ABSTRACT

CERVICAL SPINE BONE ANCHORING SYSTEM
CSBAS
PULLOUT TESTING AND COMPARISONS

by
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The purpose of this study is to prove the effectiveness of the newly designed and patented Cervical Spine Bone Anchoring System (CSBAS). It is a posterior fixation device intended to be used with spine bone-plate systems. Its purposes are to substitute for conventional bone screws, significantly decrease the neurological and vascular risks associated with screws, and have comparable bone purchase strength.

Three CSBAS sizes (10mm, 12mm, and 14mm) were compared to four conventional bone screws in six human cadaveric cervical spines (C2-C7). Post-implantation axial pullout tests of each device using an MTS servohydraulic testing machine yielded bone purchase strength.

In conclusion, analysis of test results shows that in the majority of cases the CSBAS is statistically comparable in bone purchase strength to the four typical bone screws. It is also clinically safer than screws as the CSBAS device does not encroach upon vital neural and vascular structures.

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CSBAS
PULLOUT TESTING AND COMPARISONS

by
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A Thesis
Submitted to the Faculty of
New Jersey Institute of Technology
in Partial Fulfillment of the Requirements for the Degree of
Master of Science in Biomedical Engineering

Biomedical Engineering Committee

October 1994

APPROVAL PAGE

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CSBAS
PULLOUT TESTING AND COMPARISONS

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ACKNOWLEDGMENT

The author wishes to express his sincere appreciation and gratitude to his supervisor, Professor Clarence Mayott, for his guidance, insight, and support throughout this research.

Very special thanks to Professors J. Russel Parsons and Mark Zimmerman for taking the author on board, providing him with assistance and thoughtful suggestions, and for serving as members of the committee.

The author wishes to acknowledge and express deep appreciation to Doctor Chul H. Kang and Tom Poandl for their invaluable assistance and suggestions throughout this research.

And finally, many thanks to Doctor Casey K. Lee and Professor David Kristol for their help.

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CHAPTER 1

INTRODUCTION

1.1 Brief Anatomy

The spine is a complex structure whose principal functions are to protect the spinal cord and transfer loads from the head and trunk to the pelvis [35]. The spine consists of seven cervical vertebrae, twelve thoracic vertebrae, five lumbar vertebrae, five sacral vertebrae, and four coccygeal segments [15].

A vertebra consists of an anterior block of bone called the vertebral body and a posterior bony ring known as the neural arch, containing the articular, transverse, and spinous processes (see Figure 1.1). The vertebra is a mass of cancellous bone contained in a thin shell of cortical bone. The neural arch consists of two pedicles and two lamina from which arise seven processes.

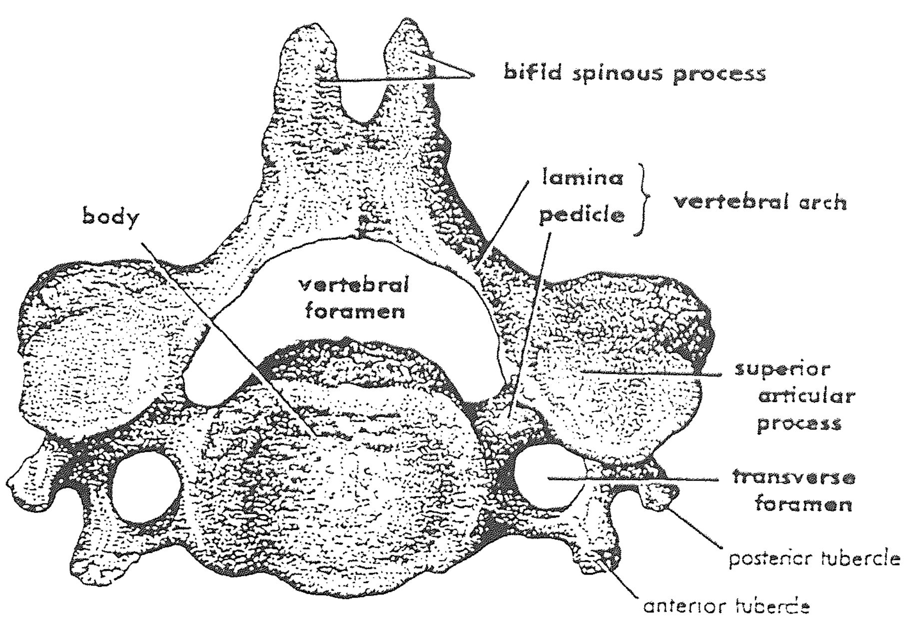

Figure 1.1 A cervical vertebra - superior view [15].

Focusing on the cervical spine, there are four crucial elements (two vascular and two neurologic) involved with its anatomy. The two neurologic elements are the spinal chord and the cervical spinal nerve roots which branch off laterally from the spinal chord (see Figure 1.2). The passage of the spinal nerves from the spinal canal to the outside of the intervertebral foramen is a complicated one[48]. The vascular elements are the two vertebral arteries which pass through foramina in the cervical spine. These two arteries are the primary sources of blood to the brain.

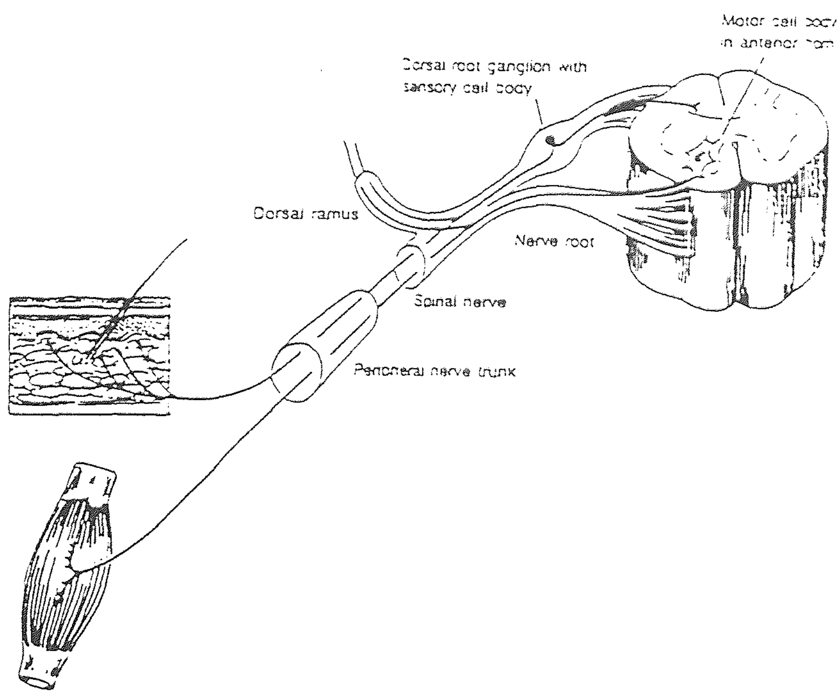

Figure 1.2 Anatomy of nerve roots, spinal nerves, and root ganglion [48].

1.2 Spinal Fixation

Spinal fixation is a term for many methods of fixation aimed at stabilizing the spine for the purpose of allowing fractured, compressed, or otherwise injured vertebra to heal. Healing is generally defined as the fusion of the vertebra at the injured site, or depending on the technique, to a bone graft or methylmethacrylate cement [49] adjoining the injured vertebra to the adjacent vertebra.

There are numerous methods of spinal fixation. Some vary depending on the level of the spine for which they are to be used. Others vary depending on whether they will be used on the anterior or posterior portion of the spine. According to White and Panjabi [48], the most common methods of fixation are screw-plate, rod, wire, and various clamp and hook-plate fixators. There are also different surgical approaches to the spine for installation of such devices of which the Cloward [9] procedure is one.

Screw-plate fixation simply involves using metal plates with holes for screws and screws which are used to affix the plates to the vertebrae (see Figure 1.3). Typically, the screws are placed through the appropriate holes of the plates and then screwed into positions on vertebrae superior and inferior to the injured vertebra. This is also done bilaterally.

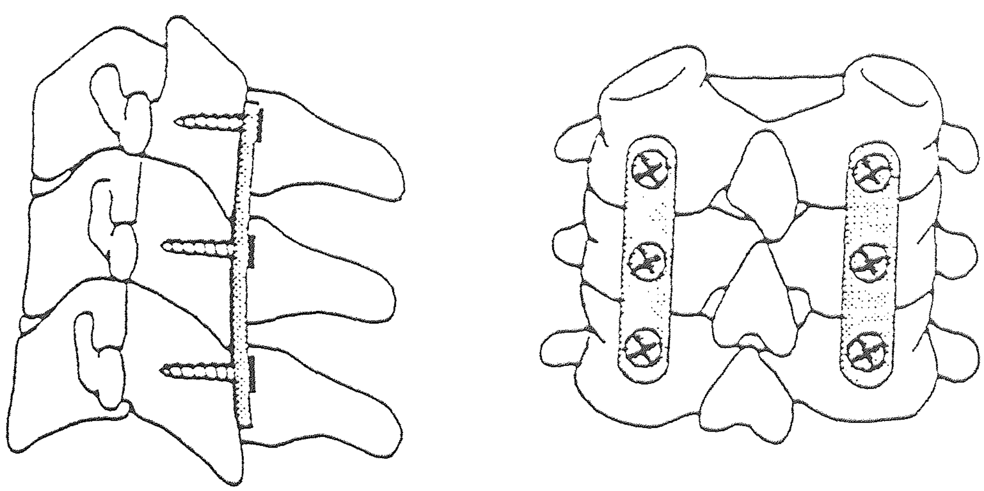

Figure 1.3 Typical posterior bilateral screw-plate fixation [48].

Screw-plate fixation is used posteriorly [3,13,19,22,29,31,37,43], as well as anteriorly [1,45]. For the anterior implants, some of the screw-plate techniques are Casper, Fuentes, Louis, Moscher, and Roy-Camille [48]. For posterior screw-plating, some techniques are Fuentes and Benezech, Roy-Camille [41], Magerl, Steffee [24], and Louis [48].

Rod fixation involves affixing rods posteriorly and bilaterally to spinal segments by means of screws, wires, clamps, or combinations thereof. The rods serve the same purpose as the plates in screw-plating (see Figure 1.4). Some techniques for this type of fixation are Harrington [20, 36, 39], Cotrel-Dubousset [8, 33], Luque [39], Edwards, Jacobs, Hartsill, Double "L", and C-rod [48].

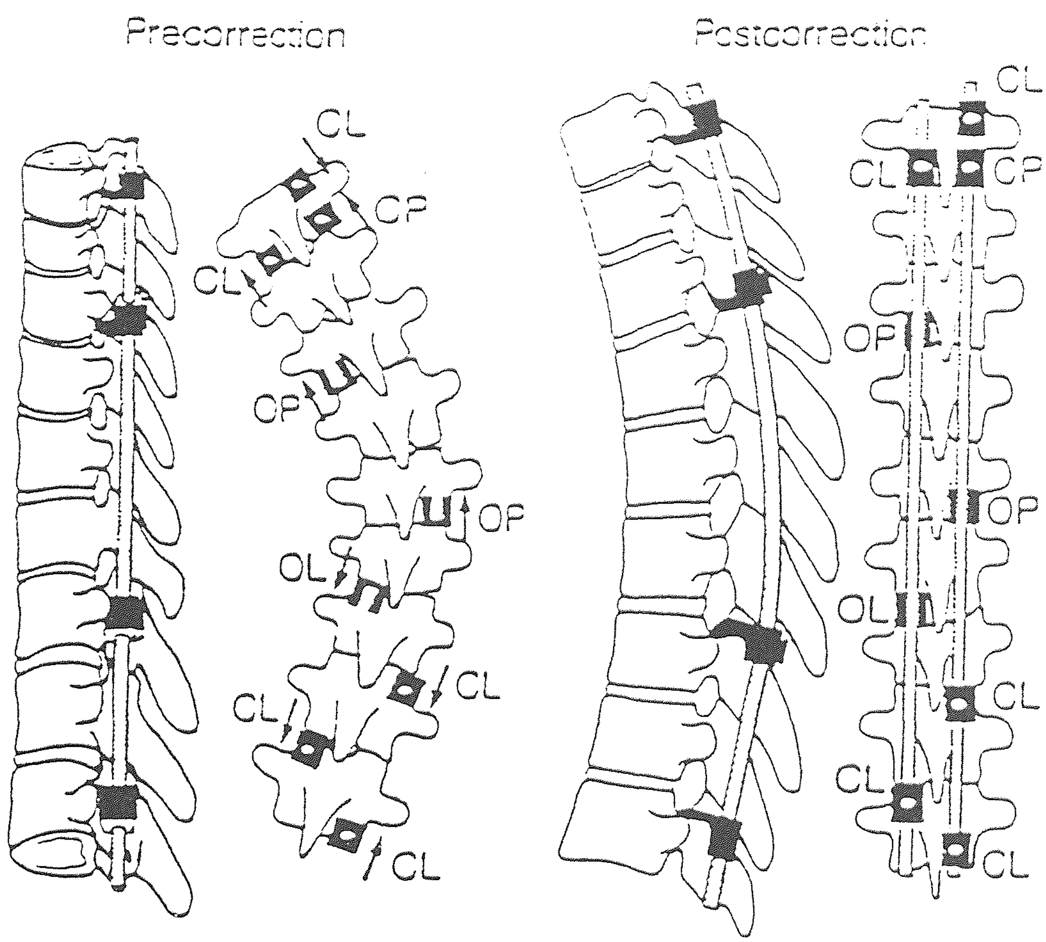

Figure 1.4 Typical posterior bilateral rod fixation [48].

