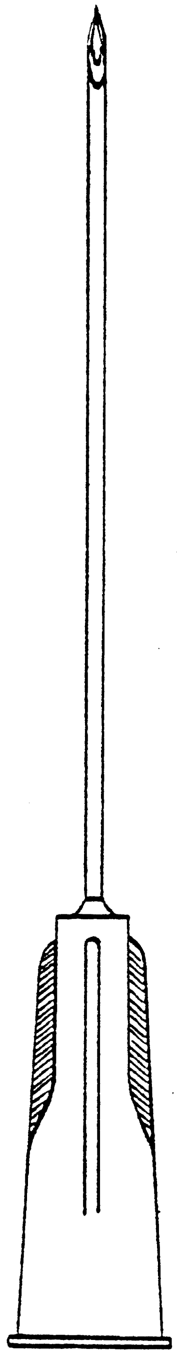
UM-HSRI-78-23

# PENETRATION CHARACTERISTICS OF HYPODERMIC NEEDLES IN SKIN AND MUSCLE TISSUE

## Phase I



Lawrence W. Schneider
Leigh S. Peck
John W. Melvin

JUNE 1978

**Technical Report Documentation Page**

| 1. Report No. | 2. Government Accession No. | 3. Recipient's Catalog No. |
|---|---|---|
| UM-HSRI-78-23 | | |

| 4. Title and Subtitle | |
|---|---|
| Penetration Characteristics of Hypodermic Needles in Skin and Muscle Tissue | 5. Report Date June 1978 |
| | 6. Performing Organization Code HSRI |
| 7. Author(s) L.W. Schneider, L.S. Peck, J.W. Melvin | 8. Performing Organization Report No. UM-HSRI-78-23 |
| 9. Performing Organization Name and Address<br>Highway Safety Research Institute<br>Huron Parkway and Baxter Road<br>University of Michigan<br>Ann Arbor, Michigan 48109 | 10. Work Unit No. |
| | 11. Contract or Grant No. DRDA-78-1223-KB1 |
| 12. Sponsoring Agency Name and Address<br>Becton-Dickinson and Company<br>Rutherford, New Jersey 07070 | 13. Type of Report and Period Covered<br>Final - Phase I<br>July 1977 - June 1978 |
| | 14. Sponsoring Agency Code |

15. Supplementary Notes

16. Abstract

Penetration characteristics of hypodermic needles in intact and excised unembalmed cadaver tissue were studied using an automatic, constant velocity, computer controlled injection device. 883 tests were performed for a range of needle lubricants, tissue, and test conditions. Force and displacement signals were digitized on-line using a NOVA 1220 computer system. These data were analyzed by computer algorithms for peak force, drag force, penetration work values, and other measures. The responses were found to be relatively insensitive to penetration velocity or angle. Forces for dry needles were 1-1/2 to 3 times greater than for lubricated needles which were comparable. BD1249-lubricated needles had drag forces that were about 1-1/2 times greater than 360-lubricated needles. The subcutaneous tissue was found to have an important influence on penetration characteristics.

| 17. Key Words | | 18. Distribution Statement |
|---|---|---|
| Hypodermic needle | Lubricant | With sponsor approval only. |
| Cadaver tissue | Calf, Buttock | |
| Excised, Intact | Fat, Muscle | |
| Force-displacement | | |

| 19. Security Classif. (of this report) | 20. Security Classif. (of this page) | 21. No. of Pages | 22. Price |
|---|---|---|---|
| None | None | 84 plus Appendices | |

SUMMARY

In this study a system and device for performing constant velocity hypodermic needle injections in cadaver tissue were developed and used. Injection parameters are controlled through a NOVA 1220 mini-computer which also digitizes force and displacement data and stores the results on LINC tape. A total of 883 tests were performed on four unembalmed cadavers covering 48 different test strata of needle lubricant (DRY, 1249, 360), tissue (intact vs. excised and buttock vs. calf), and test (2.5, 5, and 10"/second; 90 and 45 degrees to skin surface) conditions. Force-displacement curves were analyzed by computer for a number of parameters including peak force, drag force, distance at peak force, and penetration work values. Comparisons of results between different test strata were made using graphical presentations of "average" reconstructed force-displacement curves and the Student T-test for similar mean values of selected measurement parameters.

In general it was found that the resistance to penetration was relatively insensitive to velocity and angle of penetration in the ranges of 2.5 to 10 inches/second and 45 to 90 degrees to the skin surface. The magnitude of the peak force was from 1.5 to 3 times greater for dry needles than 1249-or 360-lubricated needles which were nearly identical in peak force values. Drag resistance for dry needles was 2 to 3 times greater than that for 360-lubricated needles and 1.5 to 2.3 times greater than that for 1249 needles. Drag resistance for the 1249-lubricated needles was about 1-1/2 times greater than for 360-lubricated needles.

A significant finding was that, in general, the peak forces for excised tissue were comparable to intact tissue, indicating that the main generator

of peak force is the skin. Drag resistance was also consistently greater for intact tissue than for excised tissue.

Comparisons of results for intact buttock and calf tissue indicate that the underlying tissue can have a significant effect on the force-displacement characteristics in terms of distances at which the peak force occurs and drag resistance. Penetration of the calf region, where the underlying tissue is primarily muscle, showed less displacement at peak force and higher drag resistance than penetrations at the buttock, where the underlying tissue is predominantly fat.

Peak force values for excised buttock skin were also slightly higher than for excised calf skin, possibly because buttock skin is thicker.

TABLE OF CONTENTS

TABLE OF CONTENTS (continued)

## LIST OF FIGURES

LIST OF FIGURES (continued)

## LIST OF TABLES

LIST OF TABLES (continued)

SECTION 1

# INTRODUCTION AND OBJECTIVES

## A. INTRODUCTION

In today's competitive world, the success with which a manufacturer can obtain and hold the market for his product(s) often depends on an ability to produce a product which has superior qualities to those of the competition. In the field of medical products, this is especially true, since it is more often the features of a medical device or item rather than a competitive cost which determine its market. For a company which already enjoys a large percentage of the market of a particular item, the assurance of continued and increased sales can only be guaranteed if an effort is made to continue to seek ways of improving the product. This involves not only maintaining communication and interaction with the product users through salesman and technical personnel, but also a serious research effort directed toward understanding the performance of the product(s) so that its desirable features can be improved and undesirable features reduced.

