CHAPTER 3 PROBLEM AND PURPOSE OF THE *IN VITRO* STUDY

3.1 Statement on the problem and purpose of the *in vitro* study

The purpose of this study is to introduce a testing device and a scientifically relevant method of investigating the biomechanical behaviour of mono-cortical mandibular fragment fixation at different screw angles - a concept completely original and unique in its application with distinct clinical relevance.

- The development and fabrication of a testing device to evaluate three-dimensional *in vitro* stability of mini-plate fixation of the mandible which emulates clinical relevance.
- To determine and quantify the efficacy of biomechanical stability of mono-cortical fixation employing mini-plates-inclined screw insertion (ISI) plates, designed to accommodate a screw-placement angle of 90° (control) and design innovations featuring screw-placement angles of 45°, 60° and 75° respectively. These fixation displacement characteristics will be assessed in tension, compression and torque modes of loading.
- To compare and reflect significant differences in the flexural data obtained from the various fixation systems.

Mini-plate fixation techniques, without inter-maxillary fixation, evolved as a consequence of the delineation of the intrinsic anatomy and biomechanical principles associated with deformation of the mandible in function.

The development and construction of the cantilever/torsion testing device should simplify technically challenging procedures presently employed for accurate assessment of biomechanical stability of mandibular fixation systems. Significant clinical relevance will be expressed by applying known bite force values related to operated individuals.The efficacy of biomechanical stability of mono-cortical fixation, when subjected to tensile, compressive and torsional modes of loading, should exhibit similar load displacement characteristics for both the conventional 90°, and the experimental screw plate designs featuring more acute placement angulations.[32]

The preceding résumé of the literature indicates an awareness of the factors that influence the prognosis of mandibular fracture fixation. In general, these factors are related to three areas:

(i) anatomical and surgical constraints,
(ii) analytical investigations of the biomechanical behaviour of the mandible and
(iii) biomechanical design and location of the fixation system

While the first area has enjoyed extensive investigation, the second area, which has to do with prediction of functional stability, is subject to complicated analytical methodology. The third area, which concerns the design and location of the fixation systems, is extensively but inconclusively reviewed. Very little attention has been given to:

(i) the development of less complicated methods for delineating the biomechanical behaviour of the mandible for functional stability determination of fracture fixation,
(ii) the problem of anatomical positioning of the plating system to ensure a minimal invasive surgical technique and cost effective operating time,
(iii) the introduction of new geometric plate designs according to and coinciding with known strain lines of the mandibular during function,
(iv) the design aspects of a specific plate to acquire functional stability by means of a single plate, rather than a combination of straight plates, and
(v) the relationship between biomechanical stability and the screw placement angle in mono-cortical fixation.

Since the prognosis of mandibular angle fractures osteosynthesis segments are dependent on the post-operative stability of the displaced segments, there is a need for detailed consideration of the fixation characteristics of ISI (Inclined Screw Insertion) mini-plate designs to simplify lateral plating of the ramus through intra-oral, direct line of sight, surgical technique.

CHAPTER 4 EXPERIMENTAL PROCEDURES

The materials and methods used during this study will be documented in sections, which are broadly co-incide with the lines of the investigation followed.

4.1 The Biomechanical Testing Device

The *in vitro* study was conducted using a unique, own design and manufactured jig for the purpose of compression, tension and torsion force delivery to polyurethane synthetic hemi-mandibles. The jig (Figure 15) is designed with base plates mounting it to the 2010 Zwick testing machine (Ulm, Germany). The base of the jig is slotted and allows sliding adjustment of the platform, to align the fixated test model within the 2010 Zwick Testing machine to the load-pin for delivery of either (i) compression, tension force in a downward motion or (ii) rotation – torsion force in an upward motion via the cable wheel (Figure 16).

4.2 Tension/ Compression Evaluation

The jig basically consists of two testing platforms. The one platform features a fixed vertical mounting plate for stabilising the experimental model in order to perform load-deflection by application of specific load at a standardised predetermined distance from the oseotomy site.

The vertical load induced via the load-pin as illustrated in Figure 17 in the Zwick machine, facilitates determination of the tensile and compressive (cantilever) displacement that occurs within the fixated test samples. All measuring was performed by the same operator.

The three-dimensional stability testing device that will be used for the stability potential evaluation of the fixated test module, involves the incorporation of the test jig, as shown in Figure 18 within the Z010 Zwick testing machine.The load cell 50N type 8301 (seen just above the mounted base and load-pin in Figure 18) has a 50N limit.

