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## THE DESIGN OF MECHANICALLY COMPATIBLE FASTENERS FOR HUMAN MANDIBLE RECONSTRUCTION

Jack C. Roberts, Senior Professional Staff  
John A. Ecker, Senior Professional Staff  
Paul J. Biermann, Senior Professional Staff

The Johns Hopkins University  
Applied Physics Laboratory  
Laurel, Maryland

### ABSTRACT

Mechanically compatible fasteners for use with thin or weakened bone sections in the human mandible are being developed to help reduce large strain discontinuities across the bone/implant interface. Materials being considered for these fasteners are a Polyetheretherketone (PEEK) resin with continuous quartz or carbon fiber for the screw. The screws were designed to have a shear strength equivalent to that of compact/trabecular bone and to be used with a conventional nut, nut plate, or an expandable shank/blind nut made of a ceramic filled polymer. Physical and finite element models of the mandible were developed in order to help select the best material fastener design. The models replicate the softer inner core of trabecular bone and the hard outer shell of compact bone. The inner core of the physical model consisted of an expanding foam and the hard outer shell consisted of ceramic particles in an epoxy matrix. This model has some of the cutting and drilling attributes of bone and may be appropriate as an educational tool for surgeons and medical students. The finite element model was exercised to establish boundary conditions consistent with the stress profiles associated with mandible bite forces and muscle loads. Work is continuing to compare stress/strain profiles of a reconstructed mandible with the results from the finite element model. When optimized, these design and fastening techniques may be applicable, not only to other skeletal structures, but to any composite structure.

### INTRODUCTION

During mandible reconstructive surgery many problems may be encountered when attaching thin or weakened (diseased) sections of bone to one another, or to a replacement material. Some of these problems may stem from differences in the mechanical properties of bone and the implant material, or from the fastening method. The use of bonding techniques may result in premature failure of the interface due to the reduced or weakened bone section at the interface. The use of mechanical fastening techniques could result in shearout of the thin/weak bone due to the higher stiffness of conventional fastener materials, as well as large strain discontinuities across the interfacial boundary between different materials.

Atrophy, due to stress shielding of underlying bone in metal fixation devices, is said to be the most important reason for the removal of rigid metallic plates and screws. Several investigators have proposed the use of biodegradable materials with the same properties as bone to be used in place of metal fixation devices (1-3). These biodegradable materials could be used in situations where the fixation device is no longer needed after the fracture has healed. To create a better interfacial bond between implants and bone other investigators have explored the use of porous metallic implant materials (4), and to eliminate corrosion porous polysulfone (5) and porous hydroxyapatite (6,7). Hydroxyapatite was thought to create a better bond with bone because it is one of the constituents of bone. However, in situations where the implant or reconstructed mandible must remain in place with the fixation device, it is desirable to have a fixation device that has the same properties as bone and will have adequate strength at the bone/implant interface.

Therefore, the purpose of this study was to design non-metallic fasteners having properties similar to bone for a reconstructed mandible or mandibular implant. The fastening method should "design in" the ability of the fastener to flex with bone, thus preventing bone atrophy, while providing a continuous load path from bone to the replacement. The design of the fasteners will be guided by both a physical model and a finite element model of the mandible.

## MATERIALS AND FASTENER DESIGN

### Materials

Bone has a hard outer surface (compact bone) and a soft, porous inner core (trabecular bone). This makes it similar to sandwiched composite structures used in the aerospace field. These structures consist of an highly porous inner core (usually a honeycomb material to carry shear loads) sandwiched between aluminum, glass/epoxy or graphite/epoxy face sheets (to carry the tensile or compressive loads). A comparison of the two assembled structures is shown in Figure-1. Because of the similarity in function, the implant designs will use fasteners similar to those used with sandwich composites in the aerospace field. In order to size the screws in any of the following designs, bone properties in shear (8) were used to calculate the necessary screw diameter. In order to minimize strain discontinuity between bone and fastener, the fastener will be designed to have elastic properties equivalent to that of bone. Since the fasteners will have a smaller cross sectional area than that of bone, the shear strength will need to be higher than that of bone. The screw materials that most closely met these criteria were Polyetheretherketone (PEEK) with either continuous carbon or continuous quartz fibers<sup>1</sup>. This design methodology may be a better way to select fasteners for any composite structure, not just bone.