Wiring fixation [7, 17, 26, 46] involves the use of wire to hold together various segments of desired vertebrae together with surgical grade stainless steel wires. Some of the types of knots used for this procedure are the twist, knot, bend, single-strand figure eight, and double figure eight. Figure 1.5 shows a "figure-of-eight" [48] wiring technique.

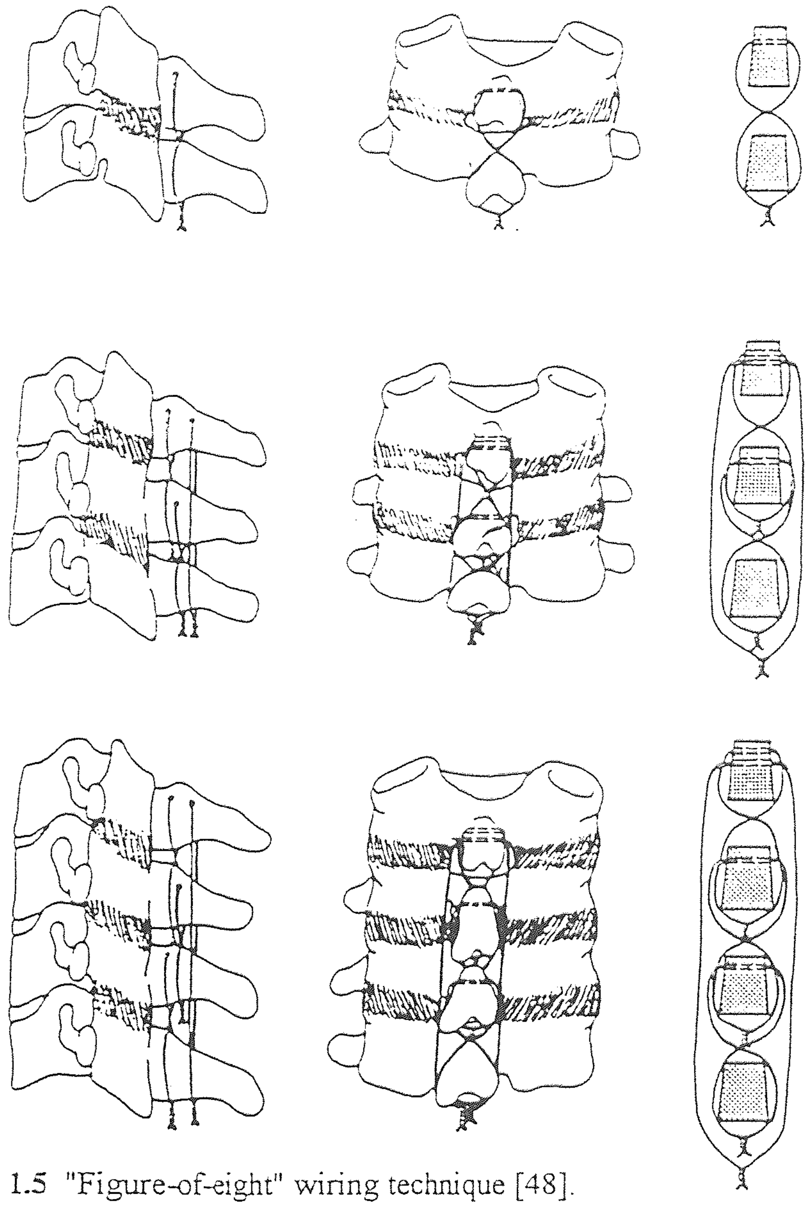

Figure 1.5 "Figure-of-eight" wiring technique [48].

Some of the different techniques of employing the wires are Robinson-Southwick, Itoh, Brooks, and Gallie [48]. The variations in techniques are a function of where the wires were used and how they were attached.

Hook-plate fixators [28, 45] are similar to screw-plate fixators in their method of attachment. The difference is that when in place, the hook-plate actually hooks around a posterior vertebral segment (see Figure 1.6). Two types of hook-plate fixators are Magerl and Halifax [48].

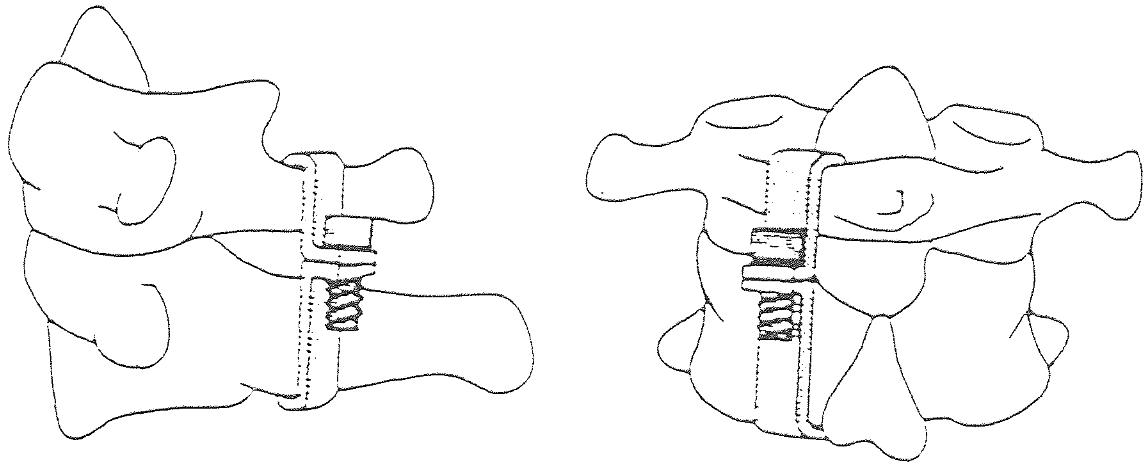

Figure 1.6 Hook-plate fixator [48].

Clamps [22, 26] are devices which hook onto superior/inferior vertebrae and are then tightened by a screw creating the clamping effect by holding two or more vertebrae in place (see Figure 1.7). Two types of clamps are the Halifax and Mitsui [48].

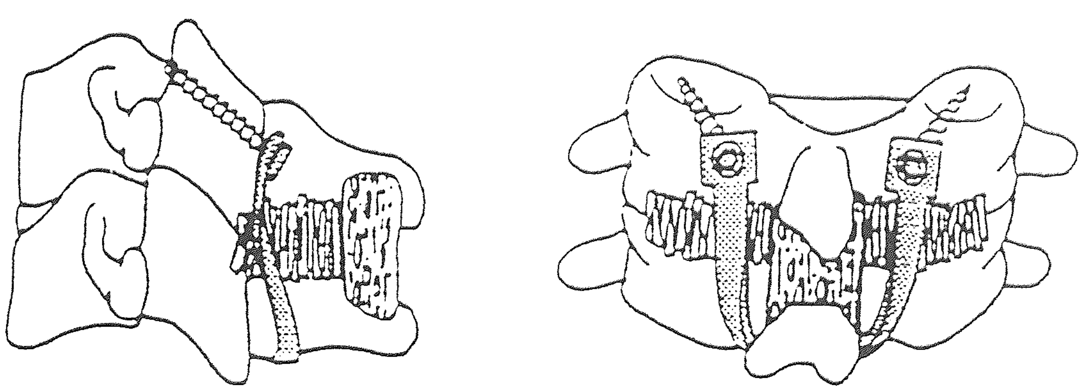

Figure 1.7 Clamp fixator [48].

In addition to the variety of spinal fixators, there are a wide range of bone screws with different sizes, thread shapes, as well as insertional techniques [21]. The screws are designed to connect bone to various fixation devices, most commonly either plates or rods [47]. Some of the screws are unicortical which means they are meant to purchase only one cortical bone layer and remain inside the bone. Some are bicortical where they purchase two cortices, in effect, piercing the bone.

The holding power of bone screws is both a function of the geometry of the screw and the properties of the bone [30]. It is noted by Kleeman et al. [30], Wittenberg et al. [50], and Zdeblick et al. [51], that bone mineral density (BMD) is a significant factor in the holding power of screws in bone, and in spinal fusion - the desired end result of spinal fixation.

1.3 The Problem

There are several problems associated with using bone screws in conjunction with the various spinal fixation devices. Cooper et al. [13], Grob et al. [26], Jeanneret et al. [28], and others [6, 8, 10, 21, 25, 32, 33, 47] noted the dangers which include occurrences of vertebral artery puncture causing brain damage or death, disruption of cervical spinal nerve root(s) causing neurological damage, as well as screw loosening, migration, and/or breakage compromising the fixator and causing post-operative complications. In lieu of the above, there is obvious room for improvement of screw and plate designs and the material used to manufacture them [32] to decrease or even eliminate some of the associated hazards.

CHAPTER 2

METHODS AND MATERIALS

2.1 Cervical Spines / Preparation

Six fresh frozen cadaveric cervical spines were used for this study. Each harvested section of spine included the occiput to the upper thoracic vertebrae. Care was taken during harvesting to maintain the integrity of the cervical spine. Consequently, the spine was detached in the upper thoracic region. Once harvested, each spine was frozen for several days until bone density analysis could be performed.

Each spine was scanned posteriorly in the frontal plane to determine relative bone mineral density (BMD) by a Dual Energy X-ray Absorptiometry machine (DEXA) by Lunar Corporation. The DEXA machine yields results in grams per square centimeter (g/sq cm). Although it is not true density, it is useful for this study because it allows for a direct comparison of the six spines with respect to a parameter closely associated with density. It should be noted that the DEXA machine was not designed to scan cervical spines. It was designed for lumbar spines where it can automatically identify each vertebra. In scanning the six cervical spines, the individual vertebrae had to be identified manually on the machine. This clearly introduced some error into the BMD readings.

Upon completion of BMD scanning, each spine was refrozen. On the morning of the day of dissection and cleaning, a spine was taken out of the freezer and allowed to thaw. Once thawed, the spine was dissected, whereby each vertebra was separated and all attaching tissues removed. Each vertebra was identified with an engraving pencil and wrapped in gauze moistened with saline. All the vertebrae were then placed in a labeled plastic bag and refrozen until further use. It should be noted that freeze/thaw cycles do not affect bone mechanics [42].

The vertebrae were required to be potted so that they could be used in mechanical testing. Potting the vertebrae allowed them to be easily incorporated into the testing jig of the MTS machine. It also provided rigid support for each vertebra during mechanical testing without compromising its structural integrity. All vertebrae were thawed prior to potting. Only vertebrae C2 through C7 were used for testing and consequently were the only ones potted. The materials used in potting the vertebrae were poly-methyl methacrylate cement (PMMA), aluminum foil, and aluminum wire meshing. A component of the MTS testing jig, a hollow metal cylinder with a three inch inner diameter and a 3-3/4 inch outer diameter, was also used to aid in the potting procedure. All potting was done under a fume hood.

