ABSTRACT

MECHANICAL EVALUATION OF PEDICLE SCREW FIXATION OF THE LUMBAR SPINE

by
Ding Lu

Pedicle screw fixation of the lumbar spine has been reported to increase fusion rates. A biomechanical evaluation of four different pedicle screw implant systems, (AO, Rogozinski, TSRH and Wiltse), was performed to compare intrinsic device stiffness under conditions of flexion-compression and forty-five degree off-axis flexion-compression. The effect on stiffness of the loosening of device members was also studied. Testing was done in load control using an electrohydrualic testing machine. UHMWPe blocks are used to simulate the vertebra.

Assuming that stiffness is directly proportional to the probability of obtaining fusion, this study allows the ranking of the systems tested in their normal loading stiffnesses and their abilities to maintain stiffness with off axis loading and unintentional loosening of components. This study indicates a ranking of the four systems tested as TSRH being the most stiff followed by AO and Wiltse. Clearly, the worst system tested, from consideration of initial stiffness, off-axial load and loosening is the Rogozinski construct.

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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

May 1997

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MECHANICAL EVALUATION OF PEDICLE SCREW FIXATION OF THE LUMBAR SPINE

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To my parents, my wife and new born baby boy Jonathan

ACKNOWLEDGMENT

The author wishes to express his sincere appreciation and gratitude to his supervisor, Professor Harold Alexander, for providing valuable and countless resources, insight, intuition and support throughout this research.

Very special thanks to Doctors David Kristol, J. Russell Parsons, Raj Sodhi for serving as members of the committee.

The author is grateful to Academic Research and Analysis, Inc for the funding of this research, the Department of Orthopaedic Surgery of UMDNJ, the Department of Mechanical Engineering and Department of Chemical Engineering of NJIT for providing all necessary materials and instruments.

The author appreciates the timely production of machine parts from the Auto-machine Laboratory of NJIT. Also, thanks to Professor Roman Dubrovsky and Professor Martin Linden, Professor John Ricci, Dr. Vincent J. Gulfo MD, Dr. Joseph T. Shen, MD, and Professor George Lei for their suggestion, to Mr. Tom Poandl, Mr. Don Rosado, Mr. Wang Zhi Yang, Mr. David L. Najjar, Mr. Daniel Yang, Ms. Margaret Miller, Ms Sarah Khalid, Ms. Maryann Fam for their help in the accomplishment of this work.

The author additionally sends his thanks to Mrs. Annette Damiano for her help in checking and correcting this thesis.

The author wants to express his gratitude to his parents for their understanding and their support of him in his studying and stay in the United States.

Finally, the author would like to thank his wife Hong Gu for her love and continuous support.

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CHAPTER 1

INTRODUCTION

1.1 Objective

The objective of this study is to evaluate the biomechanical performance with respect to stiffness of four different pedicle screw fixation devices. Disorders of the lumbosacral region are a challenge for orthopaedic surgeons. A variety of abnormal conditions affect this region. Various pedicle screw devices and techniques are rapidly gaining popularity as adjuncts to the fusion treatments of different of types of spinal deformities, tumors and trauma.

Pedicle screw fixation of the lumbar spine has been reported to increase fusion rates[1-3], presumably because of increased stiffness (rigidity) of fixation. Favorable results with fusion rates up to 100% have been published with pedicle screw instrumentation systems [4] All of these devices depend upon the ability of the screw to maintain purchase and mechanical integrity in the pedicle until solid fusion occurs. However, conflicting data have recently appeared in the literature regarding this issue. Mechanical failures [5,6] have been observed in clinical applications. Clinical and experimental biomechanical studies have also shown that these devices appear to be associated with an increased rate of complications,[7 - 9] such as short-term failure in pseudarthrosis or adjacent-level stenosis, slip progression after fusion, screw breakage, and spinal osteoporosis[10 - 13]. Long-term effects of spine fusion with pedicle screw fixation remain incompletely documented. One area of particular concern is the risk of disuse osteopenia in the vertebral bodies at the level of the fusion.[14,15] Rigid instrumentation has been shown to result in local osteopenia[13,16,17] because of decreased compressive stress in the bridged segments of the appendicular skeleton [18]

Because of the above referenced concerns, screw rod and screw plate devices used for the purpose of posterior lumbar vertebral stabilization through the lumbar pedicle are Class III medical devices and are considered by the us-FDA to be investigational or experimental forms of spinal fixation that are not yet proven to be safe and effective.

This study is an attempt to supply information about the biomechanical properties of four pedicle screw devices.

1.2 Anatomy of the Spine

The spine is a complex structure composed of seven cervical, twelve thoracic, five lumbar, five sacral vertebrae and four coccygeal segments (Figure1.1.) The length is about 71 centimeters in males and 61 centimeters in females. A vertebra is composed of an anterior block of bone, the "vertebral body" and a posterior bony arch in which is contained four articular processes, seven transverse processes, and a spinous process (Figure 1.2) The vertebra body is a mass of cancellous bone within a thin shell of hard cortical bone Studies have shown that compression is carried mainly by the vertebral trabecular bone. Between bodies are intervertebral discs that form the chief connections between bodies and act as mechanical springs. They are thicker in front than behind, (Figure 1.3), thus helping to form the convex curvatures in the lumbar region. The disc consists of two regions, the inner nucleus pulposus and the outer annulus fibrous. The nucleus pulposus is a soft, pulpy, yellowish elastic material that lies in the center of the disk. The annulus fibrous consists of a variable number of predominantly concentric lamellae, each about one millimeter thick, which are arranged so that the orientation of the collagen fibers relative to the longitudinal axis of the spine alternate with successive layers Not only do disks join bones, but they also absorb most of the energy The pedicle is the strong rounded bar posteriorly projecting from the vertebral body and contouring an oblong plate with sloping surfaces (Figure 1.2.) The posture of the vertebral column is maintained by

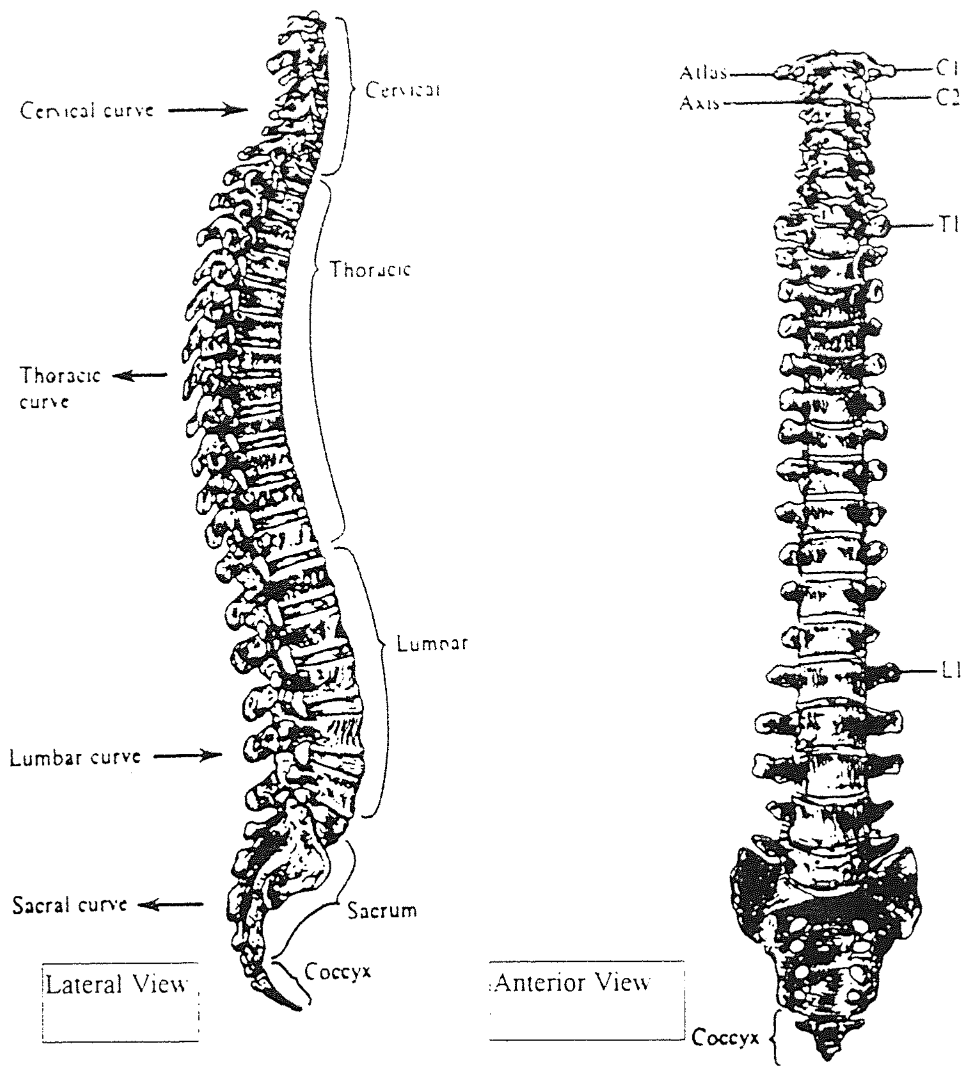


Figure 1.1 Spine Column

the intrinsic back muscles Many measurements of vertebral compression strength have been made from 2.5 kN at T-8 and 3.7 kN at T-12 to 5.7 kN at L-5.[19] Knowledge of the load-displacement behavior of the spine and its components is required for biomechanical analyses of spine function. For convenience, most tests of the mechanical properties of the spine use two vertebrae and theirs intervening soft tissues as a spinal segment The load-displacement properties are obtained by applying either test forces or moment, or both, to a point on the upper vertebra, and then measuring the resulting displacements The stiffness of a segment has been found to be in the range of 600 to 700 N/mm in axial compression [19]

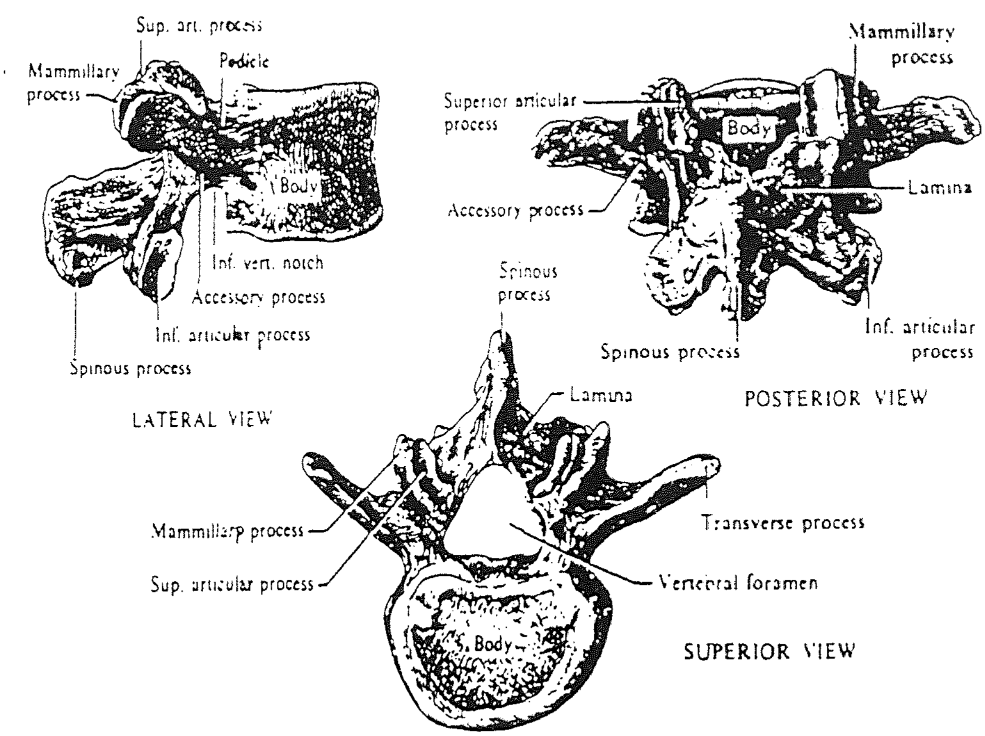


Figure 1.2 3rd Lumbar Vertebra

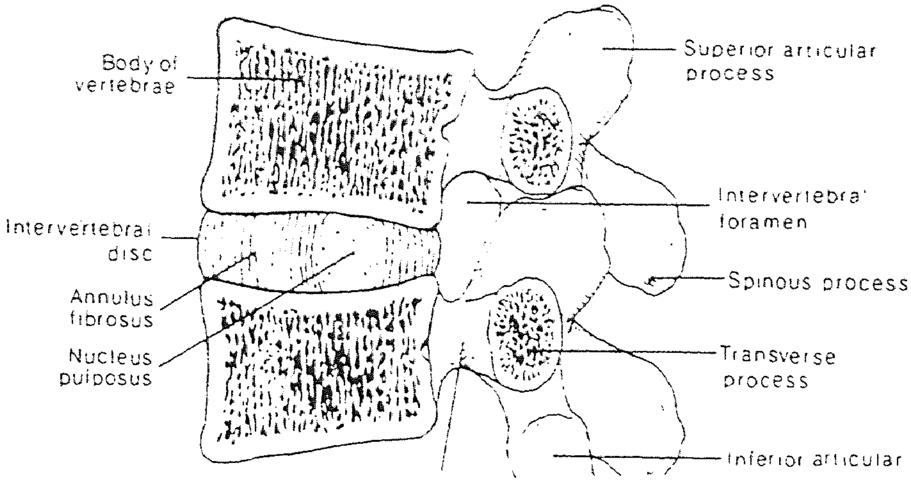


Figure 1.3 Lumbar Spine Segment

1.3 Fusion of The Spine

Spinal fusion is the elimination of movement across a segment by bony union. In the United States, the concept of spinal fusion surgery was first reported by Albee [20] in 1911 to control the progressive kyphosis associated with tuberculosis. Later, Hibbs[21] performed fusion for the treatment of scoliosis. Use of pedicle screws was first reported in the 1940s, but their success and acceptance were limited.[22] With time, techniques of spinal fusion were applied to scoliosis, fractures, and degenerative conditions.[23,24,25] Although the rate of successful fusion after posterolateral bone grafting, alone, has increase.[26,27,28] In procedures with consistently high fusion rates, attention has been directed to the instrumentation of the spine[29 - 33] to enhance fusion. It has been reported that higher fusion rates are obtained with instrumentation.[2,3] The more rigid the fixation, the higher the fusion rate [4,23, 28] A variety of instrumentation systems have been developed during the past decades The choice of anterior or posterior fusion techniques is usually dictated by which form of fixation either coupled release of soft tissue or an osteotomy, will best enable correction of the deformity, the management of complex spinal deformities, including paralytic scoliosis, iatrogenic flat back deformity, lumbar kyphosis from trauma, and severe spondylolisthesis and spondyloptosis. This led to the concept of combining anterior interbody fusion with posterior arthrodesis.

A spinal fusion, performed from a posterior approach, is done to achieve spinal stability In mechanical terms, an unstable structure is one in which a small load causes a large increase in displacement In clinical terms, an "unstable" spine is one that exhibits an abnormally large anteroposterior translation, amounting to one millimeter or more on flexion-extension radiographs The type of fusion chosen, posterior or posterolateral, should afford the greatest likelihood for fusion with the fewest amounts of risk for the patient. The pedicle has been described as the "force nucleus" of the spine, where the posterior elements converge before their communication with the anterior vertebral body This allows the pedicle, the strongest portion of the vertebral body, to act as an effective point of force application to accomplish rigid and effective segmental fixation. For the appropriate clinical conditions, It is generally believed that proper use of pedicle fixation can improve the potential for a successful fusion, insure a more effective initial surgery and, consequently, allow for earlier mobilization in the perioperative period. Although a higher fusion rate was obtained with instrumentation, or with rigid instrumentation,[4] than without instrumentation, clinical failure[6] with pedicle screw instrumentation in the lumbar spine has been reported. Evaluation of various instrument parameters such as screw size, shape, thread design, and the depth of screw insertion, as well as transverse connectors,[30, 31, 32] have been performed to gain insight into these clinical failures. The flexural compressive and torsional rigidity are major factors affecting the rate of successful fusion.

1.4 Problem

Even though internal fixation helps obtain a fusion, corrects deformities, and provides early stabilization, clinical retrospective and prospective studies have identified a significant incidence of hypermobility, osteopenia, or spinal stenosis in segments adjacent to the stabilized region[9, 34 - 38]. Short-term failure such as pseudarthrosis or adjacent-level stenosis, occurs more frequently in patients with fusion. Poor results from screw breakage, with recurrence of deformity and screw loosening, have also been reported.[39] (Figure 1.4) Osteopenia has also occurred in response to rigid pedicle instrumentation.[14,15] This may be attributed to factors such as poor design, incorrect screw-plate alignment, pre-stressing of the screw-rod-plate construct, the lack of anterior load sharing in the presence of anterior column instability, and, possibly improper stiffness of the instrumentation. Device-related osteopenia suggests that the stiffness of the devices may be an important factor in instrumental spine fusion.

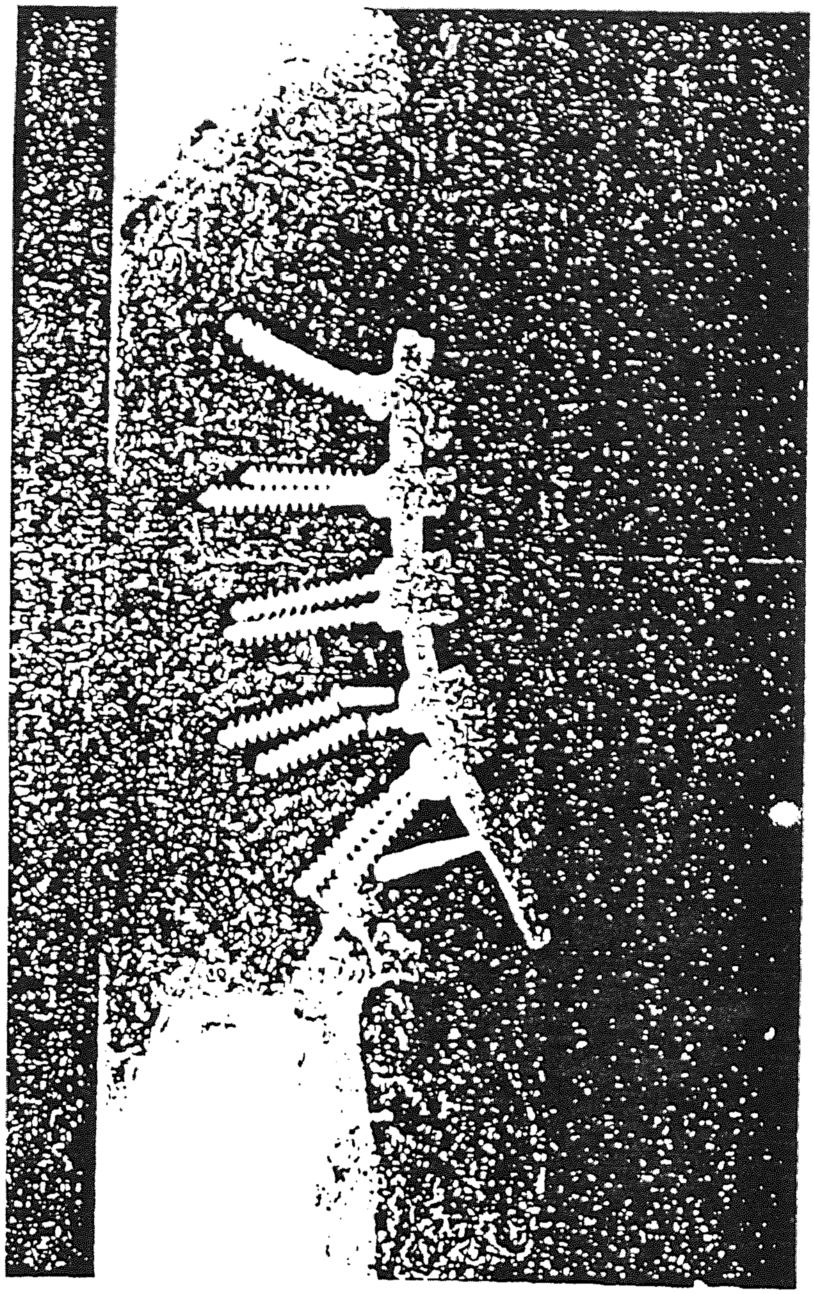


Figure 1.4 An example of screw breakage

CHAPTER 2

METHODS AND MATERIALS

2.1 Implant Devices

The internal fixation devices used in spinal surgery are metallic implants that attach to the bone and aid in the healing of bone grafts. However, these implants are intended only to assist healing and not intended to replace normal body structures. These implants are intended to be removed after the development of a solid fusion mass. In addition, it is often necessary to reduce, at least partially, the existing deformity. All metallic surgical implants are subject to repeated stresses in use, even in the absence of direct weight bearing, which can result in metal fatigue. The surgeon must be thoroughly knowledgeable, not only in the medical and surgical aspects of the implants, but also must be aware of the mechanical and metallurgical limits of surgical implants. Correct selection of the implants is extremely important. The potential for success of fusion is increased by the selection of the proper size, shape and design of the implant.