With regard to hypodermic needles, research directed toward improving the performance and acceptability through changes in physical design or lubrication must be concerned with several different but related problems including:

1) determining those features (if any) which influence the medical personnel's (e.g. nurses) like or dislike of the product,

2) determining those features which influence acceptability to the patient, both in terms of pain and tissue trauma,

3) quantifying the injection process (e.g. force/displacement characteristics) for a range of test, needle, and tissue conditions,

4) relating the quantitative measurements from (3) to the physiological and subjective results of (1) and (2),

and, 5) incorporation of results from (3) and (4) into a standard and meaningful test for comparing and evaluating improvements or changes in needle design and lubrication.

In terms of this outline of a broad research program, the work reported on in this document is concerned mainly with tasks (3) and (5).

## B. STUDY OBJECTIVES

To compare and evaluate the relative merit and effect of changes in hypodermic needles by physical design or lubrication, a standard test is needed by which quantitative and comparable data can be obtained. This standard test must not only be relatively repeatable but it must be representative of the injection process in living tissue for the results to be meaningful. Because of the large variability among biological tissues, the feature of repeatability requires that some kind of synthetic material or materials be used to represent the biological tissue. For results of a standard test to be of value, the tissue surrogate used must demonstrate similar (but not necessarily identical) response characteristics to the injection process as the biological material on which the needle will ultimately be used. For example, if the penetration characteristics are dependent on penetration velocity in living tissue, then the skin/tissue surrogate must also demonstrate a similar dependency. It need not produce values identical to those of living tissue, but it must show the same kinds of changes in quantitative characteristics to changes in penetration and needle condition variables.

It is clear, then, that development or selection of a skin surrogate as well as test protocol for a standard penetration test requires an understanding and quantification of the needle injection process in real tissue. The present study was undertaken to quantify and study the force-displacement characteristics of hypodermic needles in cadaver tissues using a variety of needle, test, and tissue conditions. The use of cadavers rather than living subjects permits larger sample sizes for each needle/test/tissue condition, thereby enabling the use of statistics to compare results, and, in addition, enables the testing of excised skin. By quantifying the force-displacement characteristics of hypodermic needles penetrating cadaver tissue using a variety of lubricants, test conditions, and tissue samples, information useful for choosing a skin simulant and test protocol for a standard needle test can be obtained. In addition the results of such an initial and basic investigation should suggest:

a) possible mechanisms involved in generating force penetration characteristics

and, b) direction for further research using both experimental and analytical approaches in order to better understand the important features of the needle injection process.

At the onset, the study had several sub-goals in line with these overall objectives. These were:

1) to compare force-displacement measurement results from needle penetrations in cadaver tissue with those in living tissue,

2) to develop a device for providing precisely controlled penetrations of hypodermic needles in cadaver tissue at constant but changeable penetration velocities,

3) to develop a procedure for collecting force-displacement data on intact and excised cadaver skin,

4) to quantify and analyze the force-displacement curves obtained from cadaver tests,

5) to describe and compare, using graphical and statistical tests, the data from different test strata in terms of measurement parameters computed in (4),

6) to test and evaluate a selection of candidate flesh simulants in terms of the cadaver data results.

The first of these tasks was performed by personnel from Becton-Dickinson. Using an injection device developed for use on living subjects, a set of force-displacement curves were obtained on one cadaver (Cad. #4) at HSRI. The comparison of these results are contained in a separate report in preparation by R. Stathopulos, et al. (5). Task 6 consisted of the collection and analysis of penetration data on three potential skin simulants in dry and olive oil soaked conditions. The results of these 266 synthetic material tests are described in a separate document (4).

The following report describes the methods, procedures, and results for tasks 2 through 5 conducted by the biomedical and biomechanics groups at the Highway Safety Research Institute, the University of Michigan, using B-D 42 (22g 1½") hypodermic needles. Section 2 contains a description of the injection device and data collection system developed as well as test protocol, tissue preparation procedures, and data handling and analysis.

Section 3 describes the results obtained from the 883 penetration tests performed on cadaver tissue while Section 4 summarizes and discusses these results, offers some possible conclusions, and suggests direction for future work in this area.

A number of Appendices are contained at the end of this report and under separate cover. Appendix A contains Figures 15 through 25 which provide graphical comparisons of test results between different test strata. Appendix B gives the summary statistics for measurement variables by test strata while Appendix C gives the same statistics for test strata where results for different penetration velocities have been combined. Appendix D gives these statistics separated by cadaver but for combined velocities. Appendix E lists the computer programs used in collecting, editing, and analyzing the force-displacement data.

Appendix F (computer printouts under separate cover) lists the individual test results by test strata.

## SECTION 2

## METHODS AND PROCEDURES

### A. INJECTION DEVICE

In order to study the velocity dependency of the force-displacement characteristics and to control other variables of the injection process between tests, a system was developed to automatically and controllably move the needle in and out of the tissue sample. Figures 1 and 2 show the basic injection device in use on a cadaver. Needle movement is produced by a linear motor actuator (Infomag Model 14) normally used in head positioning of computer disc memories. A stainless steel shaft has been fitted through bushings on the motor and attached to the moving piston of this device. At one end, a load cell (Kistler Model 901A) and luer-lok fitting for holding the needle have been attached. The other end of the shaft is coupled by a small diameter rod to the core of an LVDT (Trans-tek Model 296-000) for measuring and controlling needle position. Rotation of the shaft and needle is prevented by coupling the motor shaft to the motor platform through a sliding key mechanism.

### B. SIGNAL PROCESSING AND CONTROL SYSTEM

Figure 3 shows a schematic drawing of the signal processing and related circuitry. Needle position is controlled by the feedback circuit which uses error rate control features illustrated in Figure 4. The output of the LVDT is processed through a signal conditioner and subtracted from the desired input position signal. The resulting error signal plus its derivative provide an input to the power amplifier (Southwest Technical) which provides current to the linear motor.