Potting was accomplished in two stages. In the first stage, aluminum foil was quadruple-plied and placed into the upper portion of the hollow metal cylinder to a depth of approximately one inch. On the inside, the foil was pressed firmly against the cylinder to take on its shape. On the outside, the foil was pressed against the top of the cylinder. The result was an aluminum foil cup. The uppermost portion of the cylinder had a slightly wider outer diameter (4-1/2 inches) and contained four screw holes on its circumference, equally spaced at ninety degree intervals, and each penetrating the cylinder. Once the foil was in place, four screws were placed into the holes and screwed in until they made small indentations (one to three millimeters) in the foil on the inside of the cylinder. Following this, a thawed vertebra was selected (gauze removed) and positioned vertically with the vertebral body facing down inside the aluminum foil cup. This left the posterior portion, including the lateral masses and pedicles, exposed. PMMA powder and solvent were then mixed to a viscous liquid, poured into the foil cup filling approximately half of it (half inch), and allowed to polymerize. The first stage stabilized the vertebra in the foil cup by submerging approximately two-thirds of the vertebral body in PMMA. Once vertebrae C2 through C7 from a thawed spine were all potted, they were relabeled (with pencil on the PMMA), re-wrapped in saline moistened gauze and refrozen unless time permitted for the second stage of potting.

In the second stage of potting, if frozen, the vertebrae would first be thawed. A soft aluminum wire mesh was cut to size to fit through the vertebral foramen of each individual vertebra. Each wire mesh strip was approximately two inches long and three-quarters of an inch wide. It would be placed longitudinally through the vertebral foramen of the vertebra along its frontal plain such that approximately three-quarters of an inch of mesh would protrude on each side of the foramen. It would then be pressed against the vertebra and the PMMA base layer forming a wire mesh bridge. This bridge would help anchor the vertebra in the PMMA during testing.

Prior to pouring the second layer of PMMA, a removable water and flour mixture (bread dough), was placed underneath and around the articular processes of the vertebrae to assure that they would not be covered by cement. This was required because bicortical screws should not engage the cement when implanted for testing in the vertebra since that would give erroneous pullout strength. Once this was completed, the PMMA was mixed, poured to fill the metal cup (covering the wire mesh), and allowed to polymerize. Once set, the dough surrounding the articular processes was removed and excess foil and PMMA clipped from the upper perimeter of the now completely potted specimen. When finished, all specimens were again labeled, wrapped in saline moistened gauze, placed in their respective bags, and refrozen until testing.

2.2 Seven Bone Anchors / Preparation

Seven types of anchoring devices were tested. One AME screw design by American Medical Electronics, Inc., one AXIS screw design by Danek Medical, Inc., two Synthes screw designs by Synthes (U.S.A.), and three CSBAS anchor designs by Danek Medical, Inc. The devices were reused in multiple cadaveric specimens. Table 2.1 lists the specifications of each device.

Table 2.1 Specifications of the seven anchoring devices.

Name	Type	OD (mm)	ID (mm)	Pitch (mm/thrd)	Head Size (mm)
AME	Unicortical Screw	3.5	2.8	1.27	-
AXIS	Bicortical Screw	3.5	2.1	1.69	-
Synthes 3.5mm	Bicortical Screw	3.5	2.7	1.27	-
Synthes 4.5mm	Bicortical Screw	4.5	3.2	1.69	-
CSBAS 10mm	Unicortical Anchor	-	-	-	10
CSBAS 12mm	Unicortical Anchor	-	-	-	12
CSBAS 14mm	Unicortical Anchor	-	-	-	14

The CSBAS is made of wrought titanium 6Al-4V ELI alloy for surgical applications. Its mechanical properties are listed in Table 2.2.

Table 2.2 Mechanical properties of CSBAS material.

Tensile Strength	130 ksi (890 MPa)
Yield Strength (0.2% offset)	120 ksi (827 MPa)

All anchoring device insertions were performed on the day of testing in potted and thawed vertebrae. The four screws were all inserted in a similar fashion. The entry point on each vertebra (left and right sides) was two millimeters medial to the center of the lateral mass and directed thirty degrees laterally and twenty to forty degrees cephalad. First a pilot hole was drilled and then the screw was inserted. For the three bicortical screws, the pilot hole penetrated both cortical bone layers. For the single unicortical screw, the pilot hole penetrated only the first cortical layer and cancellous bone underneath.

Screws were turned into place in the clockwise direction until resistance to their progression was felt. At that time, they were backed out (counterclockwise) one to two turns so as not to create any pre-loading (pre-testing) stress on the engaged bone. In each case, the screw heads were left exposed so that they could be connected to the MTS testing machine grips.

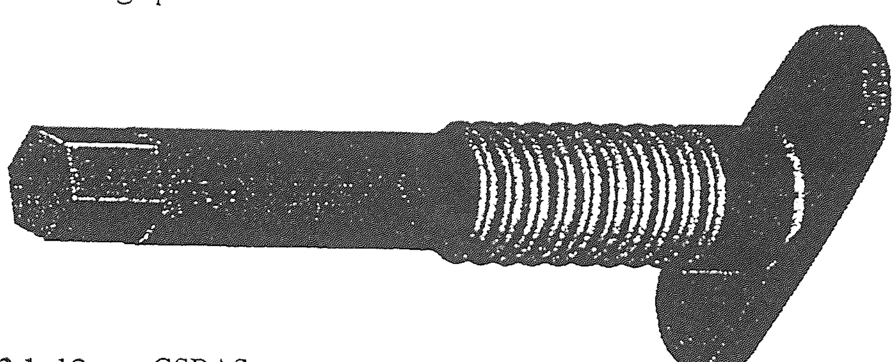

Figure 2.1 12mm CSBAS

The three CSBAS anchors (see Figure 2.1 for 12mm CSBAS) were inserted in a similar fashion. They were positioned into the middle of the lateral mass of appropriate vertebrae. For their insertion, a horizontal oval window was drilled using a guide to perforate only the outer cortical bone layer. The window had the same profile as the head but shorter in length by three millimeters. This method allowed for full insertion of the head while minimizing the removal of cortical bone. At the desired depth, (approximately three millimeters) the cancellous bone was cleared out with a specially designed tool in such a manner as to allow for the head of the CSBAS to be inserted and turned ninety degrees so as to completely engage the head with the bone. To prepare a CSBAS device for testing, its respective nut was screwed onto the threaded portion of the exposed shaft. The nut then served as the connection to the testing machine grips.

It was desired to study the performance of the CSBAS anchors as both primary and secondary devices (salvage anchors). For that purpose, the Synthes 4.5 millimeter screw was used as a comparison. Secondary testing of a device involved inserting it into the position of a primary device which had already been pulled out in testing. For the Synthes 4.5 screw no hole preparation was required. It was simply screwed into the hole left by a primary 3.5 millimeter screw which had been tested to failure. For the CSBAS anchors, secondary testing involved going through their aforementioned insertion procedures in locations of 3.5 millimeter screws tested to failure. In each case, the remaining 3.5 millimeter hole was widened to make the required oval window. CSBAS anchors were never used as primary and secondary devices in the same position even though the differences in their sizes may have allowed for such testing. In positions where the CSBAS anchors were tested as secondaries without primary screws tested first, 3.5 millimeter pilot holes were drilled to simulate primary screw failure.

2.3 MTS Machine and Recorders

An MTS (Material Testing Corporation) servohydraulic tension-compression-torsion testing device with a maximum load capacity of ten kilonewtons, specifically designed for biological testing, was used to perform mechanical pullout testing on the seven anchoring devices. A special testing jig allowing free motion in the x and y directions was used in testing to allow for mounted samples to be aligned to the MTS grips. The MTS machine was connected to a plotter and computer both of which recorded the testing data. The MTS machine produced a constant displacement of 0.1 millimeters per second and recorded the resulting resistive force in Newtons. The information, stored on a Macintosh computer and recorded by the plotter, consisted of the displacement and associated force.

2.4 Testing Procedure

To prepare the devices for mechanical pullout testing by the MTS machine they were first implanted in their designated sites on assigned vertebrae by the respective methods as were previously described. Two devices were implanted in one vertebra at one time. The potted vertebra was then placed into the cylinder which was used initially to help form the aluminum foil for potting. Four screws were screwed into place in holes located on the upper perimeter of the cylinder (described previously for potting purposes) to secure the specimen. The cylinder was then mounted on the MTS testing jig. The screw head, or nut of the CSBAS, was manually aligned with the grips of the MTS machine to allow for pure axial pullout of the selected device (pullout force directed along the long axis of the device). The hydraulic grip heads were then activated to enclose the head or nut. At this point the set-up was complete and testing could take place.

The plotter was activated first. Immediately afterwards, the MTS machine was activated. Both the plotter and specimen were carefully watched for any anomalous behaviors during testing. If such behaviors were observed, testing was immediately stopped and the problem corrected. The test was stopped as soon as complete failure was observed on the plotter or on the specimen, whichever was observed first. Complete failure on the plotter was characterized by a steep dip in the force-displacement curve without further variations. Complete failure on the specimen was characterized by the implanted device moving freely out of the engaged bone.

Once the pullout tests on one vertebra were complete and the MTS machine stopped, the MTS grips were released, and the potted vertebra removed from the testing jig. New specimens were then prepared, mounted, and tested.

2.5 Protocol

The testing protocol for the seven devices in the six cadaveric cervical spines is given in Table 2.3. In the table, A=AXIS, B=AME, C=Synthes 3.5mm, and CR=Synthes 4.5mm (Revision). 10mm, 12mm, and 14mm = CSBAS anchors.

Table 2.3 Testing protocol for seven device designs in six cadaveric cervical spines C2-C7.

SPINE 1 (#2830)

	Left			Right	
	Primary	Secondary		Primary	Secondary
C2	14mm	-		A	CR
C3	14mm	-		A	CR
C4	B	CR		14mm	-
C5	B	12mm		10mm	-
C6	C	CR		B	CR
C7	C	14mm		B	14mm

Table 2.3 (continued)

SPINE 2 (#2837)

C2	C	12mm		C	CR
C3	B	10mm		C	CR
C4	C	CR		A	12mm
C5	A	12mm		A	CR
C6	B	14mm		10mm	-
C7	A	CR		10mm	-

SPINE 3 (#2832)

C2	A	14mm		B	14mm
C3	10mm	-		B	CR
C4	10mm	-		C	10mm
C5	B	CR		C	14mm
C6	A	10mm		A	CR
C7	C	CR		10mm	-

Table 2.3 (continued)

SPINE 4 (#2913)

C2	A	14mm		B	14mm
C3	14mm	-		B	CR
C4	12mm	-		C	14mm
C5	B	CR		C	12mm
C6	A	12mm		A	CR
C7	C	-		14mm	-

SPINE 5 (#2936)

C2	12mm	-		-	-
C3	10mm	-		12mm	-
C4	-	-		12mm	-
C5	14mm	-		10mm	-
C6	14mm	-		14mm	-
C7	12mm	-		12mm	-

Table 2.3 (continued)

SPINE 6 (#2876)

C2	12mm	-		12mm	-
C3	-	10mm		-	10mm
C4	-	10mm		-	10mm
C5	-	12mm		-	12mm
C6	-	14mm		-	14mm
C7	-	14mm		-	14mm

2.6 Post-Testing Analysis

Bone mineral density readings from DEXA for vertebra C2-C7 of each spine were normalized to obtain a single BMD value for each spine. An et al. [2] concluded that pullout strength was linearly related to BMD. Consequently, the BMD values of each spine were used as comparisons to relate the six spines in such a way that the differences in their BMD readings would not play a factor in analyzing pullout test results.

Each spine's BMD was compared to the highest BMD value (Spine 1). Multiplication factors for the spines were calculated by dividing the BMD of Spine 1 by each spine's BMD. The resulting numbers were used to normalize the pullout strengths obtained in the other five spines.

For example:

Spine 1 BMD1 = 1.1705

Spine 3 BMD3 = 0.6983

The BMD normalization factor for Spine 3 is:

BMD1/BMD3 = 1.1705/0.6983 = 1.676

In each spine, pullout strength results for each device were multiplied by the spine's BMD normalization factor. Then, for each device, a mean pullout strength value was calculated utilizing the normalized data.