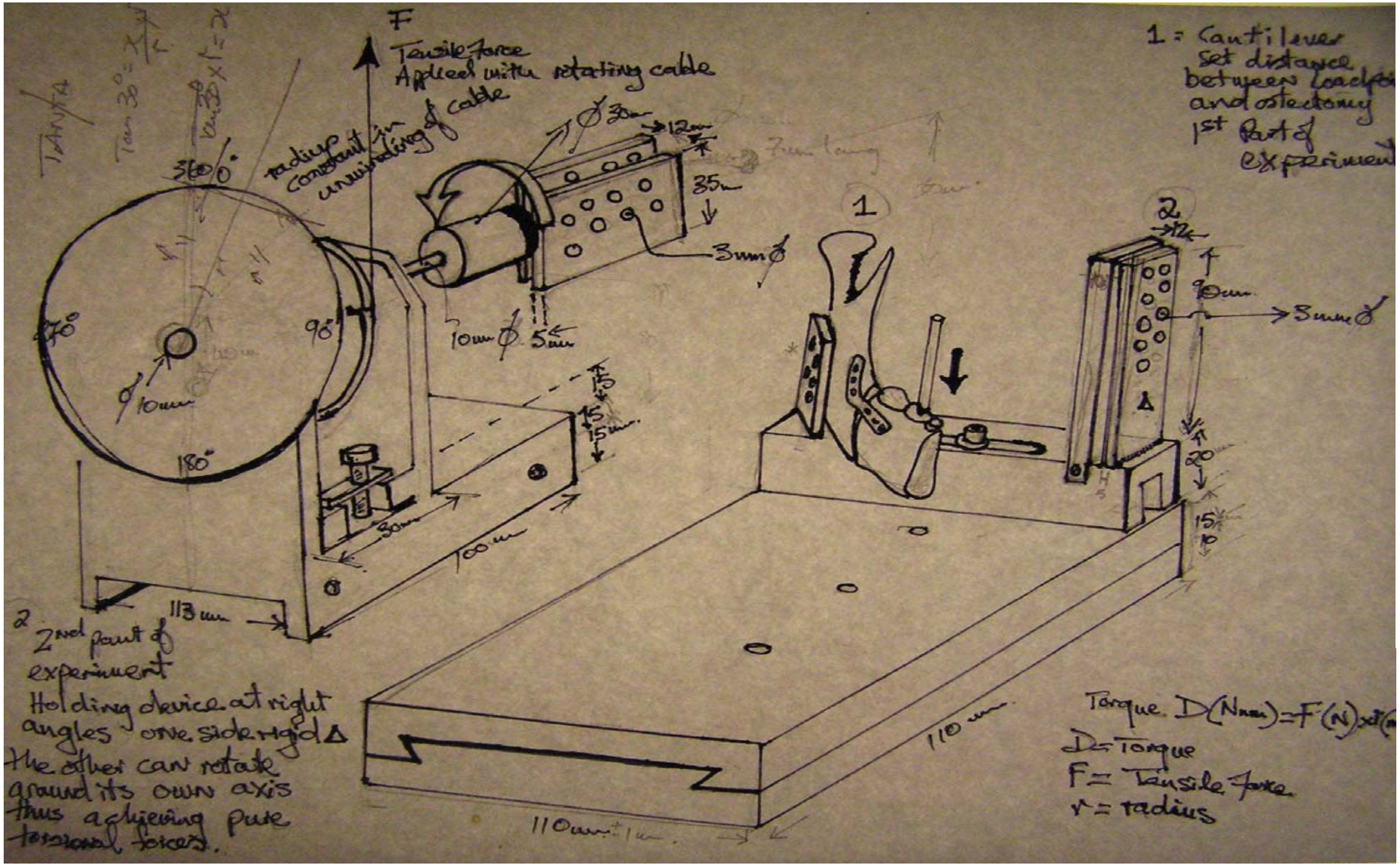

Figure 15: Design sketch of test model arrangement (own design and manufacture)

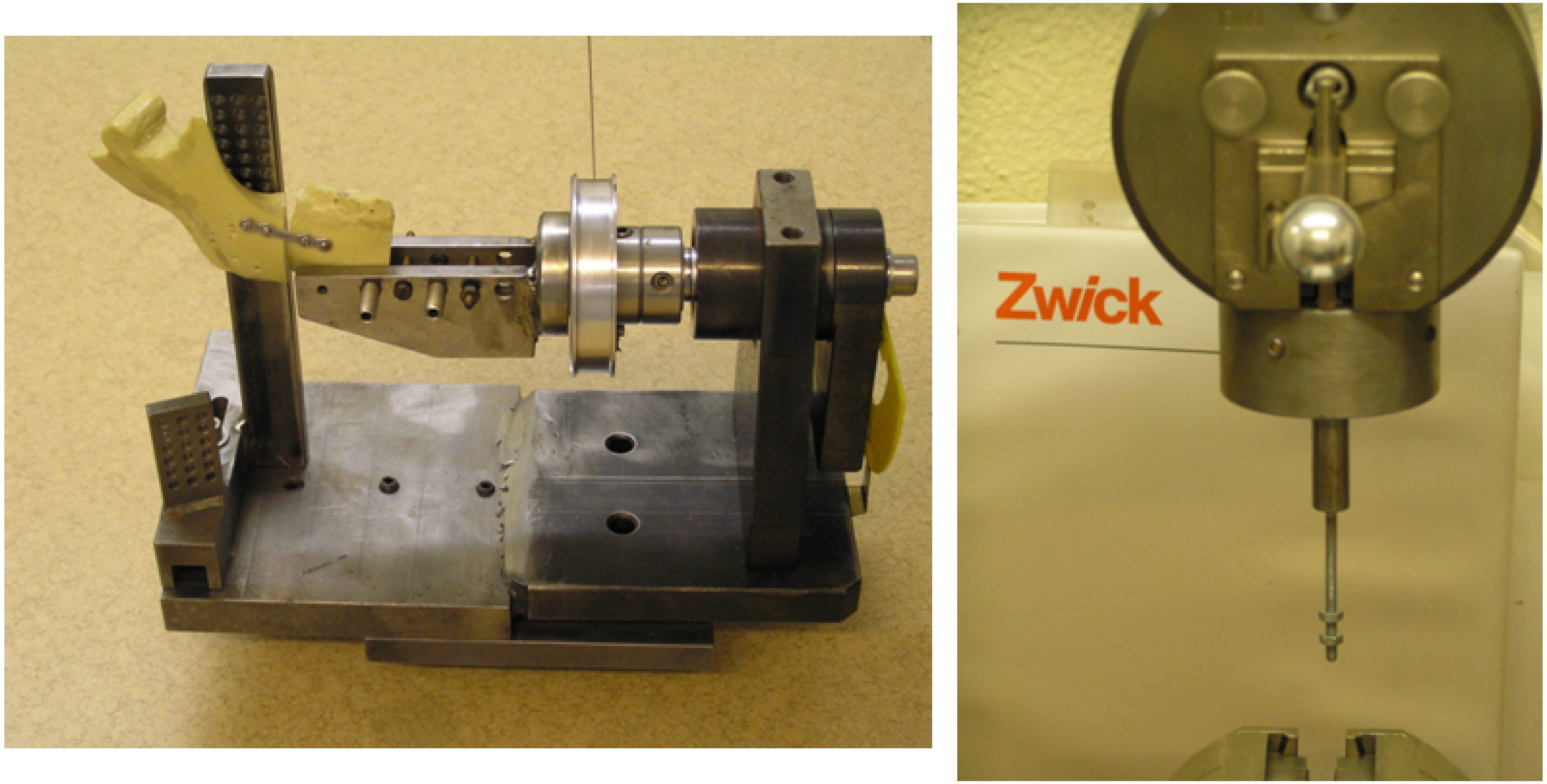

Figure 16: Actual testing device testing via cable on left and compression testing via load-pin on the right