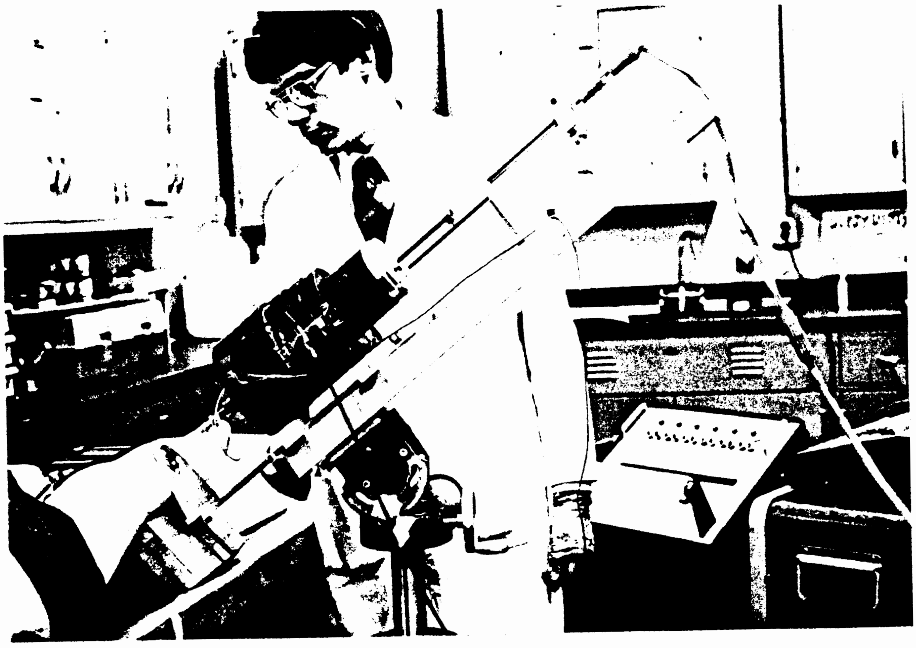


Figure 1  Automatic Injection Device in Use on Cadaver

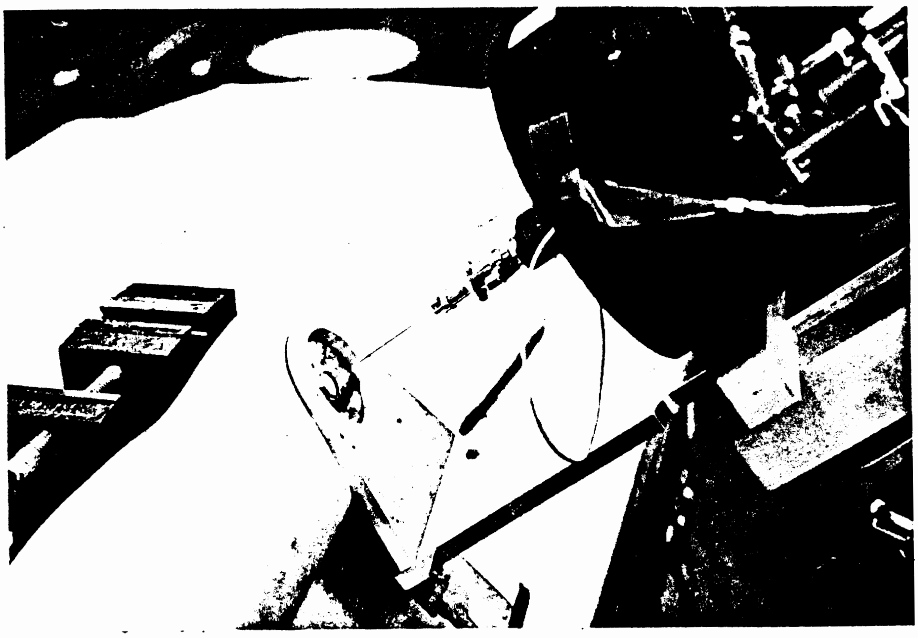


Figure 2  Closeup of Needle End of Injection Device showing Force Transducer

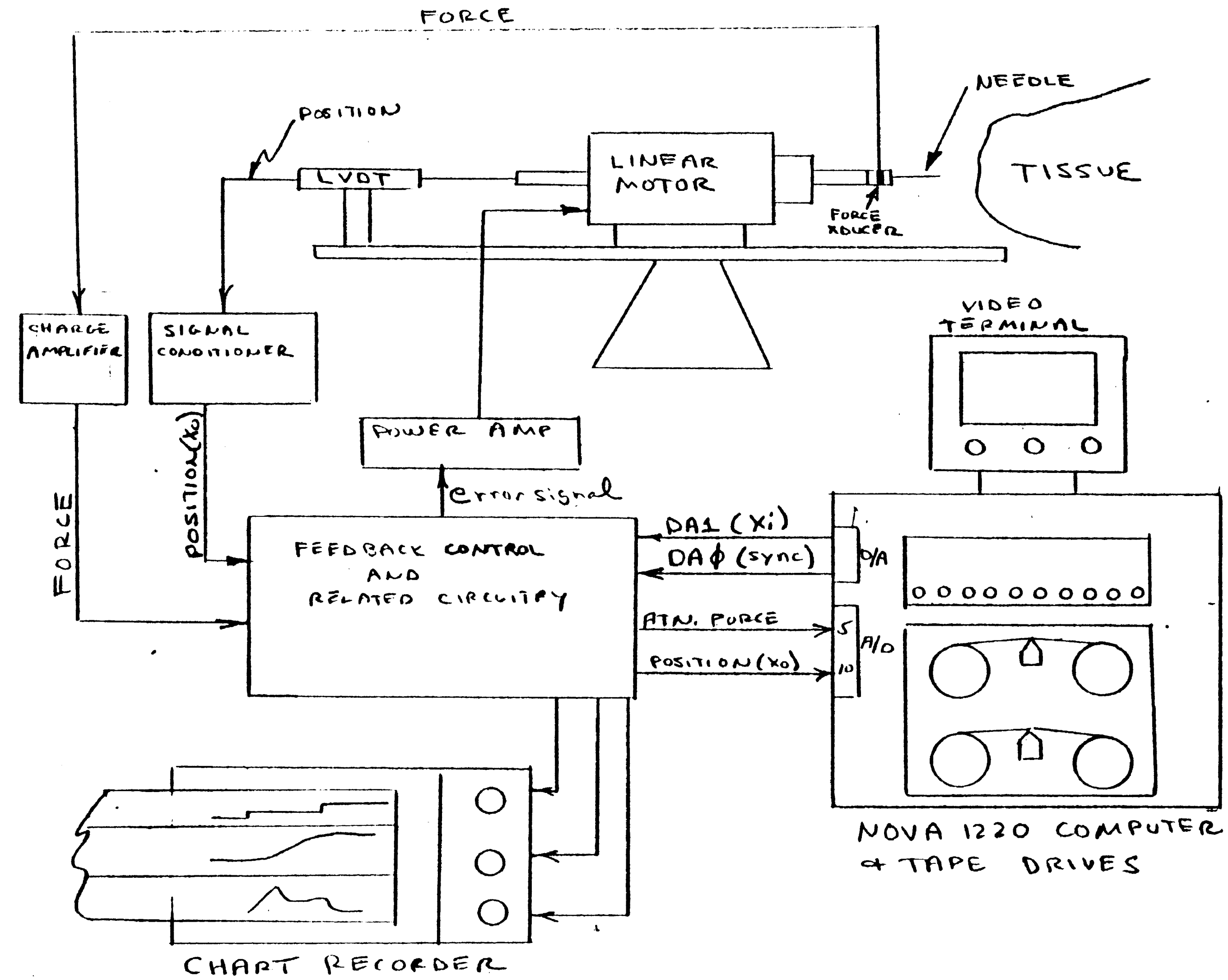



Figure 3 Schematic Drawing of Equipment Set-up During Needle Tests

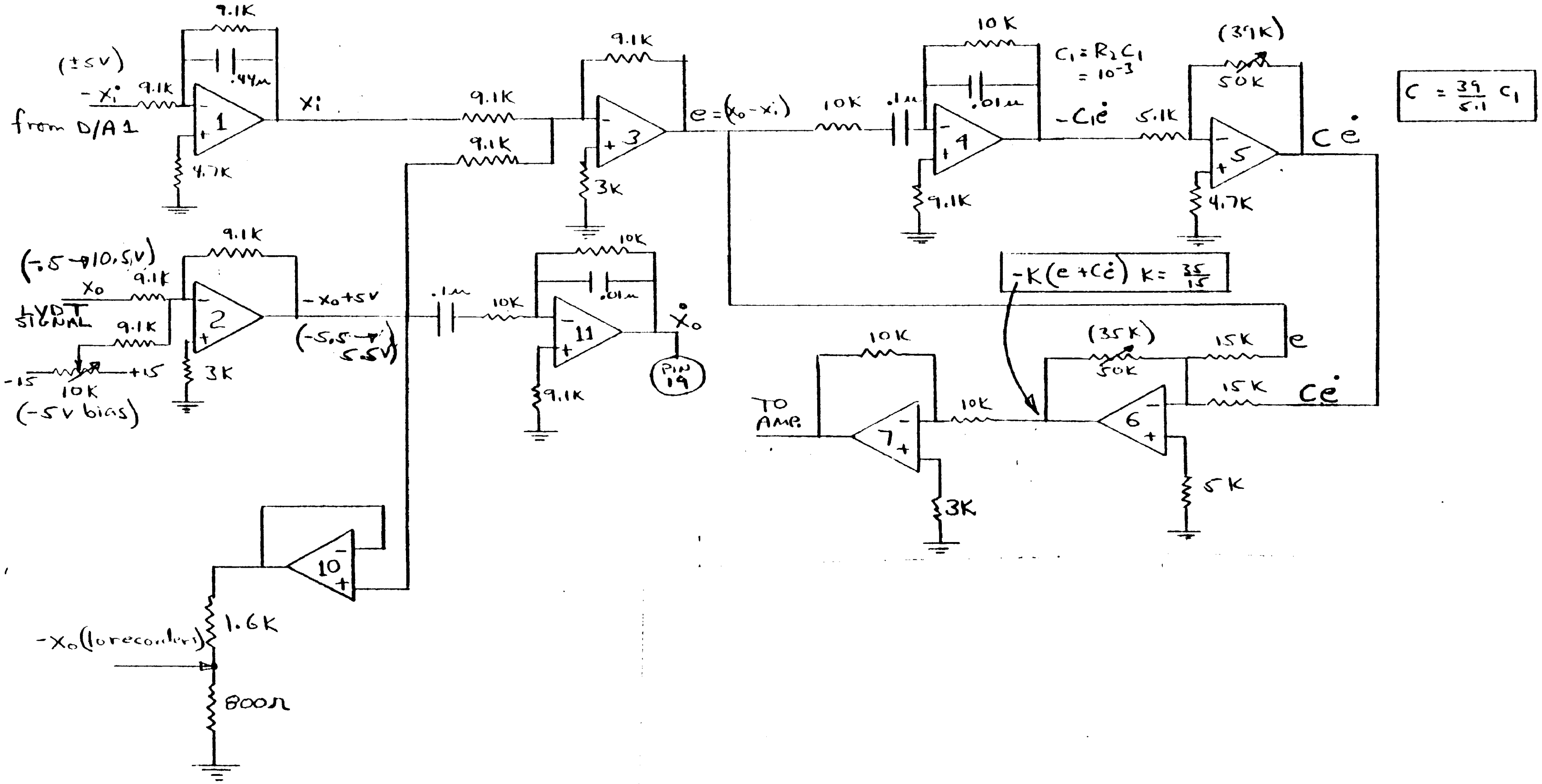



**Figure 4** Error Rate Feedback Control Circuit used to Control Needle Position. $X_i$ = input Signal from Computer, $X_o$ = Feedback Signal from LVDT.

For the series of experiments conducted in this study, the position input signal was provided by means of a digital/analog signal from a NOVA 1220 computer system illustrated in Figure 5. Thus, as will be described, needle position, velocity, depth of penetration and dwell time (i.e., time between penetration and retraction) were all under computer software control and could be easily changed by program inputs. The computer also provided for on-line data digitization of the force and needle displacement signals displayed on chart paper (Brush Recorder). As shown in Figure 3, the force output from the Kistler load cell was processed through a charge amplifier before being input to A/D Channel 5 and Brush Recorder Channel 5. The LVDT signal, in addition to being used in the feedback control circuit, was input to A/D channel 10 and Brush Recorder Channel 6. A second D/A signal from the computer was used to provide a SYNC signal denoting the penetration dwell, and retraction phases of the injection with different voltage levels. This signal was output on a third channel of the brush recorder.

