Assessment of Carbon Fibre Composite Fracture Fixation Plate Using Finite Element Analysis

SEYED H. SAIDPOUR
University of East London

Abstract

In the internal fixation of fractured bone by means of bone-plates fastened to the bone on its tensile surface, an on-going concern has been the excessive stress shielding of the bone by the excessively-stiff stainless-steel plate. The compressive stress shielding at the fracture-interface immediately after fracture-fixation delays callus formation and bone healing. Likewise, the tensile stress shielding in the layer of bone underneath the plate can cause osteoporosis and decrease in tensile strength of this layer.

In this study a novel forearm internal fracture fixation plate made from short carbon fibre reinforced plastic (CFRP) was used in an attempt to address the problem. Accordingly, it has been possible to analyse the stress distribution in the composite plates using finite-element modelling.

A three-dimensional, quarter-symmetric finite element model was generated for the plate system. The stress state in the underlying bone was examined for several loading conditions. Based on the analytical results the composite plate system is likely to reduce stress-shielding effects at the fracture site when subjected to bending and torsional loads. The design of the plate was further optimised by reducing the width around the innermost holes.

1.0 Introduction

The healing of a fracture in the forearm can be assisted by screwing a fracture plate across the fracture site. Internal fixation with rigid metal plates, screws and pins is a proven operative technique for the treatment of bone fractures. Internal fixation hardware provides excellent reduction of the bone fragments and has the necessary strength to stabilise and support the fracture, allowing early mobility of the forearm. The early fixation plates were made from 306 or 316 stainless steel due to their good corrosion resistance. However, orthopaedic industry has closely followed the aerospace industry in utilising high performance metal alloys, based on Cobalt-Chromium and Titanium alloys, which have an elastic modulus at least 10 times greater than that of bone (in the longitudinal direction), for superior implant performance and might be on the road to repeating this with advanced composite materials.

However, numerous studies have shown that these rigid metal plates interfere with normal bone physiology by stress shielding of the bone beneath the plates (1-5). The density of the living bone is always controlled by the stress conditions applied to the bone; thus if a higher stress is applied to the bone, the density of the region increases (4, 5). So if the metal plate with high modulus of elasticity, is attached to the bone with the usual screw fixation system, the stress will be transmitted by the plate to the bone directly beneath the plate leading to a high stress concentration region. Hence increasing the possibility of refracture of the bone after loading or unloading of the bone. While the use of external casting leads to general disuse osteopenia throughout the affected bone, plate fixation causes localised osteopenia of cortex beneath the plate, alters the diameter of the bone and inhibits normal bone remodelling as evidenced by the persistence of immature woven bone. A significant number of refractures has been reported after removal of rigid internal metallic plates, as a result of this alteration in bone physiology.

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Mechanical stimulus or stress in the skeleton is a major factor in maintaining the normal balance between the processes of bone formation and bone resorption. When physiological stress is diminished, osteoporosis occurs rapidly. Stress shielding occurs when two or more components with different moduli form one mechanical system. The component with the higher modulus bears more of the load and protects the other fixation devices. Although at first the rigid fixation may favour primary bone healing, the stress shielding during the later stages of healing may lead to osteoporosis with decreased bone strength (5). The degree of stress shielding is related to the rigidity of fixation (6). The actual force acting across the bone and fracture, as well as the stress concentrations in the bone depend on the dimensions and shape of the fixation device (7).

Several in vivo studies have shown the stress shielding effects resulting from the use of rigid internal fixation plates (5, 4). Mechanical changes due to internal fixation are a result of reduction in cortical bone structure by thinning of the cortex rather than by a reduction in the bone substance's mechanical properties (8). There is an initial general resorption of bone tissue followed by a reversal of the remodelling process and then long term, site-specific bone resorption. Reducing the stiffness of the device should enhance fracture healing, but a compromise must be reached between strength and stiffness as flexible plates with inadequate strength can cause pain and can result in non-union of the fracture (9).

Several alternative plate designs and plate materials have been proposed to minimise the effects of stress shielding. Uhthoff et al (10) compared the results obtained with stainless steel plates and titanium alloy plates. The titanium plates were as strong as the steel plates, but were half as stiff. They observed less stress-shielding induced bone loss with titanium. Whereas with stainless steel there was a haphazard arrangement of bone lamellae and osteons at the fracture site, often at right angles to the long axis of the bone.

In the bone fixed with titanium plates, however, the compact bone at the fracture site had a nearly normal histological structure.