### Fastener Design

For ease of assembly, the fastener design selected should allow the surgeon to insert the fastener from the buccal (outside) surface of the mandible. To reduce trauma to the patient and prevent possible infection, the fastener should be flush with the surface of the replacement mandible or mandibular bone. It may also be advantageous to have the fastener put the bone into compression to prevent atrophy. All of these design "criteria" need to be considered when selecting the optimum fastener design.

Three fastener designs are shown in Figure-2. Each design relies on a screw and a nut or nut plate to retain the mandibular replacement. The design in Figure-2A, shows a screw assembled from the lingual (inside) of the mandible into a blind hole in the replacement mandible. The underside of the head of the screw is contoured so that the assembly load is gradually spread over compact bone on the mandible's buccal (outside) surface. The prosthesis or implant has internally threaded blind holes. This design requires the use of a screw driver from the lingual side of the mandible. The design in Figure-2B, uses blind nuts installed from the lingual side of the mandible. A screw is inserted through holes in the buccal side of the replacement mandible. This design requires the blind nuts to be countersunk from the lingual side. The third design (Figure-2C) again features a screw countersunk into the replacement mandible from the buccal side. This design is unique, in that, the nuts have left hand threads on the outside and right hand threads on the inside. Thus, during assembly, no counterboring is required on the lingual side. The nuts will self lock from the buccal side by the use of a simple tool. In all of these designs a jig could be used to drill holes into mandibular bone that correspond with those predrilled in the replacement mandibular or nuts. The shear and tensile strength of the screws in any of the aforementioned designs should exceed those of bone. The compressive modulus should match that of bone to prevent strain discontinuities between the replacement and bone.

An alternative design that relies on an interference fit between a screw and a self-clinching expansion nut rather than tension as in the previous designs, is the shown in Figure-3. The self-clinching expansion nut would be made of ceramic particulate filled polymer. The nut has scores or flutes on the outer surface to allow it to separate under load. An oversized screw is inserted into an undersized tapped hole in the nut. The wall is sized such that the interference fit of the screw and cylinder causes the cylinder walls to expand and split. The wall segments are pushed outward and trapped between the fastener and compact/trabecular bone. The polymer used in this cylinder could be a thermoset or thermoplastic resin filled with enough ceramic to create a somewhat brittle material, but not brittle enough to crush under the screw compressive load. If a thermoplastic is used, enough filler would have to be added to prevent creep under compressive load. The outside surface of the cylinder could be tapered in such a way as to optimize the pressure profile on the outer surface of the fastener. The neck of the fastener could be sized to allow the driver head to be torqued off when the proper preload torque is reached. The entire installation requires only boring holes and no fastener is required on the lingual side of the mandible. The fastener design from Figure-2B or 2C is shown in Figure-4 as an example of a partial replacement mandible.

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<sup>1</sup> CPN800A-06-03 (PEEK/Long Carbon), CPN800J-06-03 (PEEK/Long Carbon), Cherry Textron, Santa Ana, CA.

## PHYSICAL AND FINITE ELEMENT MODELS

### Physical Model

A physical model of the mandible has been developed and fabricated to help with selection of the optimal fastening technique. The fabrication process involves a two step molding process. The first mold is used to fabricate the replacement for trabecular bone. Once solidified, this structure is positioned inside the second mold where a substitute for compact bone is formed over it. Once completed the external geometry of the model, formed by the mold, duplicates that of a human mandible. After evaluating many combinations, the materials that gave cutting and drilling properties similar to bone, were a foamable polymer for trabecular bone, and a ceramic filled epoxy for compact bone. The replacement mandible is shown in Figure-5 and a section through the replacement mandible is compared to a section through a human mandible in Figure-6. This physical model was drilled and cut using medical drills and saws, i.e., a Synthes drill<sup>2</sup> and a standard Micro-E sagittal saw. The replacement mandible in a dry state, cut and burned like bone. However, while under irrigation the saw blade bound in the material like it would in human bone. The replacement mandible drilled and tapped similarly to bone.

