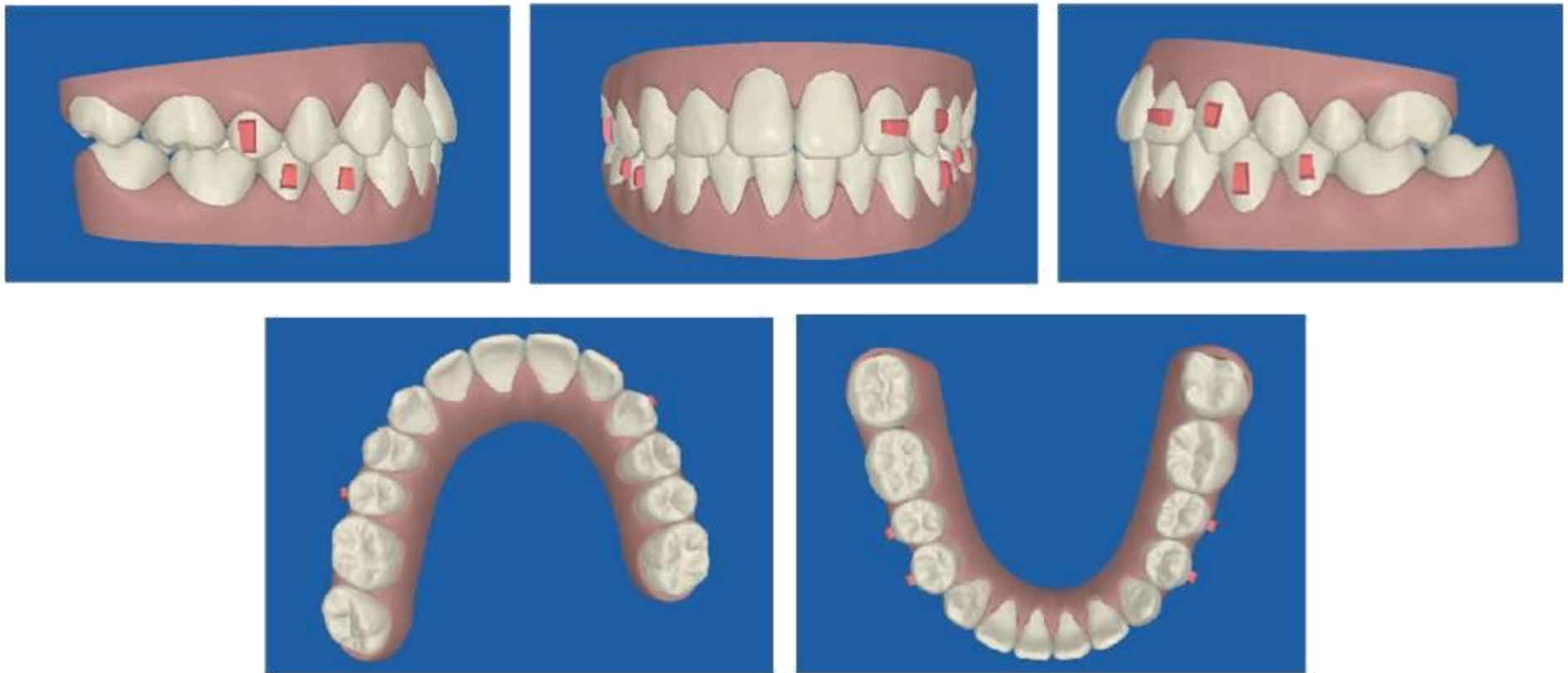
APPENDIX 1

Image 7: End of Phase 1 - panoramic radiograph



APPENDIX 1

Image 8: Phase 2 pre-treatment ClinCheck images



APPENDIX 1

Image 9: Phase 2 post-treatment ClinCheck images

9.4. Appendix 2

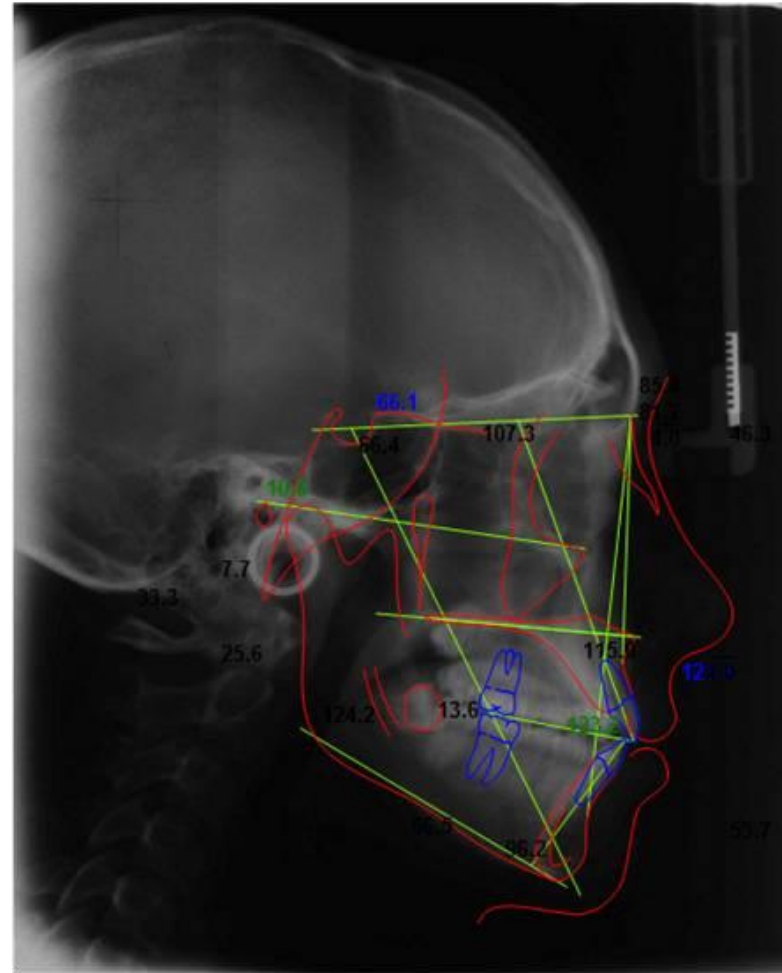
List of Images

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Image 6	End of Phase 1 – intraoral and facial photographs
Image 7	End of Phase 1 - panoramic radiograph
Image 8	Phase 2 pre-treatment ClinCheck images
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APPENDIX 2

Image 1: Pre-treatment intraoral and facial photographs, panoramic radiograph and lateral cephalometric radiograph and analysis



APPENDIX 2

Image 2: Pre-treatment lateral cephalometric radiograph and analysis



APPENDIX 2

Image 3: Pre-treatment panoramic radiograph



APPENDIX 2

Image 4: Progress intraoral and facial photographs - first day appliance was issued