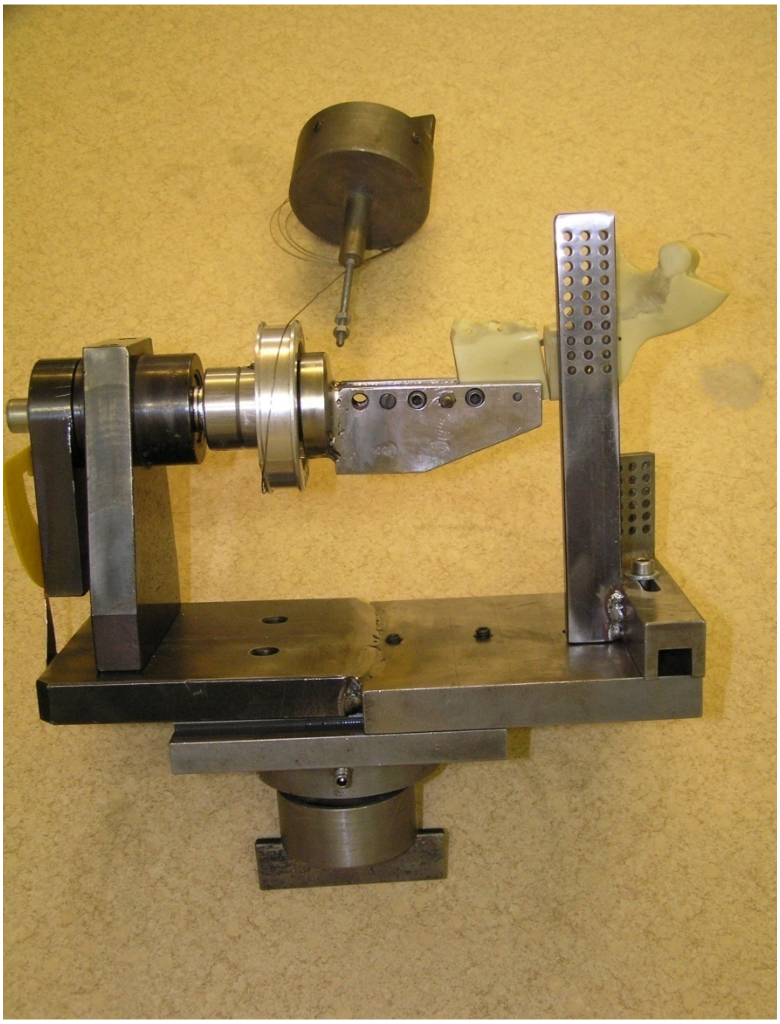

Figure 17: Load-pin experimental set-up

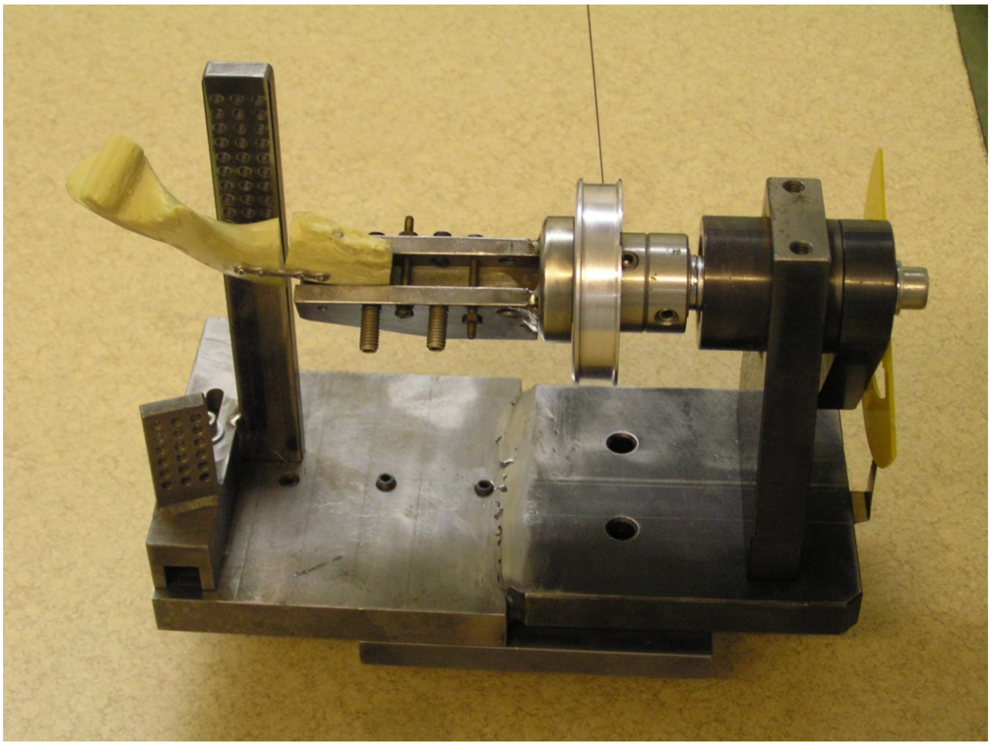

Figure 18: Test jig within the Zwick machine

Figure 19: Load cell of 50N type 8301

The upward motion delivered by the Zwick machine at a constant crosshead speed of 0,25mm/min will result in rotation of the wheel and apply a torsion force to the polyurethane test model. A downward crosshead speed will deliver a compression force to the distal fragment of the proximal distal fragment of osteotomised synthetic mandible as shown in (Figures 20 and 21).

All mandibles will be rigidly mounted to the vertical section of the base-plate allowing free movement of the distal segment when load forces via the load pin modification in the Zwick machine (Figure 21). Delivered load pin compression/tension force is applied to a prepared fossa in the occlusal surface of the first molar.

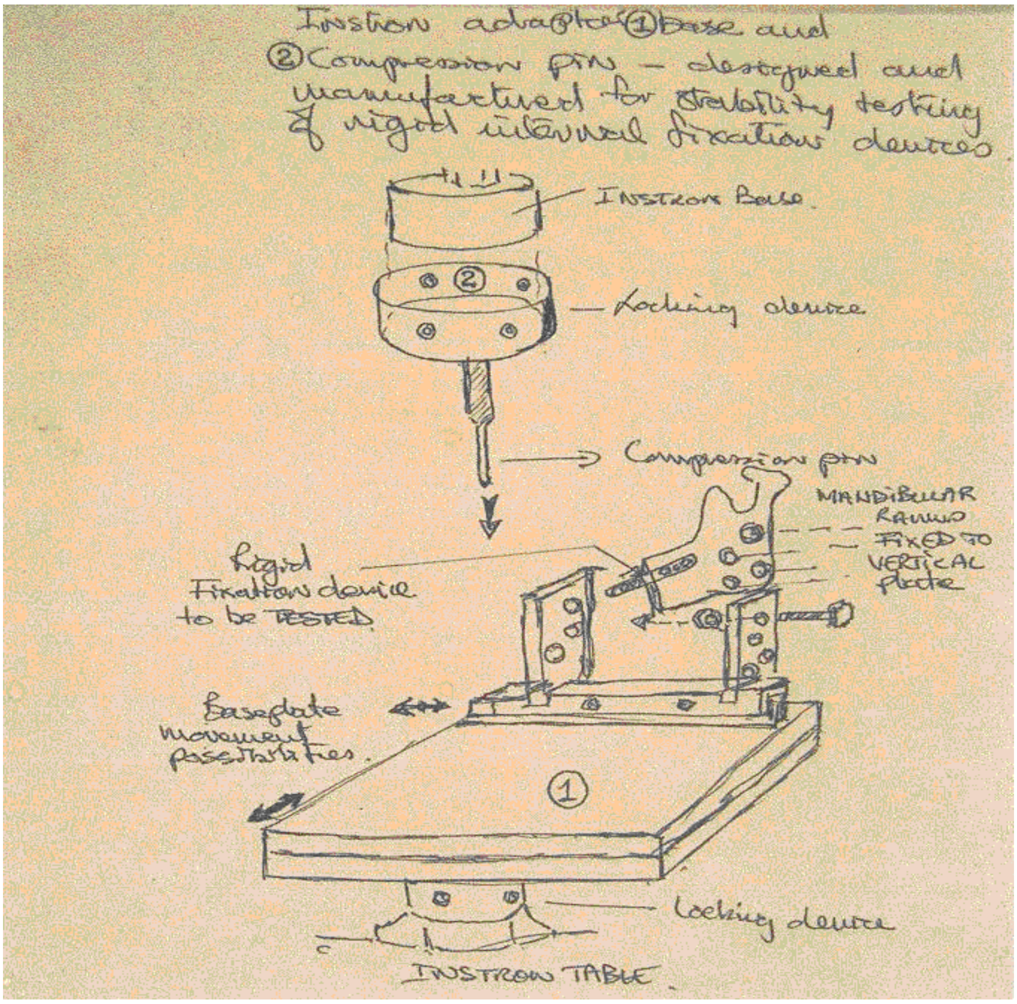

Figure 20: Design sketch of test model with mounting base for compression testing in the Zwick machine