An unpaired Student's t-test set for a 95% confidence interval was used to analyze the test results. $P < 0.05$ was the level of significance at which the null hypothesis was rejected and significant differences assumed.

Finite element analysis was performed on the CSBAS using ANSYS, a computer finite element modeling program by Swanson Analysis Systems. For simplicity and expedition of computer calculation time, only half of the CSBAS was modeled. The analyzed part included half of the shaft and one side of the head (see Figure 2.2).

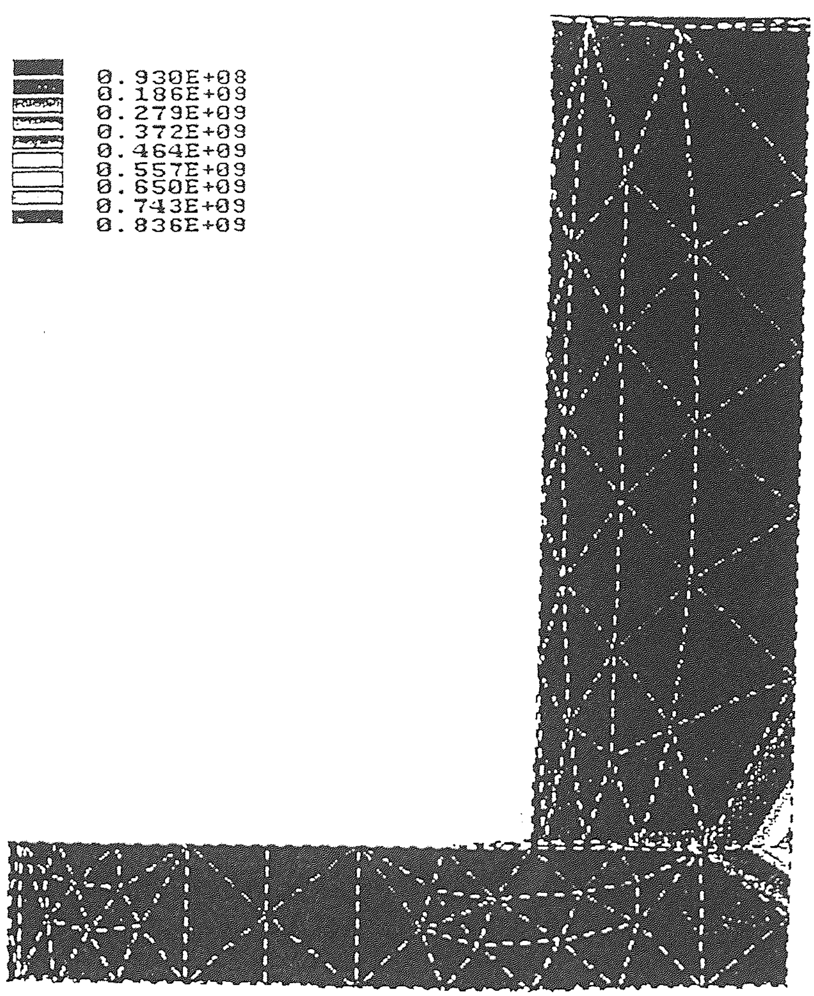

Figure 2.2 FEA mesh and stress results for a 545 Newton load.

The part was constrained on the upper portion of the head, and the load was distributed over the upper surface of the shaft. This closely simulated the actual loading conditions. The results of the analysis showed maximum stress on the part (in Newtons per square meter) due to the applied load.

Theoretical analysis was performed in an attempt to predict the test results for the seven devices. Each device's assumed surface area in contact with the bone was calculated.

For screws, the equation for thread contact area is derived from equation (16-11) of Deutschman et al. [18].

$$A = (\pi/4)(D_o^2 - D_i^2)(H/P)$$

where: A = contact area (surface area, mm^2)
D_o = outer diameter (mm)
D_i = inner diameter (mm)
H = height/depth of engaged thread = 10mm
P = thread pitch (mm/thread)

H was assumed to be a constant because the actual depth of screw insertions was not known.

For the CSBAS anchors the equation for contact area is:

$$A = (L * W) + (\pi R_h^2) - (\pi R_s^2)$$

where: L = length of head from center to center of semi-circles forming its ends (mm)
W = width of head (mm)
R_h = radius of semi-circles (mm)
R_s = radius of shaft (mm)

Since Rh is equal to Rs, the above equation becomes simply the area of a rectangle:

$$A = L * W$$

The results from the aforementioned calculations were used as comparisons to actual relative performance of the seven devices. They are listed in Table 3.2 and represented in Figure 3.1.

CHAPTER 3

RESULTS

The calculated mean bone mineral density values for each of the six spines, together with the respective spine normalization factors, is presented in Table 3.1. The DEXA BMD values for the six vertebrae (C2-C7) of each spine together with the calculated means and standard deviations are located in Table A.1.

Table 3.1 Mean BMD values and spine normalization factors for the six spines.

Spine #	1 (#2830)	2 (#2837)	3 (#2832)	4 (#2913)	5 (#2936)	6 (#2876)
BMD (g/sq. cm)	1.171	0.559	0.698	0.511	0.951	0.815
Spine Norm. Fact.	1	2.095	1.678	2.292	1.231	1.437

The bone contact area for each of the seven tested devices is listed in Table 3.2. For the four screws, a constant insertion depth (height of screw in contact with the bone) of ten millimeters was assumed in the calculations.

Table 3.2 Bone contact areas for the seven devices.

Device Type	AME	AXIS	Synthes 3.5mm	Synthes 4.5mm	CSBAS 10mm	CSBAS 12mm	CSBAS 14mm
Bone Contact Area (sq. mm)	27.27	36.43	30.67	46.52	24	32	40

The final (normalized) results of the pullout tests are presented in Table 3.3. The complete list of pullout data with unnormalized and normalized results is in Table A.2.

Table 3.3 Final results of pullout testing.

Primary Devices

Device Type	AME	AXIS	Synthes 3.5mm	CSBAS 10mm	CSBAS 12mm	CSBAS 14mm
Mean (Newtons)	364.406	527.221	655.395	234.460	419.259	542.024
Standard Deviation	89.522	170.567	209.608	96.844	153.363	187.709
N	12	12	12	8	8	8

Secondary Devices

Device Type	Synthes 4.5mm	CSBAS 10mm	CSBAS 12mm	CSBAS 14mm
Mean (Newtons)	888.294	147.560	347.682	351.957
Standard Deviation	228.416	38.890	156.077	244.075
N	17	7	8	8

Figure 3.1 is a graphical representation of the bone contact areas for the seven devices in Table 3.2. The figure is a gage for the theoretical performance of each device with respect to pullout strength.

Figure 3.2 is a graphical representation of the final results of pullout testing listed in Table 3.3. It represents the actual performance of the seven devices in pullout strength. The results of the three CSBAS anchors are from primary use.

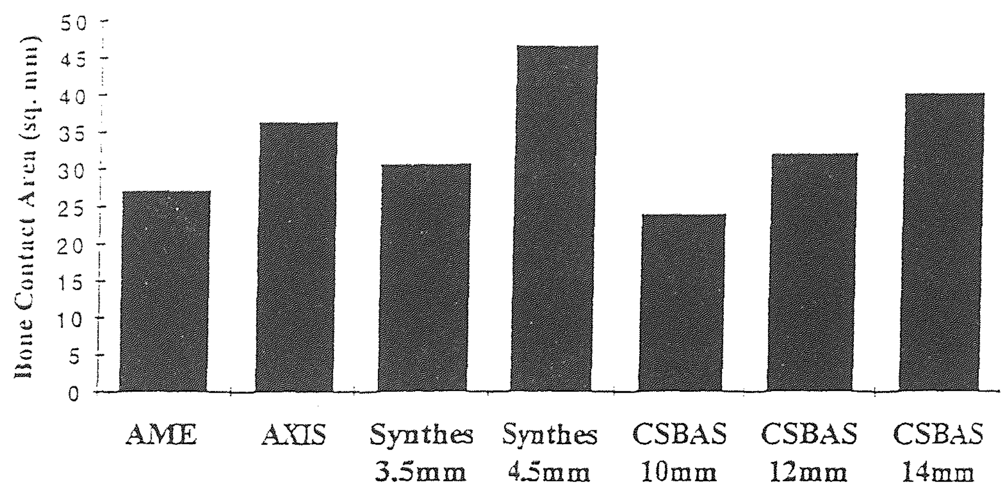

Figure 3.1 Gage of theoretical performance. Graphical representation of bone contact areas for the seven devices.

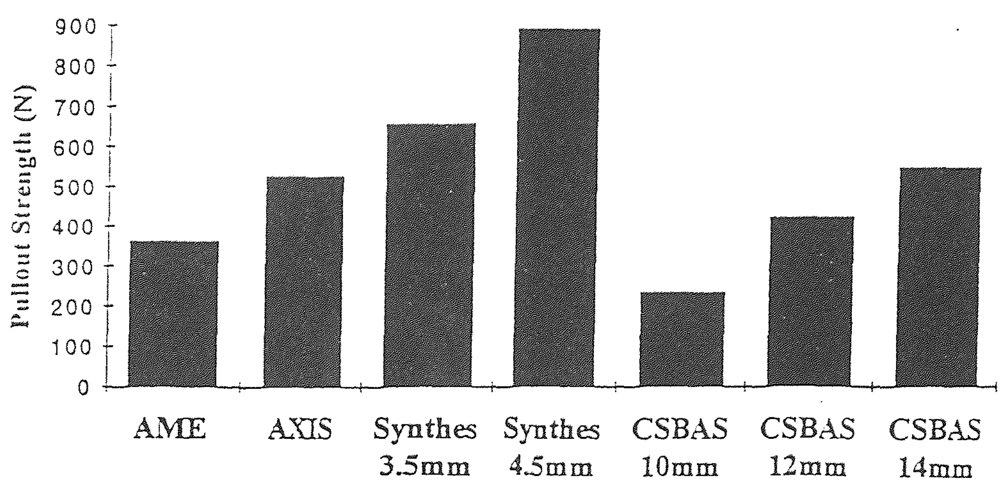

Figure 3.2 Actual performance. Graphical representation of pullout strength results for the seven devices.

t-test with a 95% confidence interval are listed in Table 3.4. Some of the names of the devices have been slightly altered for easier recognition in the table. "Pri" means primary device, "Sec" means secondary device, and "10", "12", and "14 CSBAS" are the three CSBAS sizes (in millimeters). The "Mean Difference" is the difference in the pullout strength of each two devices being compared (Device 1 minus Device 2). $P < 0.05$ is the level of significance at which the null hypothesis is rejected and a significant difference is assumed.

Table 3.4 Statistical analysis results.

Device 1	Device 2	P-Value	Mean Difference
AXIS	AME	0.0394	162.814
AXIS	Synthes 3.5mm	0.2877	-128.174
AXIS	Pri 10 CSBAS	0.0016	292.760
AXIS	Pri 12 CSBAS	0.2422	107.961
AXIS	Pri 14 CSBAS	0.8899	-14.803
AME	Synthes 3.5mm	0.0161	290.989
AME	Pri 10 CSBAS	0.0567	129.946
AME	Pri 12 CSBAS	0.4823	-54.853
AME	Pri 14 CSBAS	0.0773	-177.617
Synthes 3.5mm	Pri 10 CSBAS	0.0044	420.935
Synthes 3.5mm	Pri 12 CSBAS	0.1001	236.136
Synthes 3.5mm	Pri 14 CSBAS	0.4515	113.371
Synthes 4.5mm	Sec 10 CSBAS	0.0002	740.722
Synthes 4.5mm	Sec 12 CSBAS	0.0036	540.601
Synthes 4.5mm	Sec 14 CSBAS	0.0044	536.326
Pri 10 CSBAS	Pri 12 CSBAS	0.0265	-184.799
Pri 10 CSBAS	Pri 14 CSBAS	0.0093	-307.563
Pri 10 CSBAS	Sec 10 CSBAS	0.0732	86.900
Pri 12 CSBAS	Pri 14 CSBAS	0.3023	-122.764
Pri 12 CSBAS	Sec 12 CSBAS	0.5181	71.578
Pri 14 CSBAS	Sec 14 CSBAS	0.1851	190.067
Sec 10 CSBAS	Sec 12 CSBAS	0.0551	-200.121
Sec 10 CSBAS	Sec 14 CSBAS	0.0783	-204.396
Sec 12 CSBAS	Sec 14 CSBAS	0.9744	-4.275

Figures 3.3 and 3.4 show the finite element analysis of a 12mm CSBAS. Figure

Figures 3.3 and 3.4 show the finite element analysis of a 12mm CSBAS. Figure 3.3 shows the CSBAS loaded with a 545 Newton force (axial loading on the top of the shaft) and resulting maximum stress of 836 MPa (approximately its yield strength) at the skirt of the anchor. Figure 3.4 shows the FEA for the same device but loaded with a 250 Newton force. The resulting maximum stress is 361 MPa in the same location as before.