Woo et al (11) proposed a tubular stainless steel plate that had high bending and torsional stiffness to ensure adequate fragment control, but a low axial stiffness to allow the underlying bone to carry a higher portion of the load in the post-union phase of healing. Woo et al (11) compared the performance of a standard stainless steel plate, a thin titanium plate and the tubular stainless plate and observed similar results for the tubular plate and the titanium plate. However, the tubular plate had a much higher bending and torsional stiffness than the thin titanium plate and would provide much better fragment control in the pre-union phase of healing. The less flexible plates allowed the development of an external callus at the fracture site, which was much more robust than bone formed by direct remodelling.

As the fracture heals, the need for rigid support is diminished. Ideally, the stiffness of the fixation device should decrease as the bone strength increases. To achieve this goal, several investigators have proposed the use of bioresorbable polymer pins, screws and plates (12, 13). To substitute the metal implants for internal fixation about 40 different polymers, copolymers and composites have been developed. In responding to the complex demands on fracture plates, the use of advance composite materials potentially would enable designs that can seek optimal mechanical characteristics through modifications of fibre types, orientation and ply-stacking sequences, as well as implant geometry (14).

The experimental and clinical results have so far demonstrated some limitations of these new materials, such as poly-L-lactide (PLLA), carbon fibre composites (15). Disadvantages of carbon fibres embedded in epoxy, polyester or PMMA include; a) long term reduction in properties sometimes before bone healing has been completed, interaction of body fluids with the matrix material may degrade the properties, b) the

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release of carbon fibre fragments that can migrate into other tissues (16), c) lack of ductility that prevents reshaping in the operating room in the manner of metal implants (17). The latter problem can be overcome by selecting an alternative matrix polymer such as polysulphone, which can be reshaped to the required size, under moderate heat, in the operating room (18).

In an investigation to compare deformation behaviour of composite fracture plates made from aramid-epoxy and carbon-epoxy composites, in which 4-hole fracture plate specimens were used, it was shown that the aramid composites appeared to be less subject to catastrophic failure than carbon fibre composites (14). Also when the specimens were fastened to a plastic tube, simulating bone, the strain shielding was significantly reduced by the aramid composites relative to carbon fibre composites. Claes (22) conducted an extensive study of fracture behaviour of 6-hole plate design made from carbon fibre reinforced carbon composite. It was concluded that bending and torsional rigidities of the plate over the fracture zone must be sufficient to prevent gross motion at the fracture site, however the axial stiffness, bending and torsional rigidities must be reduced to minimise stress protection.

In order to optimise the fixation stiffness/ strength and study the effect of different fracture plate properties on the healing process Foux et al developed an experimental device called the "axially flexible plate" (AFP) system (23). The system consisted of three components: a rigid metal plate, screws and elastic inserts. The elastic inserts made of various, biocompatible polymers such as poly-methylmethacrylate (PMMA), low density polyethylene (LDPE) and poly-L-Iactide (PLLA) fill the space between the screws and the metal plate in the plate's elongated holes. The screws can move laterally towards the fracture site by deforming the cushions. The axial flexibility of the AFP depends on the insert elasticity.

Animal trials were conducted with the AFP system, to determine the optimal value for plate

axial rigidity, based on bone healing (22). In this case, the axial rigidity of the plate was varied while the torsional and bending stiffness of the plate remained constant. Decreasing the axial rigidity of the fixation plate should produce a more equitable distribution of axial compressive loads between the plate and bone while still maintaining good primary fixation. The AFP also allows some micromotion at the fracture site, which promotes callus formation and better bone healing. The optimal axial flexibility, however, may change as the fracture heals. In the early stages of fracture healing, a stiffer plate would ensure adequate fixation. Biosorbable polymers such as PLLA would allow the design of an AFP system with a constantly changing axial flexibility.

Various investigators have shown that application of a single metal plate produces a mean reduction in both axial stress and strain ranging from 28-45% of nonplated values. Foux et al (23) calculated values of P (the fraction of load carried by the bone) of approximately 50% for a standard stainless steel plate and 76% for the AFP system with PLLA inserts.

1.1 Failure of Forearm - Fracture Plate

When failures of fracture plates occur, they most commonly occur within the first 10 to 13 weeks, with the mode of failure being fatigue (25). Assuming a patient will walk between 1/2 h and 1h per day on average during this time a fracture plate used to stabilise the fracture will be loaded between approximately 162,000 and 325,000 times (26).

