An injectable bone graft substitute to enhance the primary stability of a novel miniscrew – The Sydney Mini Screw

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Introduction: Anchorage is crucial in controlling tooth movement during orthodontic treatment. Different designs have been introduced to increase the stability of miniscrews. A new miniscrew, The Sydney Mini Screw (SMS), with a hollow chamber and lateral port holes, has been developed to allow the diffusion of an injectable bone graft substitute (iBGS) into cancellous bone. The aim of this study was to analyse the optimum iBGS application with ideal chemo-mechanical properties to be used in conjunction with the novel SMS.

Method: A composite calcium sulphate and calcium phosphate bone graft substitute was examined. The effects of powder particle size, and the powder-to-liquid ratio on the injectability of the iBGS through the SMS were investigated. The viscosity, injectability, and mechanical properties of the new composite mixtures were assessed using rheology and universal compression measurements.

Results: The results showed that the optimised injectable formulation of the bone cement was acquired with the concentration of 2.5 g/ml. This concentration was readily injectable through the SMS, and its setting time was within 2–3 minutes, which is favourable for clinicians. In addition, the resulting structure fractured at 80 kPa compression stress.

Conclusion: The result of this study identified the specific particle size and powder-to-liquid ratio of the iBGS that can be used in conjunction with the new SMS to enhance the primary stability of orthodontic miniscrew applications.

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Introduction

Temporary anchorage devices (TADs) were introduced almost three decades ago as an alternative to osseointegrated implants for skeletal anchorage.1-2 TADs eliminate the need for patient compliance and provide absolute anchorage, aiding in maximising orthodontic treatment outcomes. Miniscrews are the most commonly used type of TAD and are of smaller dimension, lower cost, and can be placed chair-side. However, their failure rates remain unacceptably high and in the range of 0% to 41%.3-7 While numerous factors such as bone quality, miniscrew design, soft tissue inflammation, root proximity and surgical technique have been documented to affect primary stability, cortical bone engagement is found to be the predominant factor.4,8,9

Alterations in miniscrew design and placement techniques have been proposed to improve miniscrew success rates and acquire safer and more reproducible clinical outcomes.10,11 The results of studies
investigating different surface treatments and designs are conflicting as some show no statistical difference while others show increased stability.\textsuperscript{12,13}

Injectable calcium phosphate cements (iCPC) have been recently investigated for orthopaedic applications in dental and craniofacial procedures due to their exceptional biocompatibility, self-setting characteristic and osteo-conductive properties that allow successful repair of bone defects.\textsuperscript{12,13} No significant anchorage increase has been shown between dental implants tested with or without the addition of an injectable form of calcium phosphate bone graft substitute (BGS) in implant beds.\textsuperscript{14} However, when calcium phosphate BGS was applied in extraction sockets, it was shown to optimise angiogenesis and bone remodelling.\textsuperscript{15} Like most ceramics, calcium phosphate BGS is brittle and cannot be used alone in load bearing applications.\textsuperscript{16} A combination of calcium sulphate and calcium phosphate ($\text{CaSO}_4/\text{CaPO}_4$; Pro-Dense\textsuperscript{®}) was later introduced to address this problem.\textsuperscript{17}

In 2010, a novel orthodontic miniscrew, The Sydney Mini Screw (SMS) was designed to increase primary stability through the application of an injectable bone graft substitute through its hollow lumen into cancellous bone.\textsuperscript{20} The aim of the present study was to assess the feasibility of using an injectable BGS (iBGS) with the SMS in an attempt to enhance the primary stability of miniscrews. The ease of injection, setting time and mechanical strength of the BGS were investigated.