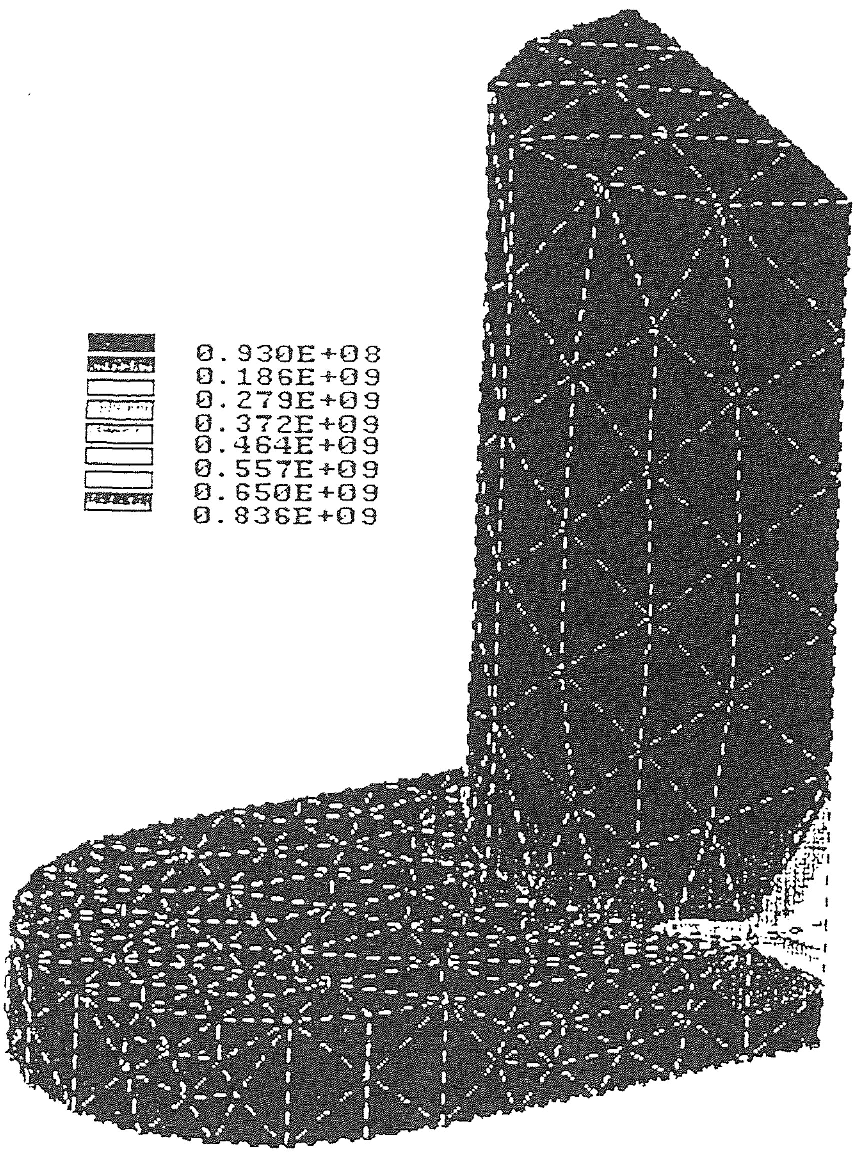

Figure 3.3 FEA of 12mm CSBAS axially loaded with a 545 N force producing stress approximately equal to the yield strength of the material (827 MPa).

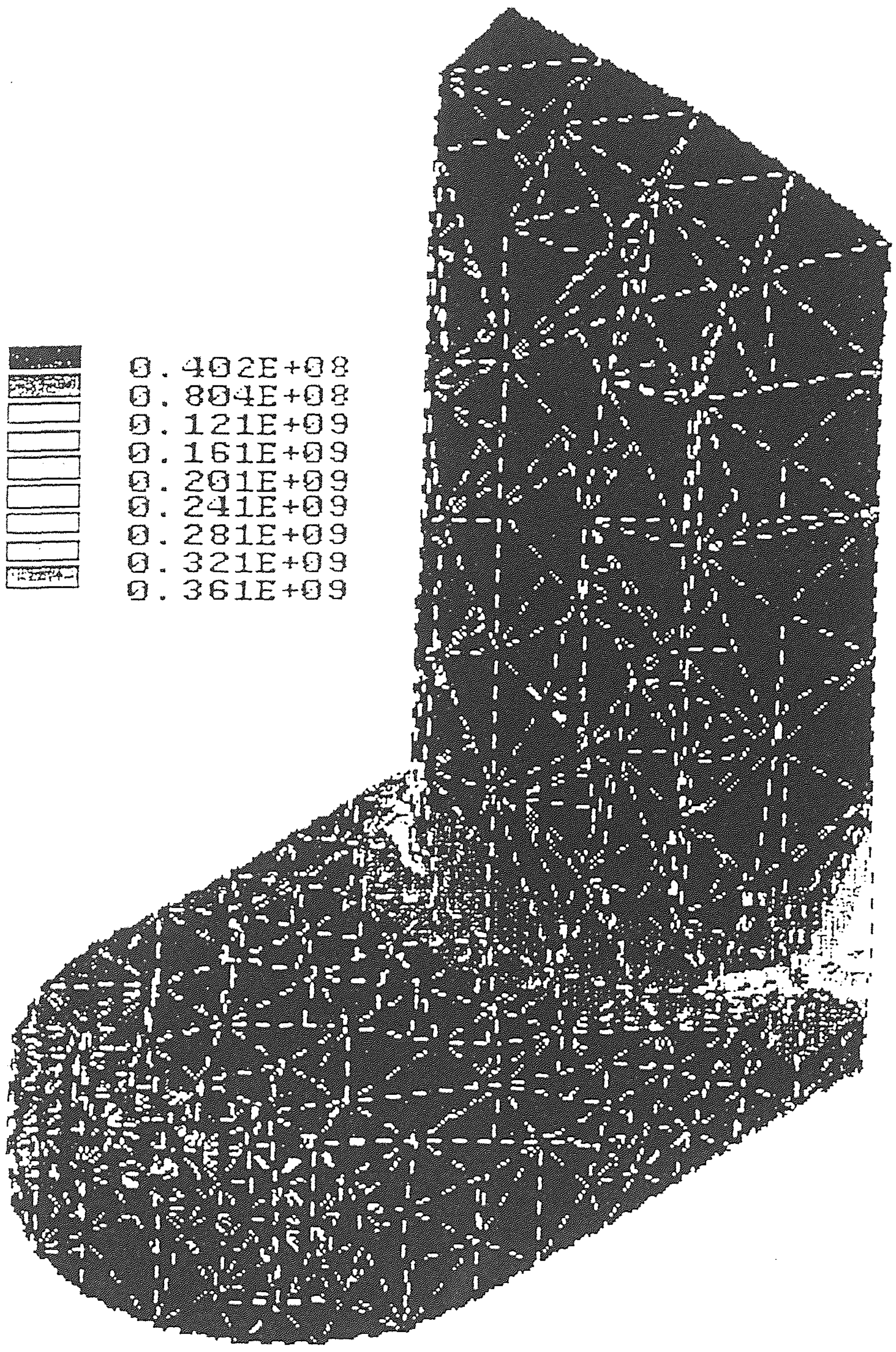

Figure 3.4 FEA of 12mm CSBAS axially loaded with a 250 N force producing a maximum stress of 361 MPa.

CHAPTER 4

DISCUSSION

4.1 CSBAS

An attemp was made to create an anchoring device that would substitute bone screws in function and decrease the hazards associated with their use. As as result the Cervical Spine Bone Anchoring System (CSBAS), a unicortical bone anchor, was developed and patented (Figure 4.1).

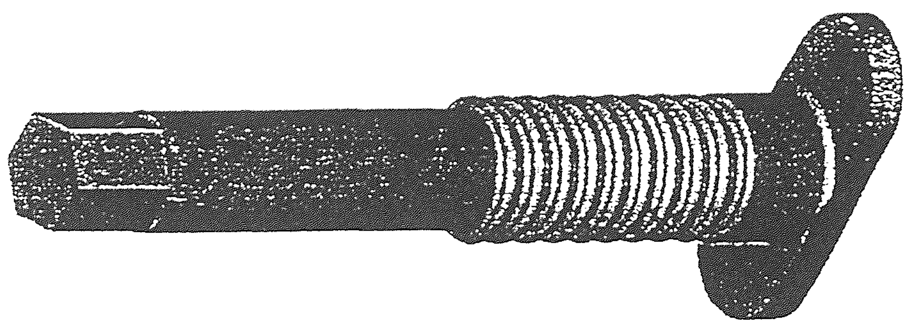

Figure 4.1 10mm CSBAS

The CSBAS is a titanium rod 21.6 millimeteres long with a hexagonal end. The other end of the rod is a flat rectangle ten millimeters long with rounded ends (the plate). A section of the rod is threaded starting 2.5 millimeters from the plate to 10.5 millimeters from the plate.

A thin cut is made into the cortical bone shell and the plate is inserted under the shell and rotated ninety degrees. The rod is then inserted into a hole in a metal plate and a nut is used to fasten the plate to the bone. Subsequent modifications to the CSBAS have included one design with a twelve millimeter plate (Figure 2.1) and one with a fourteen millimeter plate (Figure A.1). (The detail drawings for the 10, 12, and 14 millimeter CSBAS anchors are in Figures A.2, A.3, and A.4.)

4.2 BMD and Pullout Testing

Biomechanical studies have been undertaken to closely examine the mechanical characteristics of spinal fixation devices [4, 12, 38, 40]. Specific attention, less frequent however, has also been given to bone screws with respect to their anatomic considerations [47] as well as technical characteristics and differences [5, 30, 47].

Screw pullout strength has been studied by Zdeblick et al. [51] and others [5, 21, 30, 50]. The pullout strength of a screw is reported to be related to its insertional torque and the BMD of the bone into which it is inserted.

In this study, the CSBAS was tested only for pullout strength in comparison with four typical bone screws. Since the insertional torque was not measured for the four bone screws it could not be used as a quantified factor in calculating actual screw pullout strength.

BMD data was acquired for the six cadaveric cervical spines by DEXA, one among several different BMD scanning machines such as the DPA, DER [27], quantitative CT [44], DPX, DRA, and DQR [23]. DEXA yielded results in grams per square centimeter.

There have been different relationships given in literature between BMD (ρ) and bone strength. Cowin [14] provides a quadratic equation for strength from apparent density which is $\sigma = 2.45 + 15.41(\rho)^2$ for human cancellous bone in the transverse orientation and tested by the "Confined" method. For cortical bone Cowin provides strengths based on the species, location of the bone, and type of loading. Cowin discusses cortical bone strength equations in terms of viscoelastic behavior, but makes no quantitative relations of cortical bone density to (pullout) strength as with cancellous bone.