Various investigators have studied the effect of different loading conditions on the screws holding the fracture plates onto the bone (24-27). Screw loosening has been shown to be possible in vivo and has been attributed to cyclic mechanical loading (24, 25). All screws undergo mixed modes of loosening with those near the fracture site experiencing the largest loads and the greatest amount of loosening.

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Other studies have involved assessment of refracture of the forearm after removal of the fracture plate (28-30). Hidaka and Gustilo (30) reported seven refractures in 23 patients with 3 refractures occurring at the site of the original fracture, three through a screw hole adjacent to fracture site and one through a screw hole distant from the fracture site (Figure 1).

1.2 Finite element analysis of internal fixation devices

Finite element analysis is finding increasing use in the design and evaluation of internal fixation plates and screws to overcome the major weaknesses of current fixation devices: fatigue failure of the device and stress shielding of the bone. Cheal et al (32) used a three-dimensional model of a plexiglass tube with an attached stainless compression plate. Several different load cases were evaluated, including cyclic external loads and static tensile preloads in the plate and screws. The model showed that the stress shielding effects were limited to the central region between the inner screws. Also, the induced stresses from pretensioning of screws negated any stress reduction under the plate.

Koo et al (33) developed a finite element model to predict the fixation stiffness of the Dynafix unilateral external fixator at arbitrary configurations under compression, torsion, three-point, and four-point bending. It appeared that the model succeeded in predicting the relative stiffness of the neutral and non-neutral configuration in all the loading conditions. Their results also demonstrated that bending stiffness could vary substantially for different loading directions and the principle loading directions could be very different for different fixator configurations. They also concluded that a suitable finite element modelling would provide useful clinical information on the rigidity of certain configurations in stabilizing the fracture site for bone healing.

Beaupre et al (34) used a more sophisticated three-dimensional model to determine the importance of friction between the plate and the bone. In this model, the plate and bone interacted through non-linear Coulomb-friction contact elements which allowed stress-free separation under tensile loading, and depending on the friction coefficient, sliding or the development of shear stresses parallel to the interface. The bone was loaded in bending and the friction coefficient was varied from zero (frictionless) to infinity (direct coupling). This study showed that the relative motion between the plate and bone was significant, as the zero friction model was 65% more flexible than the directly coupled model. Mathematical/ numerical models have also been used to evaluate the fibre-reinforced resorbable plates for long-bone fixation (35-40). It is likely that these non-metallic materials will play an important role in the future development of internal fixation techniques.

2.0 Method

The goal of this study was to construct a detailed three-dimensional finite element model of the plate system that would capture the unique geometry of the new plate design, and would be versatile enough to study a variety of loading conditions. In this study FEA was performed to examine the mechanical performance of different six-hole fracture plate designs under two different loading conditions, namely bending and torsion. These plates were assumed to have isotropic properties with short carbon fibre reinforced thermoplastic (CFRP) composite materials.

To utilise the full potential of CFRP composites initially a plate was designed which consisted of straight parallel edges. However to provide more movement at the point of bone fracture as a control, a second fracture plate was designed with a reduced waist in the middle. But the relatively sharp corners in the waisted design (the control case) resulted in higher stress concentration. Hence an attempt was made to optimise the stress/ stiffness in the design by varying the breadth in the waist region from 8mm to 12mm in a non-linear fashion, to reduce the stress concentration in the

region, Figure 2 shows part of the waisted plate design.

The model also considered the effect of screw tightening pressure as well as a uniform pressure, simulating the bone/plate interface, on the regions of stress concentration or reduction in the plate systems. With these criteria, the model was created following an iterative process of mesh generation and mesh refinement. Boundary conditions and external loads were applied to the model, and a solution was obtained.

The implant geometry definition, FE model and solution were all performed using I-DEAS software. This was achieved by first constructing three dimensional solid models within the CAD Solid Modeller, then the geometric information was used by the Finite Element Mesh Generation task to create mesh areas and mesh volumes. Nodes and elements were then generated from the mesh volume.

The input consisted of the discretised mesh with elemental properties specifying the stiffness matrix components (elasticity tensor) in addition to the boundary conditions and loading history. The output of this program in addition to nodal displacements gave the stress state at any location of the fracture plate. In areas with high stress gradients a fine mesh was required for an accurate model solution. Mesh refinement is the process of systematically increasing the mesh density in these areas, to generate a more accurate stress contour plot where the greatest stress gradient occurs in the model. Preliminary model solutions were used to identify areas with high discretisation error. From these initial results, it was apparent that the most important area for mesh refinement was in the region surrounding the screw holes, and a second mesh was generated which had an acceptable level of numerical accuracy, i.e. the number of elements was increased to reduce the step between nodes and thus decrease errors associated with discretised models.