## C. COMPUTER PROGRAMS

The Nova 1220 computer utilized in this study can be programmed in a variety of languages. Primarily because of its fast editing and modification features, programming for this study was done using Data General's Extended BASIC. Because the control of input via the A/D channels and output via the D/A channels would be too slow under BASIC language instructions to move the needle at desired velocities, it was necessary to modify the BASIC software package to include subroutines which when called once, would carry out the injection process by simultaneously outputing signals to the D/A channels and sampling and storing information from the A/D

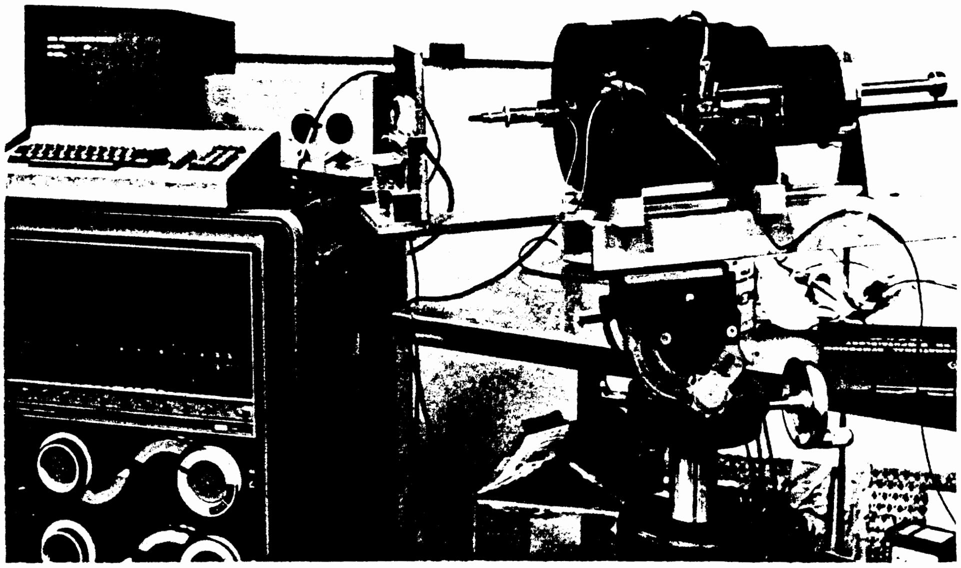


Figure 5  Nova 1220 Computer and Automatic Injector

channels with desired penetration parameters (e.g., penetration velocity, dwell time, retraction velocity, depth of penetration). This was accomplished by writing a new assembly language subroutine which when implemented by the BASIC statement "Call 40" outputs appropriate D/A signals using desired penetration parameters previously computed, and inputs and stores A/D signals on channels 5 and 10. The A/D values are stored in a literal string array (one 16 bit word per sample) by the "Call 40" and are later converted to floating point format (two 16 bit words per value) by a second BASIC subroutine, "Call 44", prior to storing data on LINC digital tape. These BASIC subroutines are contained in a new version of BASIC designed for this study called BDBAS and are listed along with other programs in Appendix E.

A number of programs were written in the BASIC language to implement the various phases of data collection and analysis. A program call "PGO" was written to document and control the needle injection experiments and write digitized data on tape. Information about the test specimen, cadaver data, test date, test conditions, needle lubricants, etc. were input by keyboard on program request and used in setting up parameters for the "Call 40" statement. This basic information about each test is written on digital tape in the tape block preceeding the digitized data. A program called "PGET" provides the ability to retrieve information and/or data about any test which has been written on tape and to redisplay these data on brush recorder paper. A third program, "WCAL", analyzes the force-displacement curves in terms of various measurement parameters described in Section E. Other programs were also written to provide various editing, tape initialization, and data checking functions and are included with these three main programs in Appendix E.

D. EXPERIMENTAL PROCEDURES

1. Tissue Specimen and Test Conditions

Figure 6 shows an overview of the various test and tissue conditions under which needle penetration tests were performed and illustrates the terminology utilized to refer to the various test parameters. The terms TYPE and SITE refer to the tissue specimen itself. Tests were conducted for both the intact skin (SMIS*) and excised skin (SKIN) in the region of the buttock (BUTT) and calf (CALF). A third category of TYPE not shown is SYN which refers to synthetic materials. For each of these tissue conditions, the three test conditions of penetration angle, penetration velocity, and needle lubricant were varied as shown. The angle conditions of 90° and 45° were used, this being the angle of the needle shaft to an imaginary plane tangent to the skin surface prior to needle injection. For each angle, the three lubricant conditions of DRY, 1249, and 360 were tested. For 90° tests, each lubricant condition was tested at 2.5, 5, and 10 inches/second while for 45° tests only 5"/second tests were performed. Considering all these test, specimen, and needle parameters, a total of 48 [2x2 x(3x3+3)] groupings or test conditions results. For each test, the dwell time (time from end of penetration to beginning of retraction) was .5 second and retraction velocity was 5 inches/sec.

The following list summarizes this abbreviated nomenclature which will be used to refer to the different test conditions or strata in the remainder of this report. Reference to a particular test group or strata will be of the form BUTT/SMIS/90/5.0 or CALF/SKIN/45/10.0, etc.