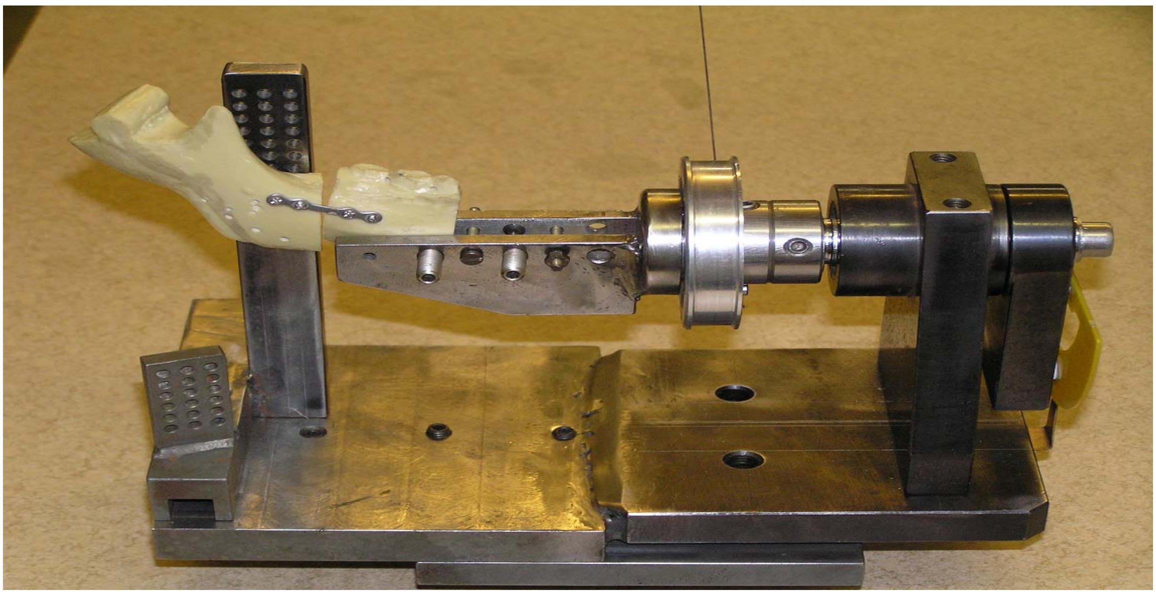

Figure 21: Photograph of three-dimensional experimental jig with fixated test module

4.3 Torque Evaluation

The second platform of the test jig consists of a rotating model holding device. This device features a round disc 4cm in diameter, located on a horizontal rotational axis with a wound steel cable with a tensile breaking force of 500 Newton. One end of the cable is fixed to the disc and the other end is attachable to the load-pin of the Zwick machine. Specific load application by the Zwick machine on the wound cable induces shear deformation on the experimental model. Torsional loads are obtained by value substitution in the following formula:[33]

$$D = F \times r$$

where D = Torque (Nm)

F = Tensile Force (N)

and r = radius of disc (mm)

The experimental validity of this formula is dependent on a constant radius. This is achieved and controlled by maintaining a constant cable to wheel angle during application and relaxing of the load.

In addition, a scale of degrees is secured to the rotating axis of the wheel to record the degrees of rotation in response to torsion loading of the model as shown in Figure 22.

Figure 22: Device used for measuring the degrees of rotation at specific torque applications

Physical displacement of the segments (gapping) was obtained from the load-displacement as computerised data obtained from the Zwick machine drawn as a graph for both the compression and torsion test modules and registered.

The relationship between gap widths and incremental torque or compression values was documented and used to produce graphic linear regression models for both face applications. Rotation was expressed as a degree of rotation to Newton torque.

4.4 Compilation of Mandible Samples

A total of 60 polyurethane synthetic mandible replicas (Synbone, Landquart, Switzerland) were used in this study. These synthetic replica mandibles simulate the human mandible by demonstrating a rigid outer cortex and softer medulla component as demonstrated in Figure 23.

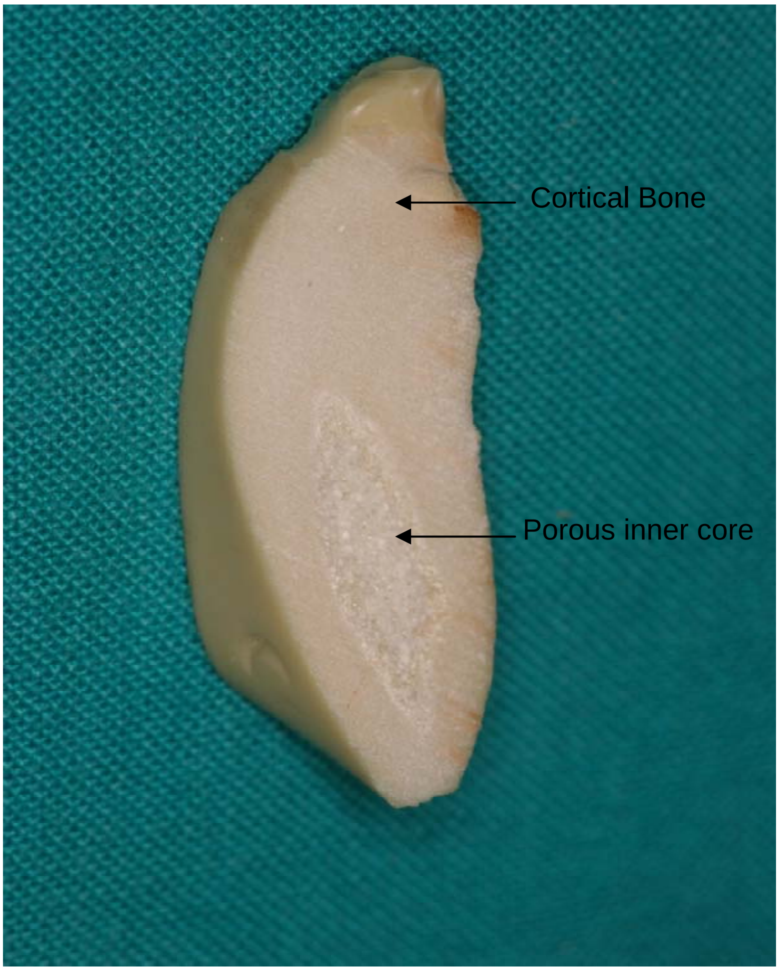

Figure 23: Polyurethane replicas with outer dense layer and porous inner core

This uniformity allows for more reliable comparison of fixation techniques by eliminating the variability normally seen in cadaveric and sheep mandibles.[33, 34] The specimens were sectioned in the midline to produce 120 hemi-mandibles for evaluation (Figure 24).