This study investigates the mechanical properties of four spinal fixation systems that are the TSRH, AO, ROGOZINSKI and WILTSE fixation systems.

1. The Texas Scottish Rite Hospital (TSRH) Spinal System is designed to aid in the surgical correction of several types of spinal conditions. The TSRH Spinal System traces its origins to research performed at the Texas Scottish Rite Hospital (TSRH) for children in Dallas, Texas. The system consists of a variety of shapes and sizes of rods, hooks, plates, bolts, and screws. The TSRH implant components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the

individual case The TSRH Spinal System implant components (Sofamor Danek Group, Inc TN) are made of medical grade Stainless Steel. (ASTM Standard F136 or its ISO equivalent) The TSRH Pedicle Screw Spinal System, designed with the variable angle T-bolt, provides the opportunity of effectively immobilizing the spine, along with a reasonable degree of correction with improvement of the "slip angle" (Figure 2.1). The TSRH pedicle screw spinal system allows easy contouring of the fixation system to improve and maintain the patient's spinal alignment and also provides easier insertion of the rods in cases where the pedicle screws are not in perfect alignment

2. A second subject implant system is the AO notched plates all screws system (Synthes Ltd., Paoli, Pennsylvanvia) which consist of 4.5 mm AO 316L Stainless Steel bone screws threaded through 316L stainless steel plates with individual holes. The screws of this system have spherical heads that allow the screws to freely pivot within the plates. (Figure 2.2.)

3. The Rogozinski Spinal Rod System (Smith & Nephew-Richards Orthopaedics Inc Memphis, TN) consists of two stainless steel (ASTM F138) rods attached to the spinal column through the use of pedicle screws. (Figure 2.3.) Cross-bars can be used to connect rods to rods to provide a more rigid construct, as well as to connect screws to rod and hooks to rod. There are several screws provided in a variety of lengths, diameters, up-angles and down-angles. Screws used with this system feature a "T"-shaped head for offset attachment to the rod using both a coupler and cross-bars to accommodate varying patient morphology. Coupling of component is accomplished with flat set screws pressing on the circular rods.

4 The Wiltse Rod systems (Advanced Spine Fixation System Inc., Cypress, CA) consist of anchor bone screws (e.g., pedicle screws), all saddles and clamps that have apertures to capture stainless steel (ASTM F138) rods that are positioned on the pedicle screws and clamped by the tightening of lock nut (Figure 2.4.)

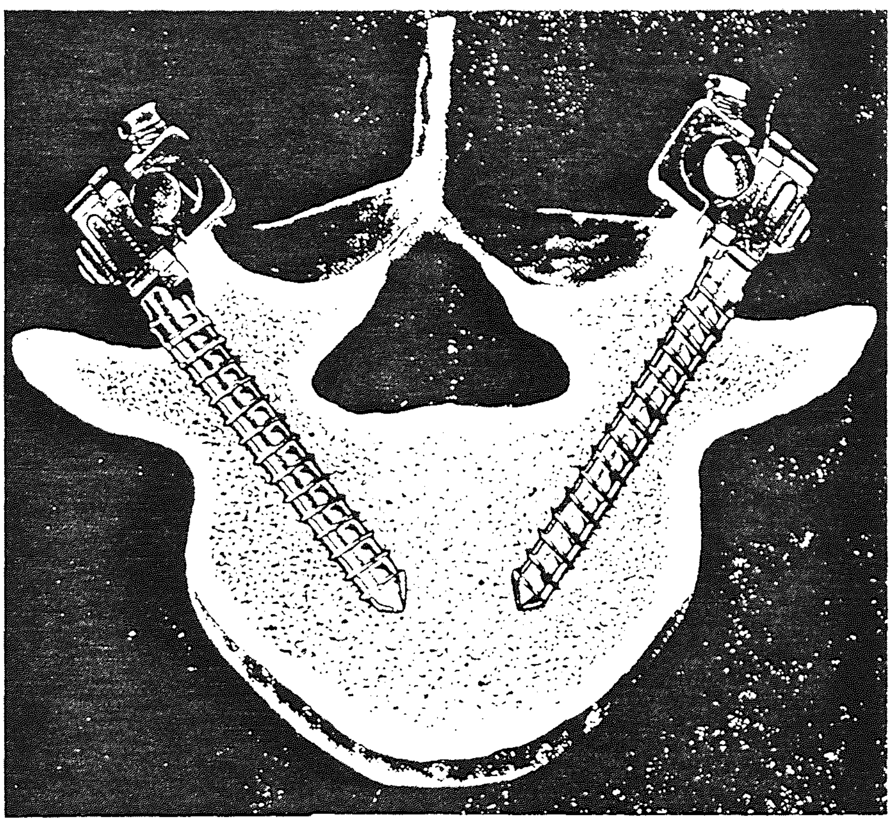


Figure 2.1 TSRH Spinal System

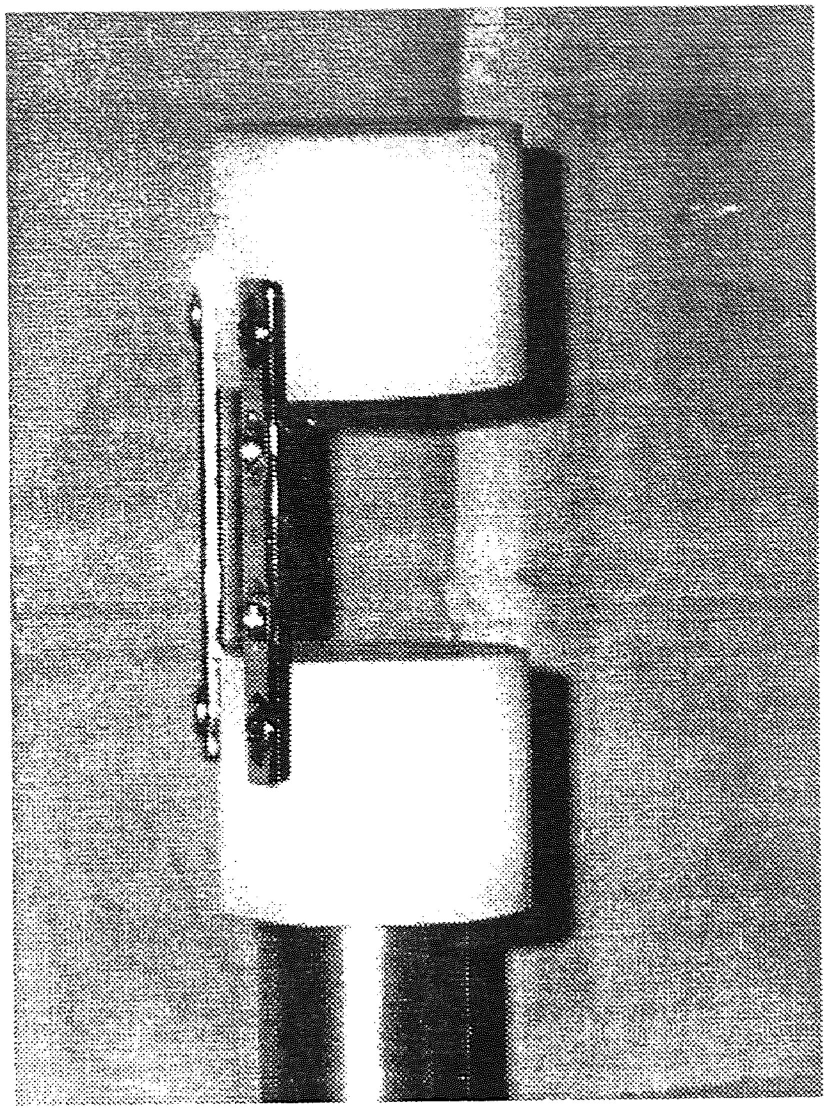


Figure 2.2 AO System

2.2 Simulated Model

A number of different methods have been utilized to analyze the biomechanical properties of instrumental fixation of the spine. In each case, either cadaveric bone or simulated vertebrae were used as the vertebral model. The advantages of biomechanical testing using fresh human spine are that they are closest to the in vivo situation, but the results

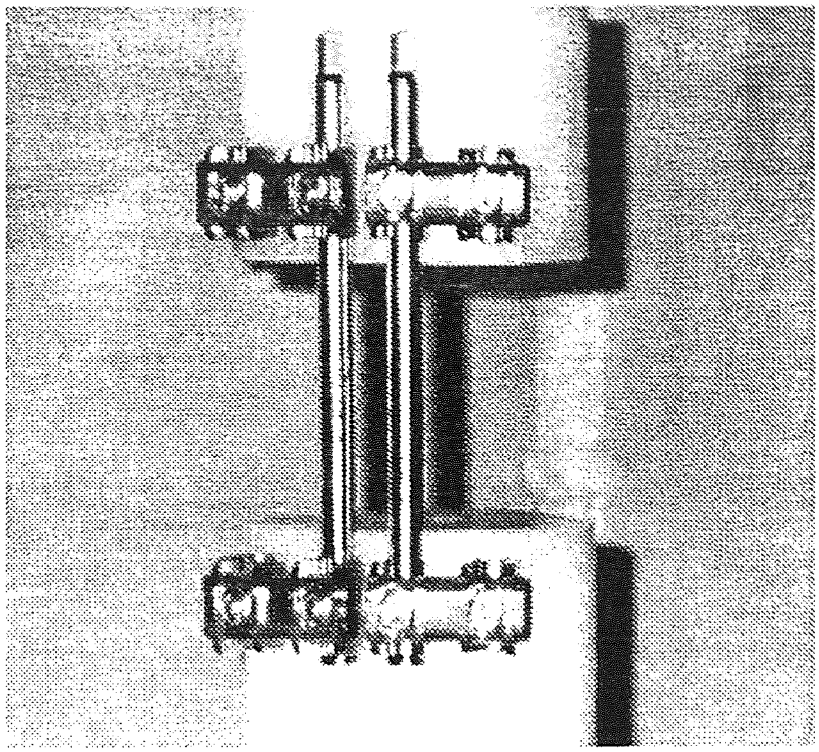


Figure 2.3 Rogozinski System

obtained display a large deviation due to the variability of the samples (patient's age, sex, state of health, specimen size, bone mineral density and method of preparation). Zinkrick, et al [40], found that the factor that appeared to play the largest role in determining the ability of a screw, inserted into a pedicle, to resist loosening was the bone density of the specimen tested. The use of simulated vertebrae is valuable in evaluating the biomechanical properties of instrumentation fixation in the spine because it provides a consistency in the fixation medium. Accurate machining of the parts (vertebral bodies) provides consistency in the analyses, eliminating the variability of the cadaveric model.

The present study, a " One Above and One Below Corpectomy Model", was performed with simulated vertebrae The pedicle screws were attached to two UHMWPe (Ultra High Molecular Weight Polyethylene) vertebral bodies. (Figure 2.5) The rods or plates

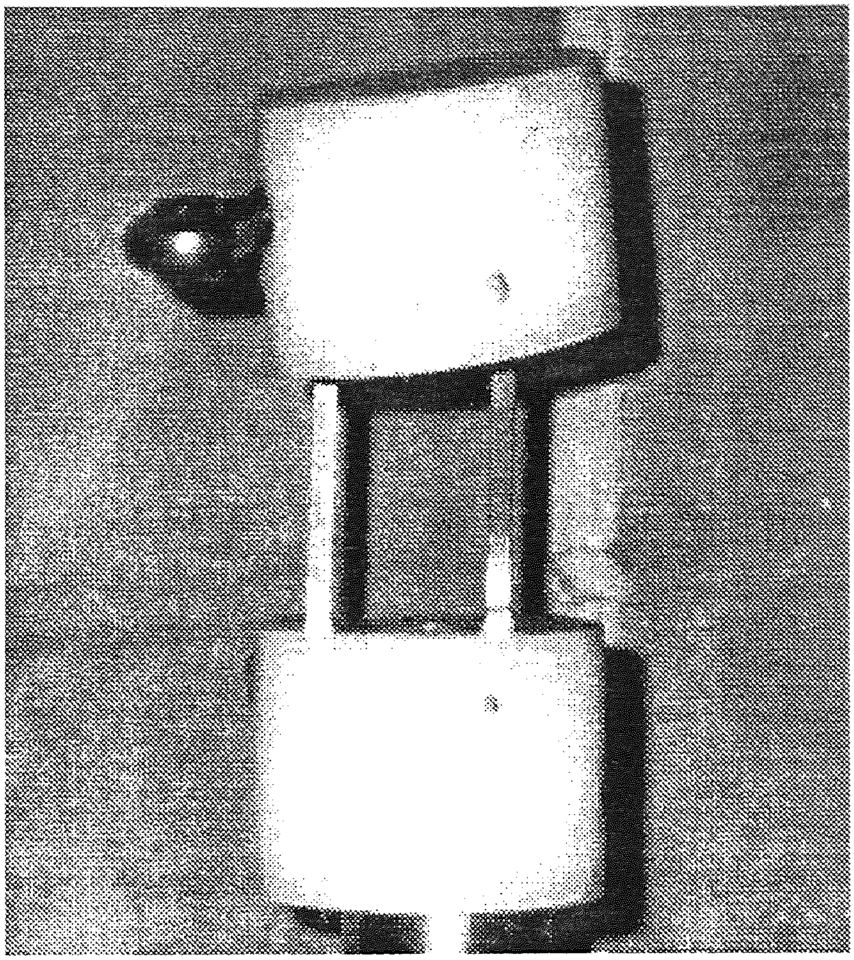


Figure 2.4 Wiltse System

were connected to the screws fixing the two vertebral bodies. (Figure 2.6.) The four types of pedicle implant systems were evaluated separately in an anterior-posterior (A-P) compressive flexure mode with bending stiffness determined for each device. Loads were applied in an A-P zero degree and a forty-five degree off-axis A-P compressive flexural mode. Additionally, the issue of decreased stiffness with device loosening was assessed by "controlled" loosening of the construct members. A total of 21 samples of four different pedicle screw implant systems (TSRH, AO, Wiltse and Rogozinski) were tested. All instrumentation, purchased from the manufacturers, was unused prior to testing.

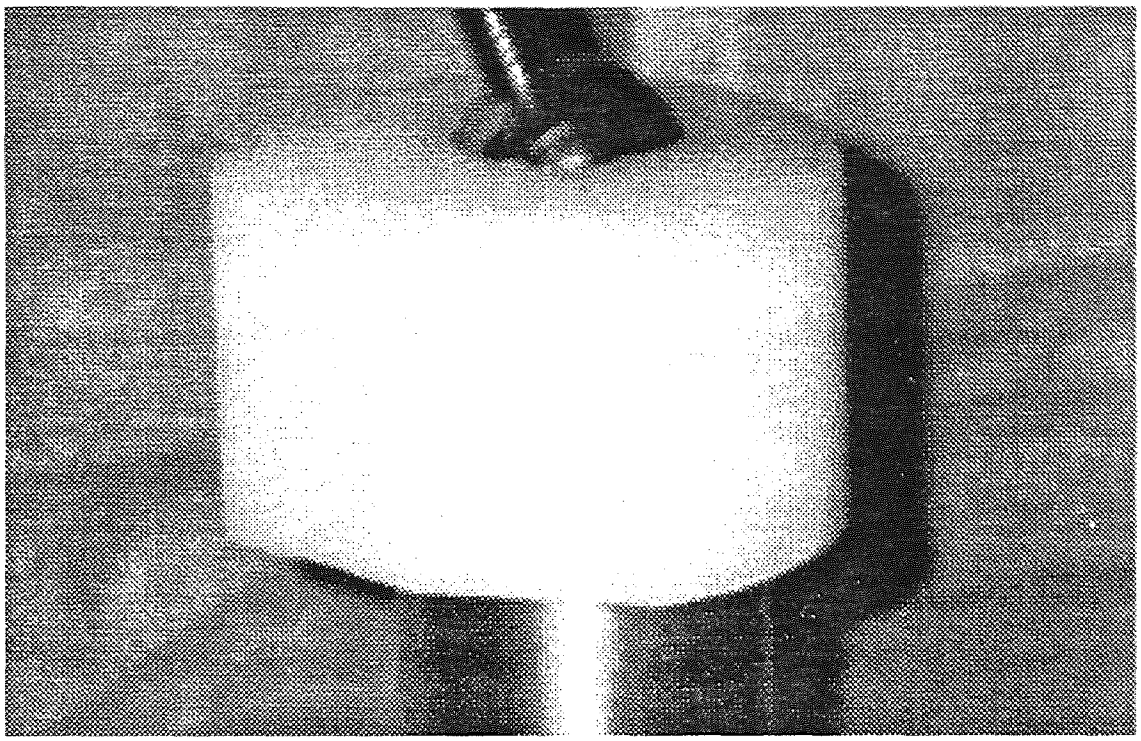


Figure 2.5 UHMWPe Vertebral Body

2.3 UHMWPe Vertebra

Ultra High Molecular Weight Polyethylene (UHMWPe) cylinders (2.5 mm in diameter, McMaster Carr, Dayton, NJ) were manufactured to simulate the vertebrae. Each cylinder was standardized and precisely machined to specific dimensions and tolerances to permit symmetrical bilateral application of a bi-level spinal implant system (Figure 2.4) (Machining was conducted by Auto-machine Lab, NJIT) Each vertebra was cut to 36.1 mm high, and two flat surfaces were cut 150 degrees a part A pre-drilled hole was taped for the appropriate pedicle screws of each instrumentation system. Each top

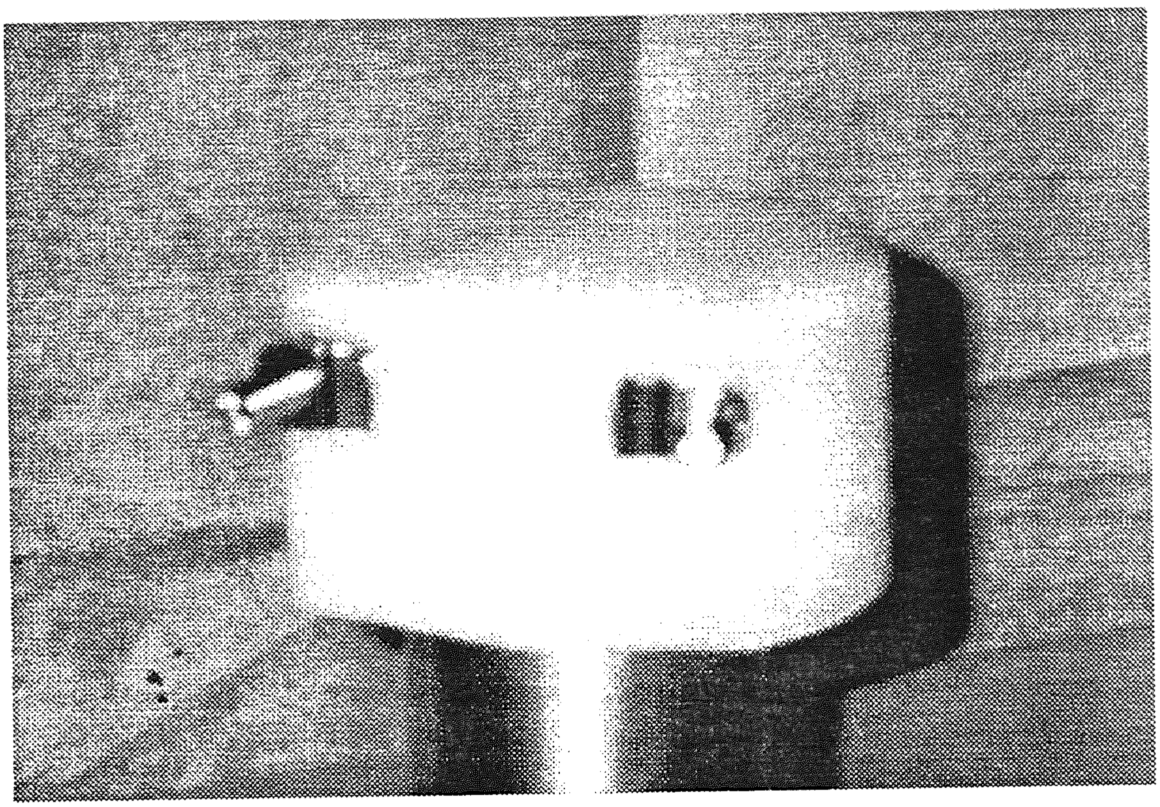


Figure 2.6 The Screw Inserted into Vertebra

vertebral flat surface contained a 25.4 mm diameter pocket milled to 18.0 mm depth permitting a consistent lever arm of 45.0 mm. Based on skeletal measurements of a two level construct, the distance between the pedicle screw axes in the cephalocaudal and mediolateral directions were kept consistently at 76.0 mm and 40.0 mm, respectively. The distance from the center of load application to the center of the longitudinal elements (plate or rod assembly) was precisely measured for each construct Measurements were performed and verified using a Precision Dial Caliper in conjunction with a 58.0 mm polyethylene spacer used between the UHMWPe vertebra to assure anterior column alignment and spacing. Torque values were generated using a Micrometer Changeable-Head Torque Wrench (McMaster Carr, Dayton, NJ), applied to each rod system construct.

