CHAPTER 7 DISCUSSION AND RECOMMENDATIONS

7.1 Discussion

7.1.1 Materials and Methodology

(a) The range of force application

The clinical relevance and therefore the credibility of any *in vitro* biomechanical stability study is dependent on the ability of the testing device to simulate human mandibular behaviour during function. [7, 14]

The bending and torsion moments exerted on the fixated fracture/osteotomy-mandibular replicas) had clinical relevance to the post-operative force range applicable during the healing period for osteotomy and fracture treated patients. The load force application for the ISI biomechanical study was in the range of 100-200N (0-10 Kg.). A 0-100 Newton force range simulated the maximum incisal-edge, and the 0-200 N range simulated maximum contra-lateral molar loading in the post - operative clinical situation. [8, 9, 11, 12]

(b) The testing device

An unique biomechanical testing device (Figure 15), which was specially developed proved to be reliable and economical as a three dimensional force applicator which rendered clinical relevant results. Torsion (TSAT) and compression (CSAT) forces within clinical relevant range was utilised to deliver a torsion force to the distal fragment of the osteotomised polyurethane hemi-mandibula whilst the proximal segment was rigidly fixated. The compression force (CSAT) was applied to the occlusal surface of the first molar of the mandibular replicas mounted in the testing device. This resulted in a positive bending motion with tension created superior in the fixated fragments and compression at the lower border of the polyurethane human mandibular replicas. [1, 2, 6]

Instead of simulating torsional moments by load application to the incisal or contra-lateral molar teeth of complete mandibular replicas,[5, 22] this study is unique in that torsion force application to the distal segment of a fixated hemi-mandibula via a clamp jig and rotating wheel is applied.

The cable was linked to the load cell of the Zwick machine with an upward constant cross-hair speed. This design for a biomechanical testing jig is unique[32] although the rotation force delivery and calculation is similar to the experimentation performed by Feller and co-workers in 2002, where acrylic blocks were used to investigate fixation stability.[33, 34] This method of torsion force delivery has a cost saving effect as the tests were conducted in hemi-mandibular segments as opposed to complete poly-urethane mandibular replicas.

(c) The ISI experimental osteosynthesis plate

This unique C-shaped six-hole plate was of own design and manufactured by Stryker Leibinger (Figure 29). It served as a proto-type for the eventually patented ISI mandibular angle plate, used in patients. The angled screw plates described by Krenkel[35] demonstrate a quadrant orientation for straight plates either in the long axis of the plate (quadrant 3) for all the plate holes, or angled at 45° and described as the screws are inserted from one side at an angle of 45° from the right of the long axis of the plate for type B/1, and for B/2 where the screws are inserted from one side at an angle of 45°from the left of the long axis of the plate. The type A - 0° slanted screw plate where the screws are inserted from one side along the long axis of the plate again have all plate holes in the same (quadrant 3) orientation (Figure 1). The 0° slanted plate described by Krenkel had washers to improve stability at the screw head plate hole interface, it was suggested that the plate holes would accommodate a screw angle of insertion between 0-180°. The ISI plate in contrast has an angled plate hole to accommodate a specific screw angle of insertion guided by the pilot hole drilled with the aid of a specific drill-guide.

The plate-holes are either rectangular to the plate surface (conventional 90° angle) or angled at 75°, 60°, and 45° to the plate surface, with a specific quadrant orientation described in this research for the first time to facilitate communication in terms of angled screw insertion (Figure 1). In the ISI plate the proximal plate holes were angled in quadrant one with lag potential for the screw bordering the fracture line and for the anterior three holes the angle of insertion was orientated in quadrant three to facilitate direct line of sight during intra-oral approach. The ISI design therefore is unique and differs from any angled screw insertion plate suggested by Krenkel.[36] Due to an absence of biomechanical stability studies in the literature specifically investigating the effect of angled screw placement at different quadrant orientations within the same plate, the results of this study cannot be compared to, or interpreted in relation to other studies. The screw angle orientation favours a more rectangular alignment to the fracture site (Figure 5) in both horizontally and vertically unfavourable fractures.

It should be noted that if the plate holes were designed according to the ”lock-plate” principle, it would allow freedom of 10° angle variation for the screw placement within a dedicated plate hole. The angled plate holes can serve as a drill guide if the pilot drill is aligned along the slant of the plate hole profile.

The biomechanical behaviour comparison for different angles of screw insertion, within the same plate profile, is a first ever performed *in vitro* study. The screws with ISI angles of 75°, 60° and 45° were biomechanically compared the conventional gold standard of screw placement at a 90° angle.

(d) The simulated mandibular fracture/osteotomy

The angle sectioning of the mandibular replicas was performed in an oblique fashion starting the cut from anterior in alveolar region of the mandibular angle to terminate in a point more posteriorly at the inferior border of the Gonion simulating horizontally unfavourable fragments. The same bone cut begun in an anterior position on the lingual aspect to terminate more posterior on the buccal aspect (lateral) thus rendering the fragments vertically unfavourable. The same cut was simulated on all models using a jig. In a recent finite element analysis for tension band fixation of mandibular angle fractures it was demonstrated that in fractures with an angle of more than 20° with the mesial surface of the proximal molar (indicative of the degree of horizontally unfavourability of the fracture fragments due to muscle pull) and no inter-fragmentary contact (load bearing), fracture mobility for both incisors and ipsi-lateral fracture molar forces was lower than 150N but fracture mobility above 150N for contra-lateral molar bite forces was registered.[36] Mono-planar mono-plating with ISI plates could prove stable enough and render better results.[37]

The *in vitro* biomechanical stability study performed by Nissenbaum and co-workers on Chacma baboons[38] (Papio ursinus), investigating horizontally and vertically unfavourable fracture stability, creates confusion as the authors interpreted the fragment displacement directions according to the direction of muscle pull-vertical for masseter and temporales muscles and horizontal for the medial pterygiod muscle pull. Many biomechanical stability studies do not pay attention to the direction of instability created by sectioned models and therefore do not relate to the clinical situation.

7.1.2 The anatomical site chosen for the ISI plate

Plate positioning would affect the biomechanical stability of a specific plate fixation. This knowledge is based on the strain lines that develop during mandibular function, which delineates the ideal osteosynthesis lines previously described.[4, 14] The ISI plate was geometrically shaped to cover the tension strain line, just below the external oblique ridge, on the lateral aspect of the mandibular angle (Figures 12 & 43).

