Introduction

The Rectangular block Implant (RBI) will possess state of the art technology and will be the first dental implant designed and manufactured in Australia. After thorough *in vitro* and *in vivo* analysis, it has finally been tailored for use in humans. The RBI represents a new concept in implant design and force distribution. The specific needs addressed by this novel dental implant are: (i) maximal utilisation of the remaining bone volume; (ii) minimisation of risk to the Inferior Alveolar Nerve (IAN) or other vital structures in or near the oral cavity; and (iii) maximisation of force distribution.

This endeavour is not designed to replace the plethora of dental implant designs that currently exist. It is aimed at providing a specialized implant fixture for complex clinical cases. The depth of the RBI will be 5.5mm, thereby qualifying it as a very short implant, suitable in cases of very low bone height.

Surgical Protocol

The exact placement of the RBI will be deliberated by a specialist team so that the artificial teeth that attach atop the implant will have adequate distribution of force and hence optimum functionality. A piezo-electric osteotomy (cutting of bone) will be prepared which will require custom-made piezo-surgical instruments so that greater bone preservation and least soft tissue damage is incurred. The dental and research team will be present at every phase of the treatment.

Pre-Operative Phase

A thorough clinical oral assessment will be performed followed by a Cone Beam Computerized Tomography (CBCT) to visualize the proposed surgical site in three dimensions.

Stage I

Local anaesthesia will be administered via IAN block and local infiltration.

Osteotomy

An incision will be made and the osteotomy site will be prepared to receive the RBI in a manner that achieves primary stability, and encapsulates the entire implant. This will be achieved using surgical guides (prefabricated to accurately assist in placement of an implant in the bone structure) as per current implant placement protocols and a specialized piezo-electric ultrasonic surgical unit (Mectron Piezosurgery, Mectron Corporation, Australia).

Consequently, a trial-fit ("dummy") implant block will be used to gauge the size of the prepared site. Confirmation of attainment of adequate seating of the trial-fit block is a pre-requisite to proceeding with implant placement.

Implant Placement

The osteotomy site will be debrided with saline, and a sterile RBI transported and seated into the site with firm finger pressure. The placement stem handle will be removed and the block implant tapped into position using the surface purchase points and the central screw shaft opening as per the trial-fit block. A cover screw will be placed.

Soft tissue flaps will be placed over their original positions and sutures will be secured over the wounds to ensure adequate primary surgical wound closure. Antibiotics and analgesics will be prescribed post-operatively.

Post-operative

Wound maintenance instructions will include soft diet, prescription medications and oral hygiene instructions. After-hours telephone number will be provided. The patient will be dismissed after the achievement of haemostasis.

Follow-Up

The patient will be reviewed post-operatively after two weeks and suture removal will be performed. The patient will be asked to return for second stage surgery after a further 12 weeks.

Stage II

As per current implant protocols, the Stage II of this treatment will be under local anaesthesia again. An initial surface incision will be made to expose the underlying cover screw, which will then be removed.

Assessment of Osseo-integration: Resonance Frequency Analysis

Resonance Frequency Analysis is a painless and non-invasive technique. It will be performed from mesial, distal, buccal and lingual aspects, and repeated five times. A reading of 80 or greater will be indicative of successful osseointegration. Upon successful osseointegration, a trans-mucosal healing abutment, designed to facilitate the healing process around the gingiva surrounding the implant site, will be inserted to allow soft tissue healing. This process will not require suturing.

Prosthodontic Phase

At two weeks post Stage II healing, impressions will be taken for the construction of the prosthetic crown. The prosthetic crown will be constructed in a laboratory: a process requiring approximately two to three weeks. The crown will then be screwed onto the abutment towards the end of this phase and checked for occlusal interferences and proper functional relationships. The patient will be instructed on proper oral hygiene maintenance generally and specifically regarding the new implant retained crown.

Long Term Monitoring

The function of the implant-abutment-crown will be monitored at regular intervals (monthly, then three-monthly then six-monthly and then yearly) over the following five years. Specific clinical parameters will be implant stability, component stability, functional capacity and peri-implant tissue health. The patient's personal satisfaction (rating out of 10, and general comments) will also be recorded.

Successfully surviving implants will be left to function indefinitely, and a further prosthetic crowns may be needed for longer term (> 5 years) function. This is a prosthodontic painless process: it will be made using the master models made from the original impressions.

The Variables of the Study

The variables that will be investigated in this pilot study will be implant stability, component stability, functional capacity, peri-implant tissue health, and patient's personal satisfaction.

Implant stability will be assessed via RFA and average Implant Stability Quotient (ISQ) values shall be recorded. Postoperative radiographs will be taken at each visit to help assess osseointegration and peri-implant bone status.

Component stability will also be investigated via the help of reverse torque wrenches to check the loss of torque and screw loosening at regular intervals during follow up visits.

Functional capacity of the implant–prothesis system shall be assessed at every visit by observing signs of wear and maintenance of occlusion during function.

Furthermore, peri-implant tissue health will be observed by carefully using a Michigan O probe and checking for periodontal signs of inflammation and bleeding on probing.

Additionally, patient satisfaction will be recorded at each follow up visit. This will include subjective responses to the RBI therapy and general comments that the patient may have.