3.0 Results and Discussion

Two separate load boundary conditions were performed to analyse the stress concentration in the two different designs. First the effect of applying a pure bending load was examined by specifying a load of 800 N at the plate end with the plate fixed across the middle cross section. The second loading condition involved a twisting moment of 2.8 Nm which was applied to each of the first three screw holes at one end, about the neutral axis of the plate cross section, with half of the plate restrained at the opposite three screw hole locations. To simulate the effect of screw head locking into the holes, a uniform pressure of 19 kNm^{-2} was specified on top of all the screw holes. To achieve equilibrium, a corresponding upward pressure was specified to represent the reaction force of the bone. The load boundary conditions specified are described in Figure 3.

To further improve the design, to reduce the stress at the edge of the holes caused by a bending load, the edge of the hole can be brought closer to the neutral axis of the implant cross section. In all the modelling this modification was considered (Figure 4).

Finite element models of the two designs were constructed and are shown in Figures 5 and 6. For the plain bending load case it was only necessary for a symmetric model (Figure 5) about the longitudinal and mid-planes to be produced. By implication, the torsional load case (Figure 6) required a complete model of the plate. These illustrations show the Von Mises stress distribution for both fracture plate designs under the two specified loading conditions. Von Mises stress is used as a fatigue criterion, since fatigue is the expected mode of failure. It should be noted that in all the models considered no portion of the model appeared to be yielding. Utilising Von Mises yield criterion showed that finite element analyses were within the elastic range. If loads were increased due to dynamic effects, then analyses including plasticity may be appropriate.

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When pure three point bending is specified the two models react differently, the maximum stress occurs at different locations. For the straight edge model the stress levels tend to be lower with the innermost screw holes carrying increased stresses, with the highest stress of 553 MPa. For the waisted edge model (the control case) the highest stress concentration occurs around the middle of the span with the stress of 641 MPa. This is an increase of 16% over the straight edge model. However the next highest stress in the waisted edge design is around the inner screw holes with a value of 225 MPa. A similar trend was also present for torsional load case. Thus the inner screw hole regions are the most likely areas for plate failure. Preliminary destructive tests on the fracture plates have confirmed these findings.

Therefore the waisted profile of the plate can be optimised further by increasing the radius to reduce the local stress in the mid span to match the stress around the inner holes. It is believed that once the waisted edge design is optimised it will eventually prove more satisfactory for general use. Although it does not appear to be as strong as the straight edge plate, because it is less rigid this can result in a better fracture fixation.

4.0 Conclusion

It is important to tailor the stress concentration and stiffness in the critical mid span, and in the areas surrounding the holes of the plate. CFRP is an ideal material for this process. The highest stresses occur in the inner screw hole regions, with a Von Mises stress of 553 MPa. To optimise the stress/ stiffness the plate can be waisted to yield a more uniform stress distribution, which will also result in a reduction of bending and torsional stiffnesses.

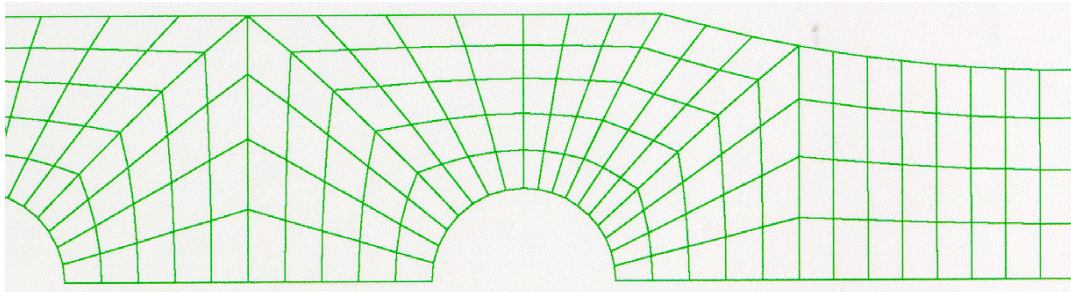**Figure 1 Forearm fractures and fracture fixation plates**