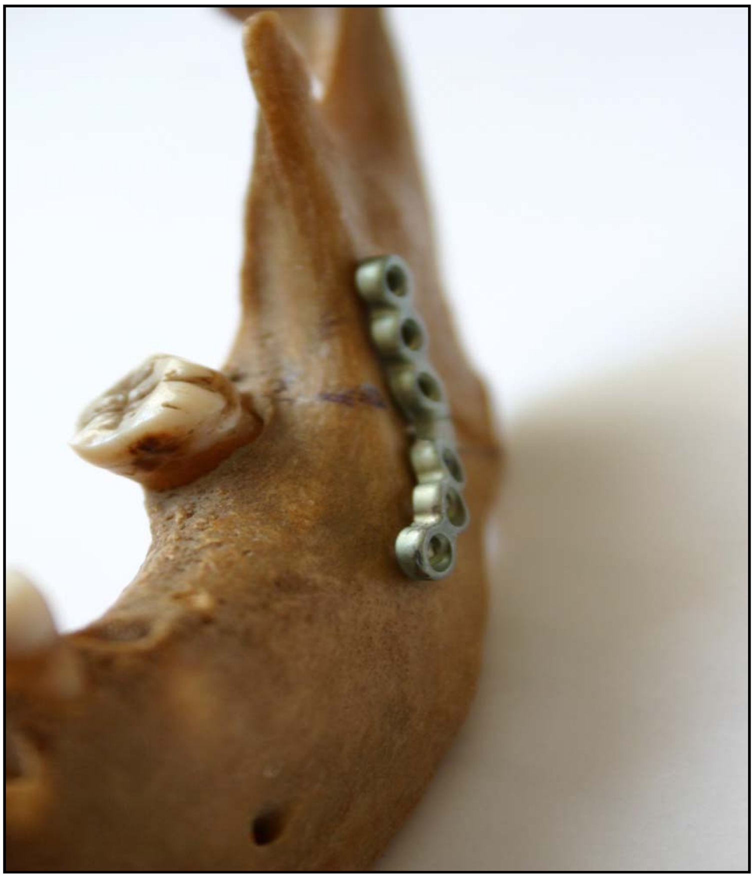

Figure 43: Position of ISI plate at the angle of mandible

Plate positioning clearly influenced biomechanical stability as described in previous studies, a superior border mono-cortical plate (Wurzburg plate) placed superior on the external oblique ridge[15] demonstrated inferior gapping[14] and demanded tension banding by placement of a second plate[39] on the infero-lateral aspect of the mandibular angle. This suggested a bi-plating technique in a bi-planar fashion if mono-cortical plates are used,[18, 22] which in turn demands a trans-cutaneous [30, 32] surgical approach as opposed to a intra-oral, less invasive procedure.[3, 4, 6] This osteosynthesis position guarantees utilization of the ideal maximum dense cortical thickness available for mono-cortical screw fixation.[27, 28] The screw length can be stepped up (increased) to 9mm for the transecting (lagging) screw resulting in a tremendous improvement in the biomechanical stability (Figure 44). The screw remains in dense cortical bone for all of its length.

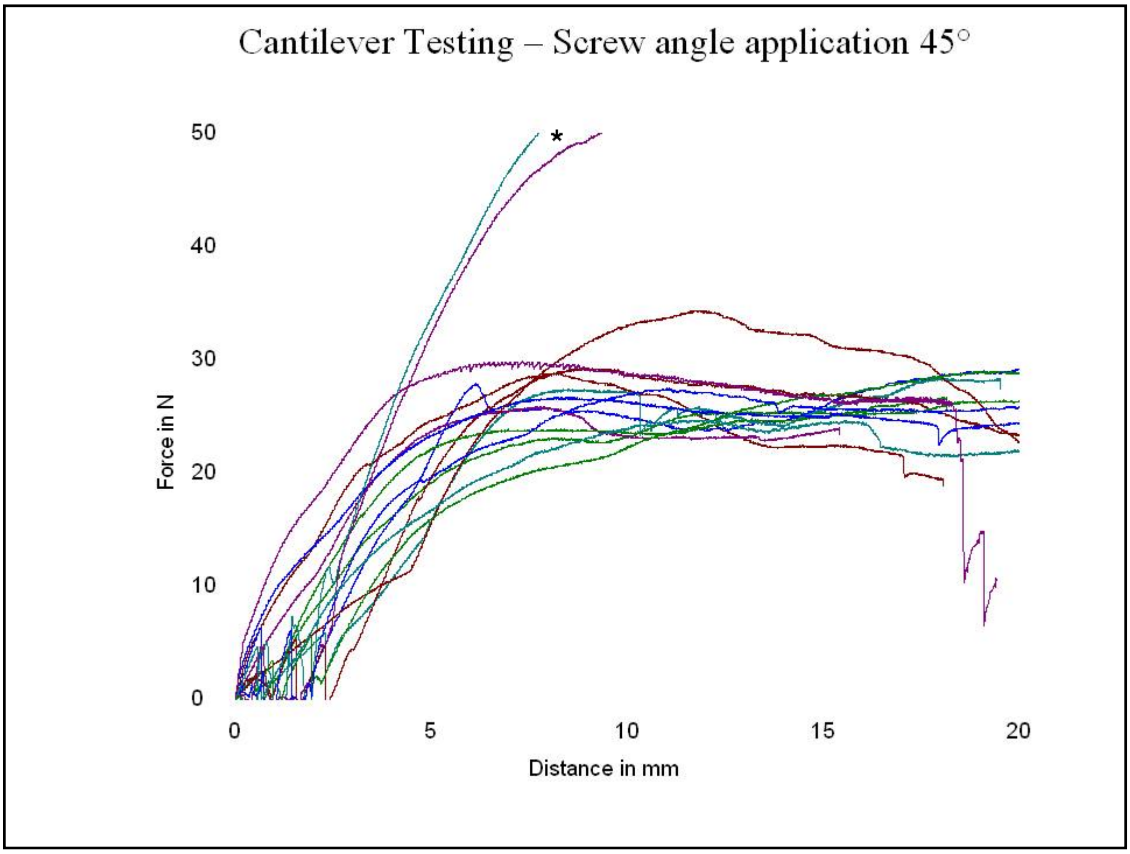

Figure 44: Effect of Screw lagging across the fracture line-stability improvement using longer (9mm) screws*

7.1.3 Independent biomechanical stability testing results of the ISI osteosynthesis system.

The independent biomechanical *in vitro* tests performed by Schieferstein using the mandibulator (Addendum 4) gave clinical significance to the ISI plate previously referred to as the MIMAS (Minimal Invasive Mono-Cortical Angle System).[29] The aim of his study was to evaluate the ISI plate as a possible new concept and compare it's stability with the plates commonly used and available in the market the Wurzburg superior border plate[15] and the bi-cortical universal fracture plate. Schieferstein measured and compared the displacement after delivery of stepwise 50N force application increments to a maximum of 250N. The force delivery mimicked muscle forces and dental forces during incisal, molar, contra-lateral or ipsi-lateral force application. Load dependant angle changes between Kirchner wires (inserted in the poly-urethane mandibules) were registered for bending (CSAT in this study) and torsion moments (TSAT). An instability factor was calculated with the formula *I = (B2+T2)x0.5*. These results proved the instability of the Wurzburg plate when ipsi-lateral loading is performed. The average stability of the universal plate proved to be 37% higher but 13% less balanced than the ISI plate (Addendum 4). These independent results proved that the ISI plate was very stable and confirmed results obtained and reported[26, 34, 39] of this in vitro study. The ISI plate has proven to have superior biomechanical stability to the Wurzburg plate. Similar to the Wurzburg plate, it has the advantage of application for an intra-oral surgical technique.