---

* SMIS = Skin/Muscle In Situ

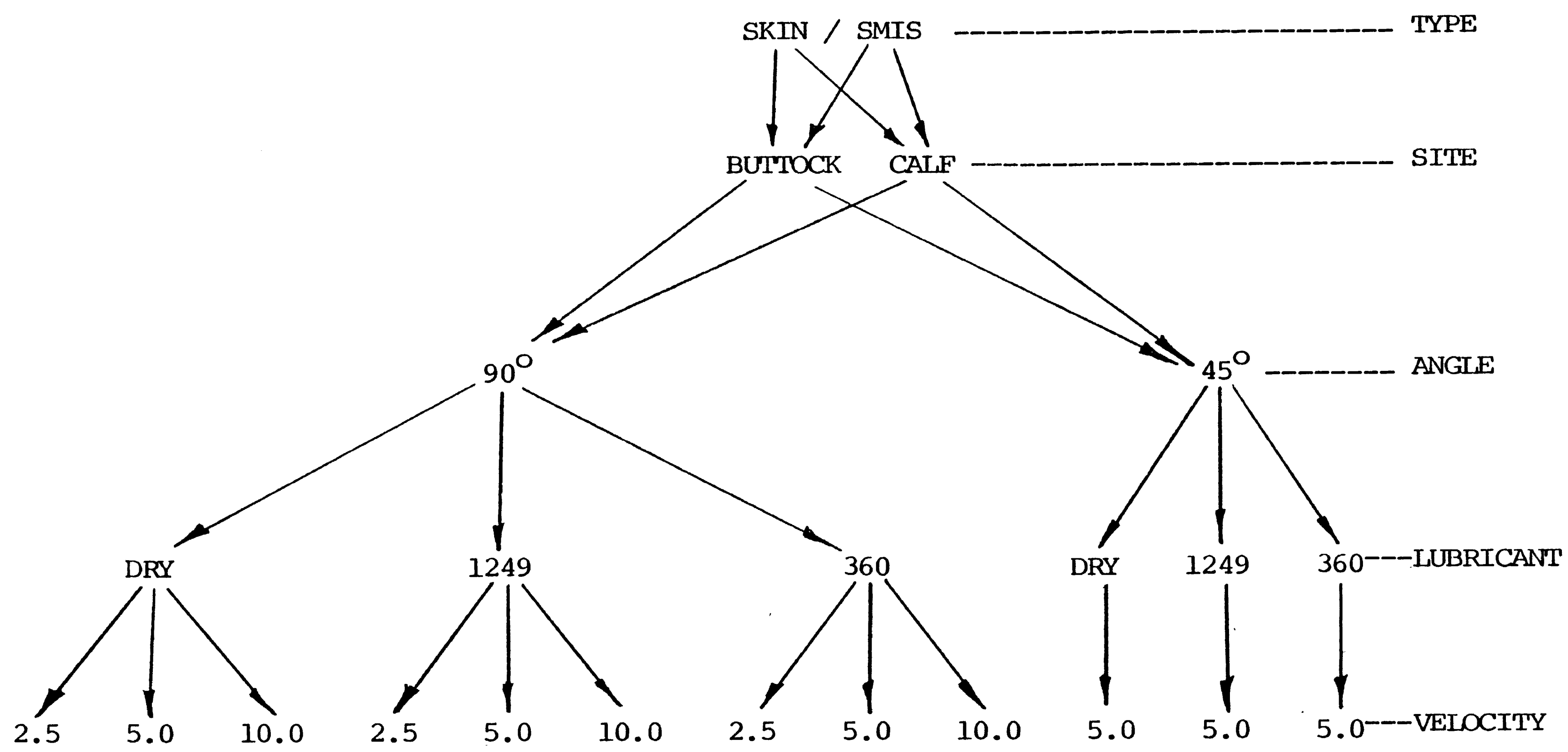



Figure 6 Matrix of Tests Performed on Cadaver Tissue. SKIN (excised tissue), SMIS (intact tissue), BUTTOCK and CALF are Tissue conditions; DRY, 1249, and 360 are Needle (lubricant) conditions; 90 and 45 (angles) and 2.5, 5.0, 10.0 (velocities) are Test conditions.

| Test Parameter | Parameter Terminology and Abbreviations |
|---|---|
| Test Site | BUTT, CALF |
| Test Type | SMIS, SKIN, SYN |
| Penetration Velocity | 2.5, 5.0, 10.0 |
| Penetration Angle | 90, 45 |
| Lubrication | DRY, 1249, 360 |

2. Test Setup and Procedures

a) Intact Skin. Penetration tests on intact unembalmed cadaver tissue were carried out in the HSRI autopsy facility. The cadaver was positioned on the autopsy table and oriented as required by means of styrofoam blocks for either calf or buttock testing. A plexiglass plate with a 1/2 inch diameter hole through which the needle could pass, was attached to the injection device platform by a movable extension and was placed in contact with the cadaver skin at the desired penetration site (see Figure 2). The plate was pushed against the skin surface with sufficient pressure to compress the tissue so that the entire plexiglass disc was in contact with the skin surface. No attempt was made, however, to measure, this contact pressure and there no doubt was some variation between tests, cadavers, and sites.

b) Excised Skin. Penetration tests for excised skin were conducted in the biomaterials laboratory using the test setup shown in Figure 7. For these tests, the plexiglass fixture is replaced with an aluminum plate to which a spring loaded clamping mechanism has been attached. Excised skin mounted between two aluminum rings is held in position by this spring clamp during a test series.

Excising of the skin is carried out in the autopsy room using the procedures illustrated in Figure 8. After cleaning and drying the skin in the region of interest, a rectangular grid of 1/4" squares is stamped