In addition to its use as a tool in the selection of the best fastening technique, the replacement mandible could also, and perhaps more importantly, be used as a training tool for surgeons and medical students.

### Finite Element Model

PDA-PATRAN<sup>3</sup> was used to create a finite element model of 1/2 the mandible as shown in Figure-7. This model consists of 7560 nodal points and 6716 solid isoparametric hexagonal elements with symmetry boundary conditions applied at the mid-plane and fixed in the condylar region. A very refined mesh was used along the buccal/lingual side in order to provide for easy modifications for incorporation of fastener devices. Both trabecular and compact bone properties were used in the model as taken from Ref. (9). Figure-8 shows stress contours in the mandible model for a static analysis incorporating a first molar point load of 250 N (1,100 lb) and appropriate muscle forces as taken from Ref. (10). MSC/NASTRAN<sup>4</sup> and COSMOS/M<sup>5</sup> will be used to exercise this model with different loading, boundary conditions and alternate material properties. The results will be compared to the physical model under similar loads. Once the finite element model has been verified, it can be used to determine the optimal fastening technique.

## SUMMARY AND CONCLUSIONS

Several fastener designs have been proposed as fastening devices for a replacement mandible. The first design simply relies on a composite screw inserted into the human mandible on the lingual surface and threaded into a blind hole in the replacement mandible. The second design consists of a composite screw countersunk into a replacement mandible on the buccal surface and threaded into a nut countersunk into the human mandible. The third design relies on right hand threads on the inside and left hand threads on the outside of a nut on the lingual surface of a human mandible to secure a composite screw whose head is countersunk and locked into the replacement mandible. The last design relies on the interference fit between an oversized composite screw and an undersized hole in a ceramic filled epoxy self-clinching expansion nut to force the ceramic to expand outward into the human mandible. These designs must be analytically modeled and experimentally verified before a final device is selected.

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<sup>2</sup> Synthes Ltd. USA, Wayne, PA.

<sup>3</sup> PDA-PATRAN finite element pre-and post-processor code, PDA Engineering, Costa Mesa, CA.

<sup>4</sup> MSC/NASTRAN finite element solver, MacNeal-Schwendler Corp., Los Angeles, CA.

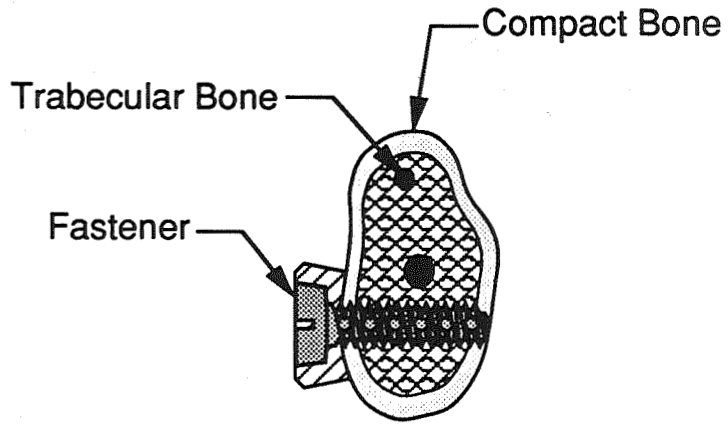
<sup>5</sup> COSMOS/M finite element software, Structural Research and Analysis Corp., Santa Monica, CA.

A physical model of the mandible was fabricated that included both trabecular and compact bone substitutes. An expanding foam was used to represent trabecular bone and a ceramic filled epoxy was used to simulate compact bone. When cut and drilled, this material acted similarly to bone. Besides being used to test the fastener designs, this substitute mandible could be of benefit to surgeons and medical students training in orthopedic surgery.