2.4 System Set Up

The systems were assembled as recommended by each manufacturer. The pedicle screws of 45 mm length were inserted into the pre-drilled flat surfaces of the UHMWPe vertebral body for each system. The screw diameters for AO, Rogozinski, TSRH and Wiltse were 4.5 mm, 6.4 mm, 6.5 mm and 6.5 mm respectively The longitudinal plates or rods were placed on the ends of the screws or bolts, and the clamps or nuts were tightened. The tightening torque used was 9.0 N/m. for AO and 11.2 N/m. for Rogozinski, TSRH and Wiltse Based upon skeletal measurements of a two level construct, the distance of the two vertebral bodies in the cephalocaudal and mediolateral direction was controlled to a distance of 36.0 mm for each construct. This model represents a corpectomy defect and worst-case scenario for instability.

The instrumental models were connected to a servohydraulic MTS testing machine by a specially designed fixture. The bottom vertebra was fixed on the load cell, and the top for the zero degree A-P loading model was loaded by a one mm diameter stainless steel ball seated 18.0 mm into the opposing pocket. This allowed a swivel angle of 150 degrees, thereby, effectively providing an unrestricted testing environment For the 45 degree loading test, the top of the loading model was connected to a joint bearing fixture. It provided an unrestricted testing environment also.

Each implant system contained the following basic components four pedicle screws, two longitudinal rods or plates and clamps or couplers and a lock nut where appropriate. Cross-linking and the interconnection screw/plate or rod mechanism changed with different systems as required by the manufacturers. All implant parts were constructed from stainless steel (ASTM F-138) except the rod of the Wiltse system which was constructed from Titianum (ASTM F136). The test protocol consisted of mounting each specimen on an MTS testing Machine, (MTS, Inc., Minneapolis, Minnesota) as shown in (Figure 2.7). Each construct was cycled five times. The load was applied at a load rate of 5-N/sec up to a maximum flexion moment of 11 N-m. All data were derived from the fifth final tests The data were collected on line, with the use of a DELL OptiPlex XM 5166 computer. (Dell Inc. Austin, Texas).

Stiffness measurements were obtained from the load/deflection curves. Because the loads versus displacement curves were nonlinear, especially at low loads and during loosening tests, average slopes were calculated and the local slope was calculated at five different loading regions.

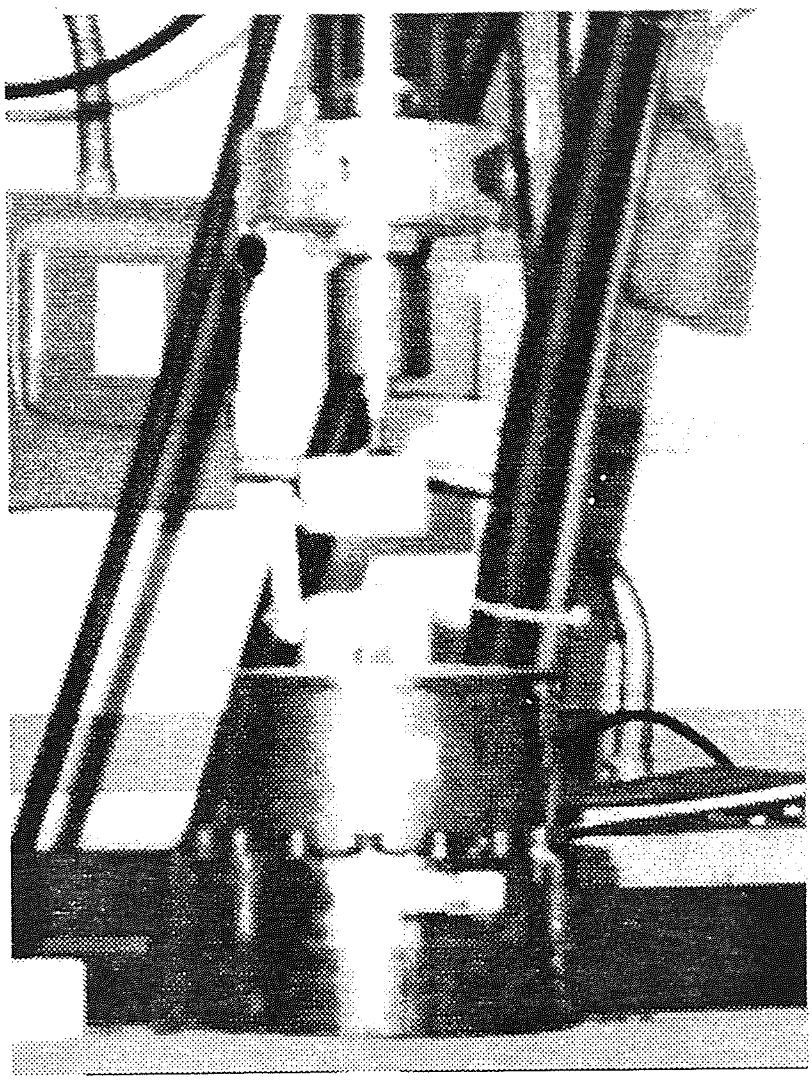


Figure 2.7 The Device Connected to Loading Cell

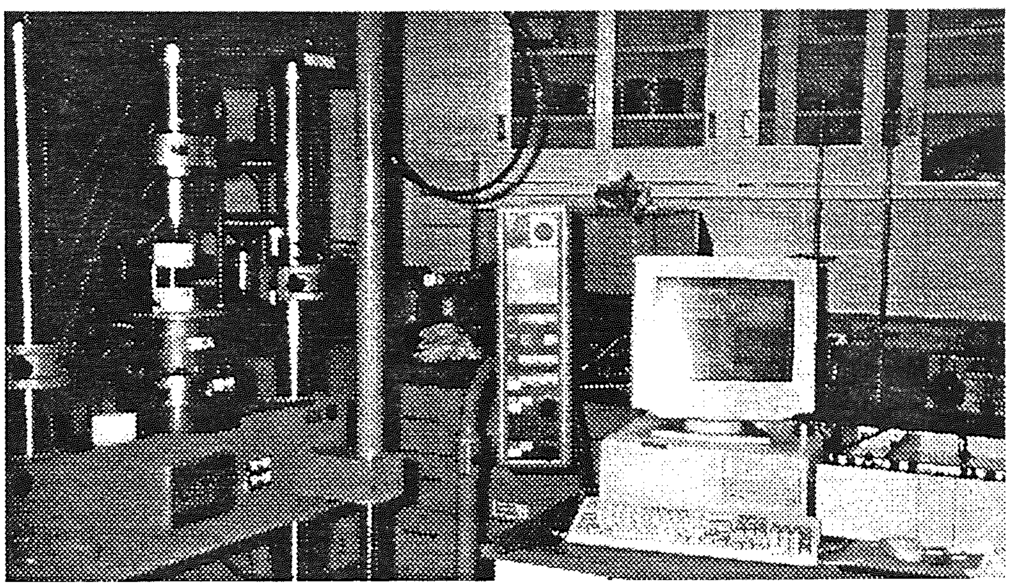


Figure 2.8 MTS Testing System

CHAPTER 3

RESULTS

The mean values of minimum, average and maximum stiffness from all samples of the same system are reported as test results

3.1 Anterior Flexion-compression

A total of 15 devices were tested: three AO, four Rogozinski, six TSRH, and two Wiltse systems. For maximum stiffness, the AO plate pedicle screw system has the highest value of 916.9 (N/mm). Next are the Wiltse at 913.3 (N/mm) and the TSRH system at 514.4 (N/mm). The lowest maximum stiffness was obtained for the Rogozinski system at 433.7 (N/mm). For average stiffness, the Wiltse device is the highest at 451.7 (N/mm). Next is the AO system at 364.2 (N/mm), and the Rogozinski system at 257.9 (N/mm). The lowest average system stiffness was measured from the TSRH construct at 247.2 (N/mm). The values of the Rogozinski and the TSRH are very close, varying by only 4 %. The AO system minimum stiffness is 152.7 (N/mm) which is the highest, next is the TSRH at 90 (N/mm), and then the Rogozinski system at 88.7 (N/mm). The lowest one is the Wiltse system at 34.8 (N/mm). (Figure 3.1).

3.2 Off-axis Anterior Flexion-compression

The purpose of off-axis anterior flexion-compression loading was to obtain comparative construct's stiffness for the four systems in a loading mode typical of activities of daily living. The off-axial load mode combines anterior flexion-compression, torsion and bending. A 45 degree off-axis was used in this test. The stiffness in the off-axis mode is reported as maximum, average and minimum values. For maximum stiffness, the TSRH construct demonstrated the highest result at 188.3 (N/mm). The AO system and the Wiltse system maximum stiffness was computed as 97.7 and 94.5 (N/mm), respectively. The Rogozinski demonstrated the lowest maximum stiffness at 79.1 (N/mm). For the average stiffness values, the TSRH is the highest at 94.7 (N/mm) and the Rogozinski is the lowest at 50.9 (N/mm). The AO and the Wiltse average stiffness are 59.2 and 56.7 (N/mm), respectively. For the minimum stiffness, the order of the result is 26.5 (N/mm) for Wiltse, 22.4 for TSRH, 21.8 for AO and 13.2 for Rogozinski. (Figure 3.2) These results show that the TSRH, the AO and the Wiltse have similar minimum stiffness. The Rogozinski construct has a significantly lower minimum stiffness value.

3.3 Loosening Study

For the loosening study, a total of 15 devices was tested with different combinations of the loosening of four components in both loading modes.

In normal A-P flexion compression loading with the loosening of one component, the maximum stiffness results are 415.1 (N/mm) for AO, 401.4 (N/mm) for TSRH, 324.7 (N/mm) for Wiltse and 269.8 (N/mm) for Rogozinski. In average stiffness values, the values in (N/mm) are 205.6 for AO, 177.3 for TSRH, 162.5 for Wiltse and 127.7 for Rogozinski. For minimum stiffness values, the values from high to low are: Wiltse -- 67.4, TSRH -- 45.5, Rogozinski -- 30.3 and AO -- 26.3. (Figure 3.3). With two components loosened, the maximum stiffness (N/mm) from high to low are: 332.5 for TSRH, 253 for Wilste, 231.2 for AO and 88.1 for Rogozinski; average stiffness are:

140.7 for AO, 131.3 for TSRH, 123.5 for Wiltse and 63.2 for Rogozinski, and minimum stiffness is 81.7 for Wiltse, 13.6 for TSRH, 6.6 for Rogozinski and 4.6 for AO (Figure 3.4). Generally, the stiffness decreased around 140 % to 280 % with only one component loosened and about 400 % with two components loosened.

In the off- axial mode, the values with loosening one component were 100.9 for TSRH, 81.6 for AO, 58 for Rogozinski and 56.6 for Wiltse for maximum stiffness. For average stiffness, the values are 57.6 for TSRH, 48.5 for AO, 36.1 for Wiltse and 29.6 for Rogozinski. In minimum stiffness calculations are 16.5 for Wiltse, 14.8 for TSRH, 12.8 for AO and 6.9 for Rogozinski (Figure 3.5). When two components are loosened, the maximum stiffness (N/mm) of the TSRH constructs is 103.2, the average stiffness is 49.2, and the minimum stiffness is 7.2. The stiffness of the AO system is 65.1, 39.9, and 5.3, respectively. For the Wiltse system the values are 22.8, 7.3, and zero, respectively. The Rogozinski system was completely loose with zero stiffness with two components loosened. (Figure 3.6). So, no data were reported here to the stiffness. (Figure 3.7)

Consequently, for the AO system, the stiffness was decreased about 180 % with loosening one component, and about 260 % with two components loose. (Figure 3.8). In Off-axial load mode, the stiffness decreased about 750 % on average with one part loosened and 910 % with two parts loosened. (Figure 3.9). For the Rogozinski device, the stiffness decreased about 200 % with one component loosened and about 400 % with two components loosened. (Figure 3.10). In off- axial loading, stiffness was decreased about 870 % with one component loose and moved freely with no resistance with two components loose. (Figure 3.11). For the TSRH system, the stiffness decreased about 140 % with one component loose and about 190 % with two components loose (Figure