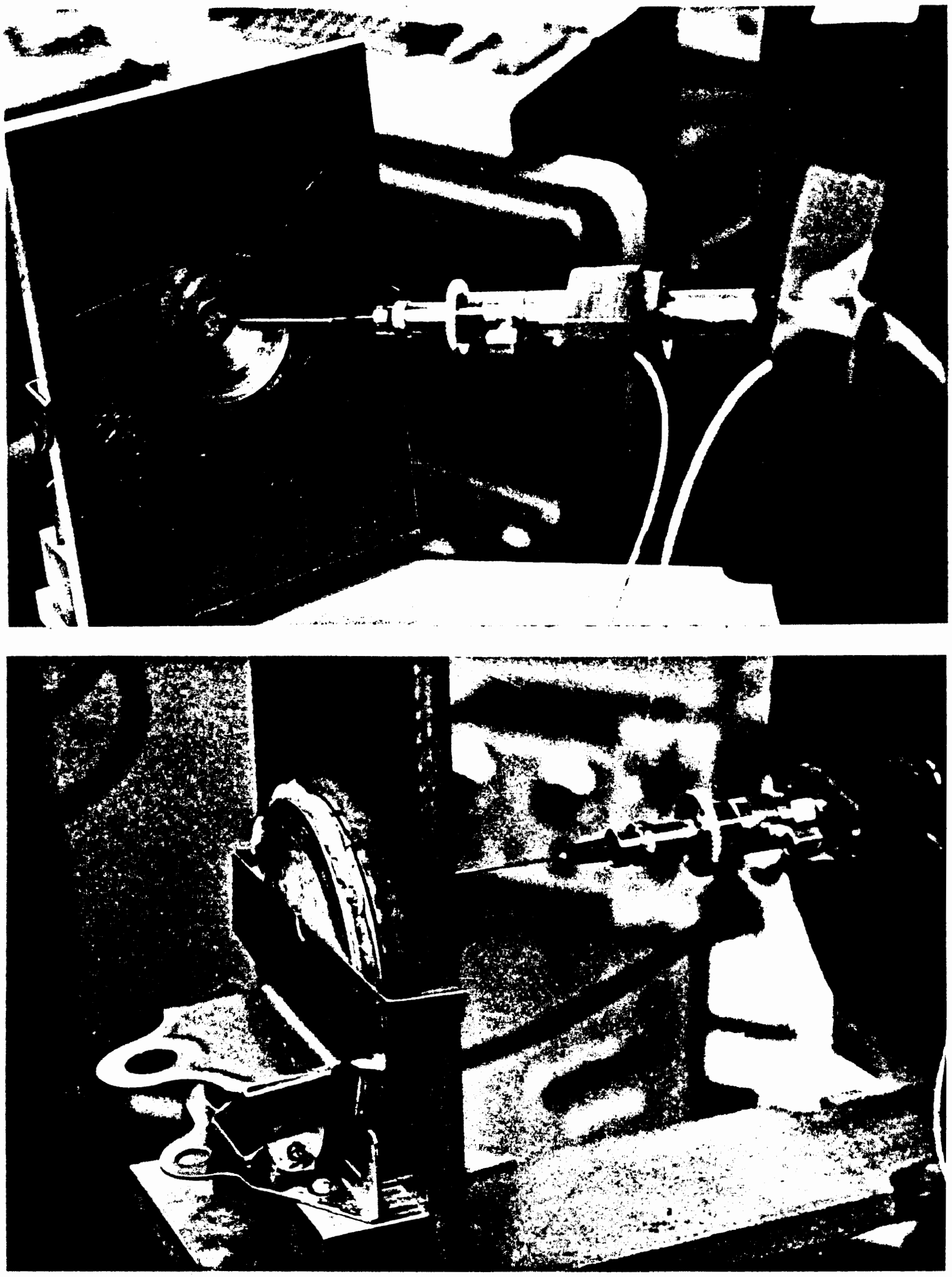
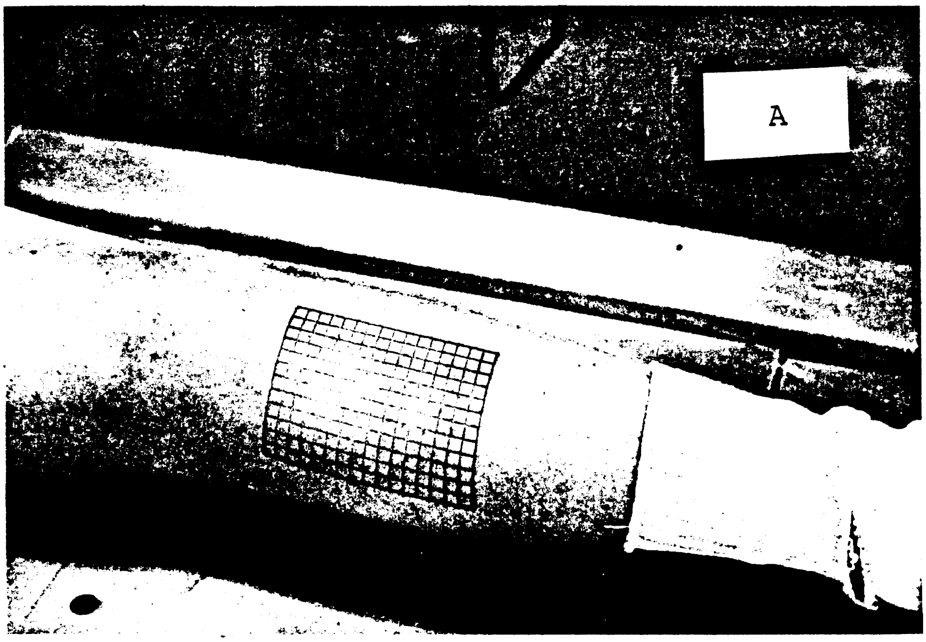


Figure 7 Test Fixture used for Excised Skin Tests.
Top - Penetration side during 45 degree Test.
Bottom - Back side showing Spring Clamp and Mounted Specimen.



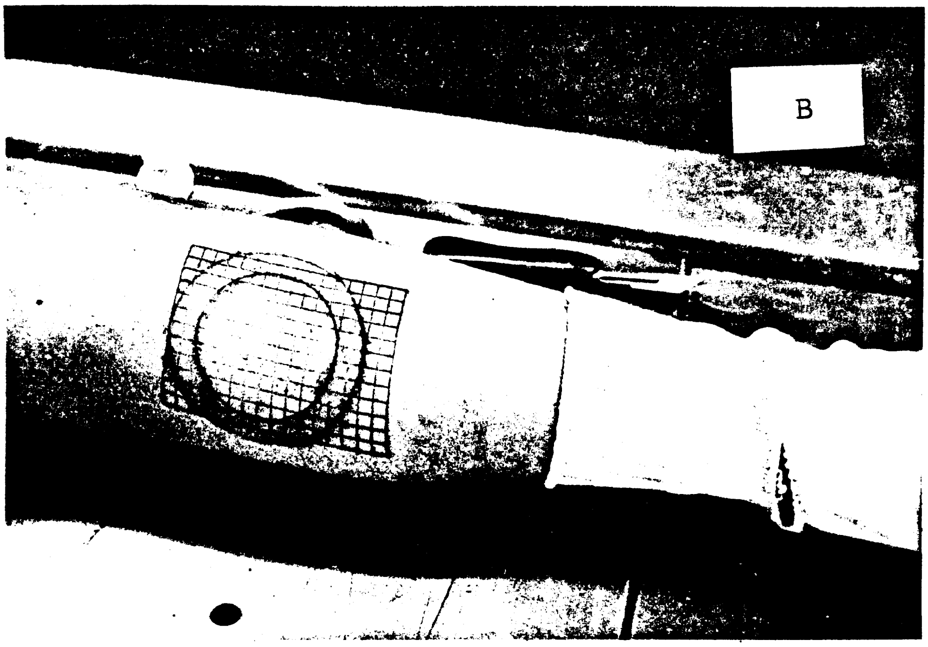




Figure 8 Procedure for Excising Cadaver Skin.
A - Grid is Stamped on Site
B - Ring is Marked and Catalyst Brushed on.