Figure 24: Hemi-mandibles for evaluation

These samples were divided into four categories with 15 specimens in each category. The different fixation categories consisted of:

- mini-plate with 90° screw placement angle,
- mini-plate with 75° screw placement angle,
- mini-plate with 60° screw placement angle, and
- mini-plate with 45° screw placement angle.

These categories will be further subdivided into two different groups, each comprising 15 samples for the three-dimensional fixation stability evaluation. The modes of loading to determine biomechanical stability, in the developed test jig for each group, are the following:

- tension and compression evaluation, and
- torque evaluation.

All mandible models were sectioned at the angle, using a reciprocating saw with blade profile of 0.9mm and segmentation template to standardise the exact site and resection width at all mandible angles. An oblique cut, simulating a vertically and horizontally unfavourable fracture line, was performed to create clinical relevance to unstable proximal fracture segments.

The elastic modulus of polymethane is 10 times less than in normal human bone and has clinical relevance. Exact rigid fixation and alignment of the osteotomised proximal and distal segments is ensured using the mini-plate positioning template.

4.5 Fabrication of Positioning Templates

An intact hemi-mandible was used for the fabrication of the polymethylmethacrylate (PMMA) localisation templates required for standardised and chronological preparation of the test samples and positioning of these samples in the mechanical testing device as follows:

4.5.1 Mini-plate positioning template

The template for standardised mini-plate localisation on the ventral aspect of the external oblique ridge is designed to accommodate two different plate positions in close proximity to one another. The upper position will be employed for tension/compression evaluation whereas torque will be derived from the inferiorly located structure (Figure 25).

This approach is primarily a cost-saving exercise which is unlikely to compromise biomechanical principles. In addition, the screw access holes on the various mini-plates will have drill guides for accurate angular preparation and predetermined depth penetration for the fixation screws.

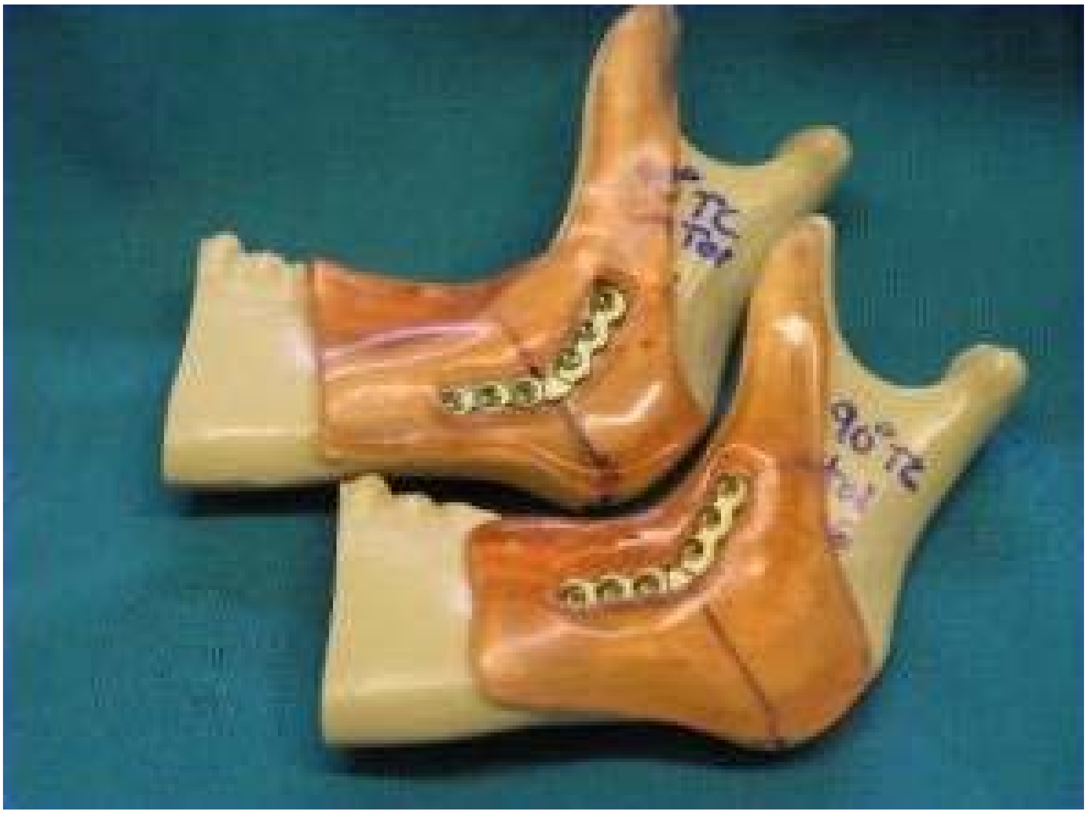

Figure 25: Upper and lower plate positions

4.5.2 Segmentation template

The segmentation template incorporates a guide groove for the introduction of standardised horizontally and vertically unfavourable osteotomy at the angles of the replica hemi-mandibles (Figure 26).

Figure 26: Upper- and lower notches for segmentation alignment

The template will feature two corresponding and linearly aligned bi-cortical engaging guiding trenches, ± 5mm in length located on the upper and lower aspects of the template allowing orientation slots to be cut into the surface of the synthetic mandibles. Standardised sectioning will be obtained by linear connection of the prepared slots after removal of the template and by employing a reciprocating saw with a blade width of 0,9mm for segmentation.

4.6 Mini-Plate Fixation Procedures

The osteotomised segments were connected (fixated) by means of the experimentally designed and prefabricated titanium six-hole curved mono-cortical fixation plates identical in profile (Stryker/Liebinger, Freiburg, Germany) as illustrated in Figure 26.