Material and methods

\textbf{The Sydney Mini Screw design}

The specifications of the miniscrew tested in this study were 6 mm in length, and an outer thread diameter of 2 mm (Figure 1-A). The design of the SMS (Patent number: PCT2009014) was based upon the clinically proven Aarhus anchorage system (Medident, Hellerup, Denmark) with the addition of a hollow centre and exit holes. Titanium cannulated cylinder design miniscrews were manufactured by Russell Symes and Company Pty Ltd, Sydney, Australia. The central cannulated portion of the screw was 0.6 mm in diameter and extended from an open head to lateral portholes. The cannula at the head was widened to 0.92 mm for a depth of 3.8 mm to accommodate the thickness of a 20-gauge syringe tip. The two lateral portholes had a diameter of 0.40 mm and were positioned between the screw threads towards the bottom of the miniscrew body.

The scanning electron microscope (SEM, EVO 50 SEM, Carl Zeiss, Germany) images of the lateral and top views of the SMS are shown in Figure 1.

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{figure1.png}
\caption{The Sydney Mini Screw [A] Front and section view dimensions (Unit: mm); [B] lateral port hole layout; [C] top view of the miniscrew head showing a custom-made chamber for internal threaded surface for 20-gauge needle connection; [D] Side view of one of the lateral port holes.}
\end{figure}
The SMS was first modelled in a computer aided design (CAD) package, the Computer Aided Three-dimensional Interactive Application (CATIA) (Dassault Systèmes, Vélizy-Villacoublay Cedex, France). The CAD model of the SMS was subsequently used for direct manufacturing and finite element analysis (FEA). Computer software, Abaqus (Dassault Systèmes, Vélizy-Villacoublay Cedex, France), assigned a mesh of elements onto the miniscrew. The material properties, boundary conditions and loading case were defined in the software. The mesh model employed the 4-node tetrahedral element type to manage the complex topography. Determined by a convergence test, the global mesh seed was set at 0.1 mm intervals with a local mesh seed at 0.02 mm for the thread tip and around the lateral extrusion holes. The material property of the SMS was a homogenous titanium Ti-6Al-4V (Grade 5), UNS R56401 of which the properties of relevance were a density of 4.43 g/ml, modulus of elasticity of 114 GPa, tensile strength (yield) of 1.1 GPa, and a Poisson’s ratio of 0.33. The 1 mm tip surface of SMS was set with fixed surface contact simulating the insertion of the miniscrew into cortical bone. In this configuration, all six degrees of freedom were bound at the tip. The loading torque was set as a moment of 1000 Nm located on the surface of SMS head as recommended by Carano et al.18

Injectable bone graft substitute

The iBGS used in the present study was a non-sterile commercially available synthetic bone graft composite (PRO-DENSE® Extremity Mixing Pack, Wright Medical Technology, Inc., TN, USA). The PRO-DENSE® material was composed of 75% CaSO₄ and 25% CaPO₄ (brushite and granular TCP) powders and glycolic acid liquid.17

Particle size

The particle size distribution of both CaSO₄/CaPO₄ powders was determined with a laser granulometer (Mastersizer 2000, Malvern Instruments Ltd., UK). Three initial measurements were performed using sodium hexametaphosphate as a suspension medium for the original particle size of the commercially available product. The commercially available iBGS was designed to pass through needles larger than 20-gauge. Therefore, the particle size had to be modified to be less than 63 μm. This was achieved by grinding the powder under dry conditions with an agate mortar and pestle. The ground powder was sieved using a stainless-steel frame and mesh of 63 μm aperture (Endecotts LTD, London, UK) to exclude particles above that mesh pore diameter.

Furthermore, the effect of different powder to liquid ratios (PLR) was examined by constant weight to varying liquid ratios to find out the appropriate combination for optimal injectability.

The iBGS was prepared under the same conditions and at room temperature prior to each experiment. The cement powders were prepared by proportioning and subsequent mixing of both CaSO₄ and CaPO₄ powders with the liquid using a flexible silicone cup and a plastic spatula, resulting in a viscous and cohesive mixture. For each formulation, iBGS pastes were prepared by mixing the cement powders and liquid by hand for 30 seconds. This resulted in a workable paste that was transferred to a disposable 1 cc syringe (BD Luer-Lok™ Tip, Singapore).