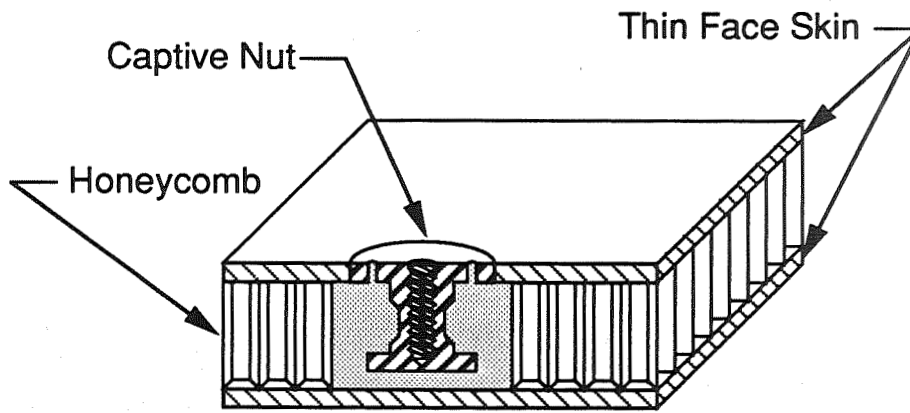
The mandible has been modeled using the finite element technique. Several different loading conditions will be applied to both the physical and finite element models and their results compared. After the finite element model is verified, it will be used to evaluate stress states in each of the fastening techniques. Once optimized for the specific design criteria, the selected fastening technique should not be limited to the mandible or other skeletal structures, but also to composite structures in general.

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Bone Architecture and Current Fastening Technique



Aerospace Fastener for Honeycomb Panels

FIGURE-1 Comparison of Fastening in bone to That in Aerospace Composites

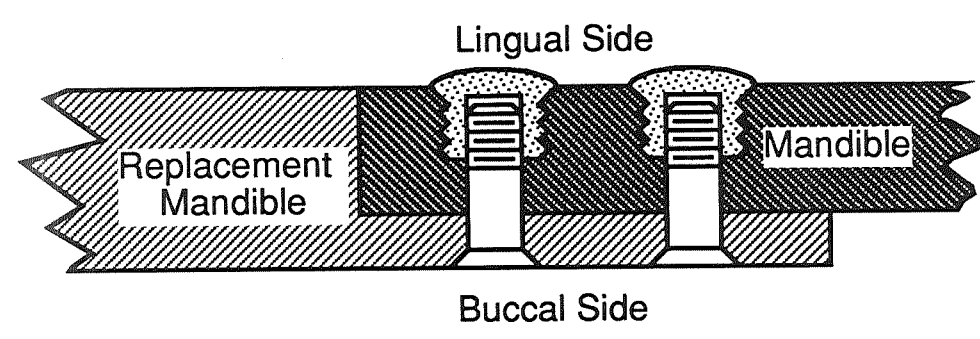
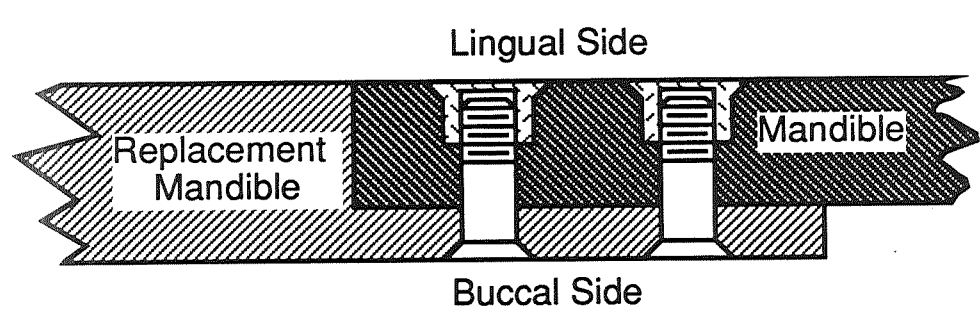
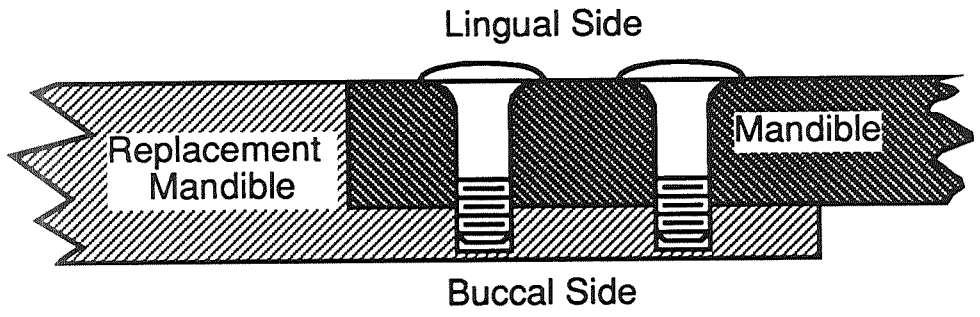