Improved fragment stability is proven for forces of tension/compression and torsion for the same screw length and diameter screws placed mono-cortically as a plating system provided the screw length (7mm – in this study) chosen initially exceeds the cortical thickness of a specific anatomical topographical site (1,7mm – longer than the cortex thickness of 4mm in the angle of the mandible). In clinical terms, longer screws for angles 60° and 45° can be used when compared to 90° angled screws, for the mandibular angle region a plate positioned on the superior-lateral aspect of the external oblique ridge (to co-inside with the known strain lines) at screw angles of 60° or 45° have a longer travel distance through mono-cortex (Table 17 – for ISI of 60°: 0.63 – 1.08mm and for ISI of 45°: 1.69 – 2.89mm). Lag screws of 9-11mm are possible due to the plate position lateral and very superior on the external oblique ridge – the anatomy here demonstrates dense cortical bone with the medullary component more inferior and thus creates lag potential in cortex for a travel distance of 9-11mm the screw travel does not transect cancellous bone at all. A screw will have to be in place, one on each side of the fracture line, before insertion of the lag screw through the plate hole close to the fracture line in order to prevent fracture fragment separation.

7.2 Recommendations for future biomechanical stability investigation and geometrical design aspects of the ISI (inclined screw insertion) systems

7.2.1 Increased sample size

Increase of the sample size to at least n= 30 for each angle group in order to confirm significance ($p<0.05$) when comparing ISI stability differences.

7.2.2 Plate Design

Outer cortex destruction of the polyurethane material can be prevented by designing experimental ISI plates with longer bridging segments. A bridging segment of at least 4mm would distance the plate hole (Figure 39 - distance XF), nearest the fracture-gap, sufficiently to permit pilot drilling for angled screw placement at angle 45° without destruction or load fracturing the bridge between fracture line and screw. (Figure 45).

7.2.3 The smart lock technology incorporated in ISI plate designs for the future

Apart from having a specific screw design the lock technology, presently marketed, permits screw placement at an angle variation of 10 degrees from the conventional 90° angled plate hole (Figure 46). The smart lock plating systems are designed and manufactured by Stryker/Leibinger and have the advantage of locking bone segments to the plate and rendering them more stable.

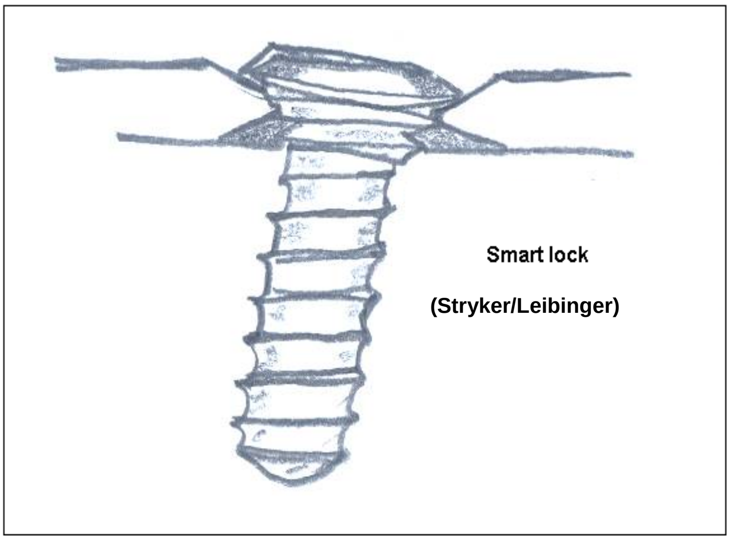

Figure 45: Screw angle variation of 10° from 90°

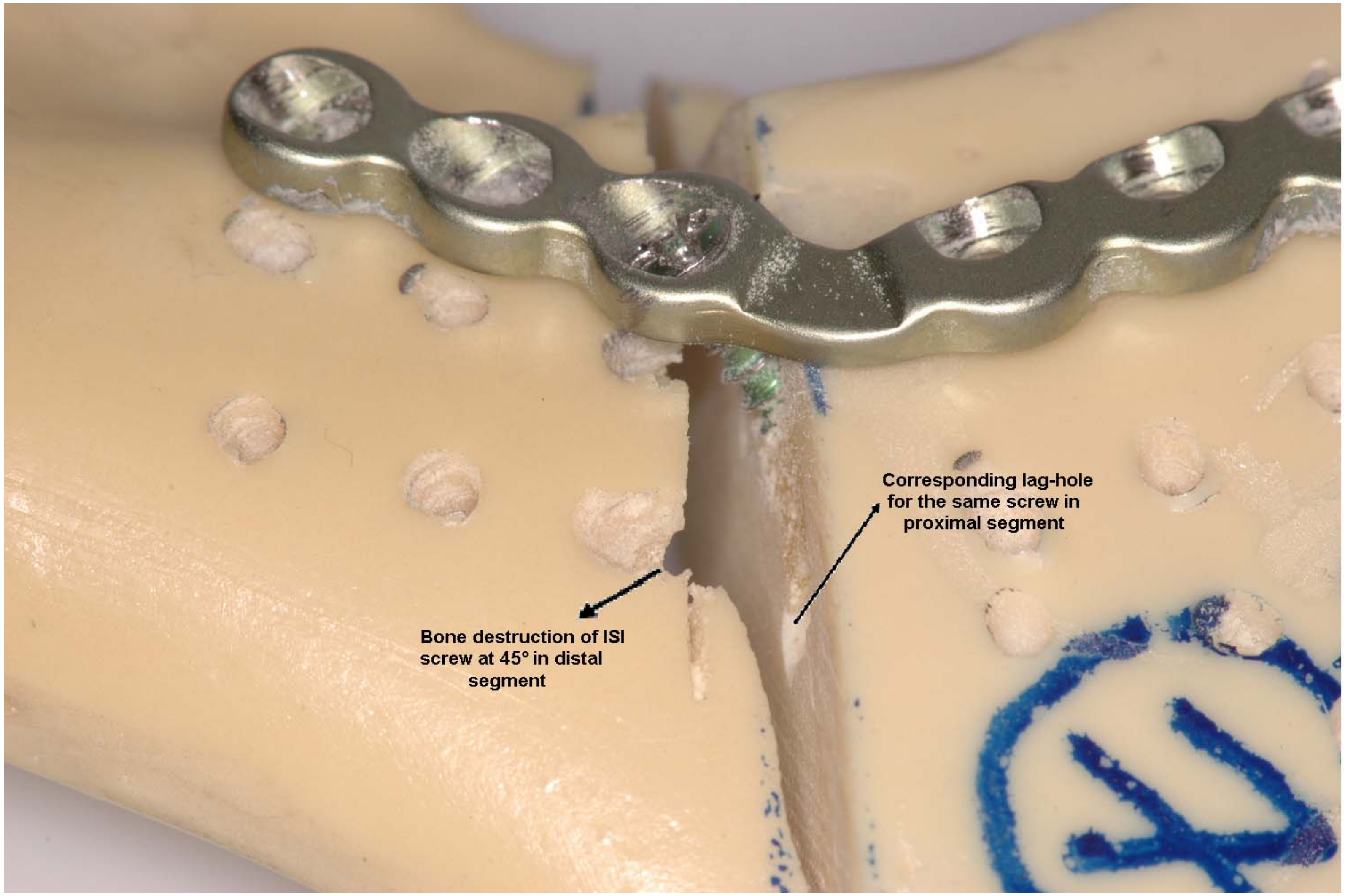

Figure 46: Bone destruction related to ISI of 45° for lag screw

An angle variation of 10-degrees, an inclined screw insertion angle of 80-degrees, is insufficient in terms of STT (screw tip travel) and STS (screw tip shifting) to promote lagging (transecting) across a fracture or osteotomy line (Figure 39).