Injectability testing

Twenty gauge, blunt-type, 10-mm-long needles with inner and outer diameters of 0.6 mm and 0.9 mm, respectively (BD PrecisionGlide™ Needle, Singapore), were trialled. Cross-section apertures of needles and miniscrew lateral portholes were observed under a microscope (Olympus VE-3 Stereomicroscope, Tokyo, Japan) with 40x magnification to confirm the absence of interfering metal particles. The handling time was 1.5 minutes, which allowed mixing and loading of the iBGS into syringes.

To assess the injectability of the different PLR, the extrusion pressure of different samples through 20-gauge needles was measured by an Instron Universal Testing machine, type 3366 (Instron®, PA, USA). A compression rate of 60 mm/min and a maximum force 200 N were set as default and all tests were carried out at 25 °C. The sample was considered injectable when complete extrusion of the paste with driving force below 200 N was achieved.

Gelling point analysis

Dynamic rheological tests such as gelling and fractural behaviour of the CaSO₄/CaPO₄ composite...
paste were performed, using a rheometric dynamic spectrometer (Physica MCR 301, Anton Paar, Graz, Austria) in dynamic oscillation mode. A parallel plate configuration was used to analyse the rheological characteristics of the paste over time. The diameter of the upper plate was 25 mm. Similar to injectability testing, iBGS samples were prepared, loaded into 1 cc syringes and extruded using 20-gauge needles. The upper plate was moved down until the gap between the two plates reached 3 mm. There was 0.48 cc of iBGS paste extruded to the centre of the bottom plate. The plates were then brought closer together to reach about 1 mm. The excess iBGS was trimmed before the rheometer was started. A temperature of 25°C and a frequency of 1 rad/sec were selected as default. The instrument was used in 1% constant strain mode.

**Mechanical property analysis**

Mechanical testing was used to determine the compressive strength of iBGS at different concentrations. The iBGS were transferred into a handmade translucent cylindrical mould with a height of 12 mm and a diameter of 6 mm, following the standard testing guideline of the American Society for Testing and Materials (ASTM) ASTM C-773. After two hours, the cylindrical specimen was removed from the mould and the dimensions were calculated. Measurement was performed using an electronic digital calliper (MAX-CAL; micrometer MFG, Co., Ltd, Japan) with an accuracy of 0.01 mm. The compressive strength was tested using an Instron Testing Machine 3366. A total of nine cylinders were tested using a crosshead speed of 1 mm/min until obvious specimen failure was observed. This was indicated by a substantial drop in the load curve.

**Results**

**Finite element analysis**

FEA testing indicated that the 1.9 mm SMS with 0.4 mm diameter lateral ports under a torsional load (similar to bone insertion) exhibited maximum stress. The macro- and micro-structure of the examined miniscrew is shown in Figure 1. The maximum tension stress achieved was 441 MPa as shown in Figure 2. The margin of safety for this design is approximately 150% above the design load, thus it performed well within all normal clinical parameters with an acceptable safety margin.

**Particle size distribution analysis**

Particle size distributions of calcium sulphate and calcium phosphate particles before and after grinding are shown in Figure 3. Upon grinding, the median size of the CaSO\(_4\) and CaPO\(_4\) powders decreased from 22 \(\mu\) to 16 \(\mu\) and 160 \(\mu\) to 45 \(\mu\) respectively.

**iBGS mixing and injectability testing**

Attempts using the commercially available iBGS in the pilot studies resulted in blockage of the small needles. Therefore, other than changing the particle size, the powder/liquid mass ratio of the iBGS was also gradually varied from 2.3 mg/ml to 3.1 mg/ml. Decreasing the liquid to create mixtures with a PLR higher than 3.1 mg/ml resulted in granular and unworkable pastes that could not be injected with a force \(\leq 100\) N.\(^{19}\) Therefore, for further evaluations and optimisation, iBGS concentration was limited to below 3.1 mg/ml.

![Figure 2.](image)
The extruded volume of the paste at different concentrations was measured (Figure 4). It was shown that 1 ml of the paste was extruded for the mixtures with a concentration of 2.3 mg/ml to 2.7 mg/ml. A further increase of powder concentration resulted in incomplete extrusion of the mixture (0.8 ml). For each test, maximum force for extrusion and at failure was also recorded (Figure 4).