Currey [16] provides technical elastic moduli, failure properties, and fracture mechanics values for compact (cortical) bone. For cancellous bone Currey provides a formula for compression strength of $\sigma_s = k' \rho^2$, where ρ is apparent density and k' is a constant. However, Currey claims that it is only an empirical observation. Furthermore, Currey describes that although it is known that the tensile and compressive strengths are the same for cancellous bone, "it is not true for fully compact bone, of course."[16]

Coe et al. [11] examined the influence of BMD on several different thoracolumbar fixation devices and found that the correlation coefficient for Cotrel-Dubousset pedicle screws was 0.37 ($P < 0.001$), and for Steffee pedicle screws was 0.48 ($P < 0.001$). Although the study showed significant correlation between bone screws and BMD, it did not produce an equation directly relating the two.

Kleeman et al. [30] found a moderate correlation ($R^2 = 0.59$, $P < 0.001$) between pullout force of cancellous bone screws and apparent bone density by a power law relationship of the form $0.065^{1.37} - 1.77$. However, the equation was not a pre-existing one but the result of a derivation for a best-fit curve based on their data.

An et al. [2], in an effort to determine the relationship between BMD of the vertebral body and pullout strength of the vertebral screw found contradictory results to the power law relationship of BMD to pullout strength. A regression analysis of the data produced a positive linear correlation between the BMD and screw pullout strength ($r = 0.75$, $P < 0.001$). The BMD values were obtained similarly to the ones in this study - by DEXA.

It is interesting to note that of the studies done with screws, either BMD or the contact area of screws with bone is omitted in technical considerations. Clearly, BMD affects the pullout strength as already mentioned. But pullout area is also an important factor and should be incorporated into the BMD-screw strength relationship.

Due to the lack of consistency in the literature regarding the relationship between BMD and bone screw pullout strength, it was decided that a linear relationship would be used in this study. The rationale for using a linear relationship was that the spine segments would be equated such that the BMD differences would not be a factor in the pullout strengths of the devices.

4.3 Primary and Secondary Devices

"Primary devices" refers to bone anchors used in initial fixation. As noted in section 1.3 however, they are prone to failure. When the primary anchors fail by either loosening, migration, or breaking, they have to be removed and replaced. If they come out on their own, they must likewise be replaced. Once out, the devices leave a hole. In order to re-establish fixation, a larger device must be inserted into the hole. Consequently there are secondary, or salvage devices.

In this study the CSBAS was used as a primary device and as a secondary device. As a primary, it was compared to two bicortical screws (AXES and Synthes 3.5mm) and one unicortical screw (AME). As a secondary, it was compared to a larger bicortical screw (Synthes 4.5mm).

4.4 Test Results

The results of the pullout testing show the 10mm CSBAS to be the weakest of all the primary devices (234.460 N). Statistically, however, it is not significantly different from the AME unicortical screw ($P > 0.05$) which is the weakest of the three primary screws (364.406 N). The AME is significantly weaker than both the AXIS and Synthes 3.5mm screws with $P < 0.05$ for each. The 10mm CSBAS is also significantly weaker ($P < 0.05$) that the two larger primary CSBAS anchors.

The 12mm CSBAS (419.259 N) is stronger than the AME and 10mm CSBAS but weaker than the other primary devices. Statistically though, it is not significantly different from any of the primary devices with the exception of the 10mm CSBAS.

The 14mm CSBAS (542.024 N) is the second strongest of the primary devices (next to the Synthes 3.5mm). Statistically it is only significantly stronger than the 10mm CSBAS. Otherwise it is statistically comparable in strength to the other four devices.

In secondary device testing, the 10mm CSBAS performance had not changed. It was the weakest of the four devices (147.560 N). This time however, there was no statistical difference in strength with the 12 and 14mm CSBAS anchors. The 12mm CSBAS came next (347.682 N), followed by the 14mm CSBAS (351.957 N), the strongest of the three anchors. The Synthes 4.5mm proved to be the strongest of the four secondary devices, both in mean pullout strength (888.294 N) as well as statistically ($P < 0.05$ for each anchor).

In general, it can be concluded that the CSBAS is a bone anchor that competes favorably with typical bone screws. Although the three CSBAS sizes are all significantly weaker than the secondary Synthes 4.5mm, there is the advantage of it being unicortical. This is especially important when considering that they will be used as salvage anchors in an area already compromised by the failure of a primary device. Bicortical screws would add to the hazards of correcting the primary device failure. Unicortical devices, as mentioned previously, would not encroach upon vital neural structures.

As primary devices, the 12 and 14mm CSBAS anchors are statistically comparable in strength to the strongest tested screw (Synthes 3.5mm). Here again they have the advantage of being unicortical and therefore inherently safer than bicortical screws.

4.5 Theoretical Comparisons

It was believed that for each device, its area in contact with the bone would be a good predictor of pullout strength if BMD variations in the spines would be excluded. Since BMD variations were accounted for linearly, this hypothesis was tested, but only qualitatively.

Because the insertional depth was never measured for the four screws tested, a ten millimeter depth was assumed for them. The areas were calculated based on the surfaces of the devices directly related to pullout strength. For the screws, the calculated area was that of one side of the engaged threads - the side that would actually push against the bone during pullout testing. For the anchors, the area of the shaft side of the plate in contact with the bone was calculated.

The data of Tables 3.2 (areas) and 3.3 (pullout strengths) is graphed in Figures 3.1 and 3.2 respectively. Qualitatively, a general trend is seen in the two figures. With the exception of the AXIS screw, the trend in the areas (Figure 3.1) is mirrored in the pullout strengths (Figure 3.2). It appears that bone contact area can indeed predict performance.

It must be noted that this finding is based on a linear relationship between BMD and pullout strength, and an assumed constant screw depth of ten millimeters (in contact with the bone).

4.6 Stress Analysis

Finite element analysis was performed on the CSBAS using ANSYS, a computer finite element modeling program by Swanson Analysis Systems. It was desired to see where the maximum stresses on the CSBAS would occur and what those values were. This topic gained importance when, during testing, one 14mm CSBAS broke. While being pullout out of the bone, one side of the plate broke off and remained in the bone while the rest of the anchor come out. In subsequent testing, another 14mm CSBAS bent during testing in the area where one side of the plate is in contact with the shaft.

A model of the 12mm CSBAS was studied. In Figure 4.1, the constraints are shown for the model. The arrows on the flat portion of the rod represent symmetry about the y-axis. They are not constraints. The model was tested with different loads until the maximum stress, approximately equal to the yield strength for the material, was observed on the device. The final load was 545 Newtons producing a stress of 836 MPa at the skirt of the anchor (see Figure 3.3). (The yield strength for the material is 827 MPa.) Displacement was observed in the same area as with the bent 14mm CSBAS (figure not available). In a similar set-up, the 12mm CSBAS was tested using a 250

Newton force (Figure 3.4). It produced a maximum stress of 361 MPa in the same position. Displacement associated with the 250 N force is shown in Figure 4.2. (Close-ups of Figures 3.4 and 4.2 are in the Appendix as Figures A.4 and A.5 respectively.)

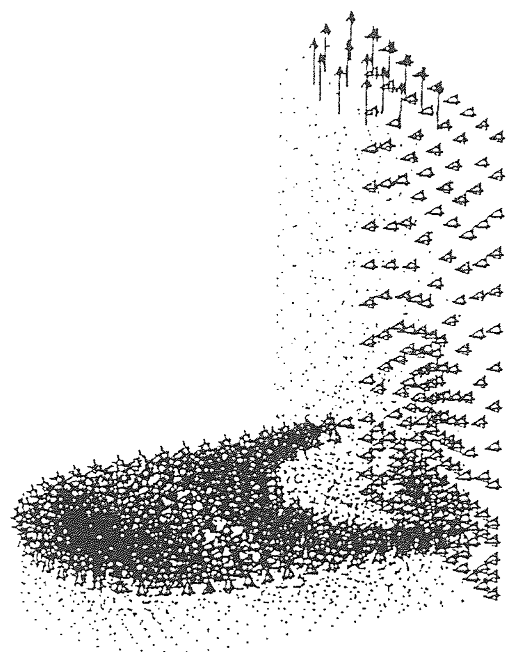

Figure 4.2 Constraints and symmetry arrows for the 12mm CSBAS modeled on ANSYS.

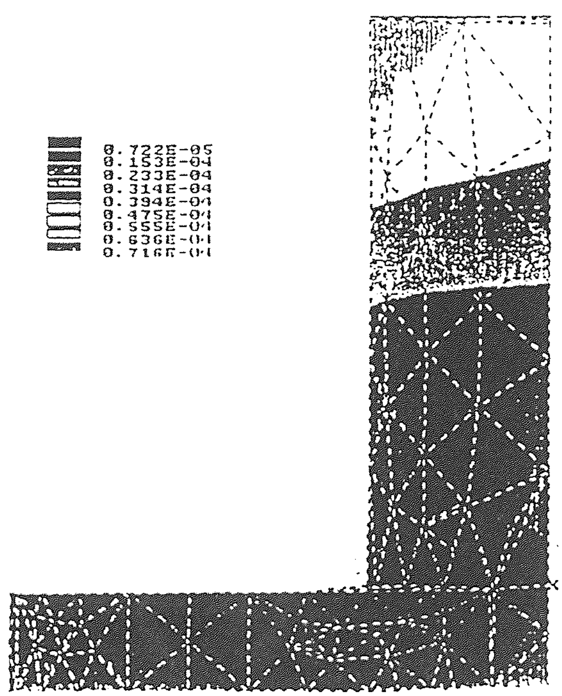

Figure 4.3 Displacement of 12mm CSBAS due to 250 N axial force. Maximum displacement is 7.16 μm at the top of the rod.

It is interesting to note that from observation of the CSBAS, the maximum stress would be expected to occur at the crotch (where the plate meets the shaft). FEA modeling, however, showed that it occurs at the skirt (part of the plate where the shaft is exposed). Although not intuitive, this result is correct. The skirt of the anchor itself is not held in the bone. Therefore, it is not restrained during pullout. Since that is where the most bending can take place, that is the site of the highest stress.

4.7 Comments, Recommendations, and the Future

Careful consideration must be given to selecting the proper CSBAS size for use in the cervical spine. The CSBAS head must be optimal for the desired location. It cannot be too large so that upon insertion the head would protrude out of the lateral mass. This would induce premature failure and possible complications, if not completely destroy that side of the lateral mass simply by its attempted insertion. Likewise, it cannot be too small since that would not take advantage of the available bone and therefore produce a lower pullout strength than what would otherwise be possible in that area.

The insertional technique of the CSBAS was described as being more difficult than that of the screws. Specifically, it was hard to drill the oval window in the bone in the exact location desired. Thereafter, it was difficult to remove the cancellous bone in the ninety degree region around the window such that the CSBAS could fit properly inside (make a ninety degree turn under the cortical bone layer). It may therefore be beneficial to design a better method with accompanying tools to make insertion of the CSBAS easier.

The results of FEA modeling suggest that the design of the CSBAS should be modified. Either a larger round should be made in the area where the plate meets the rod, or the plate should be made wider than the diameter of the rod, or both.

Future testing of the CSBAS will evaluate its biomechanical effectiveness as used with a plate construct in a cervical spine model in comparison with screw-plate constructs for the same model. Non-destructive load-displacement tests on whole spinal segments will be performed as well on severely unstable models with a 50% loss of interior vertebral body height. Some of the specimens would then be further tested to failure and others would be fatigue tested to failure.

CHAPTER 5

CONCLUSION

The purpose of this study was to prove the effectiveness of the newly designed and patented Cervical Spine Bone Anchoring System (CSBAS). It is a posterior fixation device intended to be used with spine bone-plate systems. Its purposes are to replace conventional bone screws, significantly decrease the neurological and vascular risks associated with screws, and have comparable bone purchase strength.

Six spines were used in the study. Their BMD values were related to pullout strengths with a linear relationship.

Theoretical analysis was performed using anchoring device bone-contact area to predict pullout strength. A qualitative comparison suggests that bone contact area can predict relative pullout strengths of devices.

Three CSBAS anchors (sizes 10, 12, and 14mm) were compared as primary devices to three primary bone screws, and as secondary devices (revisions) to one secondary bone screw. The results of the tests show that the primary 12 and 14mm CSBAS anchors are statistically comparable in strength ($P > 0.05$) to the Synthes 3.5mm screw, the strongest of the six primary devices (655.395 N).