T = 0



T = 2mths 2wks



T = 5mths 0wks



T = 7mths 1wks



T = 8mths 1wks



T = 10mths 0wks



T = 10mths 2wks



T = 10mths 2wks
Completion Phase 1



Comparison to Initial

APPENDIX 2

Image 5: Progress intraoral photographs



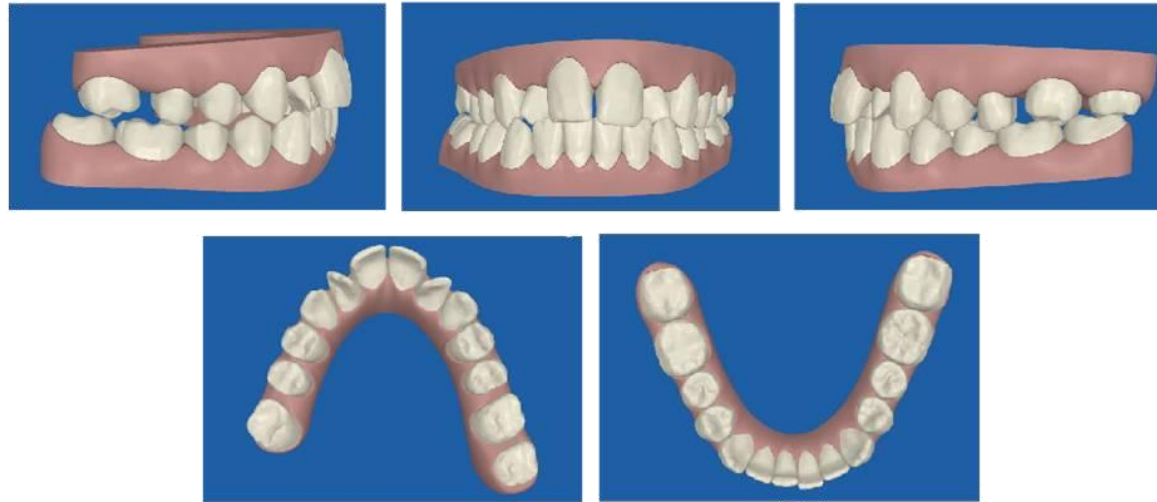
APPENDIX 2

Image 6: End of Phase 1 – intraoral and facial photographs



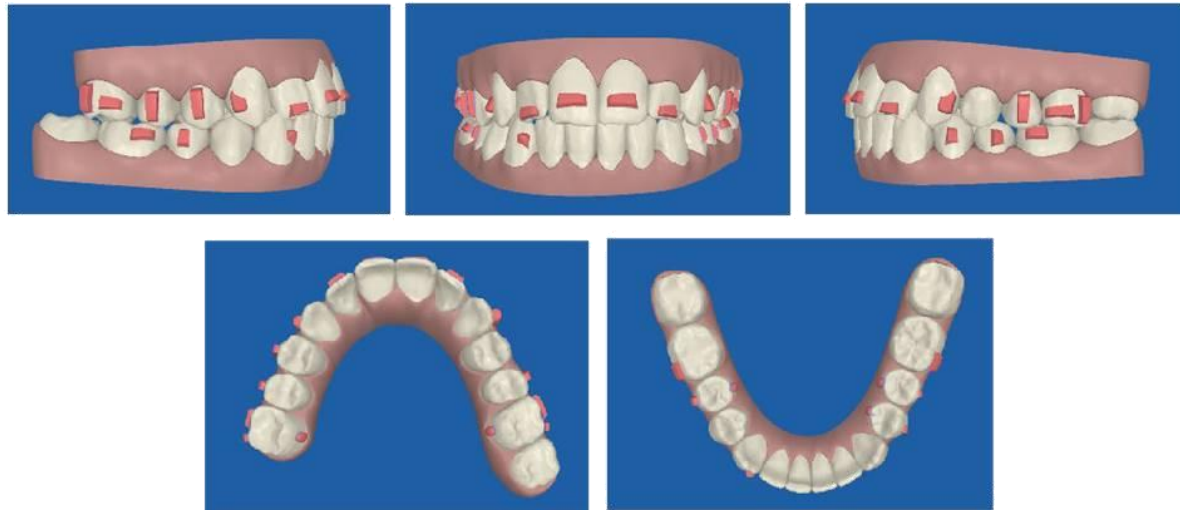
APPENDIX 2

Image 7: End of Phase 1 - panoramic radiograph



APPENDIX 2

Image 8: Phase 2 pre-treatment ClinCheck images



APPENDIX 2

Image 9: Phase 2 post-treatment ClinCheck images

10 FUTURE DIRECTIONS

The intention of this thesis was to investigate the application of magnet force delivery in the two principle facets of orthodontic treatment, tooth movement and orthopaedic treatment. The use of magnetic forces were examined in two situations – facilitating tooth movement in combination with clear sequential aligners and orthopaedic correction with a new magnetic functional appliance, the Sydney Magnoglide.

In this thesis the force-displacement characteristics of a range of magnets were measured in one dimension, the vertical dimension, with the surfaces parallel to each other. If the magnets were applied clinically as attachments in combination with clear sequential aligners it is unlikely that such conditions would be replicated and it is possible that the magnets could be offset in all three planes of space. Since both forces and moments work in all three planes, the effective force system acting on a tooth should be represented in three-dimensions. 3-D forces and moments generated by magnetic devices have been measured in previous investigations. Therefore, a recommendation for future research is the characterisation of the three-dimensional force-displacement and moment-displacement diagrams of the most ideal magnetic attachments identified in this investigation.