It can be expected that orientation of screw angle within quadrant 1, 2, 3 or 4 as illustrated in Figure 1 in a plate hole, when applied differently in consecutive sets of angled plate-holes will change the spatial orientation of the screws in bone to benefit biomechanical stability. It is suggested that a plate should be manufactured with plate-holes designed according to the smart-lock principle. The plate-holes should be angled at a 55° (not 90°) in more than one quadrant orientation for screw insertion in the same hole. The smart lock ridge within the plate-hole will allow a 10° angle variation in screw angle placement. The variation of ±10° will permit screw placement at 65-45° in either quadrants 3 or 1 for the same plate-hole and allow the ISI plate. Quadrants 1&3 would be designated for use in the left half of the mandibular as apposed to the right half of the mandibular if the quadrant orientation were to be in quadrants 2&3. Screws placed at 90° angles to the bone surface, by contrast, have the same spatial orientation and can never be ideally angled to an oblique fracture line (Figure 5 A and B).

Tissue retractability and bone morphology at a specific anatomical site will determine plate-hole design and direct line of sight will dictate the quadrant orientation for plate-hole, pilot-hole and subsequent screw placement.

It is recommended that a “smart-lock” principle application could reduce the plate profile and in a 55° angled plate hole, will allow placement for screw variation within 10° accuracy, between 65° and 45° without the aid of a drill guide. The clinical relevance of ISI based on the “smart-lock” principle would allow screw locking and screw angle deviation between 45° and 65° without use of a drill guide and render biomechanical more stable fixation with minimal tissue tension using a direct line- of-vision for drilling or screw application without use of transbuccal or stab incisions.

Geometry of plate designs for angled screw insertion will be shaped specifically for an intended anatomical site and will have right sided and left side application versions and cannot be produced as standard straight plates as they do not conform to the stress lines for all possible anatomical sites.

7.2.4 Additional Instrumentation

Holding and drill guide instrumentation should be of low profile and will not aid in exact screw hole angle drilling unless accommodated by tissue retraction, which for intra-oral application is very limiting. Early product surveillance of a drill-guide /holding device proved it to be insufficient but pilot drilling without it was possible due to direct line of sight drilling in the angled plate-hole. Angled screw seating need not be exact when smart-lock screws and plate-hole designs are used as it allows a ten degree deviation.

The surgical intra-oral technique for ISI requires a certain amount of tissue retractability in the region of application. The direct line of application has a distinct advantage above trans-buccal or angled screwdriver applications (Figure 3).

7.2.5 Plate Geometry Related To Anatomical Positioning

Positioning and shape of osteosynthesis devices are important in creating biomechanical stability for fracture or osteotomy fragments.

An anatomical topographic study, similar to that conducted for the ISI plate should be the bases to contribute and dictate the geometric design of new plates conforming to existing strain lines as is the case in the marketed ISI plate with the plate hole angle orientation varied in the upper and lower sections of the plate – quadrant 1 for the ramus (upper) section and quadrant 3 in the corpus (lower) section of the curved shape of the ISI plate to adapt to the surgical angle of the mandible. Future plate designs for specific anatomical fracture positions in the mandible should also conform to the topographical aspects and accommodate structures such as the mental nerve.

A specific inverted Omega plate design (Addendum 6) to circumvent the mental nerve at the mental foramen with angled plate holes orientated in quadrant one (1) screws angled from front to back, clear of the nerve and with lag potential (Figure 47).

A y-shaped plate design for angle fractures will combine the effects of a superior border and lateral mono-cortical plate in a bi-planar fashion and will define a new term “bi-planar, mono-plating” (Figure 48). The geometry conforms to the strain lines during function and the tensile strains will be transmitted from superior arm to lateral/inferior arm of the plate conforming to the mandibular angle anatomy and will resist torsion forces better than a single superior border plate.

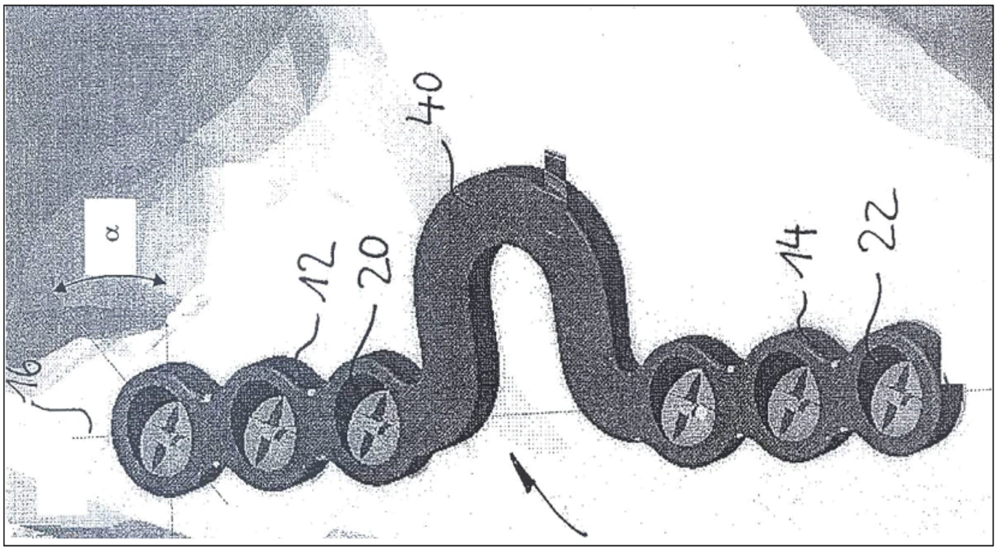

Figure 47: Inverted omega plate around Foramen mentalis

The mandibular angle y-shaped plate has a specific geometry to correspond with the strain lines in the mandibular angle (one strut for the superior border and the other for the lateral aspect of the external oblique ridge).