The results of the injection test showed that iBGS samples with concentrations greater than 2.7 mg/ml were not injectable through a 20-gauge needle. Therefore, concentrations above 2.7 mg/ml failed to exhibit a fundamental property and consequently were considered not suitable for use in conjunction with SMS.

Accordingly, for further evaluations and to optimise the gelling point and the mechanical properties of iBGS, only concentrations ranging between 2.3 mg/ml to 2.7 mg/ml were used.

**Gelling point**

The gelling point of the paste with different powder concentrations was assessed using the rheology test. Increasing the powder concentration from 2.3 mg/ml to 2.7 mg/ml resulted in a longer setting time, 62.5 seconds compared with 85 seconds (Figure 5). Therefore, increasing the PLR led to slower gelation.

The results of the rheology test were also used to determine the fracture point of the iBGS (Figure 6). Increasing the concentration of the powder from 2.3 mg/ml to 2.7 mg/ml resulted in a decrease of fracture point by approximately half. Therefore, increasing the concentration of the powder in the mixture resulted in formation of a more brittle material.

**Mechanical property analysis**

The mechanical properties of the paste also play an important role in obtaining a workable iBGS that is clinically applicable. Therefore, more concentrated pastes (2.3 mg/ml, 2.5 mg/ml, and 2.7 mg/ml) were selected for further analysis. Results from the rheology test were in agreement with the result gained from the compression test in which the ultimate failure load for the cement pastes decreased from 415 N to 300 N by increasing the concentration of the powder from 2.3 mg/ml to 2.5 mg/ml (Figure 6).
Discussion

The feasibility of using iBGS in conjunction with a hollow miniscrew was investigated in the current study. The CaSO₄ component in the composite CaSO₄/CaPO₄₂₀ iBGS has been reported to exhibit fast-degradation allowing enhanced vascular infiltration and bone deposition.²¹ Both of these properties are of great benefit to enhance the osseointegration and the primary stability of a miniscrew following its insertion.

The initial results of the injectability tests warranted modifications to the design of the SMS. A slight increase in the overall size of the miniscrew allowed the use of a larger gauge needle,²² increasing the injectability of the BGS. A wider miniscrew hollow port with an internal diameter of 1.4 mm matched the outer diameter of a 20-gauge needle, which is known to be used for endodontic root canal fillings and to seal furcal perforations.²²,²³ In the present study, the secure fit of the 20-gauge needle at the head of the miniscrew allowed optimum seal during injection of the BGS. These modifications minimised the tendency for the iBGS to extrude from the top of the miniscrew and allowed better delivery of the material through the miniscrew and into the cancellous bone.

The preliminary trials also suggested that the loss of pressure within the internal chamber of the miniscrew was the key to the injectability of iBGS. It was

![Figure 5. Gelling behaviour of the paste with concentrations of (A) 2.3 g/ml; (B) 2.5 g/ml; and (C) 2.7 g/ml and (D) the effect of paste concentration on the gelling time.](image1)

![Figure 6. Effect of paste concentration on (A) fracture point and (B) ultimate failure load.](image2)
hypothesised that by reducing the number of lateral portholes across the body of SMS, higher pressure will be distributed to each porthole and, therefore, overcome the frictional force according to Darcy’s Law. Furthermore, miniscrew fractures are more likely to occur during its insertion or removal if the patient has very dense cortical bone, and when smaller sized miniscrews are used, as the material is weaker. It was therefore plausible that the weakest point in this novel miniscrew design would be around the lateral extrusion portholes when the SMS was under torsion. The initial FEA confirmed this, with the highest tensile stress expressed adjacent to the lateral portholes during torsional loading. For this reason, the design of the SMS was modified after initial testing to include fewer portholes for better extrusion of the iBGS, and to reduce the risk of fracture. The FEA analysis then confirmed that the improved design of the SMS could be considered for in-vivo testing.