Figure 3.1
NORMAL LOAD

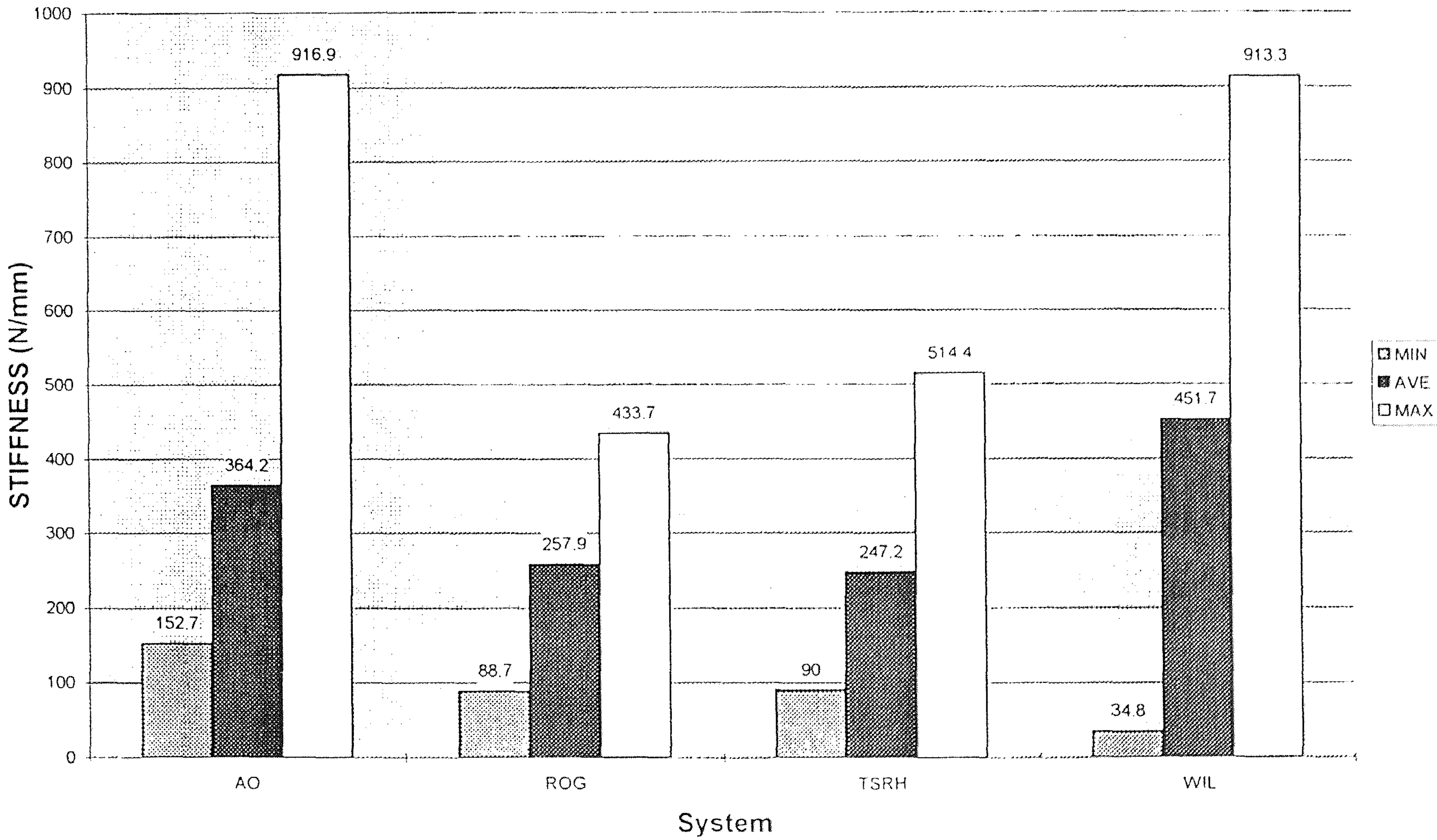


Figure 3.2
45 DEGREE LOAD

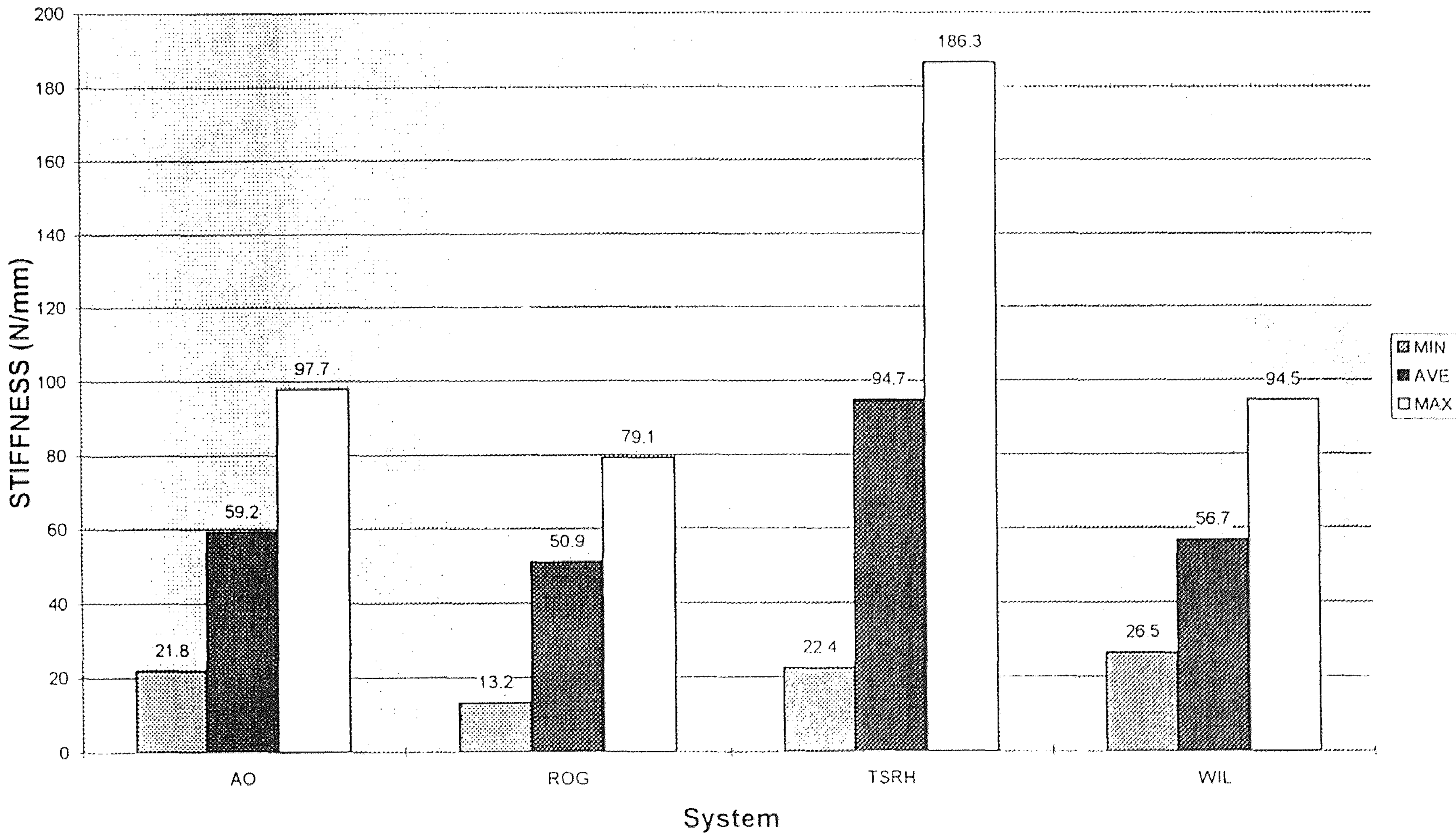


Figure 3.3
NORMAL LOOSENING ONE PART

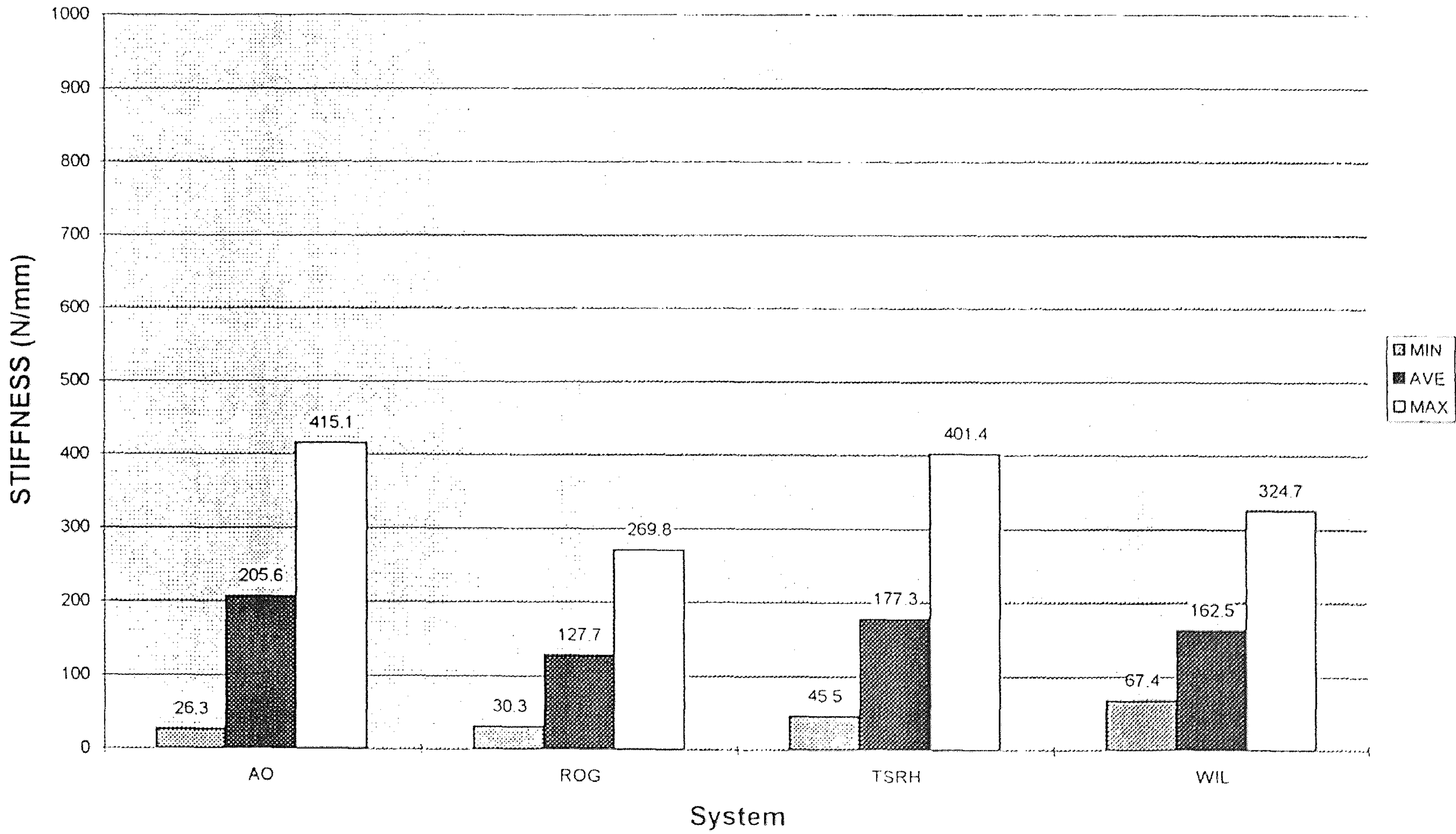


Figure 3.4
NORMAL LOOSENING TWO PARTS

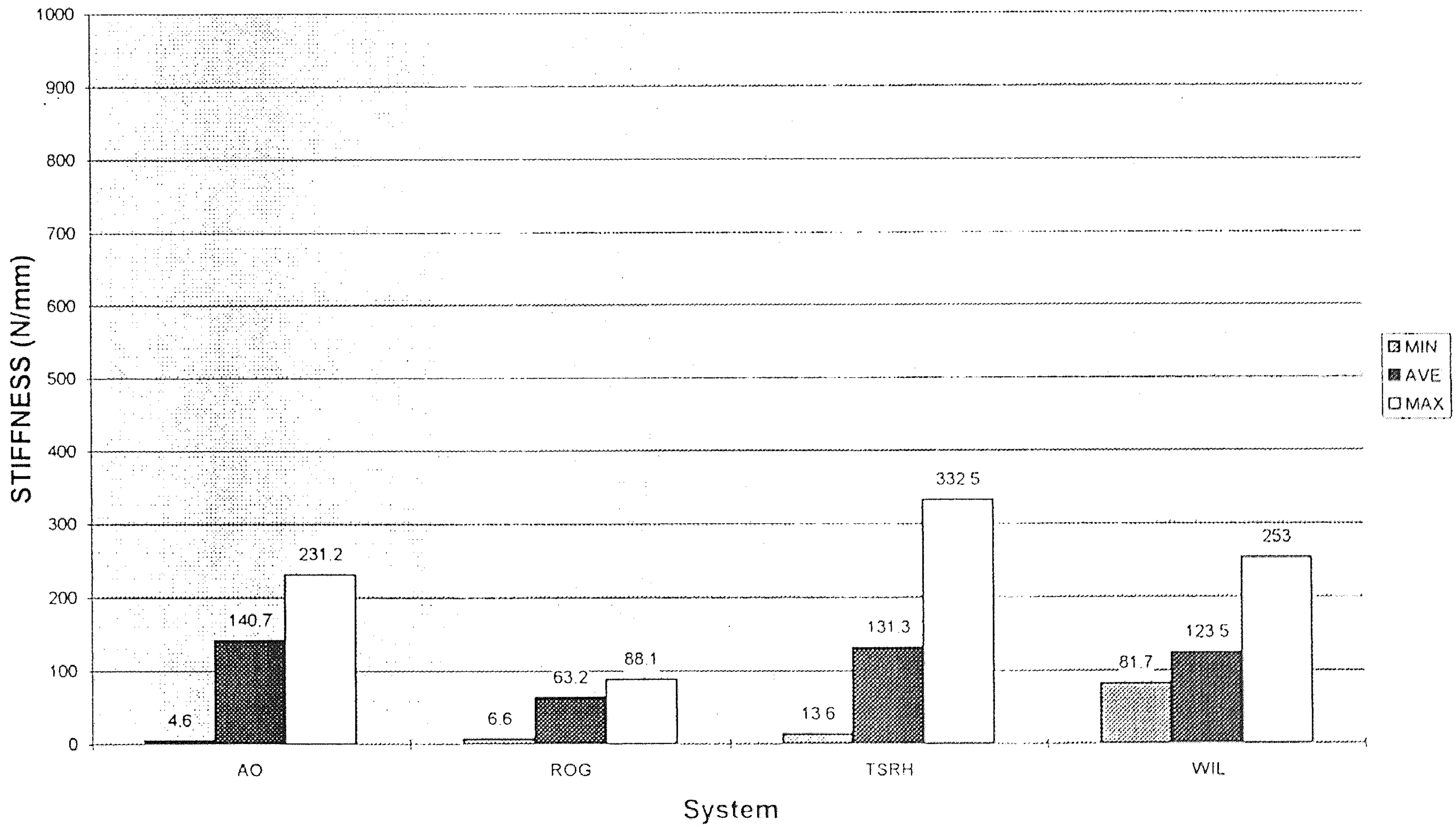
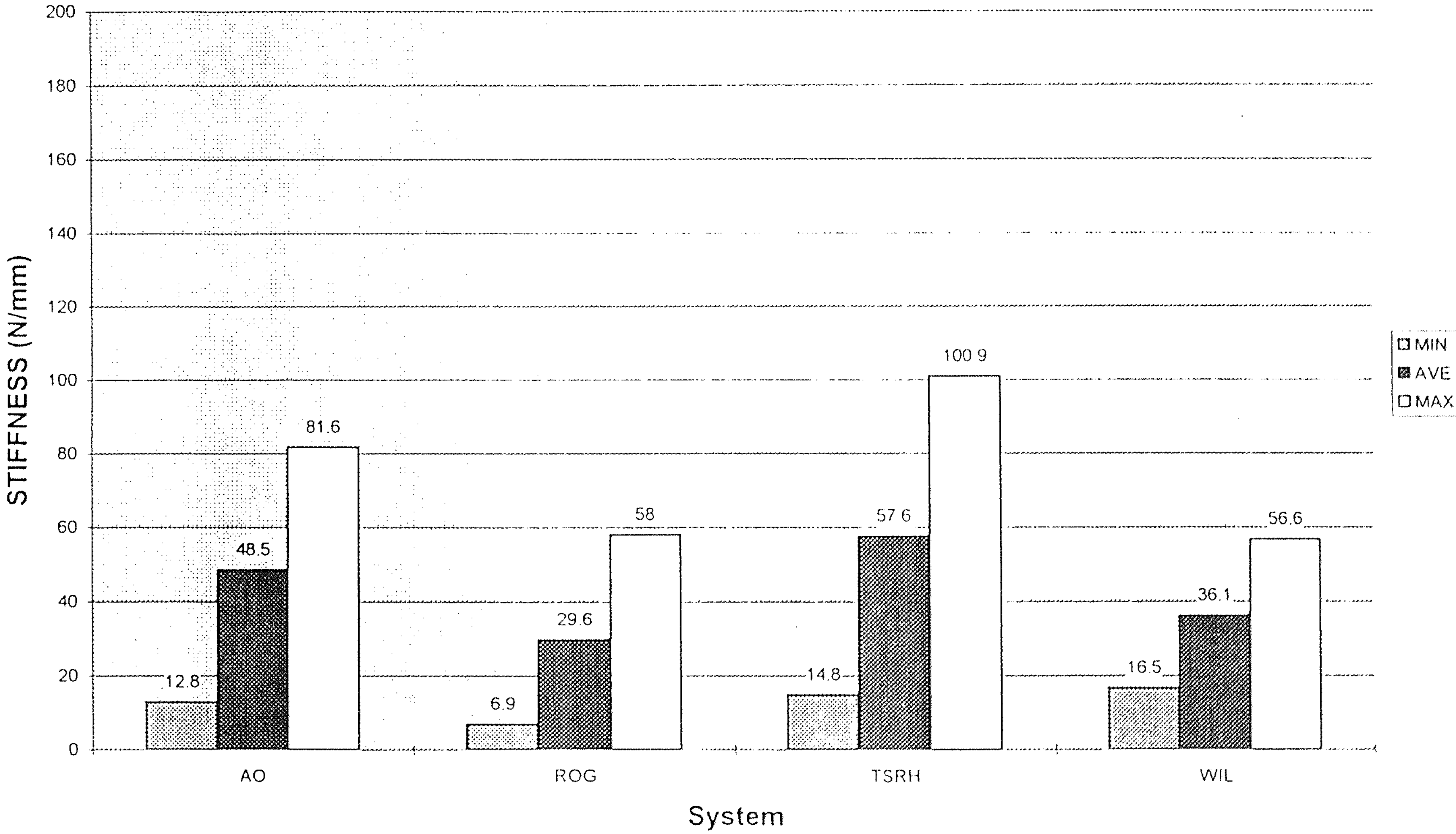