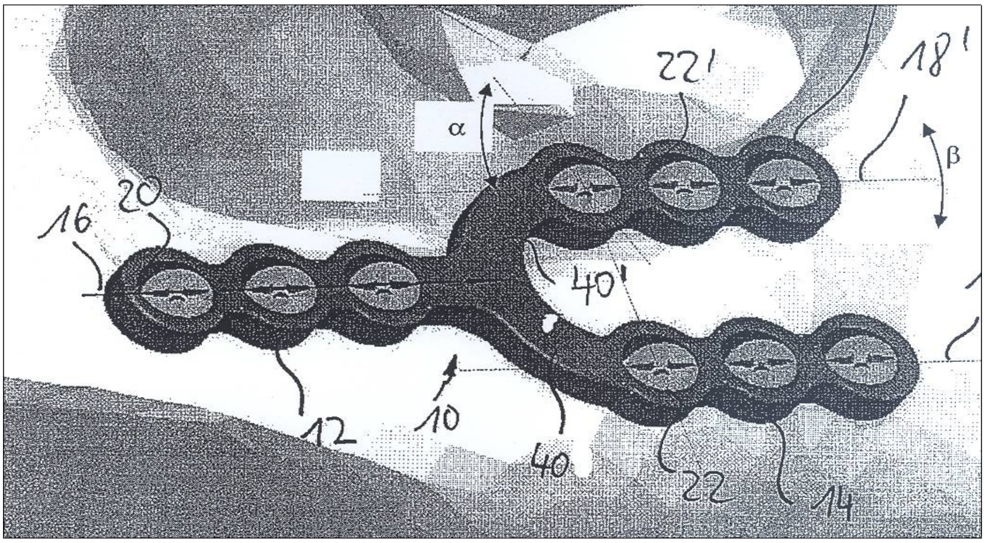

Figure 48: Y-shaped bi-plainer mono-plate

There is a distinct demand to change the plate geometry to coincide with the strain lines (Figure 49) such is the case with the C-shape ISI plate along the ideal osteo-synthesis lines in the mandible according to the functionally stable plating principles.

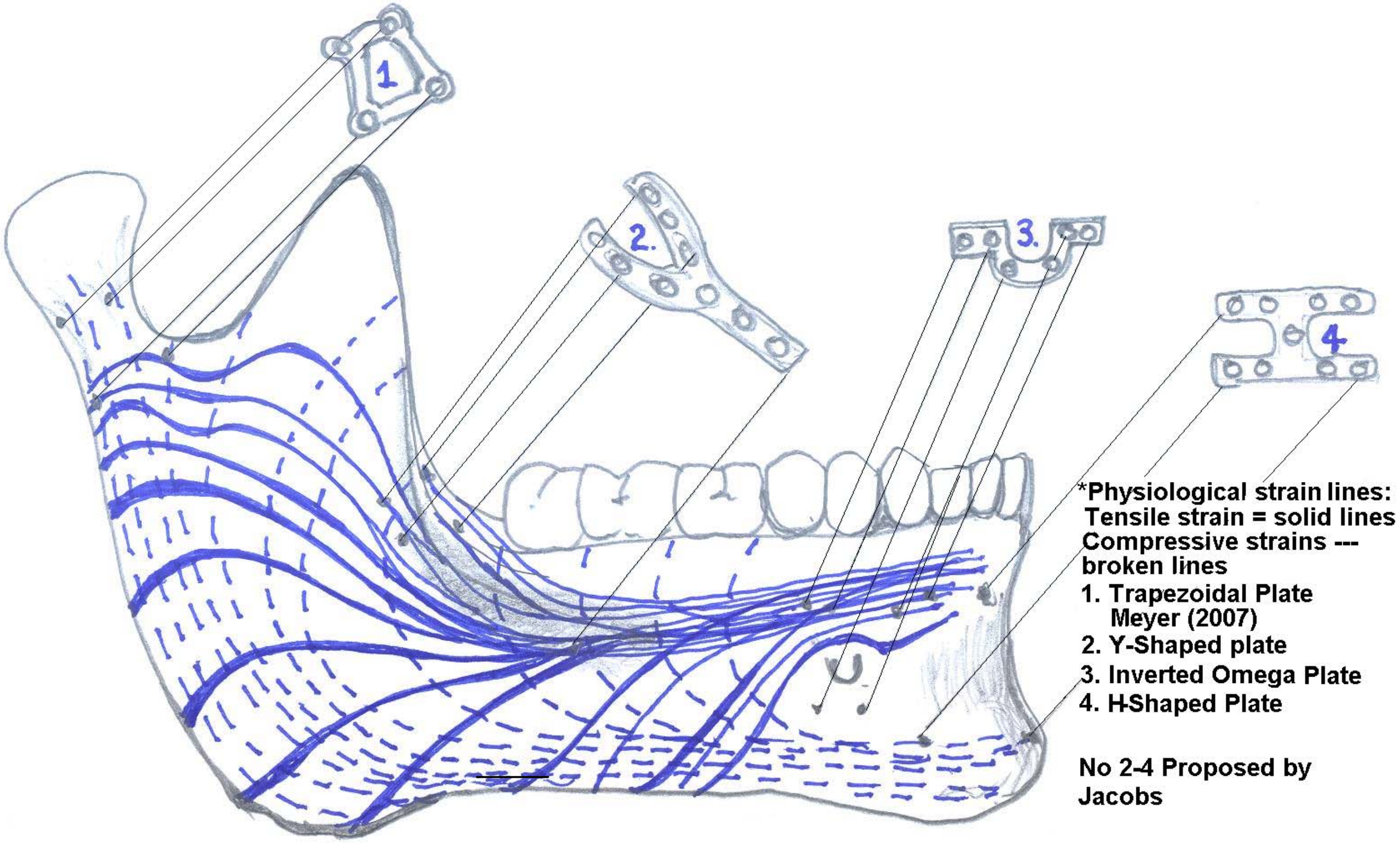

Figure 49: Proposed geometric designs according to physiological strain lines

Angled screw application with different orientation quadrants as in the patented ISI plate should be bio-mechanically compared to other mono-cortical conventional rectangular screw plates placed in a bi-plating, bi-planar or bi-plating mono-planar fashion as is the case with present research, mostly *in vitro* studies.[18 – 20] Ideally a clinical prospective study would confirm clinical relevance, at present the only study of this nature demonstrated clearly that bi-plating for angle fractures had no proven benefit to the patients.[39]

The angled screw and plate hole can be applied in any plate geometry such as the 2.0mm three-dimensional curved angle strut plate,[30] by changing its geometry to a Y-Shape to conform with strain lines during function at the mandibular angle (Figure 49). Angled screw application will benefit any mono- or bi-cortical plating system if designed specifically to conform with a certain anatomical topographical area of interest where strain lines are taken into consideration to conform to the established principles of functional osteo-synthesis. The plate shape will be unique and the angles of the plate-holes ideally inclined at between 65° - 45° angles of insertion and orientated in a specific quadrant (Figure 1), either parallel to the long-axis of the plate or diagonal (coronal) to it. The specific quadrant will align the screw angle diagonal to the fracture line and orientate the screw for lagging, across the fragments (Figure 50).