FIGURE-2 Proposed Fastener Designs for Replacement Mandible

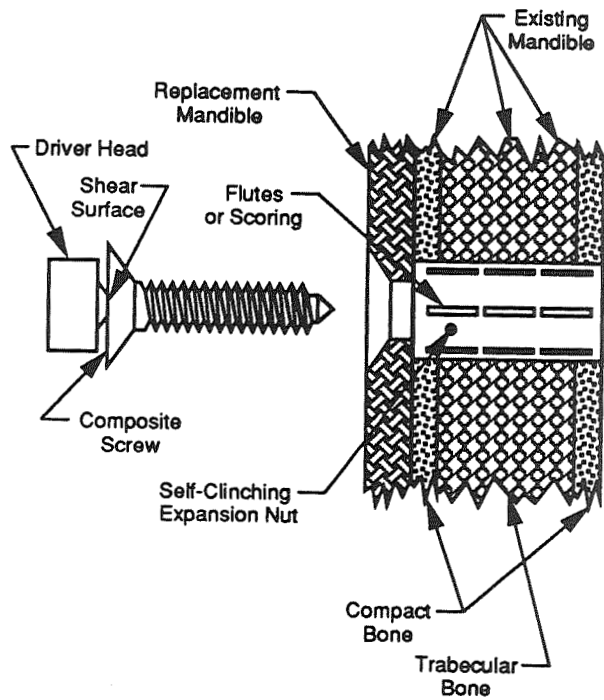


FIGURE-3 Alternative Fastener Design That Relies on an Interference Fit

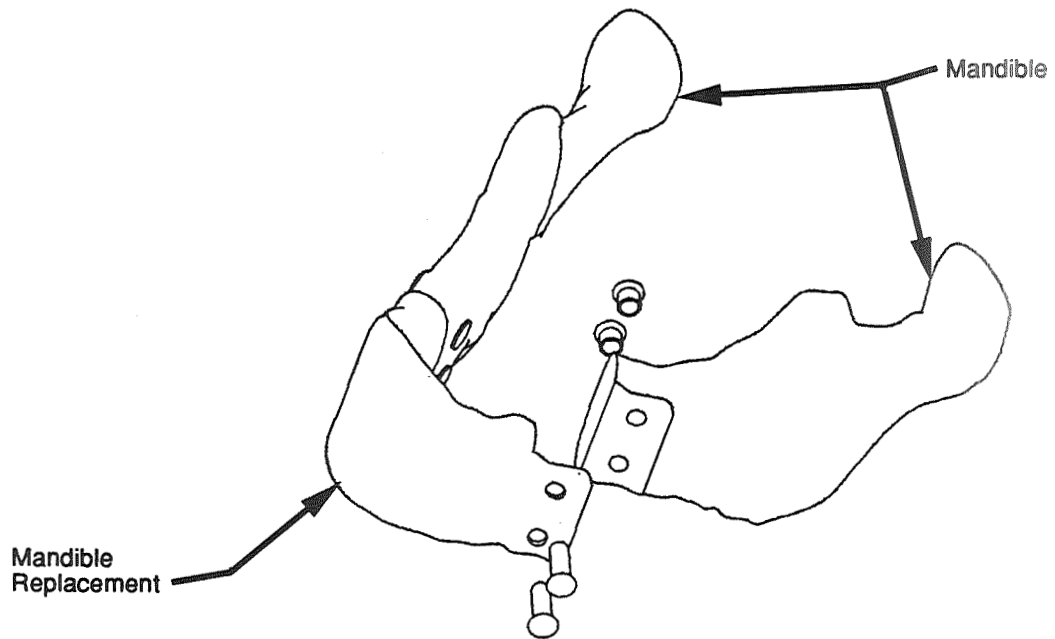


FIGURE - 4 Partial Replacement Mandible With PEEK Composite Fasteners





Figure - 5 Replacement Mandible

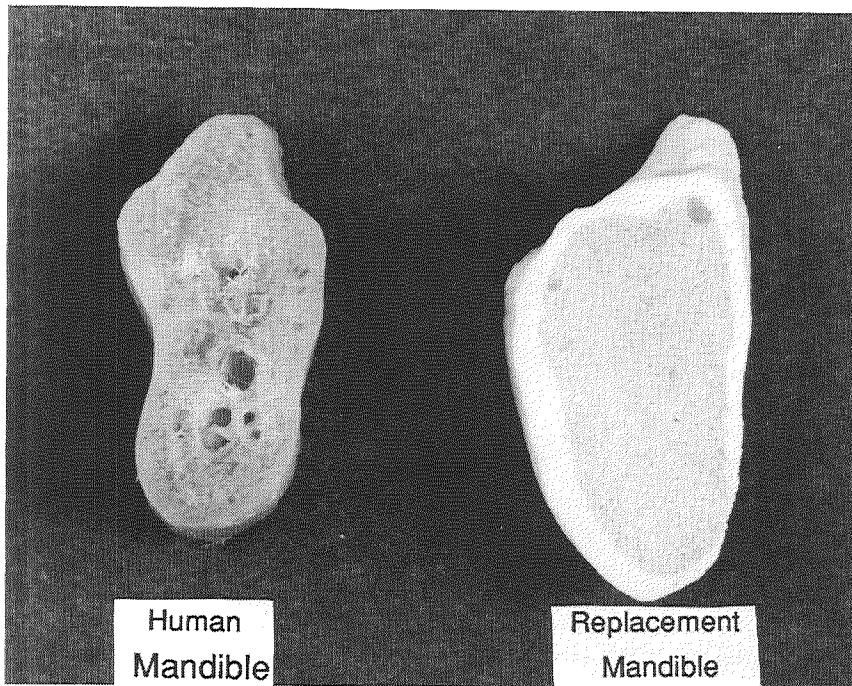


Figure - 6 Section Through Replacement Mandible Compared to Section Through Human Mandible