Figure 3.5
45 DEGREE LOOSENING ONE PART



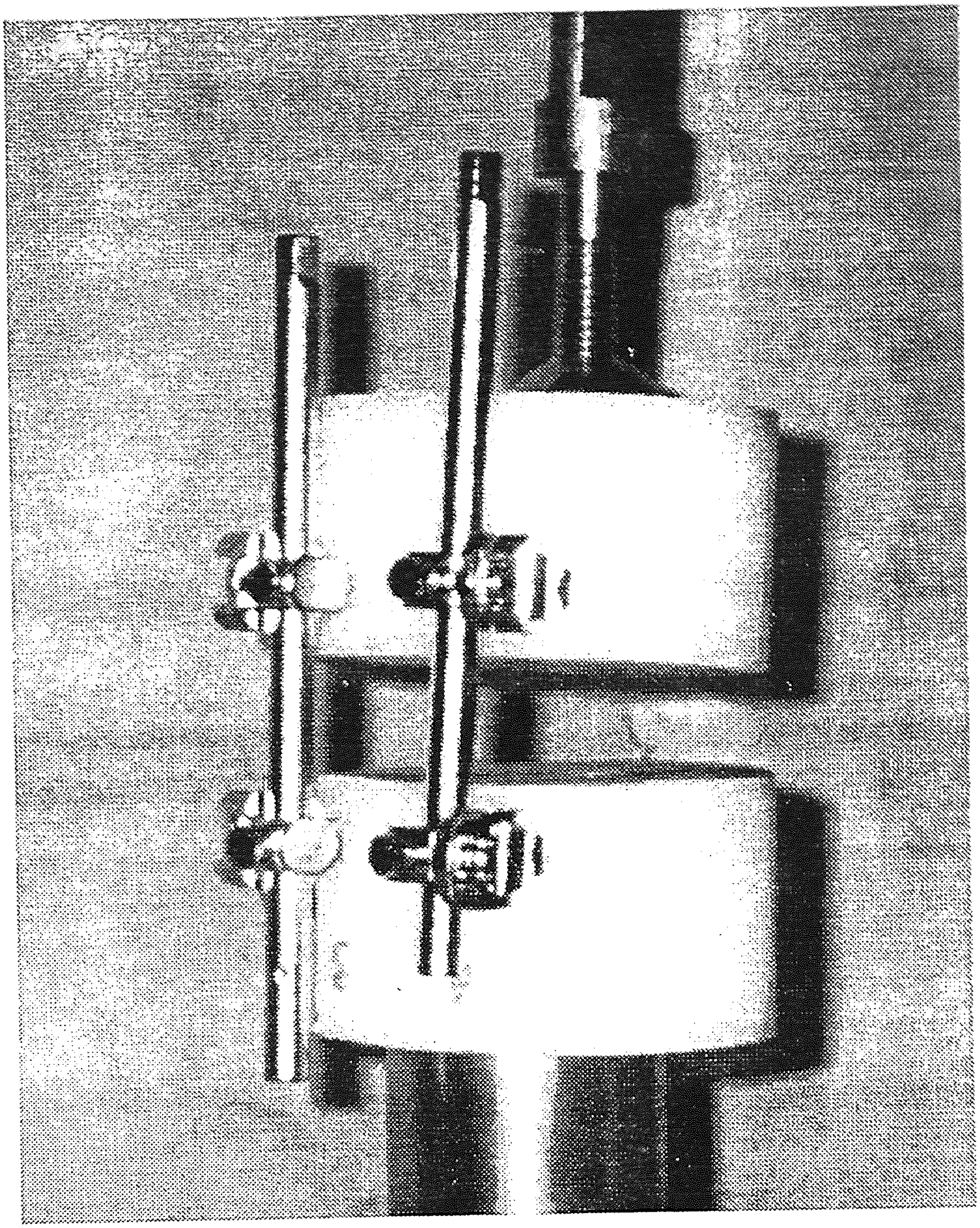


Figure 3.6 The Device Slides off with Loosening Two Parts

Figure 3.7
45 DEGREE LOOSENING TWO PARTS

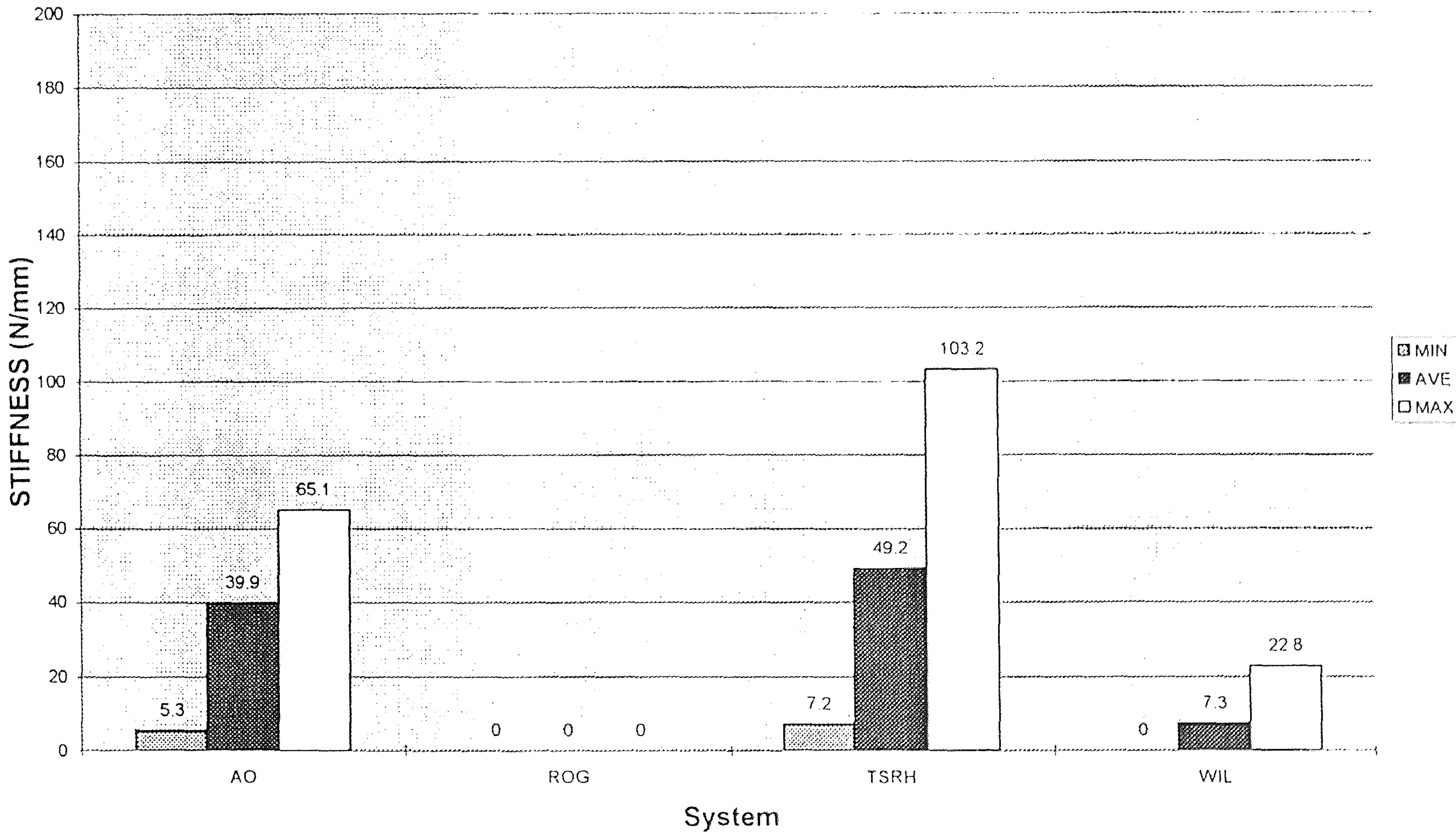


Figure 3.8
AO Normal Vs Loosening

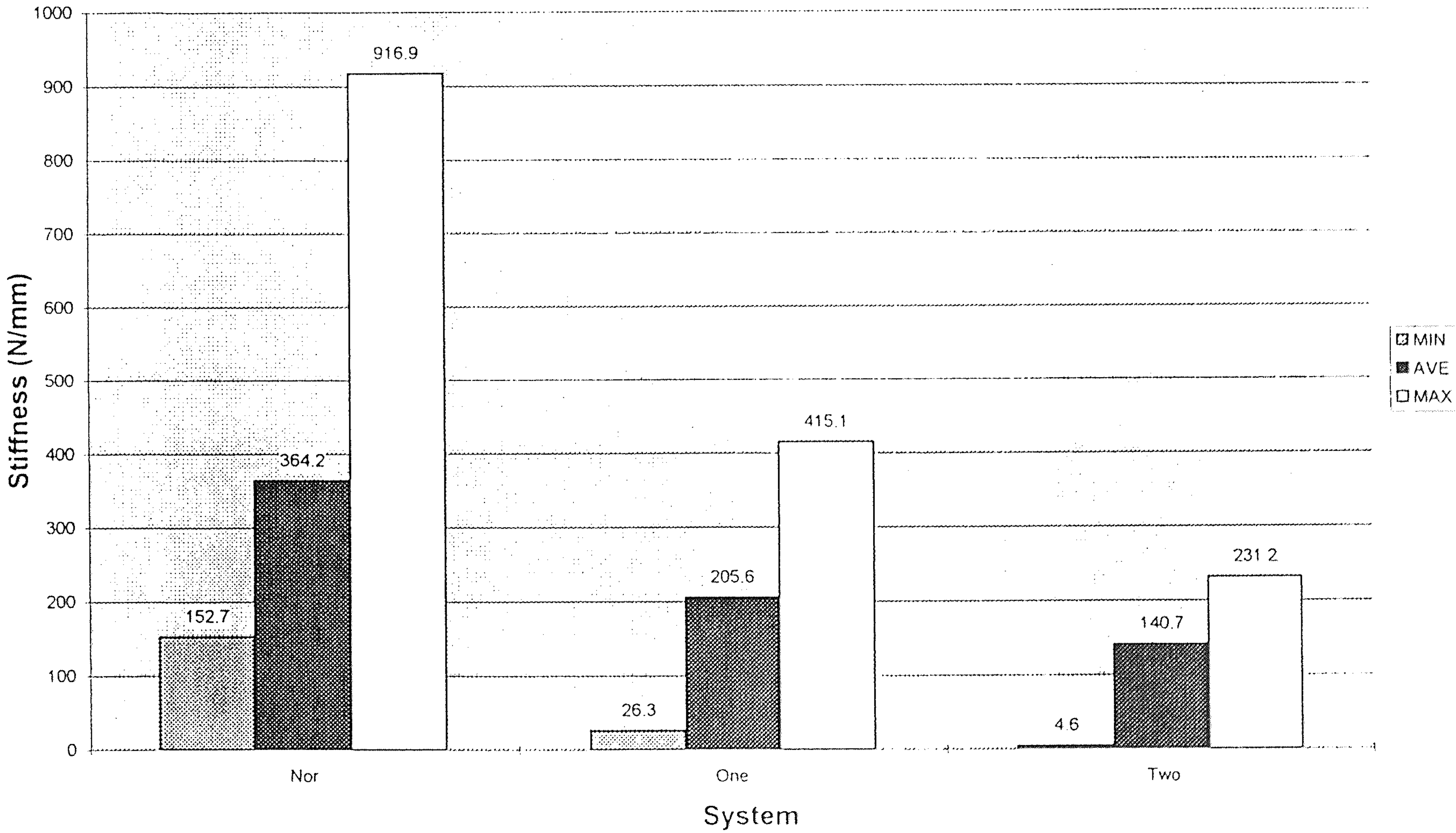


Figure 3.9
AO 45 VS LOOSENING

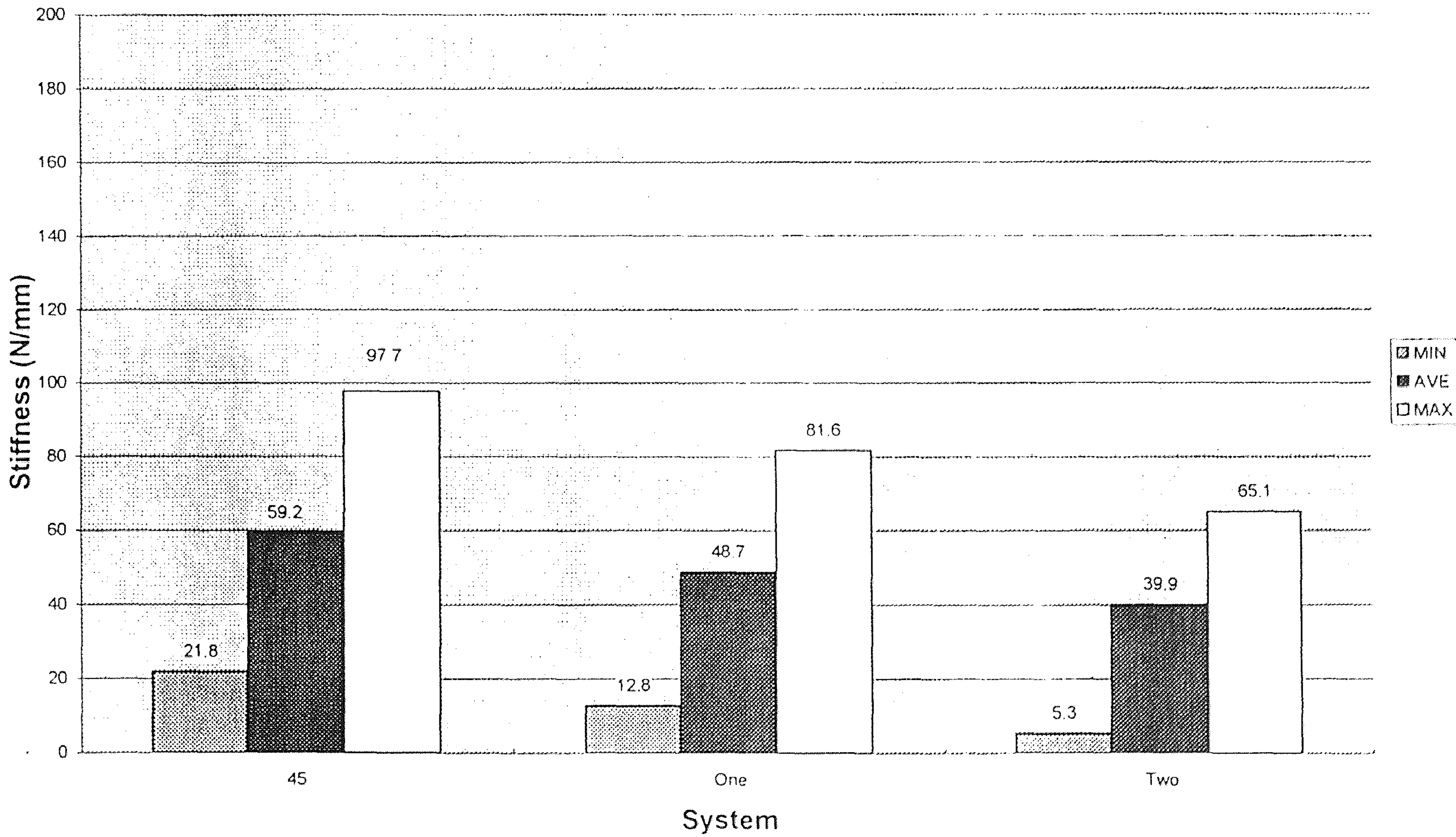


Figure 3.10
ROG NORMAL VS LOOSENING

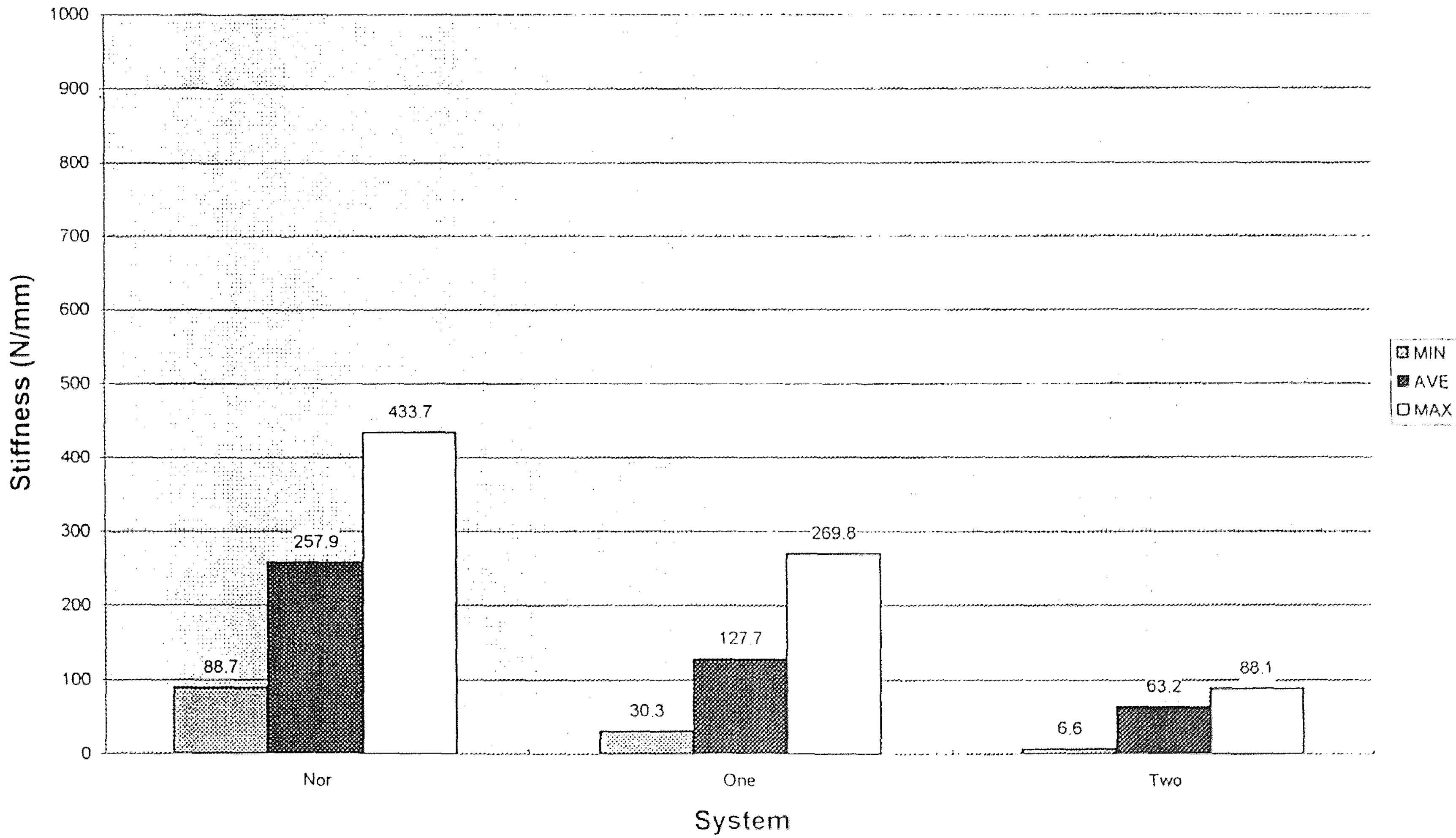


Figure 3.11
ROG 45 DEGREE VS LOOSENING

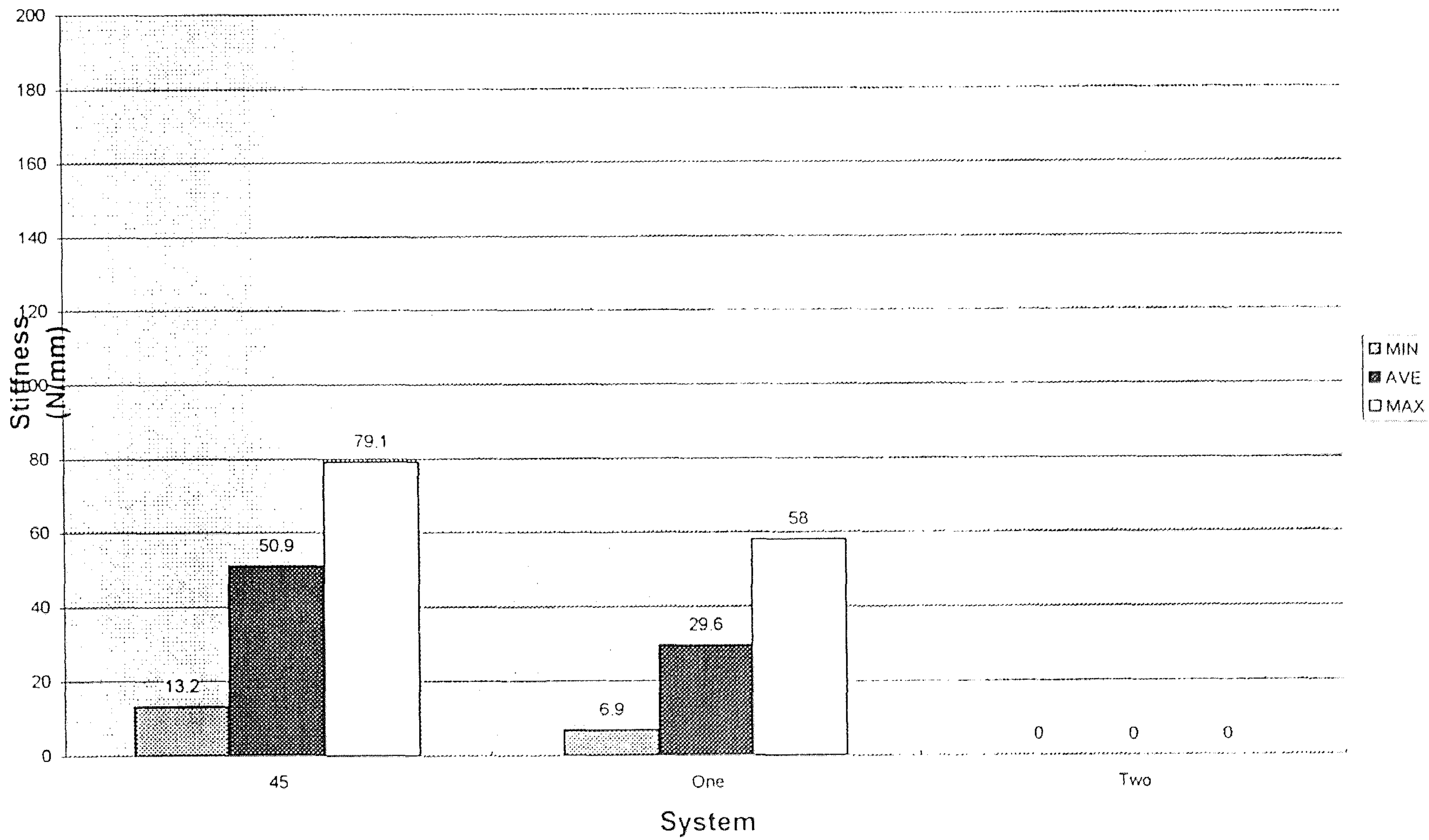


Figure 3.12
TSRH NORMAL VS LOOSING

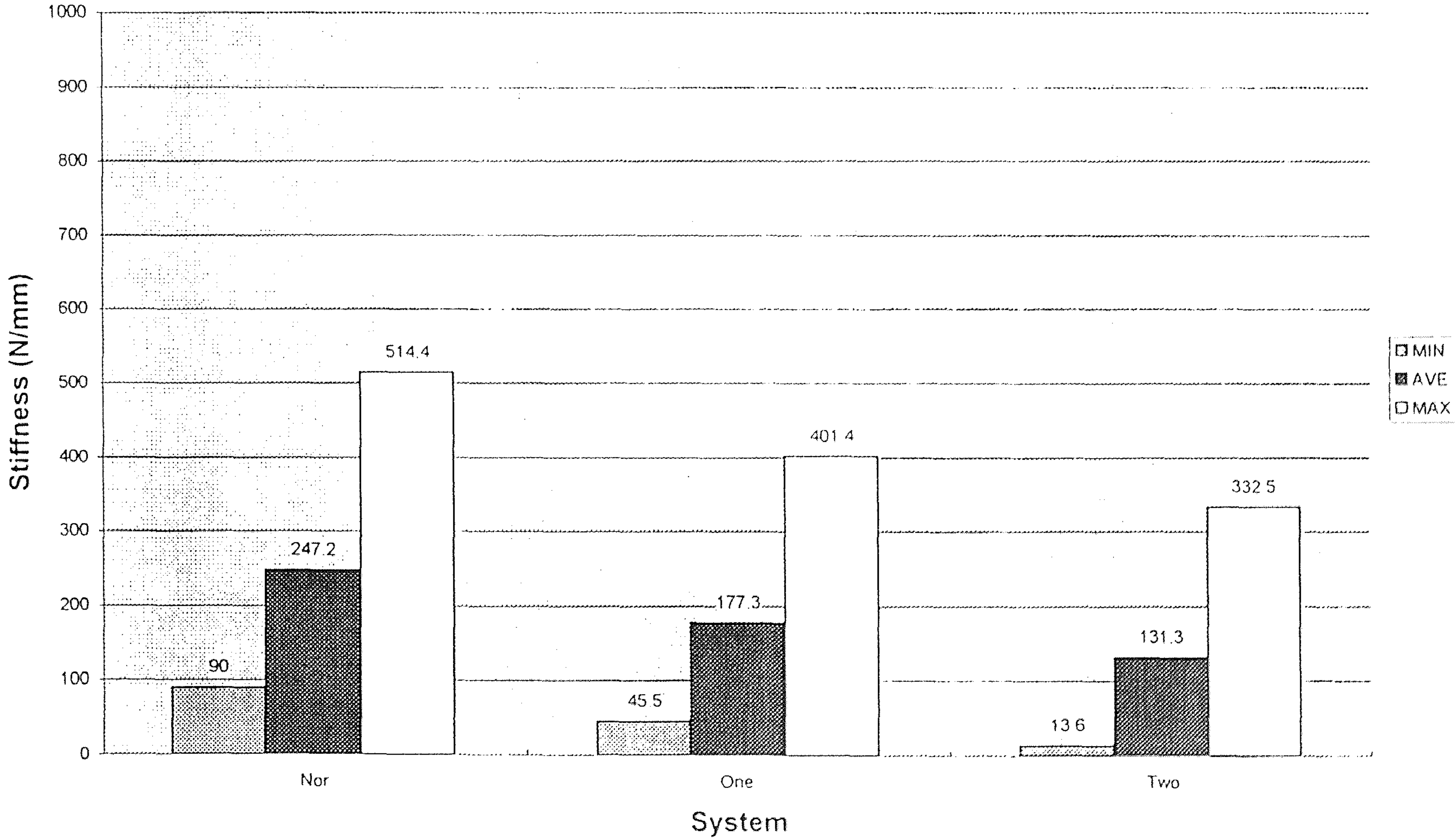


Figure 3.13
TSRH 45 DEGREE VS LOOSENING

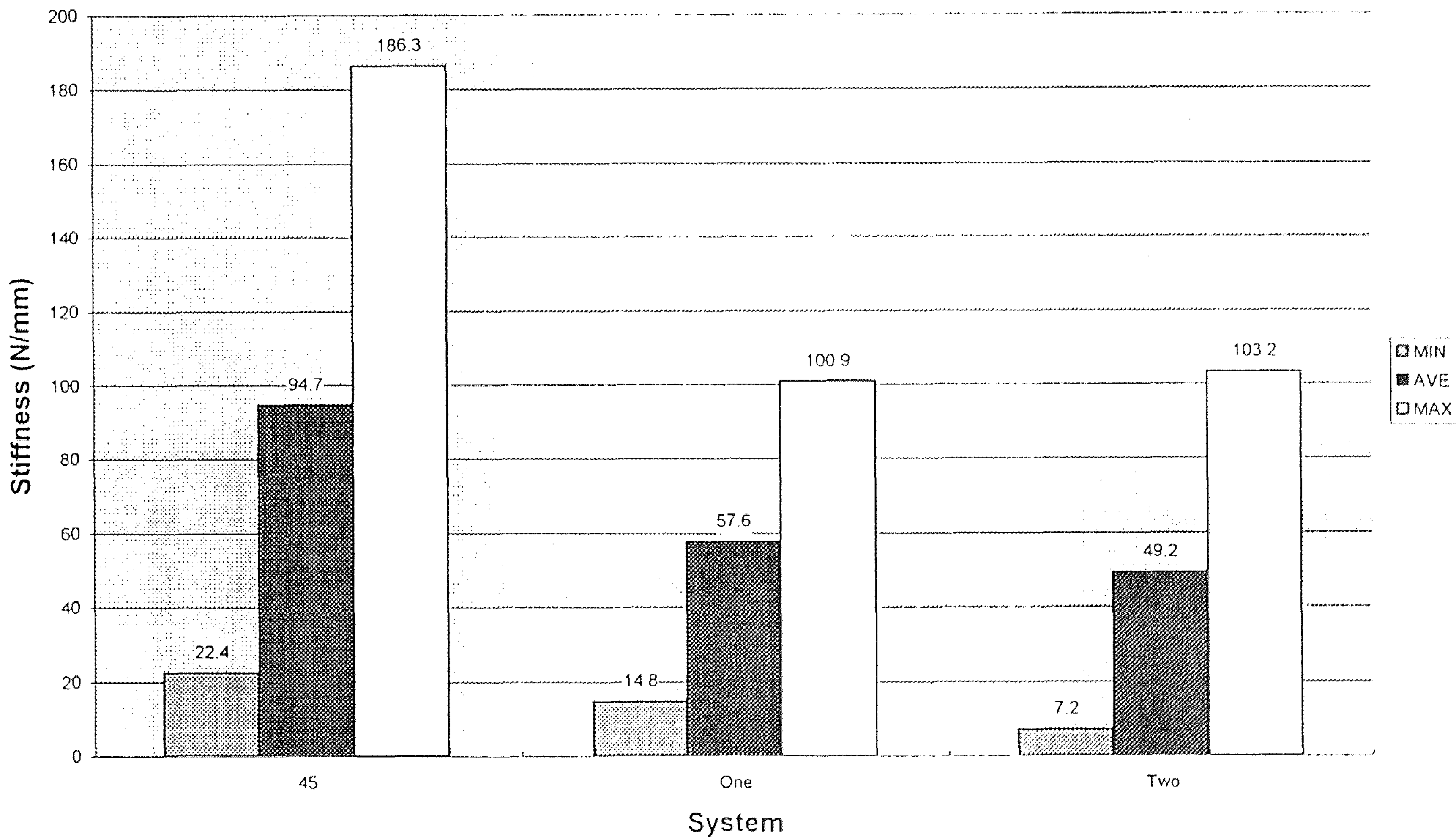


Figure 3.14
WIL NORMAL VS LOOSENING

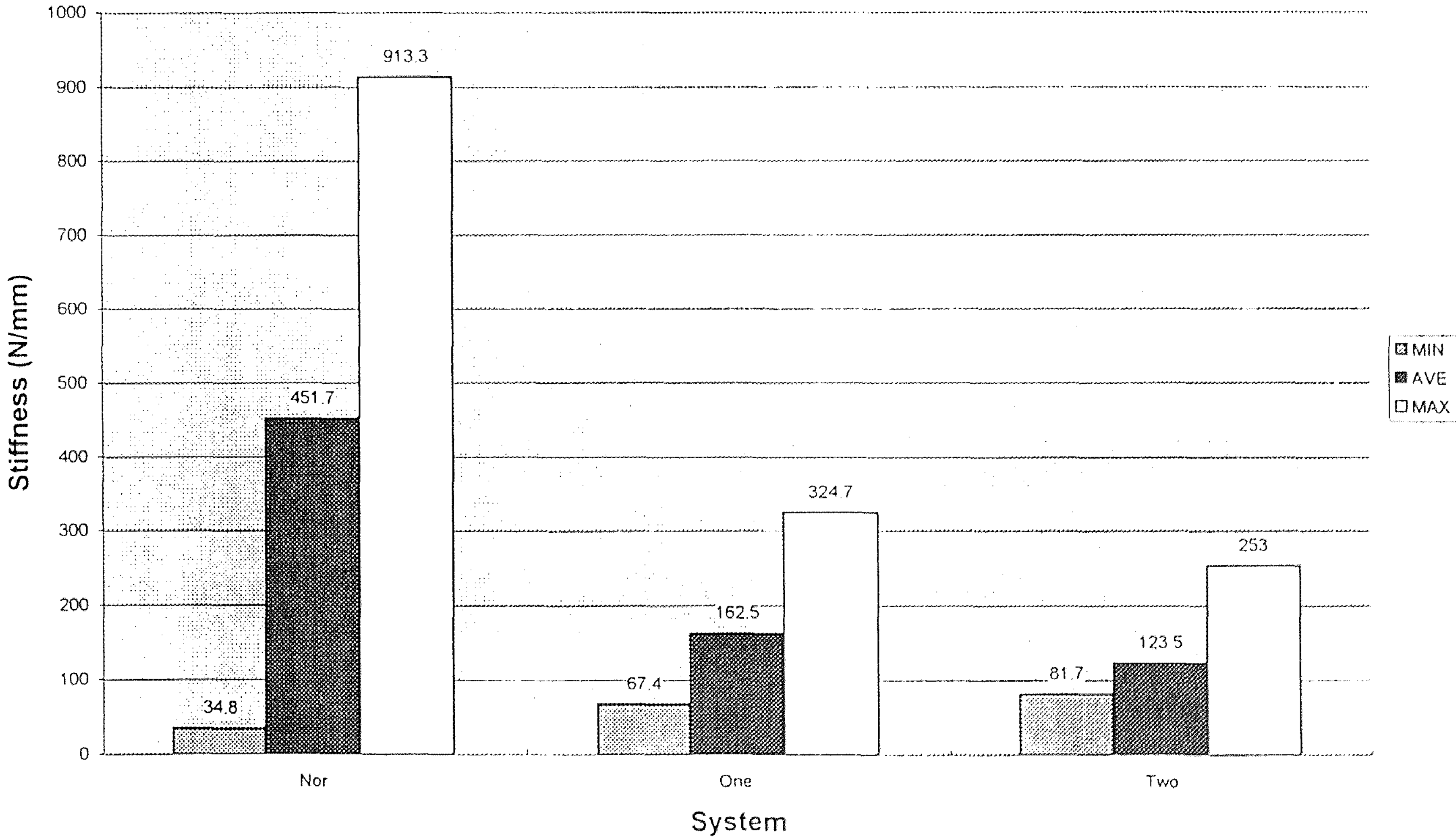
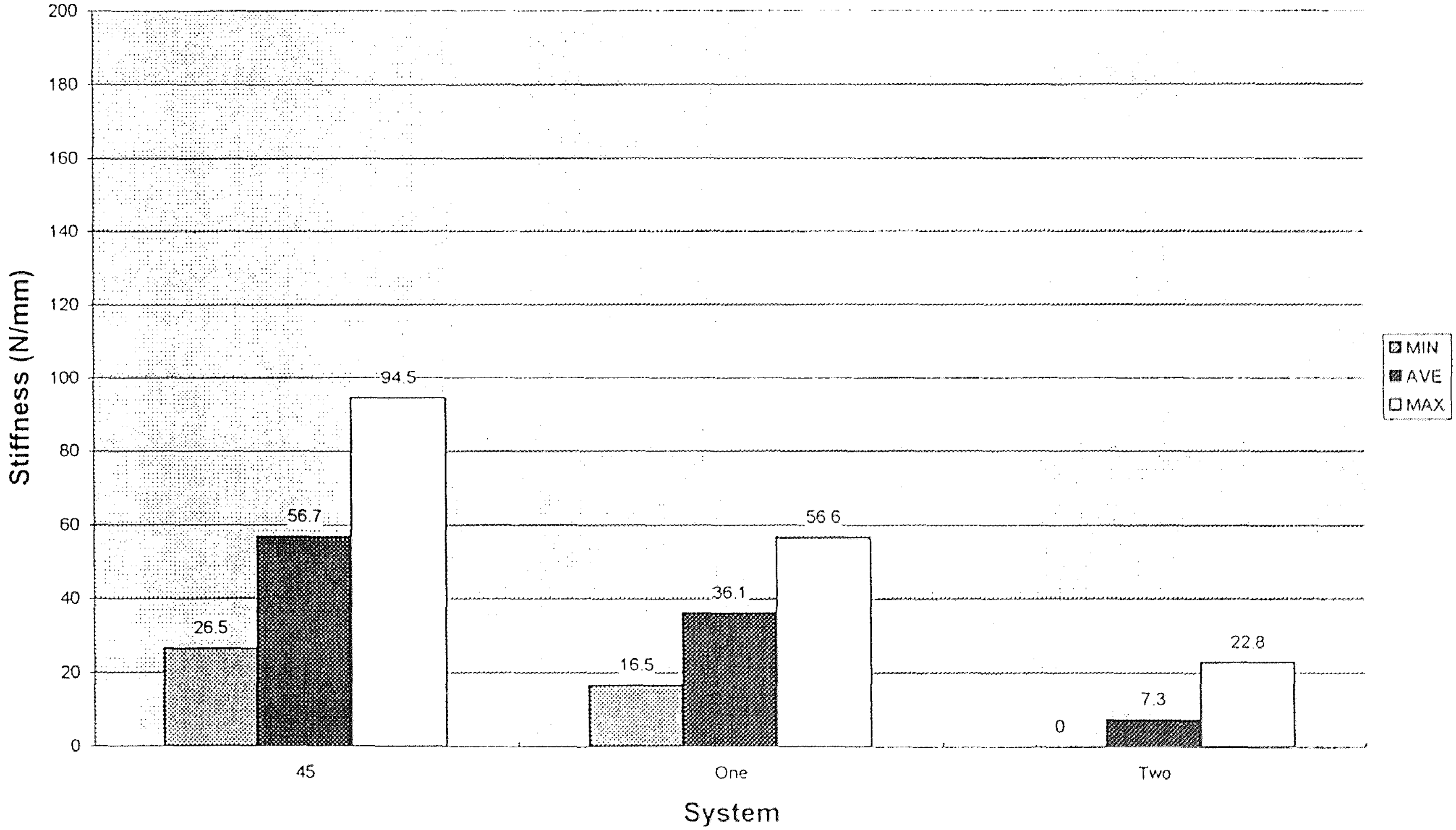


Figure 3.15
WIL 45 DEGREE VS LOOSENING



3.12). In off- axial loading, stiffness was decreased about 430 % with one component loose and about 500 % with two components loose. (Figure 3.13). For the Wiltse device, the stiffness decreased about 280 % with one component loose and about 370 % with two components loose. (Figure 3.14). In off- axial loading, stiffness was dramatically decreased about 1260 % with one component loose. The system had zero stiffness with two components loose. (Figure 3.15).

CHAPTER 4

DISCUSSION

Although the literature contains a number of reports of the mechanical testing of pedicle screw fixation devices, the effects of off axis loading and device loosening have not been previously assessed. Ultra High Molecular Weight Polyethylene (UHMWPe) was chosen as the model vertebrae because it provided a consistent fixation medium. Consistency was achieved because the UHMWPe vertebrae were pre-machined to predetermined specifications: the degree of pedicle angulation, interpedicular distance, and distance between construct levels all represented clinically realistic conditions. All hardware was symmetrically aligned on the blocks and tightened to the manufacturer's specifications. The total corpectomy defect model provided a "worst case scenario". Mechanical testing of these devices demonstrated a large degree of variability in construct stiffness. Since the load-deflection response is not linear, it was decided to report three stiffness values; minimums, maximum and mean. In all tests, the stiffness decreased with increased loading, the effect being most dramatic in the final 20% of force. Figure 4.1. (An example of stiffness decreased at the final load area.)

4.1 Anterior Flexion-compression

Cunningham et al.[42] reported the stiffness of the Rogozinski and TSRH systems in a test setup similar to that used in this work. Comparing the Rogozinski device tests, reveals that

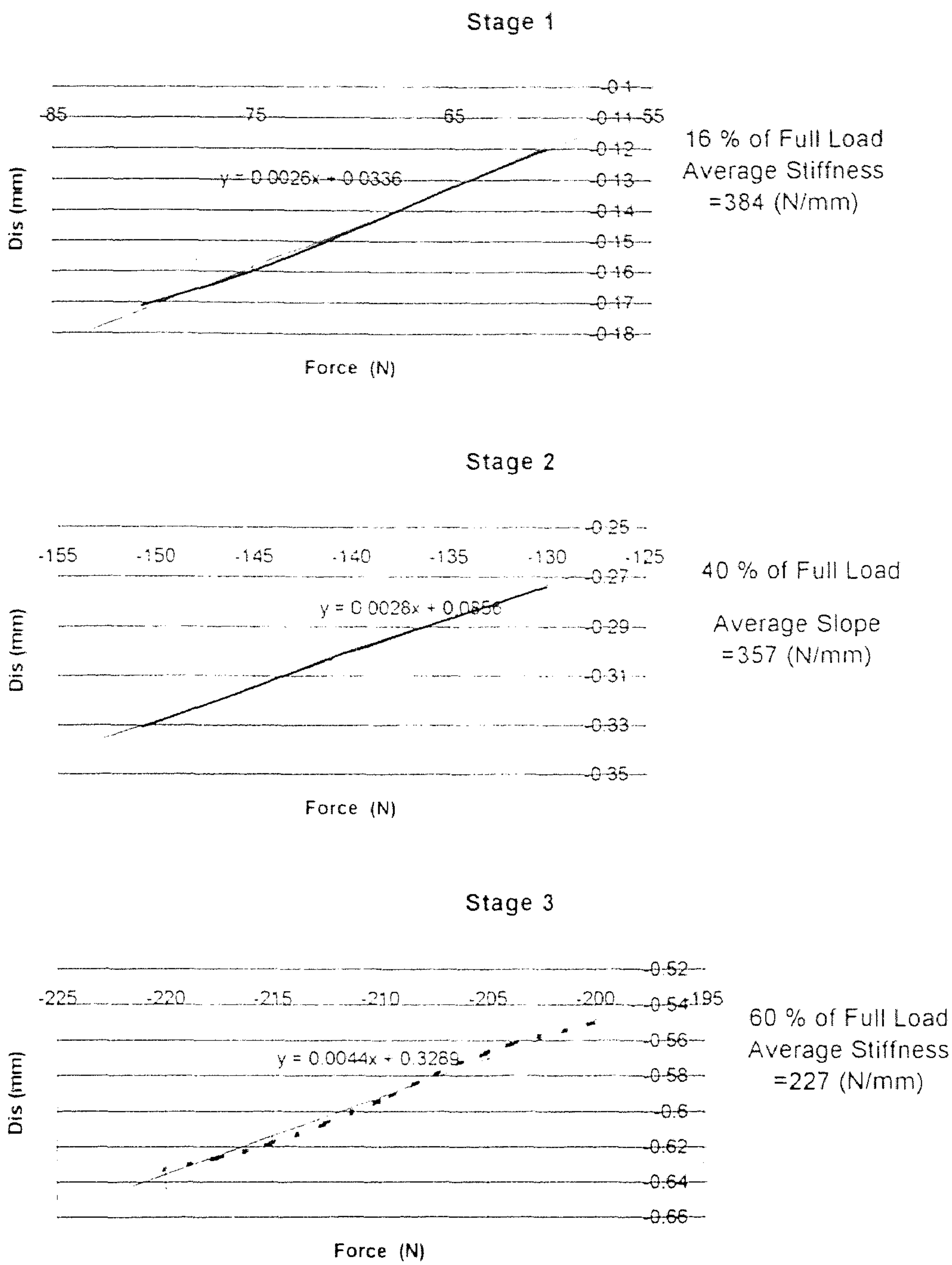