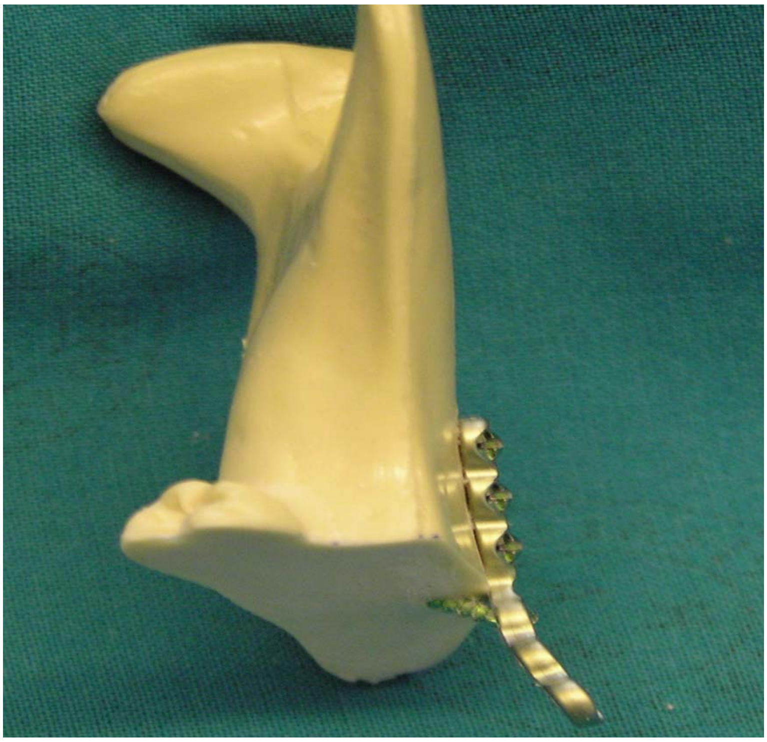

Figure 50: Lag effect of ISI at 45^0

7.2.6 Plate Geometry, Functional Stable Osteosynthesis and Strain lines

Square and rectangular three-dimensional plates were introduced[40] to the market and it was demonstrated by Meyer[41] that, three-dimensional rectangular plates provided the best biomechanical stability for sub-condylar fractures as a near perfect design, however, not completely conforming to the principles of functional stable osteosynthesis as advocated by Champy.[3, 18]

The tensile strain lines for the sigmoid notch area, running parallel to the curvature of the notch, were defined and described by Meyer,[42] from this information a trapezoidal three-dimensional 4-hole and 9-hole, condylar fracture mini-plate was designed. The plate geometry conformed to normal strain lines under function for the mandible, but do not accommodate inclined screw insertion to benefit a submandibular or temporal surgical approach to condyle neck fractures of the mandible.

The motivation to move away from near-perfect plate geometry, straight and three-dimensional plates on the market at present, a specific plate geometry for a specific anatomical area should be designed to conform with the normal strain lines in a specific fracture situation. Inclined Screw Insertion (ISI) will further benefit biomechanical stability and promote lagging across fracture lines through the principles of Screw Tip Shifting and Travel, in the mandibular angle and symphesis region. The plate geometry should accommodate the mental nerve and straddle the angle of the mandible in two planes – superior and lateral to the external oblique ridge rendering it more stable to lateral (torsion) forces of displacement.

Plate-hole angulations in quadrants 1&3 will ensure intra-oral surgical technique for application and removal of angled screws, through a direct line of vision without the use of a trans-cutaneous technique.

Straight plates fixed in different positions along ideal lines of osteosynthesis are inferior solutions to optimal screw angled plates of specific geometry for optimal biomechanical stability. Newly designed plates with the geometry conforming to functional strain lines will result in a reduction in the amount of implant material and number of screws used and would benefit patients treated due to biomechanical stability.

A y-shaped plate design for angle fractures will combine the effects of a superior border and lateral mono-cortical plate in a bi-planar fashion and will define a new term “bi-planar, mono-plating” (Figure 49). The geometry conforms to the strain lines during function and the tensile strains will be transmitted from superior arm to lateral/inferior arm of the plate conforming to the mandibular angle anatomy and will resist torsion forces better than a single superior border plate.

7.2.7 ISI – Quadrant Orientation and Lag-Effect of ISI

Mandibular angle fractures could benefit from angled screw hole plate designs when plating the lateral aspect of the ramus, high up on the caudal aspect of the external oblique ridge of which the patent ISI plate is an example. The ISI plate has 60° angled plate holes orientated differently for the plate holes in the proximal and distal segments to facilitate direct line of vision, intra-oral application and has improved biomechanical stability as demonstrated by comparative studies in the Mandibulator (Addendum 4).

Superior border plating according to the principles of Champy[3] will benefit from lagging (Figure 50) of the screw adjacent to the fracture line with a screw angle orientated in quadrant 3 (Figure 1), parallel to the long-axis, for 4 or 6 - whole application, this will result in a lag-plate design with an expected three-dimensional biomechanical stability improvement.

A lag–screw, mono-cortical plate to the benefit of symphesis fractures should be designed based on ISI principles with plate geometry H-shaped and aligned according to functional strain lines for the specific anatomical site (Figure 49).

Plate geometry has to conform to physiological strain lines and be specifically designed, for a designated anatomical location, would have Inclined Screw Insertion (ISI) with a specific quadrant screw angle orientation to facilitate intra-oral surgical technique to have a direct line of vision for screw and drill application to accommodate a specific extra or intra-oral surgical approach. The specific angle of screw insertion would also promote lagging in the regions of the symphesis and angle of the mandible - these plates will be lag plates with superior biomechanical properties. The only plate recently designed for the market with a geometry which conforms to strain lines in the mandible is trapezoidal in shape and is proposed for the treatment of sub-condylar fractures.[42] The plate geometry designs, as suggested, conform to strain lines and have inclined plate-holes, orientated in specific quadrants for a screw angle placement of 45°-65° (the freedom of angle created by the smart-lock principle without use of a drill-guide) to promote lagging through a intra-oral application for plate 2 and 3 (Figure 49). The quadrant orientation of the plate–hole and screw-angles are quadrants 3 for plate Nos. 2 and 4 and quadrant 1, for plate No. 3. The plate geometries for ISI titanium fixation mini plates co-inside with ideal lines for osteo-synthesis, enhance biomechanical stability and is applied through a intra-oral surgical technique establishing it as a cost effective treatment modality for fracture or osteotomy segments.

The clinical significance of angled screw insertion for the ramus section of a reconstruction plate, lag-plating in the symphesis, mandibular angle and in condyle fracture plates is of high clinical and biomechanical significance.

The lower limit for inclined screw insertion would be an angle of 45° and it is proven that an angle of 30° would result in plate lifting (Figure 39).

It is also proven that a screw angle application of 75° due to minimal screw-tip shifting and travel (Figure 39) would have no significant benefit when compared to conventional rectangular screw insertion and has no transecting (“lag”) potential. A same screw application distance of at least 5mm from the fracture line for inclined screw insertion is defined in order to prevent pilot drill destruction of the outer cortical plate or screw tearing through the cortex as seen during experimentation with ISI angles of 60° and 45° using the experimental ISI prototype plates (Figure 32).

The difference in the experimental ISI plate design and the clinical patentable ISI prototype used in the EPS (early product surveillance) is a longer connecting bar between the upper and lower plate-holes to prevent pilot drill destruction and/or subsequent tearing of the screw through the cortex on the edge of the fracture line when force is applied (Addendum 5).

If Inclined Angle Screw Insertion (ISI) is applied in a clinical situation the screw transection across the fracture line (“lagging”) results in significant and dramatic biomechanical stability improvement of the fixation provided that screw-tearing or pilot drill destruction of the outer cortex is prevented (Figure 45) by means of the ideal plate design (see point D and distance X E in Figure 39). Screw “lagging” is possible for ISI in quadrant three (Figure 50), with the optimal line sight for direct drilling. ISI in quadrant one is aimed at the engagement of thicker bone on the lower border of the mandibula in the symphesis regions.The freedom created by ISI and pilot drilling at what you see through the plate hole will have the advantage of not using a drill guide.