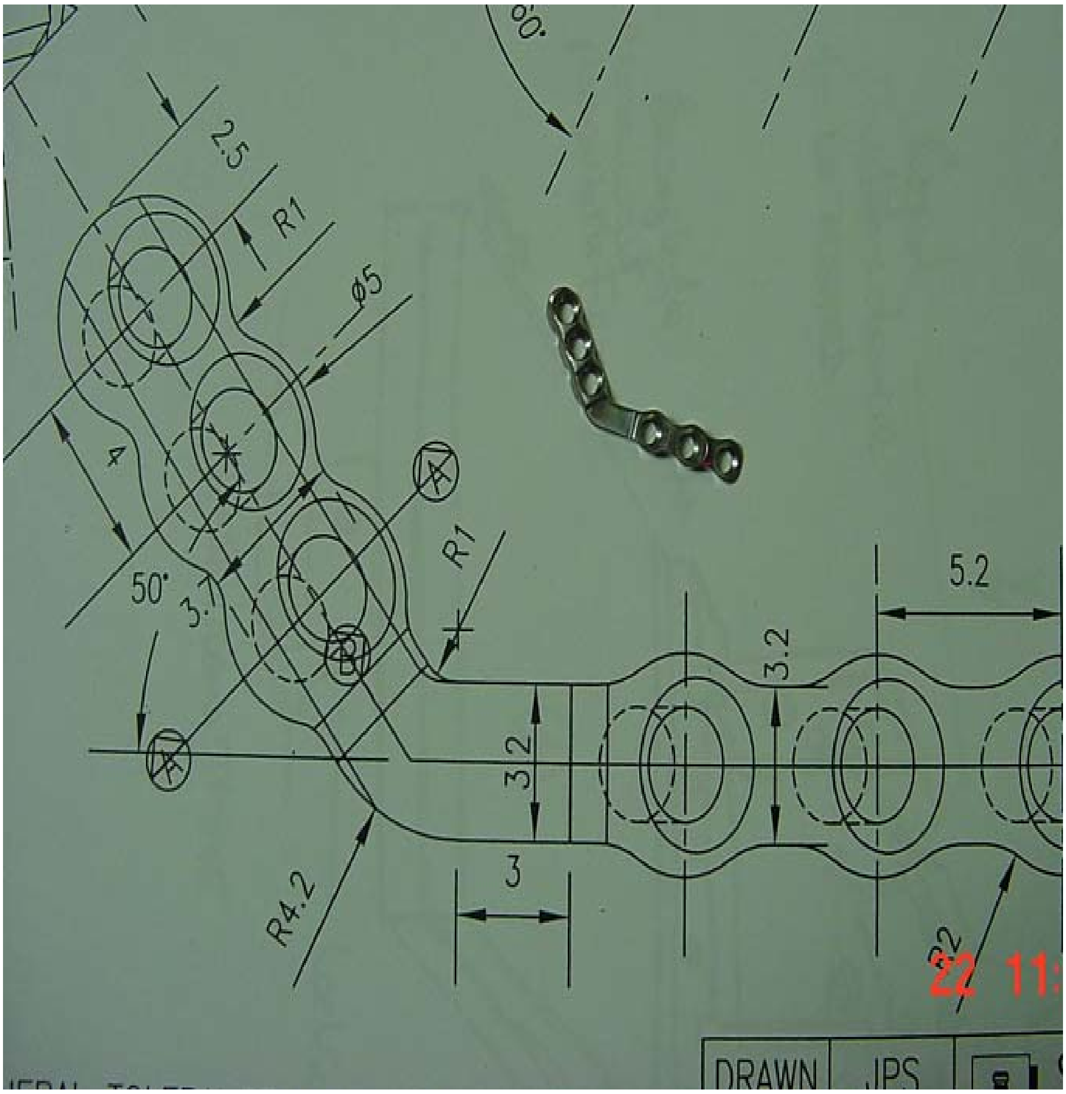

Figure 27: A curved mini-plate illustrating ISI (Inclined Screw Insertion) with plate holes at 90°, 60° 45° or 75

These mono-cortical plates have plate holes at 90°, 75°, 60° and 45° to the plate surface and are 2mm thick in profile. One hundred and twenty plates were used in total, 15 in each angle category for the biomechanical evaluation of the two groups of compression and torsion.

Dedicated drill guides were manufactured one each at angles 90°, 75°, 60° and 45° and used to ensure an exact angle for pilot drilling with 1.5mm drill prior to standard identical 7mm screws of 2mm diameter placement (Figure 28 and 29).