In secondary testing, the Synthes 4.5mm screw (888.294 N) was significantly stronger ($P < 0.05$) than the three CSBAS devices. In each case however, it is believed that the CSBAS anchors have a definite advantage over the strongest screws since they are unicortical and the screws are bicortical. The unicortical property of the CSBAS makes it a safer device. It is therefore concluded that the CSBAS is as effective, and safer than conventional bone screws used in the cervical spine.

APPENDIX

Table A.1 BMD Values for all vertebrae (g/sq. cm).

Spine #	1 (2830)	2 (2837)	3 (2832)	4 (2913)	5 (2936)	6 (2876)
C2	1.167 ± 0.03	0.450 ± 0.03	0.504 ± 0.03	0.467 ± 0.03	0.949 ± 0.03	0.782 ± 0.03
C3	1.114 ± 0.03	0.450 ± 0.03	0.757 ± 0.03	0.447 ± 0.03	0.956 ± 0.03	0.855 ± 0.03
C4	1.196 ± 0.03	0.601 ± 0.03	0.706 ± 0.03	0.524 ± 0.03	0.943 ± 0.03	0.810 ± 0.03
C5	1.137 ± 0.03	0.508 ± 0.03	0.723 ± 0.03	0.532 ± 0.03	0.853 ± 0.03	0.858 ± 0.03
C6	1.172 ± 0.03	0.563 ± 0.03	0.694 ± 0.03	0.616 ± 0.03	1.008 ± 0.03	0.755 ± 0.03
C7	1.237 ± 0.03	0.552 ± 0.03	0.806 ± 0.03	0.478 ± 0.03	0.994 ± 0.03	0.827 ± 0.03
N	6	6	6	6	6	6
Mean	**1.171**	**.0559**	**0.698**	**0.511**	**.0951**	**0.815**
Std Dev.	0.0434	0.0778	0.1034	0.0612	0.0544	0.0408

Table A.2 Complete pullout data for the six spines.

	Primary Devices					
	AME	AXIS	Synthes 3.5mm	CSBAS 10mm	CSBAS 12mm	CSBAS 14mm
Spine 1	247.494	617.838	523.366	182.310		531.901
	294.046	859.389	638.773			769.404
(x1)	567.345					930.667
	635.175					
Mean	436.015	738.614	581.070	182.310		743.991
Std Dev.	193.742	170.802	81.605	-		200.594
N	4	2	2	1		3
Spine 2	158.999	219.484	268.995	139.778		
	239.007	225.873	287.319	106.727		
(x2.096)		273.690	425.644			
		351.149	544.022			
Mean	199.003	267.549	381.495	123.253		
Std Dev.	56.574	60.756	128.957	23.371		
N	2	4	4	2		
Spine 3	166.696	192.335	152.0	239.014		
	201.349	115.0	182.229	190.343		
(x1.676)	306.942	165.0	273.633	154.362		
Mean	224.996	157.445	202.621	194.573		
Std Dev.	73.052	39.217	63.329	42.484		
N	3	3	3	3		
Spine 4	132.865	311.971	320.526		227.602	365.0
	37.335	185.005	625.983			110.0
(x2.292)	119.204	294.758	137.857			
Mean	96.468	236.911	361.455		227.602	237.5
Std Dev.	51.664	68.875	246.624		-	180.312
N	3	3	3		1	2
Spine 5				64.557	487.5	305.0
				96.598	398.0	295.0
(x1.231)					500.0	224.951
					370.0	
					367.360	
Mean				80.578	404.572	274.984
Std Dev.				22.656	94.933	43.617
N				2	5	3

Table A.2 (continued)

Spine 6 **(x1.437)** **Mean** **Std Dev.** **N**					175.146 63.037 119.092 79.273 2	
Final Results **Mean** **Std Dev.** **N**	 **364.406** 89.522 12	 **527.221** 170.567 12	 **655.395** 209.608 12	 **234.460** 96.844 8	 **419.259** 153.363 8	 **542.024** 187.709 8

	Secondary Devices			
	Synthes 4.5mm	**CSBAS 10mm**	**CSBAS 12mm**	**CSBAS 14mm**
Spine 1 **(x1)** **Mean** **Std Dev.** **N**	675.083 1041.621 1153.252 1198.355 72.754 828.252 469.710 5		311.150 311.150 - 1	352.057 352.057 - 1
Spine 2 **(x2.096)** **Mean** **Std Dev.** **N**	265.432 426.951 690.217 739.576 470.0 518.435 195.664 5	105.814 105.814 - 1	360.0 116.505 36.759 171.088 168.391 3	

Table A.2 (continued)

Spine 3 **(x1.676)** **Mean** **Std Dev.** **N**	89.544 428.156 453.787 332.500 325.997 166.051 4	114.269 82.5 98.385 22.464 2		
Spine 4 **(x2.292)** **Mean** **Std Dev.** **N**	309.253 711.852 436.599 485.901 205.778 3		248.386 235.093 241.740 9.400 2	230.03 396.835 202.685 276.517 105.092 3
Spine 5 **(x1.231)** **Mean** **Std Dev.** **N**		94.811 55.556 58.207 126.397 83.743 33.608 4		
Spine 6 **(x1.437)** **Mean** **Std Dev.** **N**			90.989 108.294 99.642 12.236 2	129.780 91.451 64.751 105.296 97.820 27.151 4
Final Results **Mean** **Std Dev.** **N**	 **888.294** 228.416 17	 **147.560** 38.890 7	 **347.682** 156.077 8	 **351.957** 244.075 8

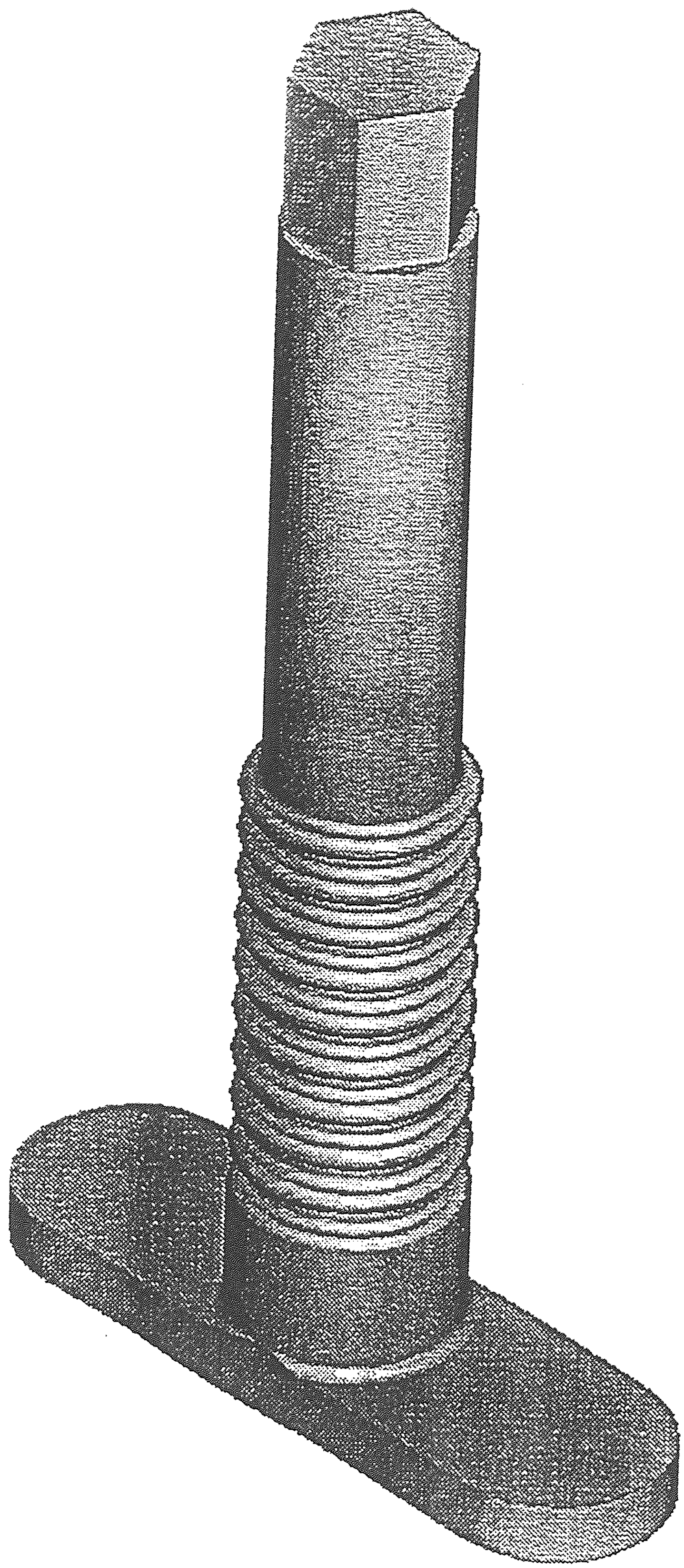

Figure A.1 14mm CSBAS.

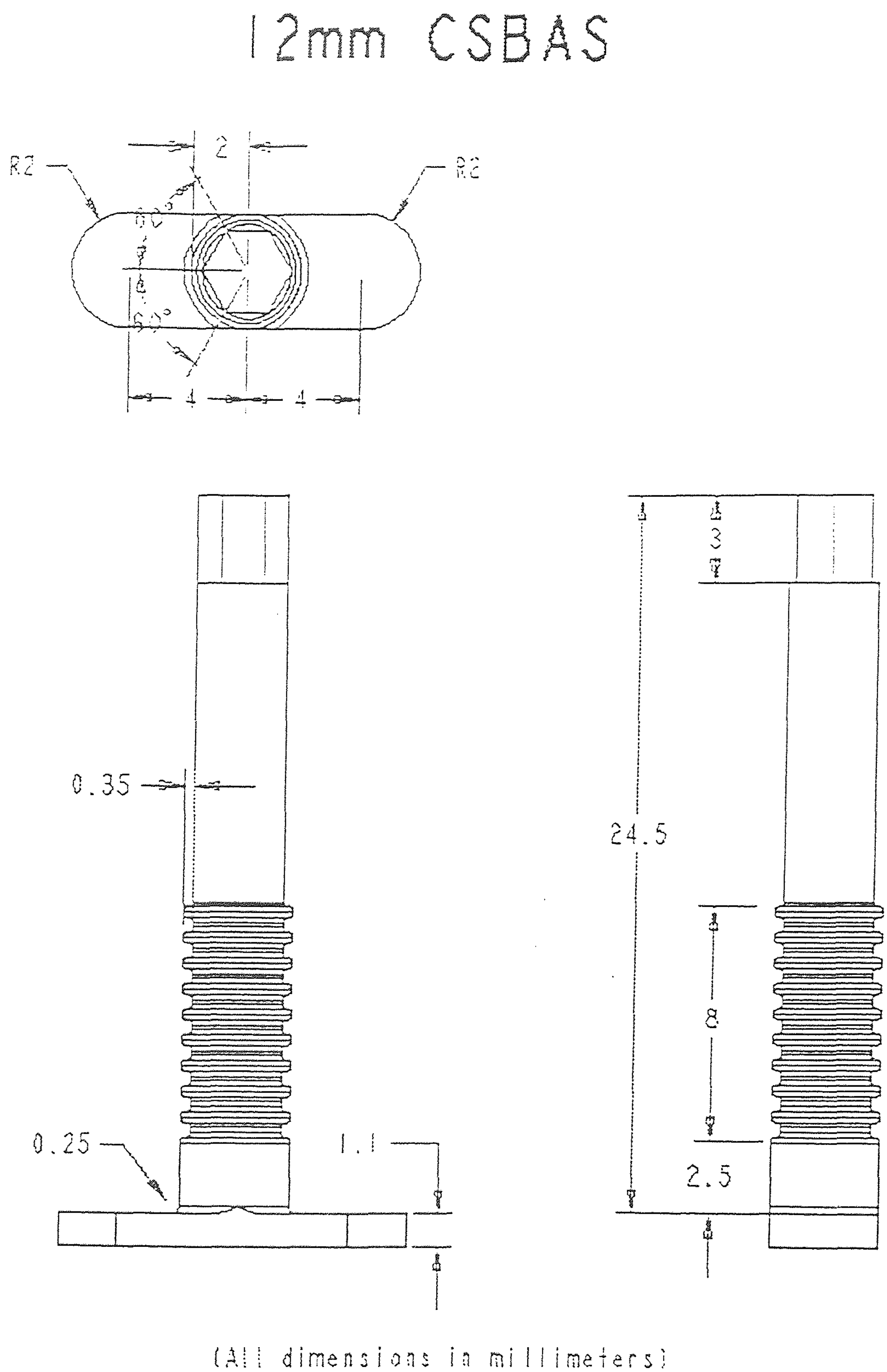

Figure A.2 Detail drawing of 12mm CSBAS.