Figure 2   Part of the waisted fracture plate (a quarter model) showing the mesh density and reduction in the plate breadth
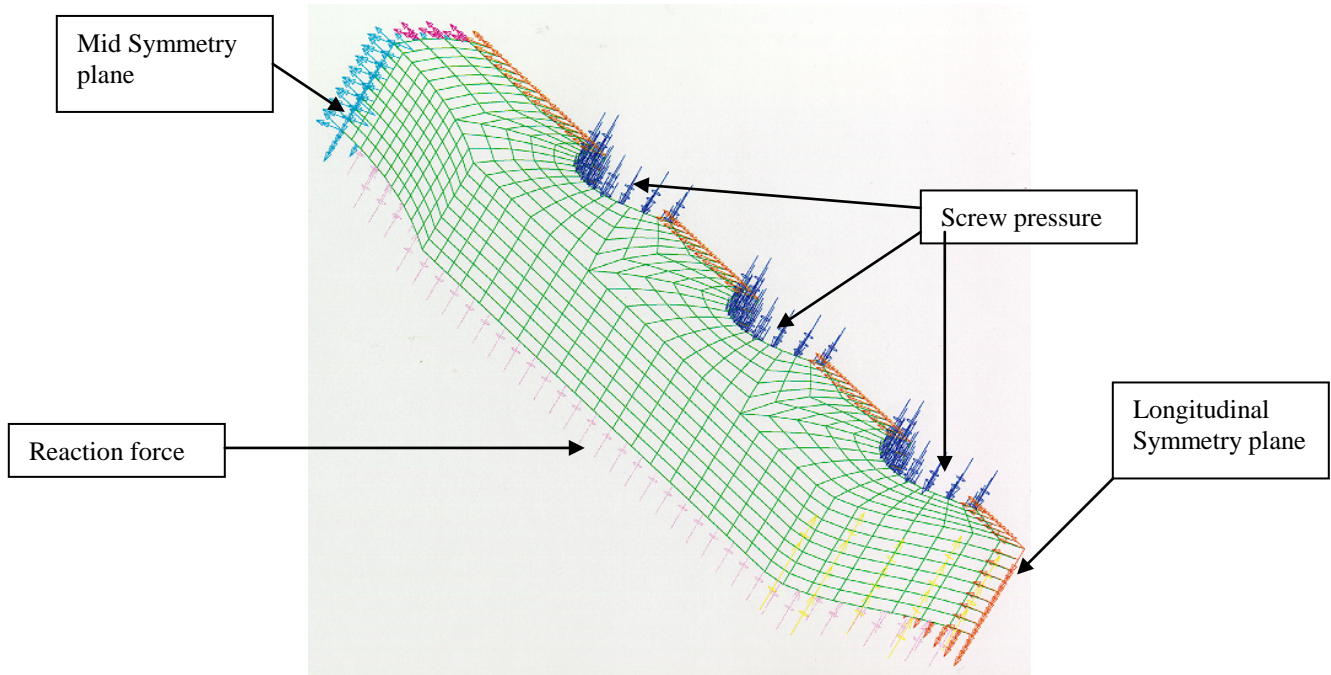
Figure 3 Load boundary conditions applied on a quarter fracture plate model showing the effect of screw and the bone pressure on the fracture plate.
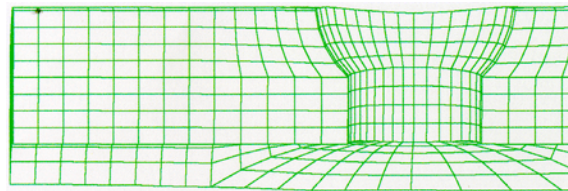