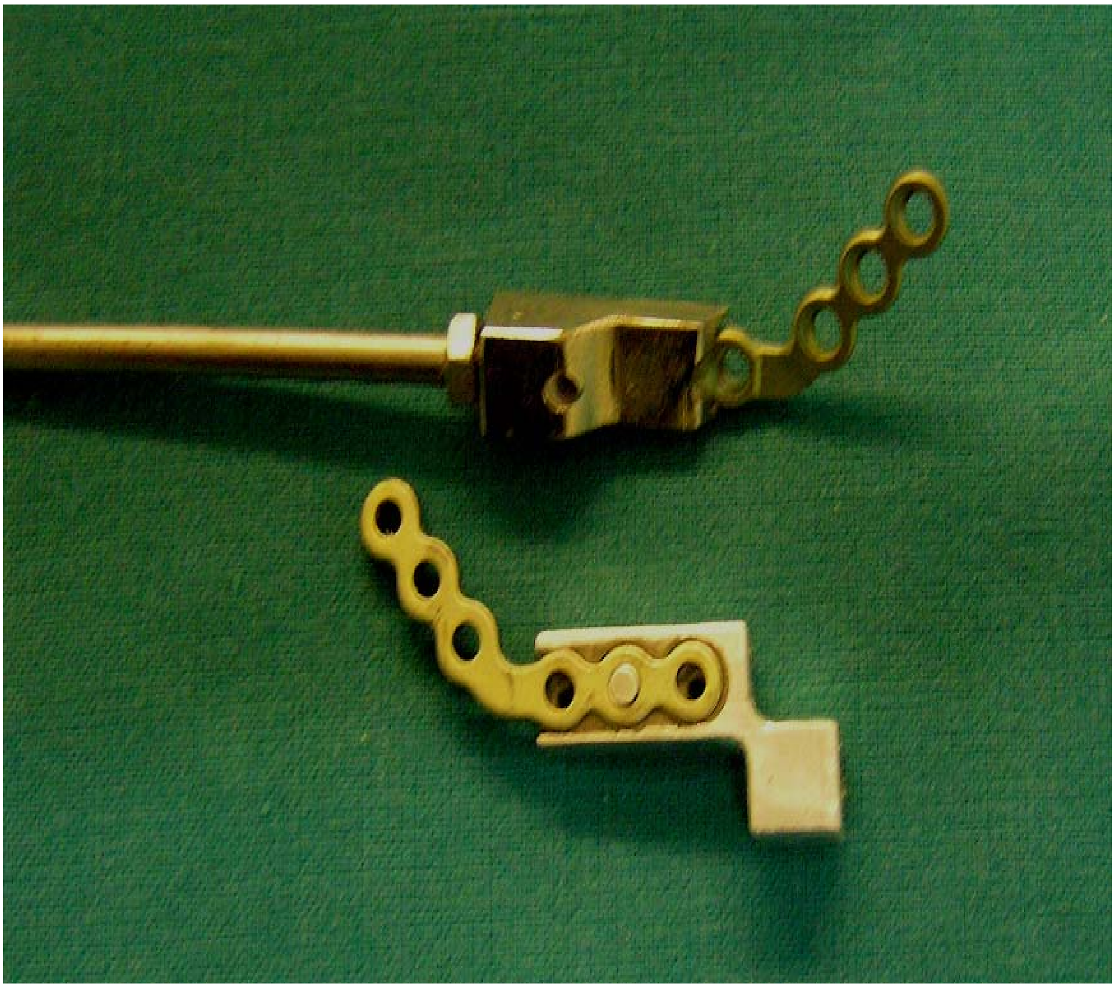

Figure 28: Dedicated drill guides

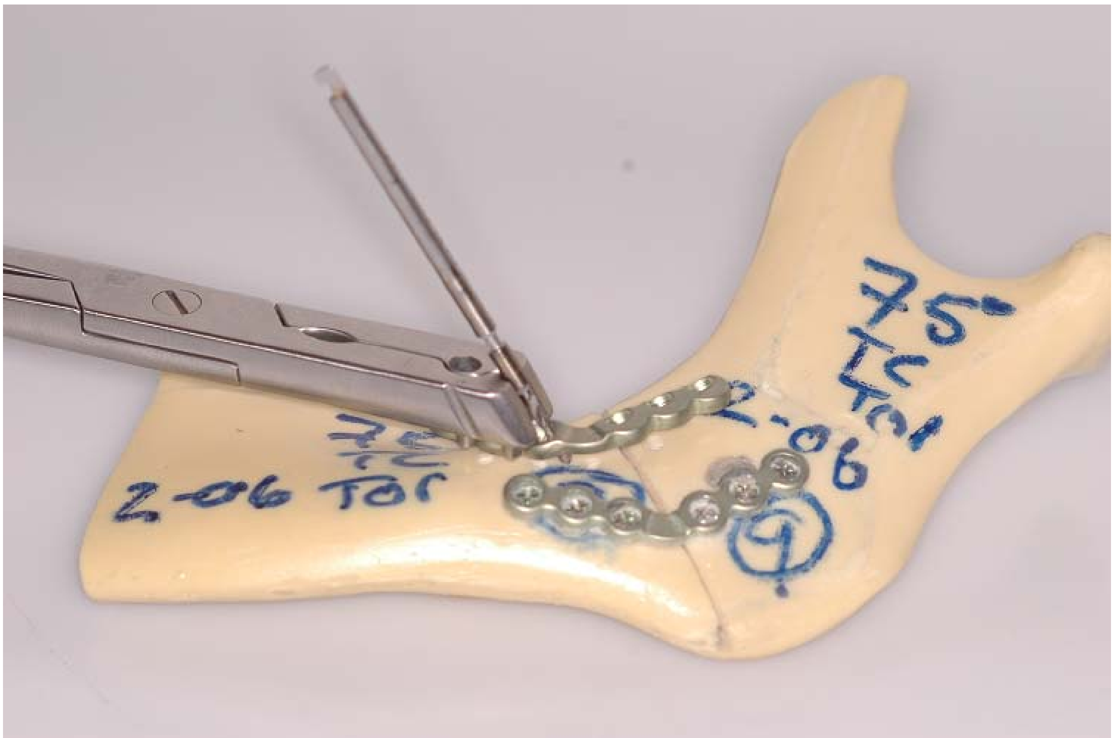

Figure 29: Pilot drilling with aid of drill guide

The different mini-plates were positioned and held in position by the preformed positioning templates prepared screw holes and each screw tightened to predetermined standardised interfacial pre-loads using the calibrated torque screwdriver (Figure 30).

Figure 30: Calibrated torque screwdriver, pre-set at 40 N/cm together with a certificate of calibration

The completion of preparative procedures on the hemi-mandibles necessitated accurate localisation and fixation of each individual test specimen in the testing device for three-dimensional flexural load-displacement evaluation.

4.7 Load Displacement Evaluation

All the load displacement tests were conducted in the Zwick machine. The experimental jig with the mounted test models were incorporated within the testing machine by means of adaptor plates. The resistance to the applied tensile, compressive and shear loads was regulated. A progressive load up to a maximum of 35 Newton was applied to simulate clinical conditions. One Newton in the test machine is equal to 10 Newton clinically.

These loading parameters are clinically relevant and based on studies of bite force measurements in postoperative patients. The assumption made is that meaningful information regarding mechanical behaviour was obtained within the 0-300 Newton range which is clinically significant for incisal edge loading and 0 to 200 Newton range for contra-lateral loading.

The velocity of the crosshead travel was regulated at 0,25mm/min. Furthermore, a tension-compression load cell of 50N capacity was calibrated and used throughout this investigation (Figure 19). Before each test, the experimental jig containing the test model was secured to the lower base of the Zwick machine and calibrated to obtain a zero deflection value on the chart recorder. The load displacement characteristics were recorded on the computerised chart recorder. From the known deflection values on the chart recorder, it was possible to derive the stability values of each fixation design relative to the magnitude of the applied load.

Before experimental stability determination of the prepared test models, five unprepared intact hemi-mandibles were used as controls to define the limitations of the substrate (synthetic mandible replicas) and testing jig.

Incremental load displacement testing with zero, five, fifteen, twenty-five and thirty-five Newton were conducted to determine the stability of fixated test samples for two modes of load applications, tested as tension/compression and torsion.

Furthermore, the amount of physical displacement of segments (gapping) that occurred during the two modes of loading was obtained as load displacement graphs.

For the purpose of interpreting the comparative results, all variables were standardised e.g. screw lengths, torque and diameter. Curved mini-plates with a profile of 2mm, and angled screw holes machined at 90°, 75°, 65° and 45° were designed, manufactured, intended for mono-cortical fixation and bridging of the sectioned polyurethane mandibles as in figure 31.
The ISI mono-cortical titanium plates differed only in angle of screw holes 90°, 75°, 60° or 45° angles (Figure 31)

The ISI plates were precisely positioned, prior to fixation, using a positioning template for either compression screw angle testing (CSAT) or torsion screw angle testing (TSAT). The gold standard for the comparative, compression/torsion biomechanical testing of the ISI (Inclined Screw Insertion) was the conventional rectangular (90°) screw placement.

The pilot drill within the inclined screw hole of the ISI plate demonstrates the 45°angle of the plate hole where the plate profile is 2mm to accommodate this dedicated angled plate-hole (Figure 32).

Biomechanical evaluation of angled screw fixation when applied as a mono-cortical plating system at the lateral aspect of the mandibular angle (according to the Champy, ideal line for osteosynthesis) has never been investigated before and is expected to yield meaningful information with high clinical relevance as a system that can be applied via intra-oral surgical technique (Figure 12). Screw lagging across the fracture line and longer screw application as a result of angulation is predicted and would result in superior biomechanical stability if compared to conventional 90° screw placement.