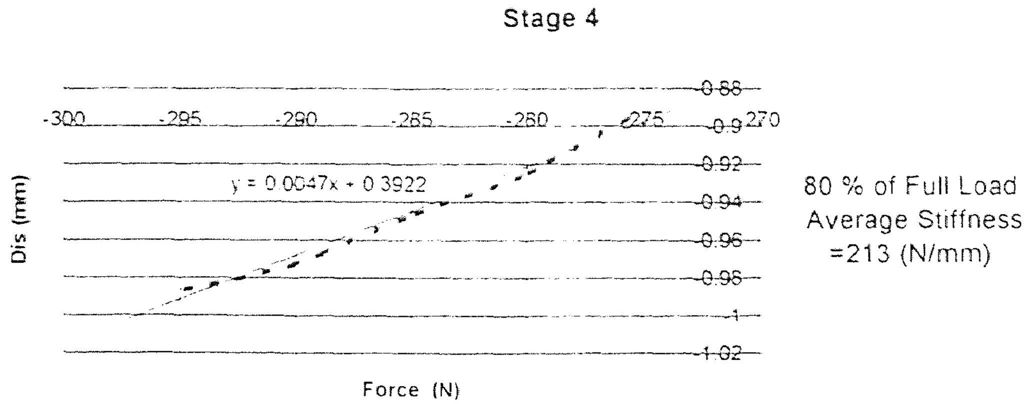


Figure 4.1 A sample of stiffness decreased with load increased



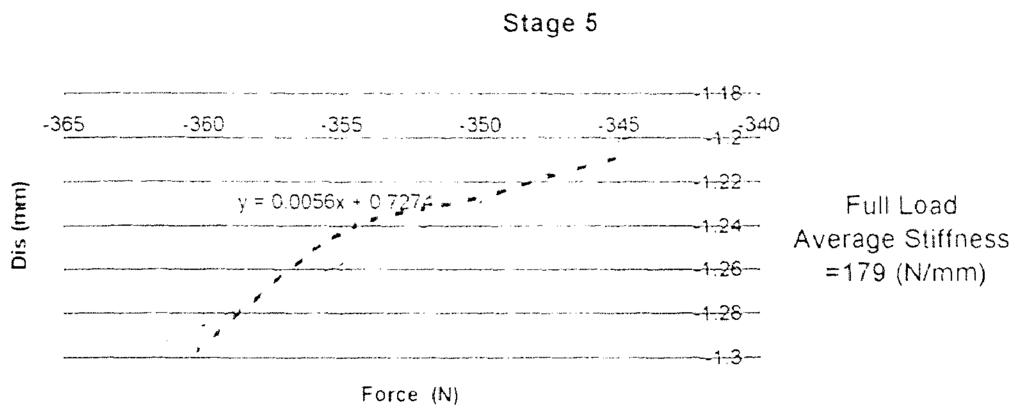


Figure 4.1 (continued) An example of stiffness decreased with load increased

the average stiffness determined from the current work was 3.7 times greater than that reported by Cunningham, et al. This discrepancy in results is most probably due to the differences in the testing methods. The test of this work utilizes a fixed lower vertebra. Cunningham, et al. allowed both vertebrae to freely rotate. The present author found that this test mode is unstable and allows rotation as well as A-P bending, significantly decreasing the measured stiffness. William L. Carson et al.[43] reported an average stiffness for the TSRH system of 393 N/mm In their test, a nylon bolt was used to simulate the bone They used a 6 5 mm diameter screw and a 6.35 mm diameter rod The force was applied at a 25 mm distance from the longitudinal rod The average stiffness from the current study is 514 4 N/mm Differences are most likely due to the considerable differences in test methods

Richard B Ashman et al[44]. present results for the AO notched plate system Fresh human cadaveric spines from T11 to L3 segments were utilized A pure axial load of 450 N force was applied at a load rate of 15 N/sec The 4 5 mm diameter pedicle screws were used in their test with "one above and one below" model The construct stiffness of the AO system was reported to be 121 N/mm The stiffness reported in the current study is much higher than that of Ashman, et al result, most probably because of the considerable differences in the elasticity of the bony versus polyethylene attachments

4.2 Off- Axis Anterior Flexion-Compression

As with the normal loading mode, the stiffness decreased with increasing load The TSRH system demonstrated a higher stiffness than any of the other systems in off axis loading The lowest values were obtained with the Rogozinski system. In this 45 degree off-axis loading mode, the force caused combined axial flexion-compression, torsion and lateral bending. One would expect that during the activities of daily living a patient would apply these combined loading modes to the spine. A system that demonstrates greatly decreased stiffness under such loading, may be inferior to other alternatives Relatively, the TSRH system demonstrated the best result with changing load direction. Its stiffness decreased by 2.7 times from the normal loading case. The poorest results were obtained with the AO and the Wiltse systems They demonstrated as much as a 10-fold decrease in stiffness In some AO tests, there was a sudden change of the slope during load application (Figure 4.2.) This is probably due to the spherical cavity in the plates that allows rotation of the mating sphere.