7.3 The anatomical study related to the geometric ISI plate design

Measurement of the surgical angle in a sample of human South African dried mandibles was performed to determine the geometry of the ISI plate for internal fixation in the mandibular angle region.

The curved shape of the ISI miniplate has to conform to the surgical angle of the mandible[43] (The angle formed by the anterior border of the ramus of the mandible and the external oblique ridge, is called the surgical angle of the mandible).

The superior border plate placement for angle fixation is considered to be just above and medial to the external oblique ridge in the retromolar fossa region, when this area could not be employed (ridge too narrow, impacted mandibular third molar, alveolar fracture, subject too young, etc.), the ISI plate is indicated and can be applied as high as possible on the lateral surface of the mandible just below the external oblique ridge (surgical angle). The retromolar fossa is defined as the triangular depression between the ridge called the temporal crest that runs from the tip of the coronoid process on its medial side to the bone just behind the third molar tooth and the anterior border of the ramus.

The ISI mini-plates are curved in a C shape to fit the surgical angle of the mandible. Measurement of the surgical angle is therefore essential to enable manufacturing of an universal fracture plate at the determined angle when applied to the angle of the mandible for fracture or osteotomy fixation. An universal C-shaped plate manufactured at the maximum determined surgical angle would be ideal to fit most fracture situations in the angle of the mandible if applied to the lateral aspect (Figure 51).

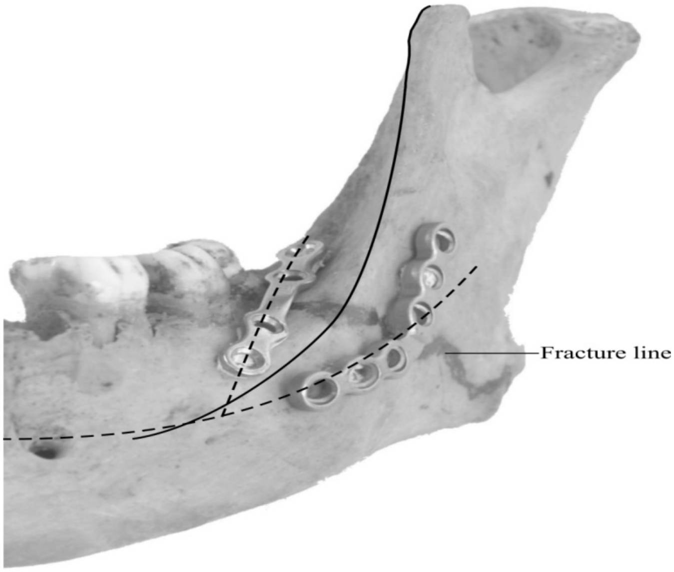

Figure 51: ISI plate geometry dictated by the surgical angle of the mandible

To the best of our knowledge, there is no record of an anatomical study determining the surgical angle of the mandible. The purpose of this anatomical study was to determine the surgical angle of the mandible, which has implications for the geometric design of the ideal angle of the C- shaped, curved ISI mini-plate positioned at the ventral (inferior- lateral) aspect of the external oblique ridge, on the same vertical plane.

A total of 133 human mandibles with intact first and second molars at least on one side, were randomly selected from the Pretoria Bone Collection: a modern South African skeletal sample (111 black males, 12 black females, 6 white males, and 4 white females) (Figure 52).

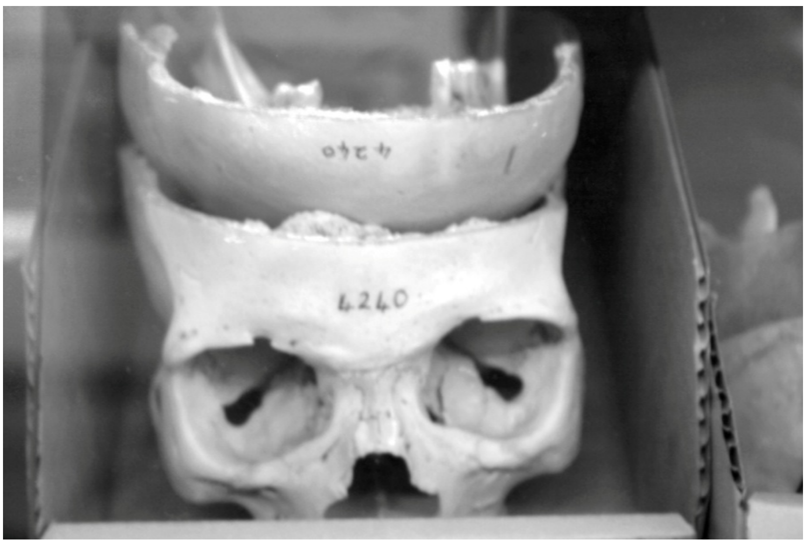

Figure 52: Sample of the Pretoria Bone Collection

The surgical angle was measured and expressed in degrees. The maximum angle measured was 150º, a plate manufactured at 150° or more obtuse will accommodate all the possible variations in our study group when applied to the lateral aspect of the mandible along and inferior to the surgical angle.

One hundred and eleven of the specimens belonged to black males, 12 to black females, six to white males, and four to white females. Their ages ranged between 23 and 87 years. Measurements were taken with a soft lead wire contoured along the anterior border of the ramus of the mandible through the most concave aspect of the surgical angle and continuous with the external oblique ridge, to a point coinciding with a perpendicular line drawn from the most posterior aspect of the first molar or the most anterior aspect of the second molar (Figure 53).

Figure 53: The right lateral aspect of the mandible.
The bold solid line indicates the placement of the wire along the surgical angle.

The contoured wire was traced onto paper. Point A was marked on this line – determined by a line drawn perpendicular from the posterior aspect of the 1st molar or anterior aspect of 2nd molar onto the point of intersection with the traced external oblique line. The extent of inversion of the external oblique ridge in a 2nd plane was measured as the vertical distance from the paper and the contoured wire in millimetres (mm) (Figure 54).

Figure 54: Soft wire contoured along the external oblique ridge, placed on a flat surface to reflect the amount of plate bending required.

A tangential line was drawn from point A to the coronoid process. The point of contact between the tangential line and the coronoid process was point C. From line AC, point B was established as the deepest point or most concave aspect of the surgical angle: in other words the largest distance from line AC. A triangle was constructed between ABC where angle B represented the surgical angle, which is the junction between the body of the mandible and the ramus at the origin of the external oblique line (Figure 55).