The bioactivity and osteo-conductivity of BGS in the osseous environment have shown promising results in orthopaedic and dental applications. CaSO₄ and CaPO₄ are commonly used for fixation or repair purposes in orthopaedic surgery. In the present study, the particle size of the iBGS was optimised to assure its complete and convenient extrusion through the 20-gauge needle. Phase separation caused filter-pressing; hence, in the present study, the cement was deemed injectable once the paste was extruded uniformly in a single phase composition. Two strategies to reduce filter-pressing of iBGS when using such small gauge needles include decreasing the mean particle size of the powder, and modifying the PLR. The inner diameter of the 20-gauge needle is 600 μm. Therefore, it was decided that the average particle size in the cement powder should be approximately below 100 μm to allow easier flow of the cement. The average particle sizes for CaSO₄ and CaPO₄ determined by the laser granulometer were below 100 μm and still within the acceptable range for convenient delivery of the biomaterial. Theoretical models were developed to investigate the effect of different parameters, such as particle size, on the injectability of the bone graft substitutes. Baroud et al. stated that an increase of the PLR and a decrease of the particle size of the powder component contributed to improving the injectability of calcium phosphate pastes. The result of the present study confirmed that although smaller particle sizes were known to have higher reactivity, it also helped reduce or even eliminate the filter-pressing phenomenon by improving the injectability of the paste through very thin cannulae.

In addition to particle size distribution, the extrusion efficiency and the solidifying time were also of great importance to assure convenient thumb-driven extrusion of the iBGS. The extrusion efficiency and the injectability of the bone graft substitute, prepared with different concentrations, were also assessed. The results from the present in-vitro study in a simulated physiological condition showed that the extrusion efficiency significantly dropped upon increasing the concentration above 2.7 mg/ml (p < 0.001). Hence, for the other tests the PLR was kept within the range of 2.3 mg/ml to 2.7 mg/ml.

For clinical applications of iBGS, the post-mixing behaviour of the biomaterial should also be thoroughly assessed and evaluated, since fast bone graft solidification would block the needle and affect the delivery process adversely. To systematically investigate the gelling time of the iBGS, rheological behaviour was assessed using an oscillatory rheometer. The gelling point of the CaSO₄/CaPO₄ was similar to the estimated initial setting time of the material, while the fracture point was closer to the start of the final setting of the material. The time between those two measurements indicates an estimate handling time for clinical applications. The present study sample demonstrated a rapid gelling, which needed to be taken into account when developing the setup for the dynamic test. These results showed that elevating the concentration of iBGS from 2.3 mg/ml to 2.5 mg/ml significantly increased the gelling time by nearly two fold. This effect might be due to the presence of space hindrance in the iBGS in the higher concentration. Further increase of iBGS concentration from 2.5 mg/ml to 2.7 mg/ml had no significant effect on its gelation time. However, the iBGS prepared with PLR of 2.7 mg/ml was brittle and displayed the ultimate fracture load of 300 N. Those prepared with 2.5 mg/ml had a higher ultimate fracture load of approximately 350 N. Therefore, these results suggested that the iBGS prepared with 2.5 mg/ml of solid content is the optimum formulation as an injectable biomaterial to enhance the primary stability of SMS.

Hong et al. investigated the stability of miniscrew types that were defined by different shapes and thread count for comparison with a miniscrew of hollow design. The hollow miniscrew, similar to the
SMS, was reported to show enhanced stability with better torque level and lateral displacement values. The improved primary stability was provided by an increased cortical bone-to-implant contact surface and bone formation within its internal chamber. The combined use of the hollow SMS with iBGS requires evaluation in future in-vivo studies.

Conclusion
The present study is the first to demonstrate the possible use of injectable bone graft substitutes with a novel hollow miniscrew for orthodontic applications. Using a finer powder and modifying the powder-to-liquid ratio significantly improved the rheological properties and injectability of the chosen bone graft substitute. Further in-vivo studies will be required to confirm the applicability and stability of The Sydney Mini Screw and injectable bone graft substitutes.

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