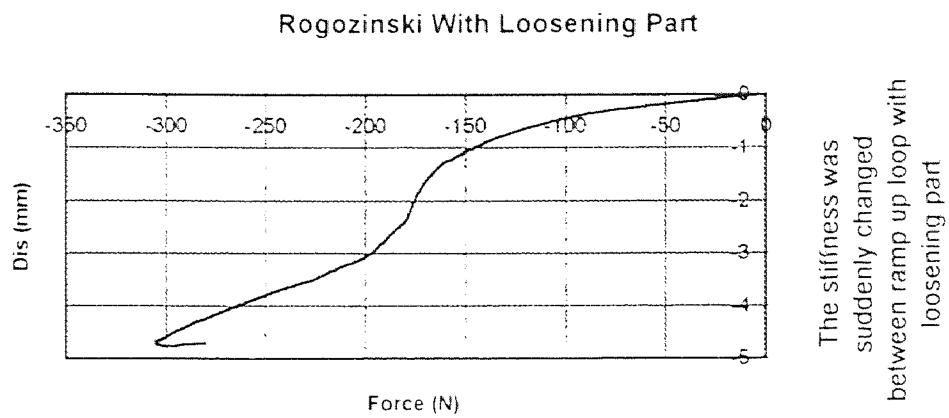


Figure 4.2 Stiffness Suddenly Changed with Member(s) Loosening

4.3 Loosening Anterior Flexion-Compression

Loosening one or two members in all systems tested resulted in considerable decreases in device stiffness. In normal loading, for all systems except the Wiltse construct, the minimum stiffness values were the affected the most. They dropped to virtually zero when two members were loosened. The 45 degree loading mode did not demonstrate as large percentage drops for all of the systems, except the Rogozinski system. Loosening two members and applying off axis loading to this system resulted in a completely loose (zero stiffness) construct. Keeping in mind the holding mechanism for this device, where a flat set screw is tightened against a round rod (line contact), this result is very disturbing. High levels of corrosion noted in the attachment region of implanted devices combined with the inherent instability of this attachment scheme make it highly probable that a number of Rogozinski devices may have greatly decreased, if not zero, stiffness *in vivo* (Figure 4.4 to 4.11).