The use of small magnetic attachments was proposed to enhance the capabilities of clear aligner therapy. Given that appropriate force levels have been verified, clinical investigation of this technique is now warranted. Future research is needed to identify an ideal coating material that effectively seals the magnets, has minimal thickness and is aesthetically acceptable.

A prospective study was conducted to determine the skeletal and dental effects of the Sydney Magnoglide. The design of the appliance has evolved to improve efficiency and patient comfort. Further research that compares the outcomes of different versions of the Sydney Magnoglide would be beneficial as it will elucidate the ideal design of the appliance.

Furthermore, the ideal intensity of the force that should be used in a magnetic functional appliance has not been determined. Analysis of the magnetic forces generated by various versions of the Sydney Magnoglide has not been performed. Therefore, a recommendation for future investigation would be to determine and compare the spatial force/displacement (F/D) and moment/displacement (M/D) diagrams of the Sydney Magnoglide. A detailed analysis of the forces generated by different versions of the Sydney Magnoglide would also help to determine the optimal appliance design.

Construction of the Sydney Magnoglide is less technically demanding than cast splints required for the Herbst appliance. However, the correct configuration of the magnets makes it more technically demanding than conventional Twin-blocks. Therefore, a study that compares the effects of the Sydney Magnoglide to a similar appliance without magnets is also a worthwhile investigation.

Lastly, the evidence available from tests of the safety and biological properties of magnets suggest that the risks of biological harm are negligible. The current evidence indicates that coated NdFeB magnets are acceptable for clinical use. However, several authors have acknowledged the need for additional studies to be conducted on the biological effects of magnets, as contradictory findings exist in the literature. Therefore, research on the biological effects of magnets is another possible direction for further study.