Figure 4 Improved design of the hole (positioning screw head closer to neutral bending axis) to reduce the stress at the edge of the holes caused by a bending.
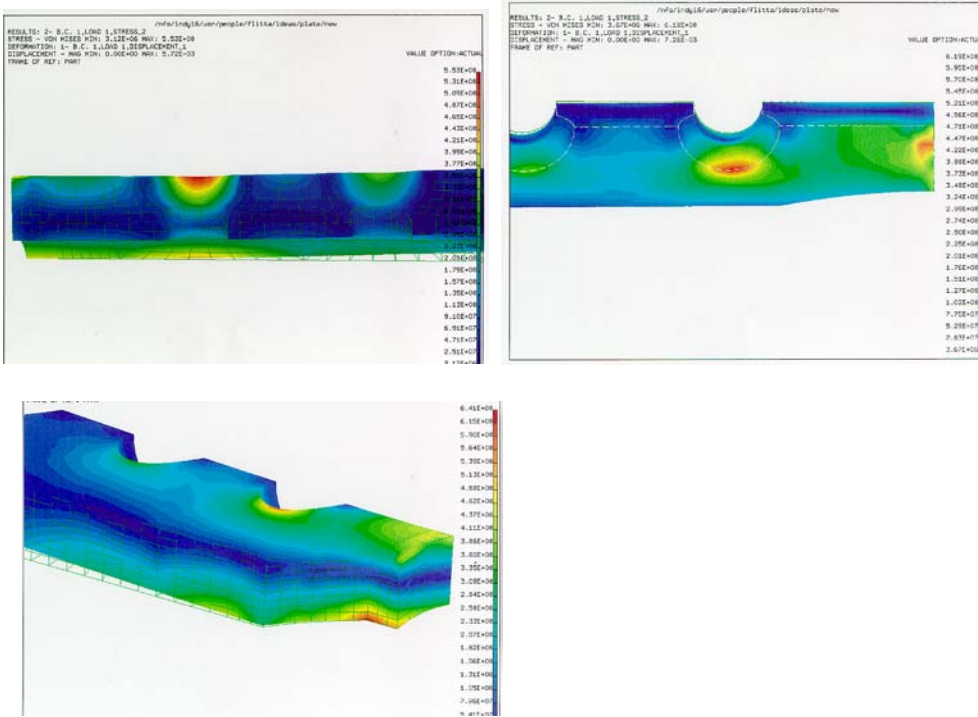
Figure 5 Von Mises stress distribution on straight edge and waisted fracture plate models loaded in pure bending
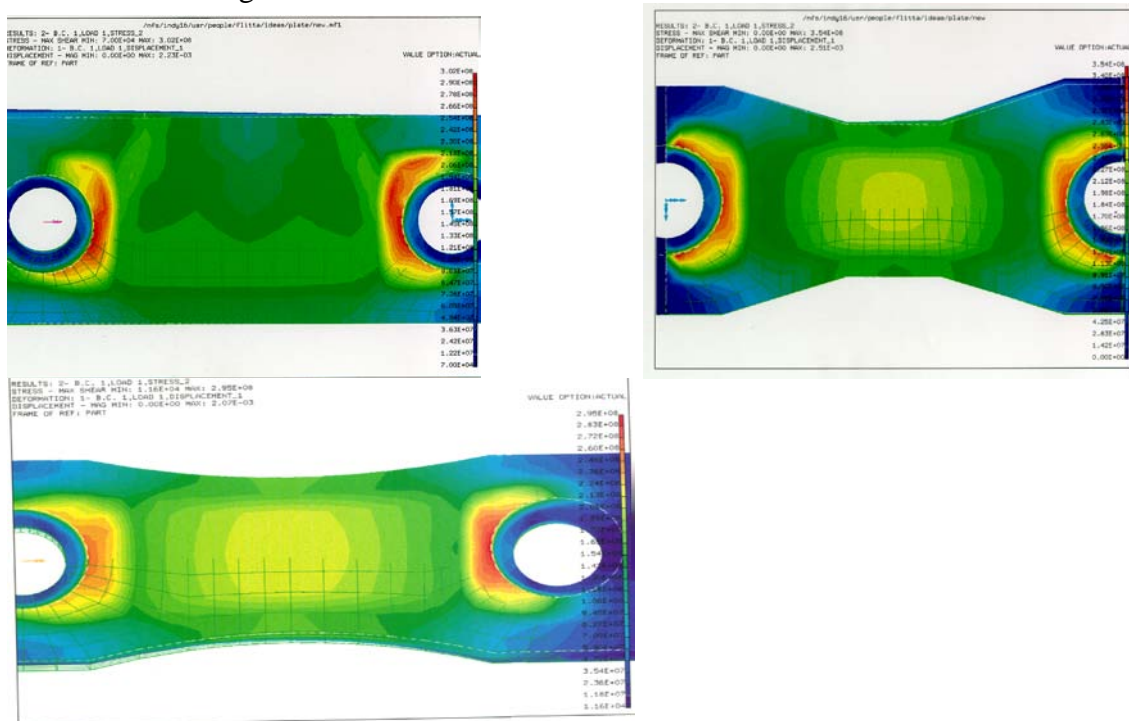

Figure 6 Von Mises stress distribution on straight edge and waisted fracture plate models loaded in torsion

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