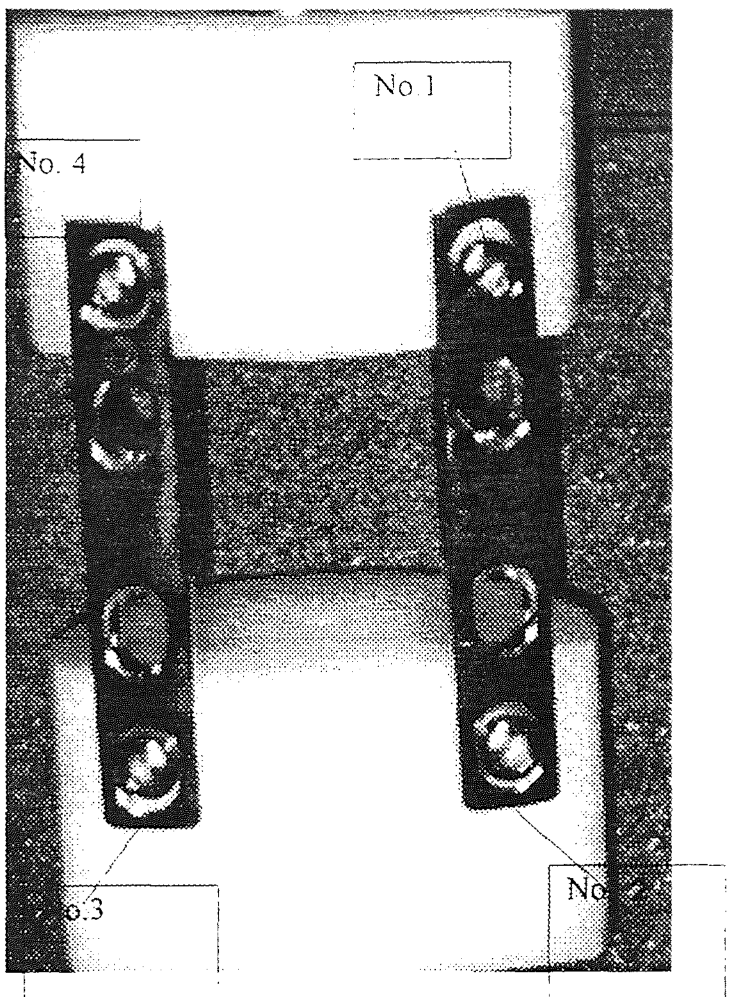


Figure 4.3 The number position of the loosening parts

Figure 4.4
AO VS INDIVIDUAL LOOSENING

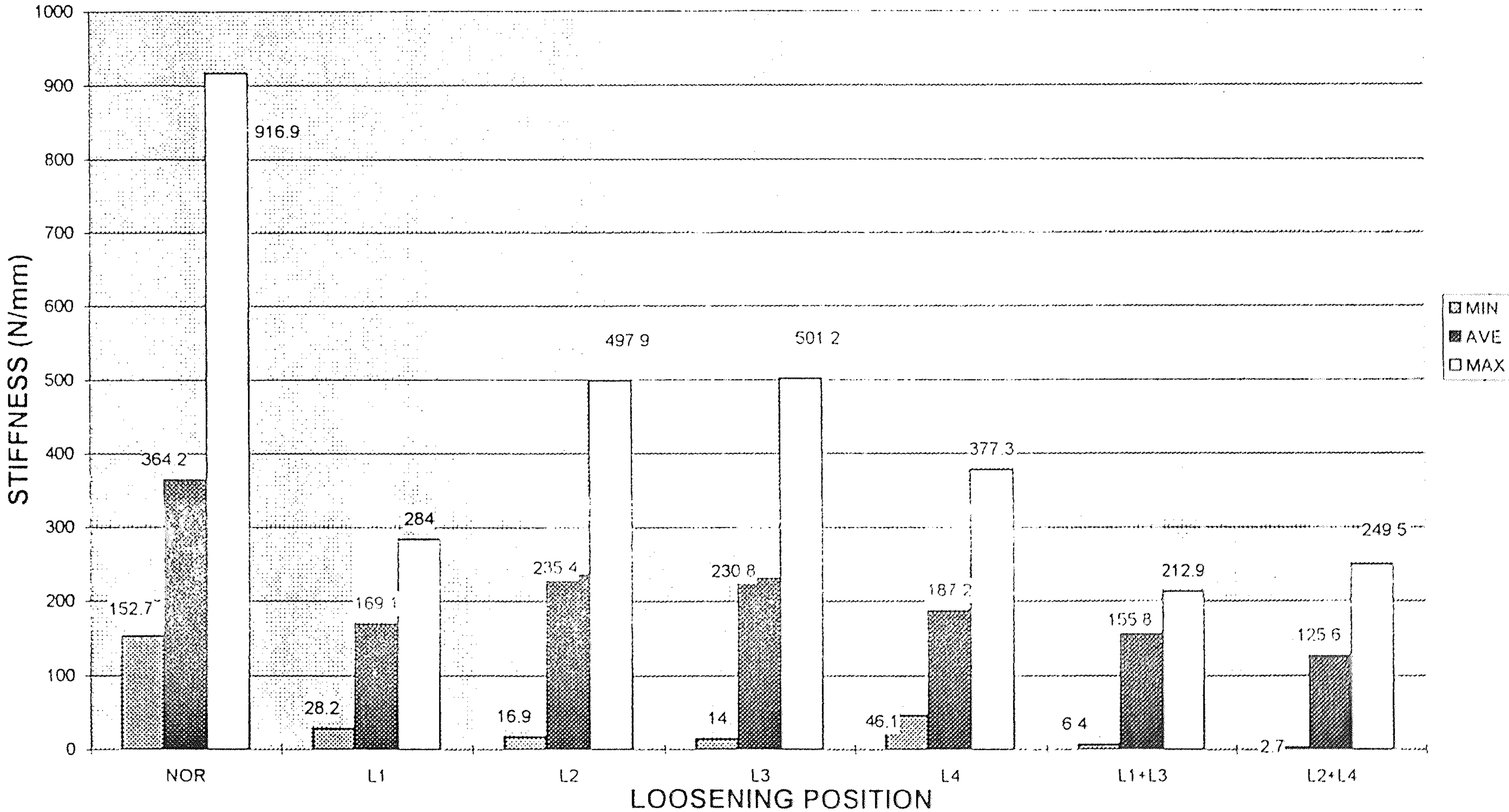


Figure 4.5
AO 45 DEGREE VS INDIVIDUAL LOOSENING

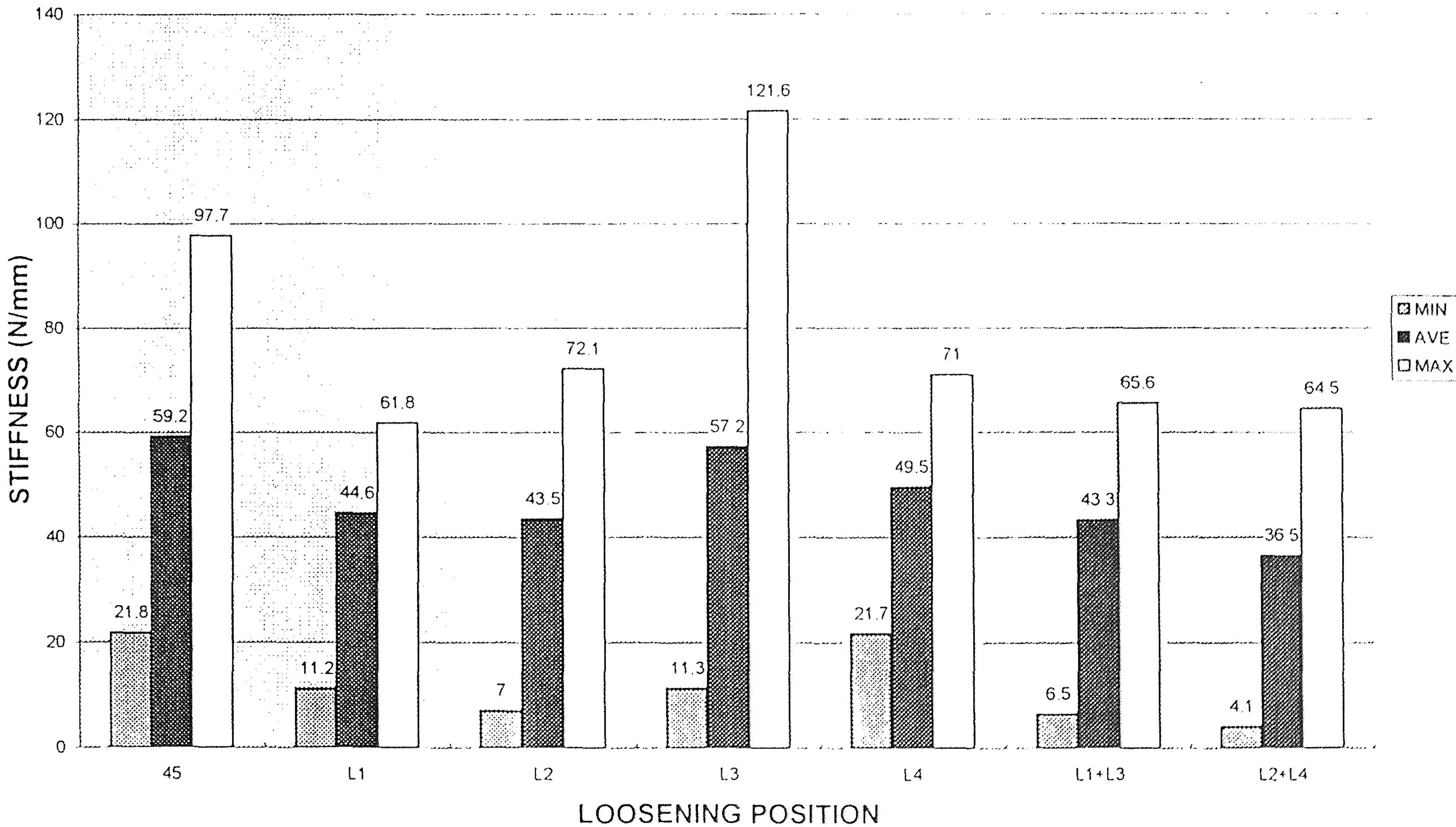


Figure 4.6
ROG VS INDIVIDUAL LOOSENING

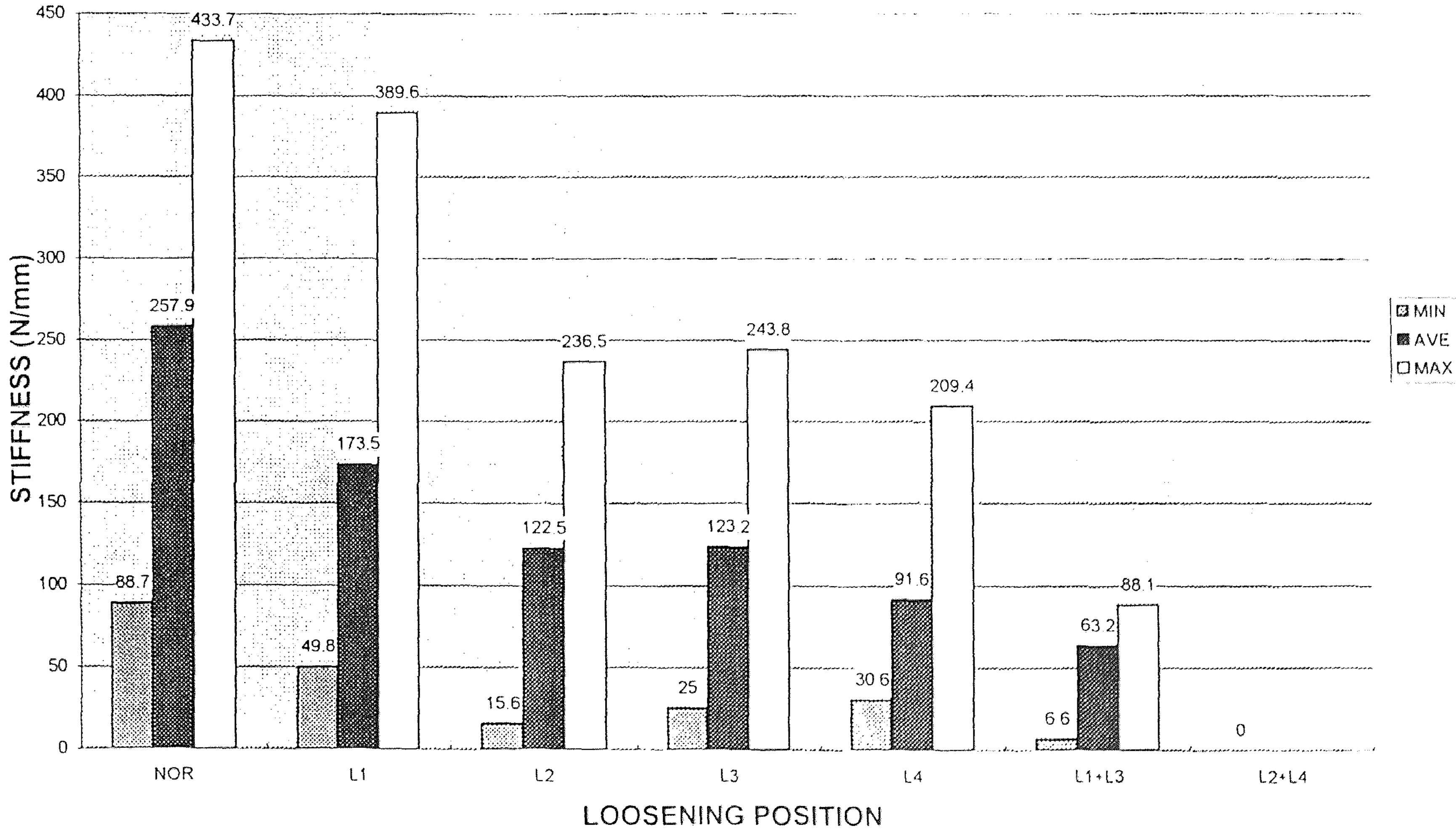


Figure 4.7
ROG 45 DEGREE VS INDIVIDUAL LOOSENING

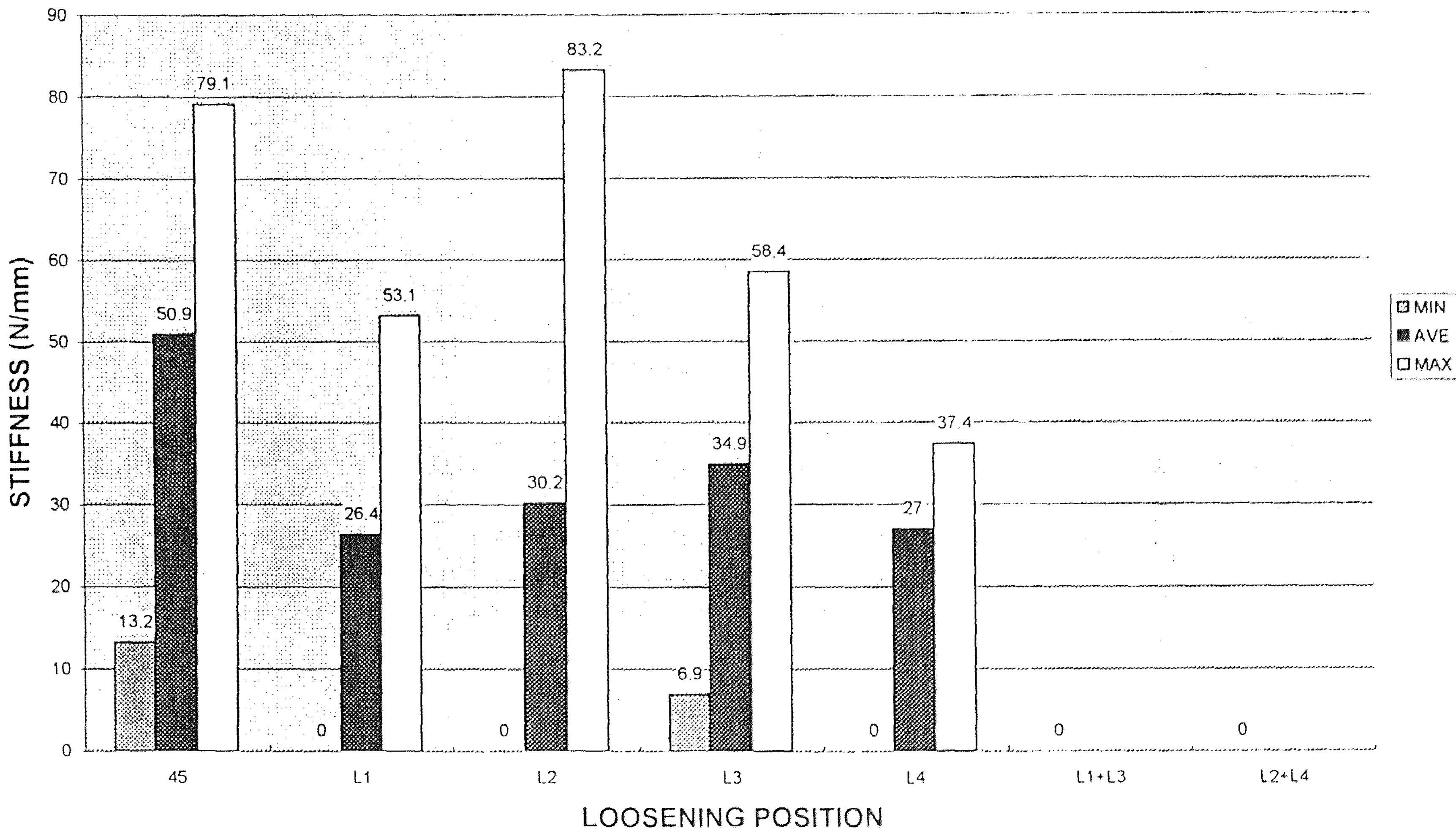


Figure 4.8
TSRH VS INDIVIDUAL LOOSENING

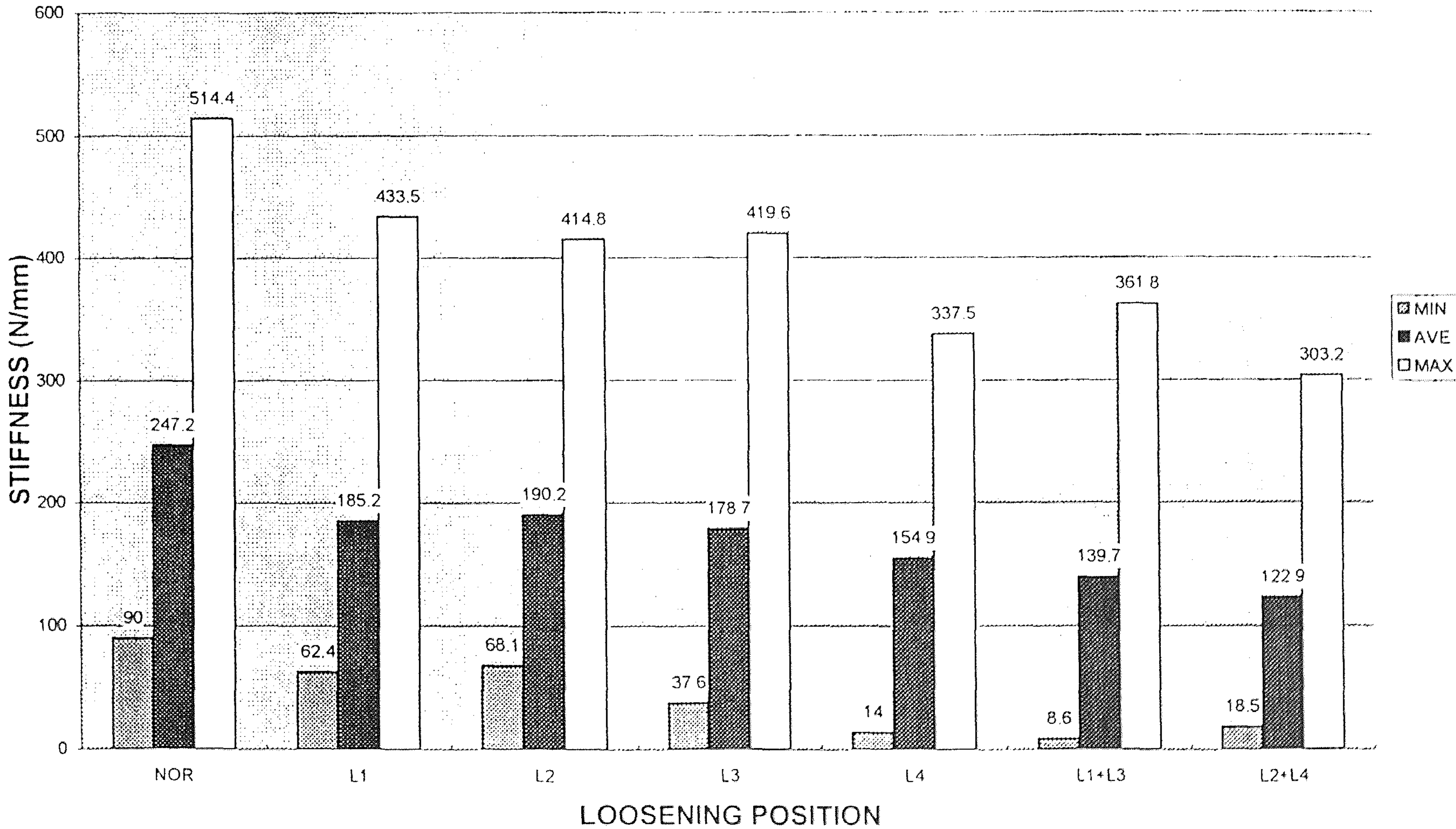


Figure 4.9
TSRH 45 DEGREE VS INDIVIDUAL LOOSENING

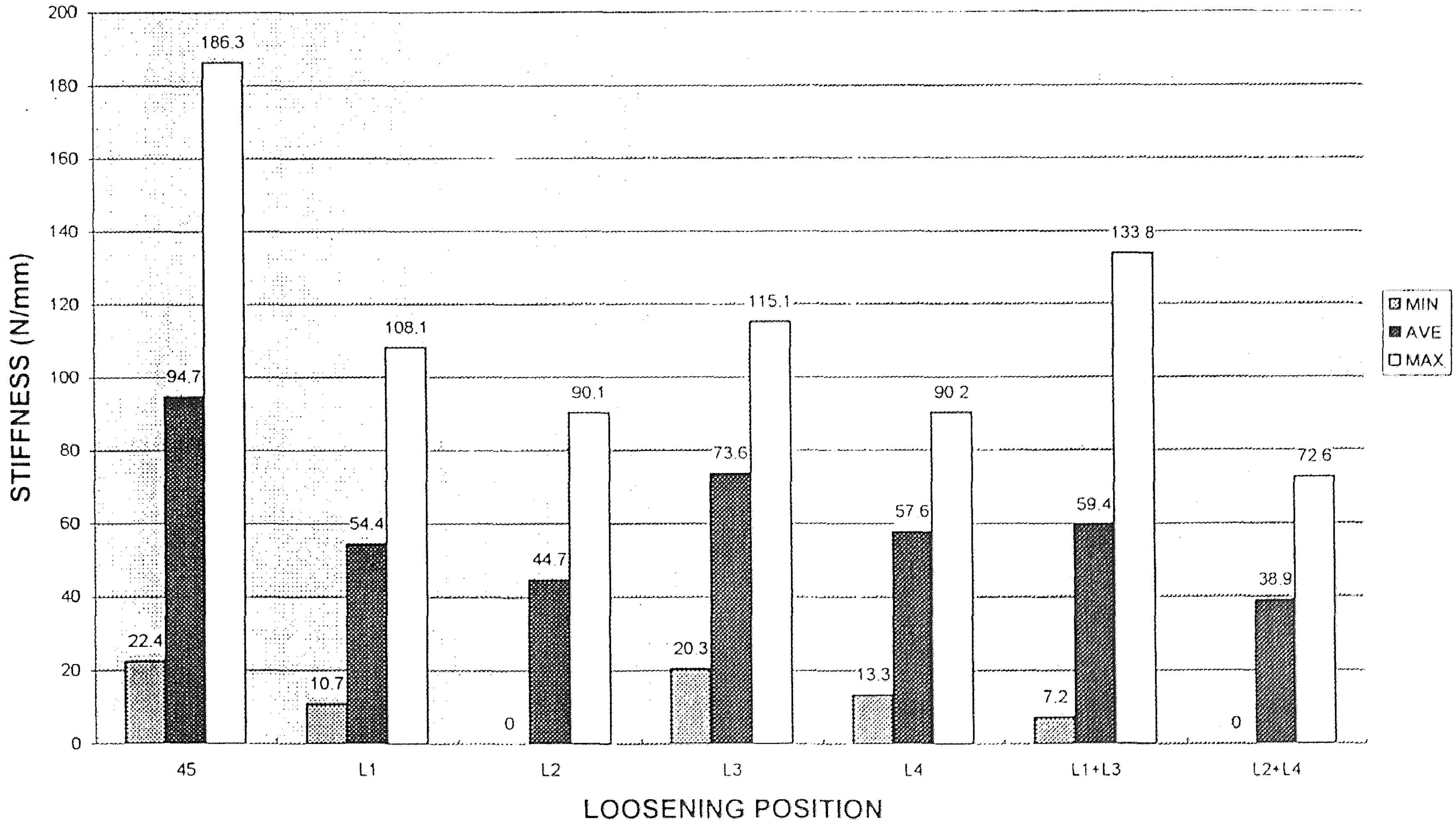
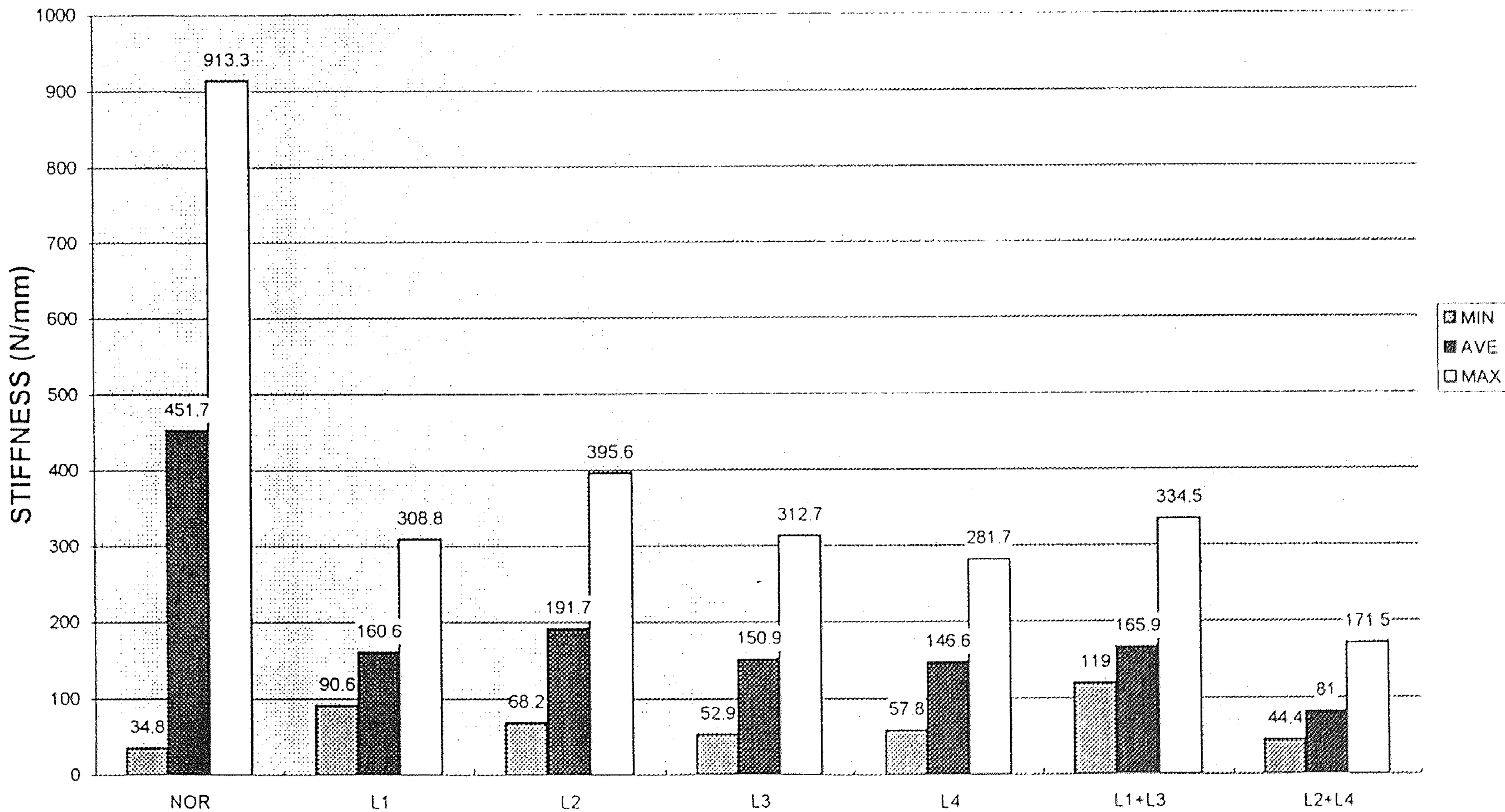
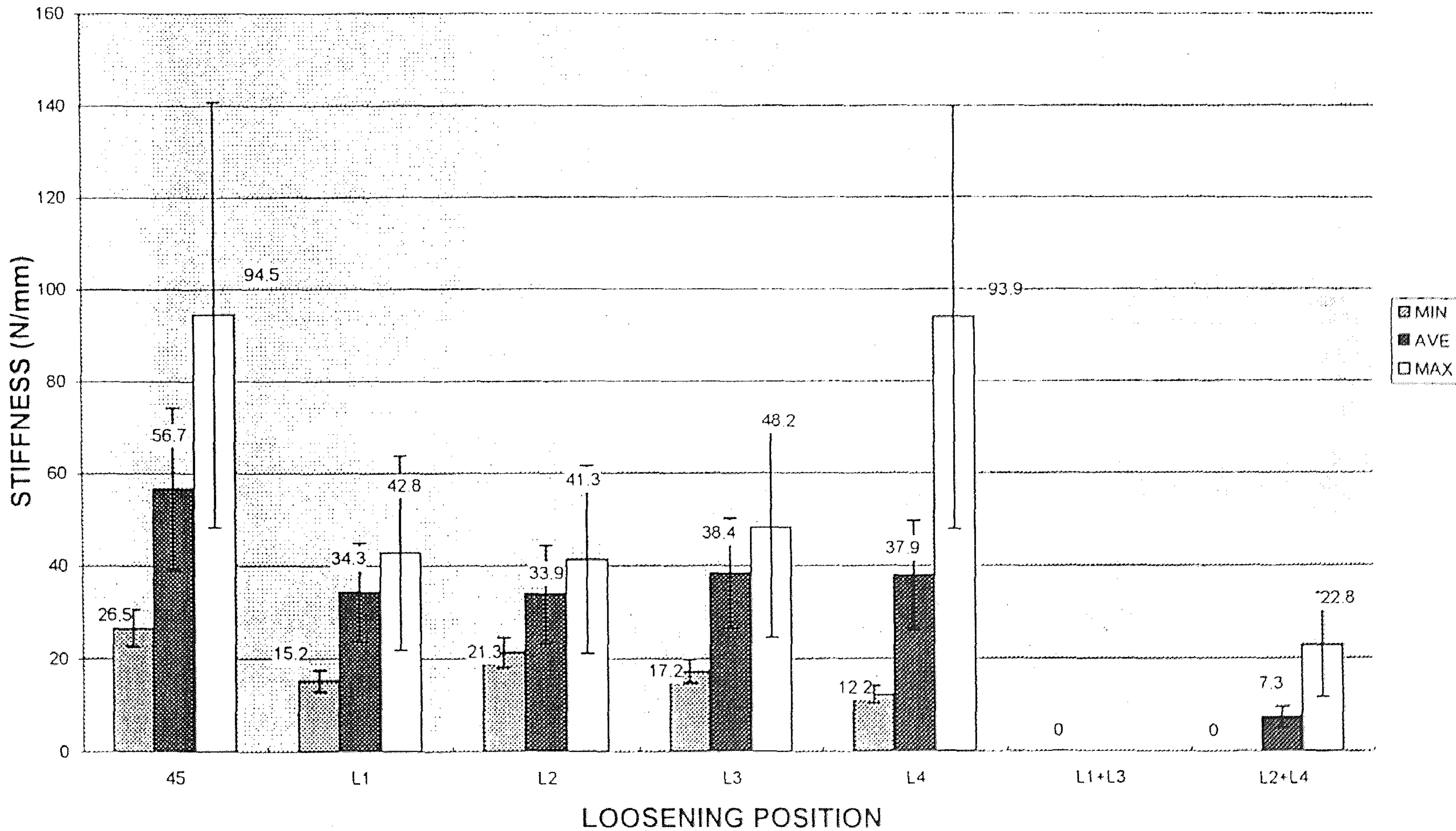


Figure 4.10
WIL VS INDIVIDUAL LOOSENING



LOOSENING POSITION

Figure 4.11
WIL 45 DEGREE VS INDIVIDUAL LOOSENING



CHAPTER 5

CONCLUSION

This dissertation presents an internally consistent study of four different pedicle screw fixation devices in two different loading modes. It also, for the first time, investigates the effect on stiffness of the loosening of one or two members, a situation that must occasionally be expected in the *in vivo* environment. The study clearly indicates that the stiffness of the rod constructs is not always superior to the stiffness of plate systems in anterior flexural compression, although, the effect of cross-links was not studied. Additional testing comparing these same devices with transverse fixation would be useful. Changing loading direction and loosening attachment members significantly affects the stiffness of pedicle screw devices. The AO construct changed significantly with changed load direction and loosening The TSRH demonstrated relatively less decrease in stiffness from changes in load mode and loosening. Generally, the Rogozinski device demonstrated the poorest result. This was probably due to the large number of components and attachment points in a typical construct.

Assuming that stiffness is directly proportional to the probability of obtaining fusion, this study allows the ranking of the four systems tested in their native normal loading stiffness and their abilities to maintain stiffness in the face of off axis loading and unintentional loosening of components. Generally, from the point view of stiffness, this study indicates a ranking of these systems as TSRH being the best followed by AO and Wiltse. Clearly, the worst system tested, from consideration of initial stiffness, off-axial load and loosening is the Rogozinski construct.

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