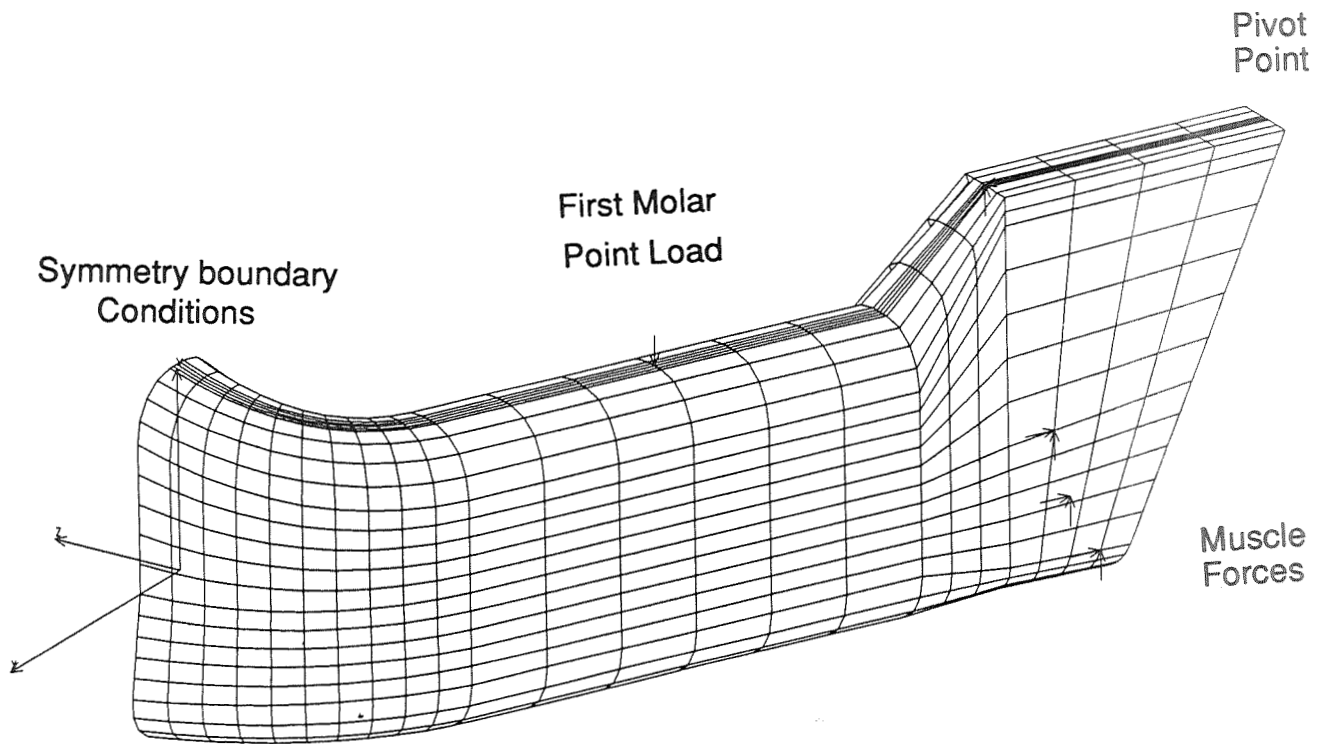


Figure - 7 Finite Element Model of 1/2 The Human Mandible