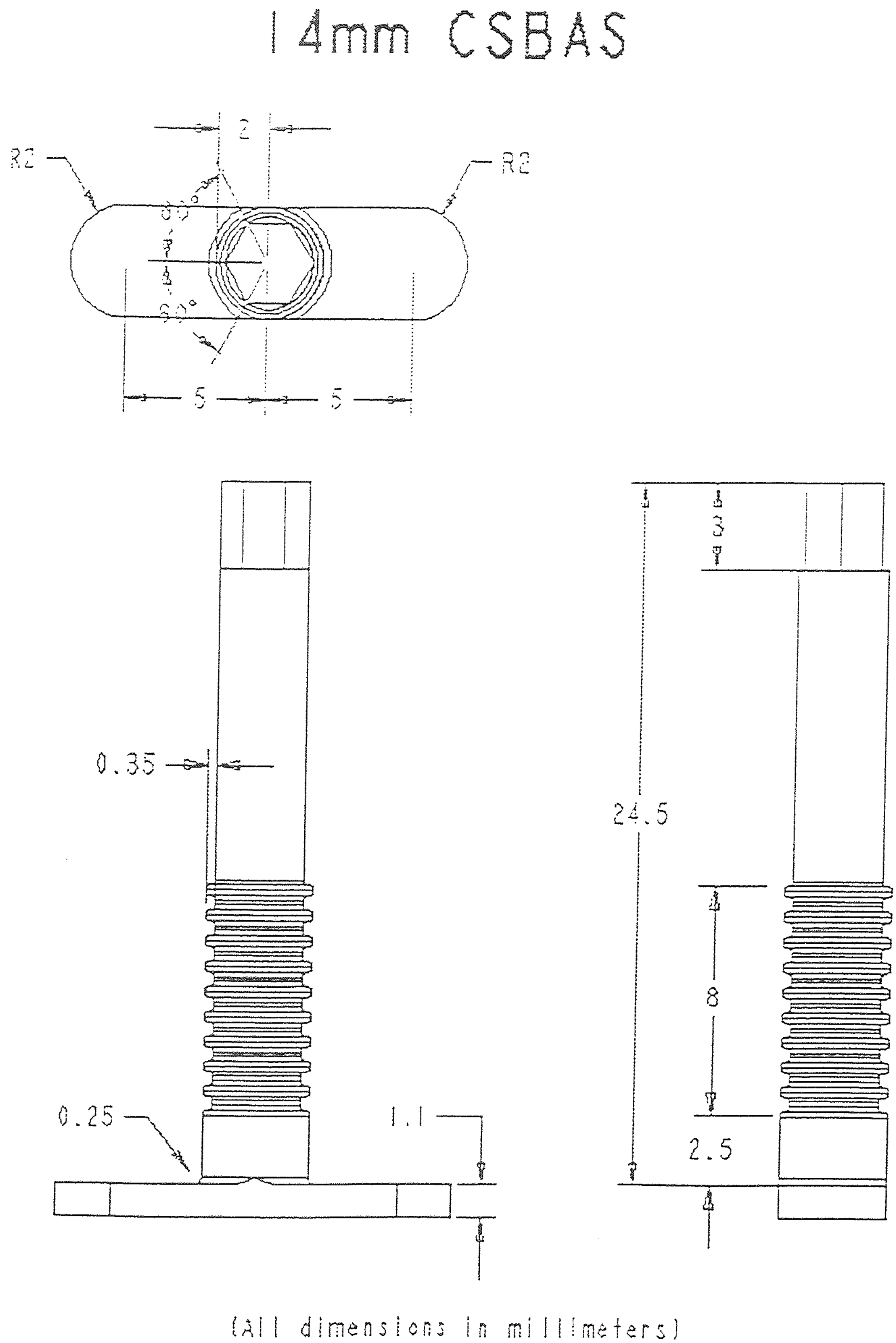

Figure A.3 Detail drawing of 14mm CSBAS.

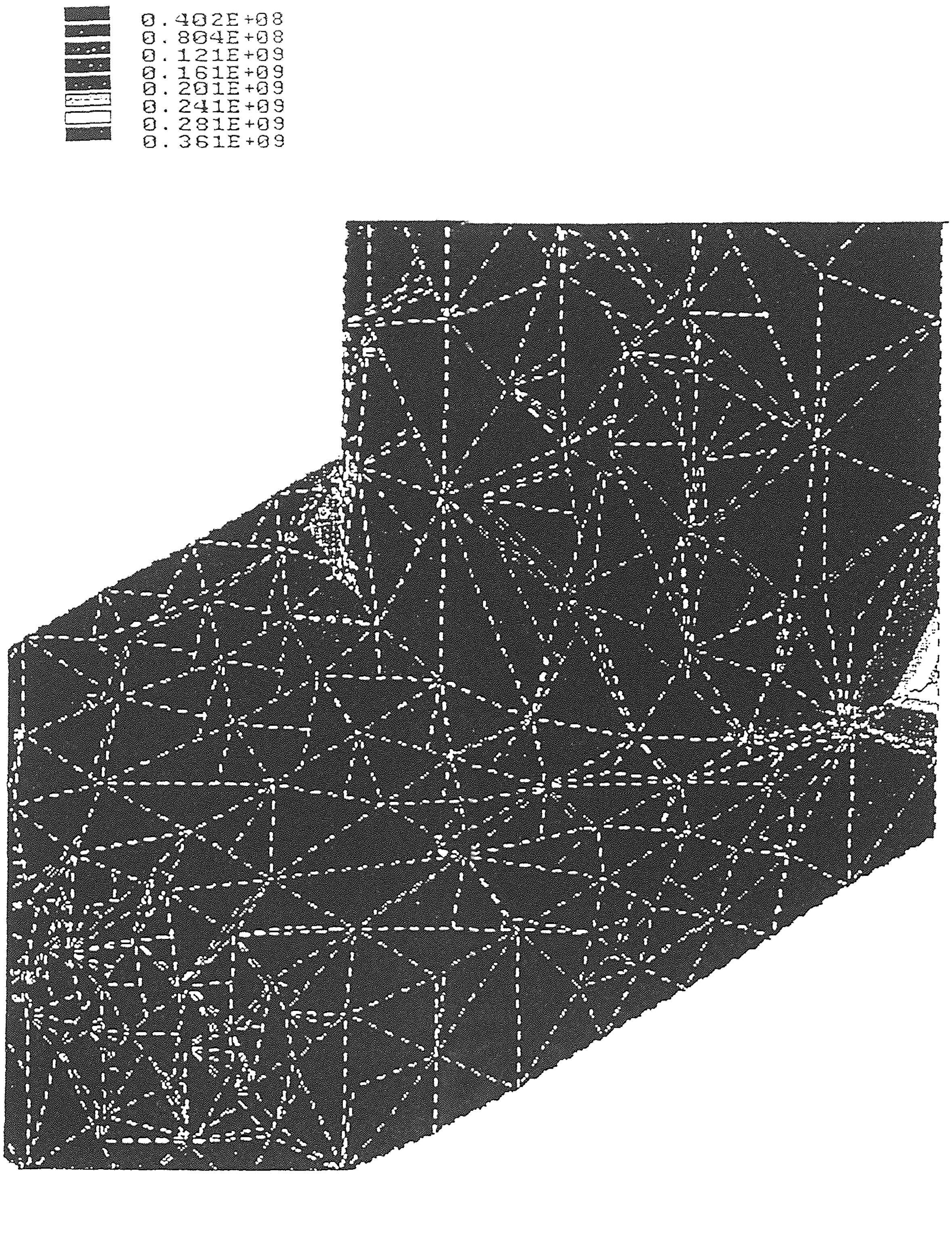

Figure A.4 Close-up of Figure 3.4

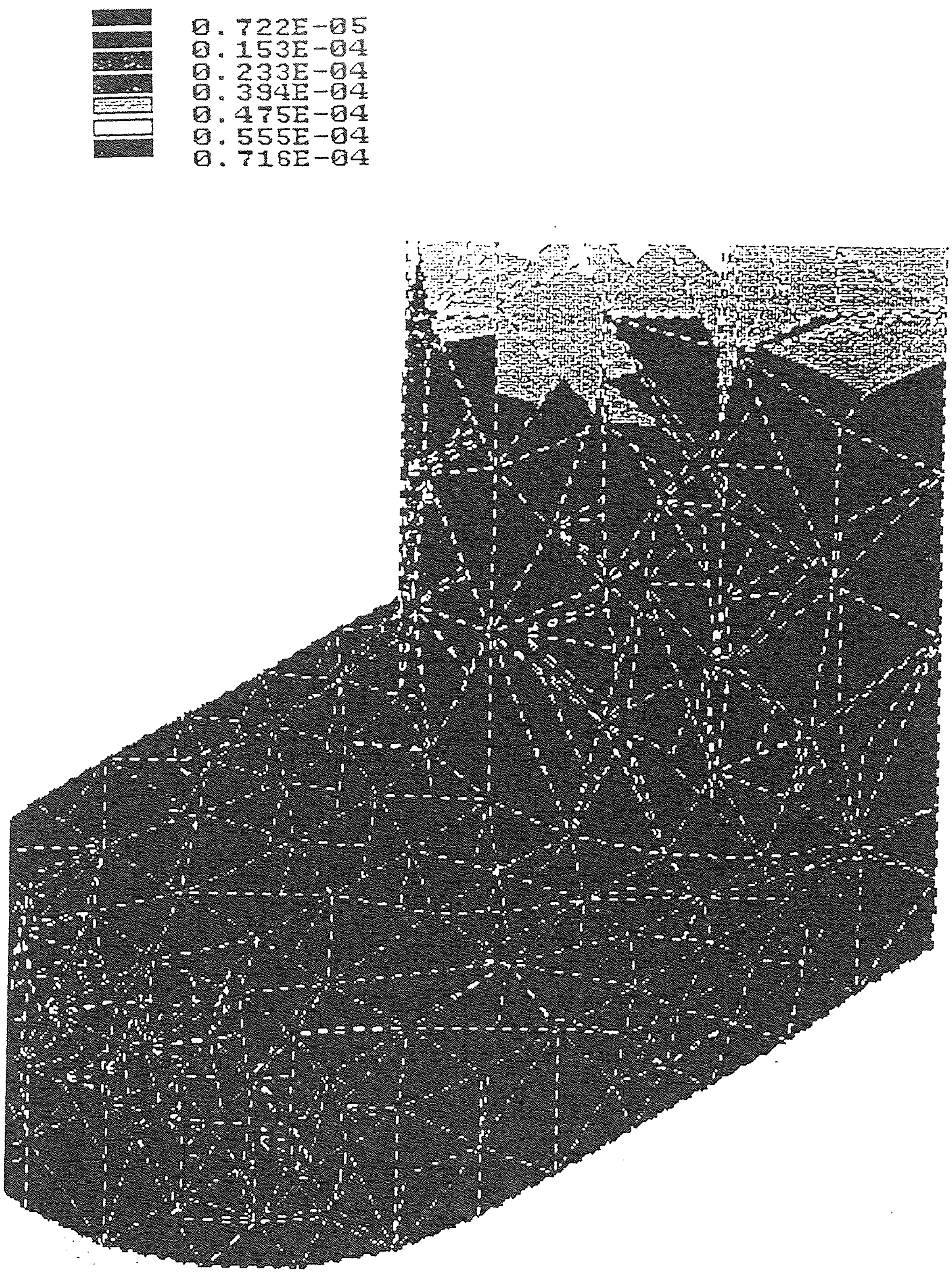

Figure A.5 Close-up of Figure 4.2

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