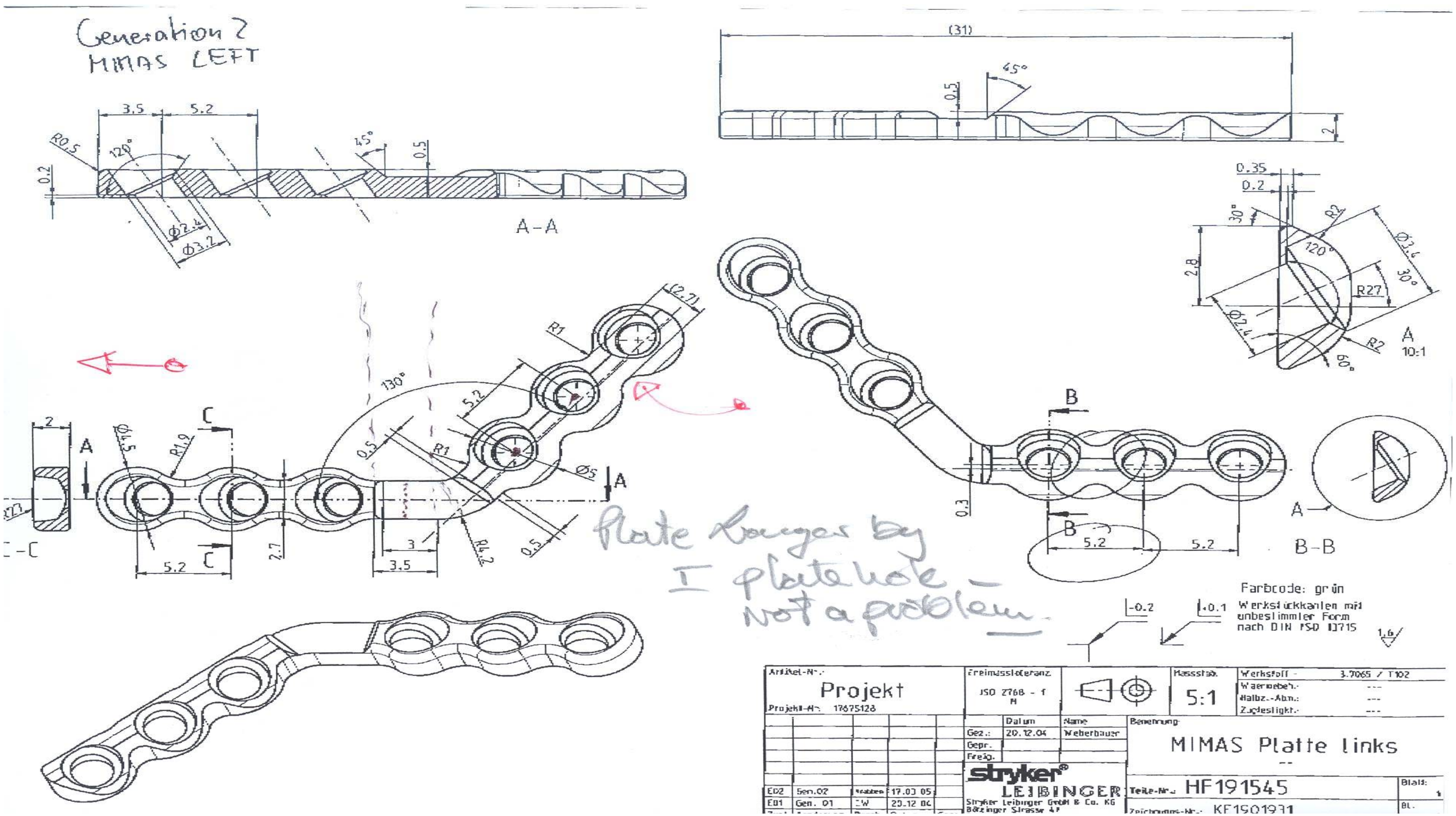

Figure 31: Design sketches for angle screw holes in L-shaped (ISI) mini-plates

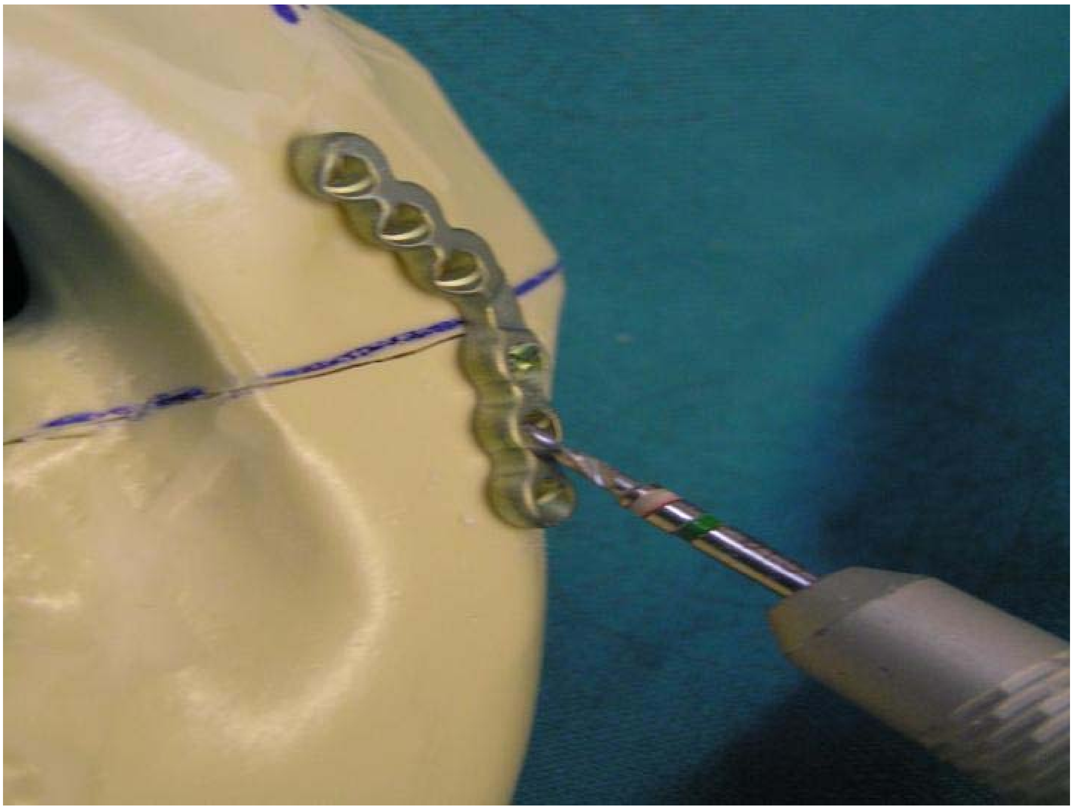

Figure 32: Pilot-drill, used to demonstrate the angled screw-holes in ISI plate