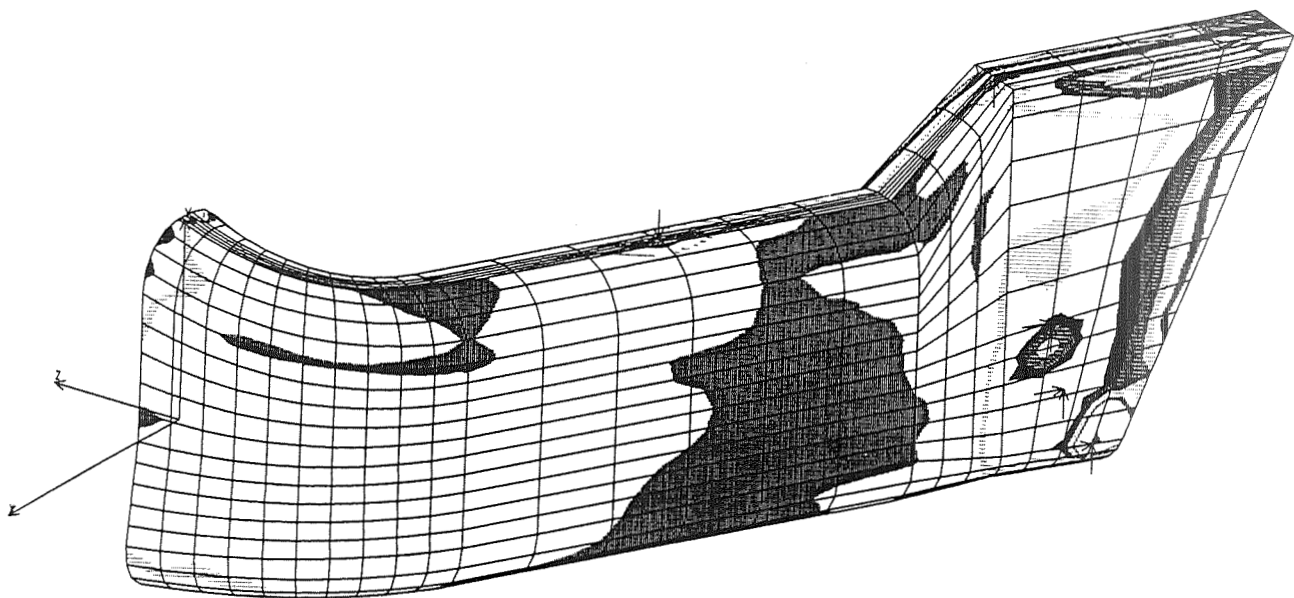


Figure - 8 Stress Contours in a Human Mandible Under a 250 N (1,100 lb) Point Molar Load