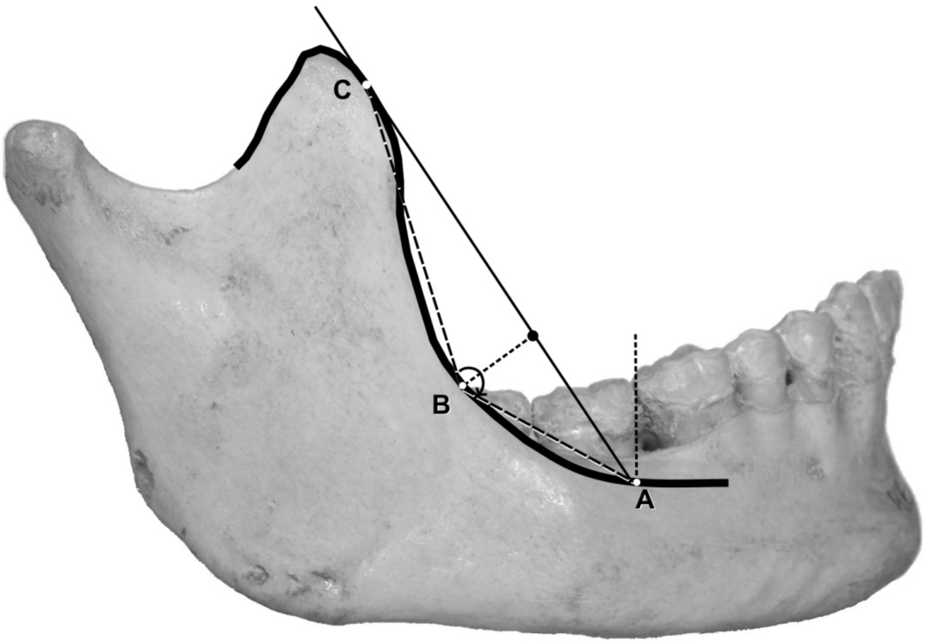

Figure 55: Trichonometrical calculation of the surgical angle

This angle represents the minimum angle at which a C-shaped plate is to be manufactured in order to fit the lateral aspect of the mandible below the external oblique ridge when treating mandible angle fractures. The mean and standard deviation were determined for all of the measurements. The one-way ANOVA with Scheffe and LSD as post hoc comparisons was calculated to determine whether the differences between the groups were statistically significant.

Two independent researchers were used to evaluate this unique, newly applied measurement method to evaluate surgical angle within the same sample of dried cadaver mandibles. The purpose was to correlate the repeatability of the measurement method. The inter-rater agreement or reliability between the measurements done by the two researchers was assessed by the interclass coefficient where each of the two researchers measured the surgical angle of 20 randomly selected mandibles. Only the black male group of 111 individuals was used for this analysis, as the other groups were too small to use for statistical purposes. The inter-rater agreement as measured by the interclass correlation coefficient was found to be 0.997, which suggests almost perfect agreement. It further suggests that the test procedure is highly repeatable and measurements by these two researchers are interchangeable.

A one-way ANOVA was computed to detect significant differences if any between the mean measurements of the four population groups. No statistical significant difference between the measurements of the surgical angle amongst the population groups and sexes could be demonstrated. Although not all the groups were well represented, there was a statistical significant difference between the average ages of blacks (males and females) and white females, which were much older. In addition there was a statistical significant difference between the average ages of black females and white males. The average surgical angle of the white female group was larger than those of the others, although not significantly different.

The result of the surgical angle measurement obtained is summarized in table 18.

Table 18: Tabulation of the average age, surgical angle and maximum angle measured in degrees, of the various population and sex groups. The standard deviation (SD) is given in brackets in each case.

	Population group	Average age in years	Average surgical angle in degrees	Maximum angle measured
Surgical angle	Black males (n=111)	54.14	137.30 (6.31)	150
	Black females (n=12)	46.83	136.08 (4.32)	144
	White males (n=6)	61.17	137.83 (3.92)	144
	White females (n=4)	71.25	142.50 (4.2)	148
	All (n=133)	54.32	137.38 (6.06)	150

An universal C-shaped fracture plate (one plate fits all) manufactured at the maximum surgical angle measured, simplifies plate selection for the surgeon and results in cost savings. The average angle of 136.62 to 142.5° dictates that the universal plate should be manufactured at an angle more obtuse than 142.5° to accommodate most variations. As the maximum angle measured was 150º, a plate manufactured at 150° or more obtuse will accommodate all the possible variations in our study group when applied to the lateral aspect of the mandible along the surgical angle in treatment of mandibular angle fractures.

The amount of inversion of the external oblique ridge reflects the amount of bending required to contour the curved mini-plate to the lateral aspect of the mandible. This is of value so as to indicate the degree of rigidity (resistance to bending without stability compromise) of the plate needed for ease of handling by the surgeon. In our study we found that the average amount of inversion of the external oblique ridge, and thus bending required from the curved mini-plate, was 2.83 mm.

Although the sample does represent very low numbers in the female groups and white males, it is well represented in the black male group. Measurements of the surgical angle in black males are particularly relevant to the population group in our care. According to personal experience of fractured mandibles in our department, there is a predominance of black male cases, which gives credibility to this study.

The white female group, only represented here with four members, had a larger average surgical angle and was significantly older than the other groups. The relationship between age and surgical angle has not been fully investigated in this study.

It can be concluded that the maximum surgical angle measured in this sample of mandibles from the Pretoria Bone Collection was 150º. An universal plate manufactured at 150° or more obtuse will accommodate all the possible variations in our study group when applied to the lateral aspect of the mandible along the surgical angle in treatment of mandibular angle fractures. Further studies may be conducted to improve the numbers in the groups not well represented. The relationship between age and surgical angle should be further analyzed.

7.4 Surgical technique for ISI plate fixation.

The operative technique instructions below for the patented ISI plate is summarized in the surgeon's manual as developed through this research.

CHAPTER 8 CONCLUSION

The scientific contribution of the ISI principle

A six-hole mono-cortical trauma plate with angled plate holes, in different angle quadrant orientations for each segment was designed and tested as an unique patentable concept, applied trans-orally at the ventral aspect of the external oblique line defined as a Champy strain line in the angle of mandibula.

ISI (Inclined Screw Insertion) is clinically defined in terms of screw tip travel (STT-with clinical relevance to screw length) and screw tip shifting (STS with clinical relevance to the lag-potential of a screw) as new terminology used to implicate improved biomechanical stability compared to 90^0-angled conventional screw insertion.

New designs of plate geometry for application to specific anatomical regions of the mandibula are suggested (Addendum 6). The designs are dictated by the known strain lines of the mandibula during function and aimed at using a single plate with a specific geometry rather than several straight plates to cover the strain lines. This approach is more cost effective and minimises the amount of titanium used. This design is developed for an intra-oral application and therefore a transbuccal approach is not required.

A quadrant description for angled screw placement is formulated to benefit future communication in terms of plate-hole and screw angle orientation and to standardise terminology.

Presently there is no angled screw plating system on the market which opens a vast unexplored field of investigations to be attended to. Comparative biomechanical studies can now be restricted to application angles of between 65°- 45° angles based on the findings of this study.

Angled screw application in a mono-or bi-cortical plating system will clinically render superior biomechanical stability to conventional 90^0 angled screw systems. This unique biomechanical study establishes new concepts in terms of inclined screw insertion (ISI), torsion screw angle test (TSAT), compression screw angle test (CSAT), screw tip shifting (STS), and screw tip travel (STT).

An unique biomechanical stability testing device is designed and manufactured to investigate the in vitro efficacy of rigid fixation systems with high clinical relevance and significance when applying compression, tension and torsion forces to fracture simulations in synthetic polyurethane mandibula replicas. This device proved efficient and cost effective during biomechanical testing as the only available stability testing device in South Africa for future *in vitro* studies.