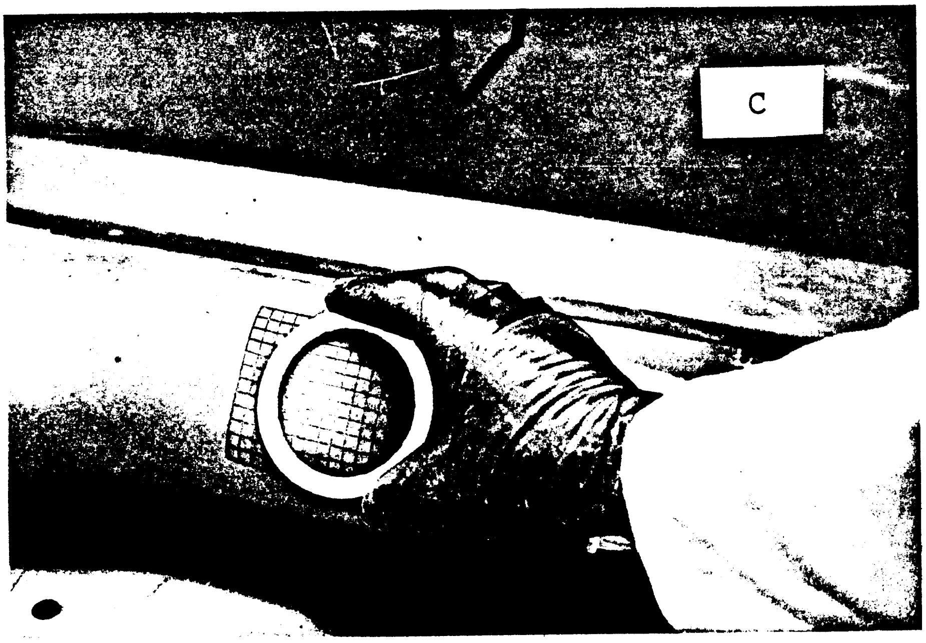



Figure 8 (continued)
C - Aluminum Ring is Cemented in Place
D - After Excising by Cutting Around Ring, Excess Fat is Removed and Second Ring Cemented to Inside.

on the skin surface. Next, an outline of an aluminum ring is drawn over this grid and Eastman 910 catalyst is brushed on the skin in this ring area. Eastman 910 cement (or other "super glue") is then applied to the ring and the ring is pressed firmly on the skin. After the glue has set (about 1 minute), the skin is excised around the ring, the subcutaneous fat carefully removed, and a second ring is glued to the underside by a similar procedure. In this way, the normal skin tension is maintained as closely as possible without the complications of measuring and reconstructing skin tension. The stamped grid provides a measure of changes in skin tension before and after excising.

3. Experimental Protocol

For either the intact or excised (SMIS or SKIN) tests, once the test specimen is in position, the procedures are essentially the same. With the program tape on tape unit 0 and data tape on unit 1, the program "PGO" is loaded and executed. The program first requests information of a general nature such as test date, type of test (SMIS, SKIN, or SYN), cadaver age, sex, height and weight, time and cause of death, and test site (BUTT or CALF). Next, the program requests information on the needle type (B-D 42 22 gauge, 1.5" length for these tests) and lubrication. Lastly, the program requests penetration information such as penetration depth, penetration velocity, dwell time, retraction velocity, and penetration angle. Prior to the first test (or at any time between tests), the needle can be advanced or retracted in variable increments (as small as 1/1000 inch) in order to establish skin contact position. In all tests of this study the needle startup position was established at 1" from skin contact, thereby providing time and distance to bring the needle to the desired velocity with minimum acceleration (i.e., to minimize force noise) prior to penetration. This smooth startup was achieved by an algorithm included in the "Call 40" subroutine (see Section C) which increases the rate of outputing D/A signal increments in a non-linear manner until the desired velocity is reached. Also, included in the program "PGO" is a calibration routine which can be called at any time and which provides both force and displacement calibration pulses.

Once the necessary information has been entered and skin contact and startup position established, the computer awaits input of the letter "G" plus carriage return to begin the first test (i.e., to implement "Call 40"). Upon completing a test, the data may either be written on tape or discarded. In either situation, the penetration test can be repeated, in which case only changes in lubrication or penetration velocity are requested. If a new type of test requiring more general changes in the test condition information (e.g., site, type, depth) is desired, the test is not repeated and the computer requests other information. If the previous test is discarded the test number is not incremented. Each test number is composed of two hyphenated numbers such as 5-19. The first number indicates the LINC data type number while the second is the test sequence number on that tape.

For the intact (SMIS) skin tests, the complete injection device must be physically moved between injections to insure that the needle does not enter a hole previously punctured. Upon completion of a test, the new puncture was marked with a felt tip pen and the device moved approximately 1/4" from this mark. For the excised (SKIN) skin tests, the tissue sample itself was moved by releasing the spring clamp and rotating the aluminum rings. Again each puncture was marked with a pen to prevent repeating a penetration in a previous puncture.

E. DATA ANALYSIS

1. NOVA Computer Computations.

Infrequently (e.g., when the needle contacted a bone), the sampled force and position data were discarded. After most tests, however, these data were written onto the digital tape on tape unit 1, and a record of these tests was maintained in a directory (block 1) of that data tape. While force and displacement are sampled throughout the complete injection cycle, only data from the penetration phase were saved on tape in order to conserve space and yet obtain sufficient resolution for accurate analysis. Both the force and position signals were sampled (by Call 40) every 1/720 inch, although only every 4th point was saved corresponding to a point every 1/180 inch. These distances correspond to 2.2, 1.1, and .55 msec between points for 2.5, 5, and 10"/second velocities respectively. As previously mentioned, the test information describing important parameters about each test was written in the block immediately preceding the digitized data. The variables which make up the test matrix (TYPE, SITE, ANGLE, LUBRICANT, VELOCITY) were also coded into simple interger numbers by "PGO" in order to simplify test statification in the data analysis.

Figure 9 illustrates typical force-time and displacement-time signals recorded and digitized during each test. Since the velocity is maintained constant during penetration, the force-time curve is also a force-displacement curve and the two terms will be used interchangeably in the remainder of this report.

The simplest analysis of these data would consist of computing the peak force value attained during each penetration and using these for comparisons between test strata and as a criteria for needle performance. This, in fact, may be adaquate and possibly all that is useful or meaningful in designing new needles and lubricants. It is also likely, however,

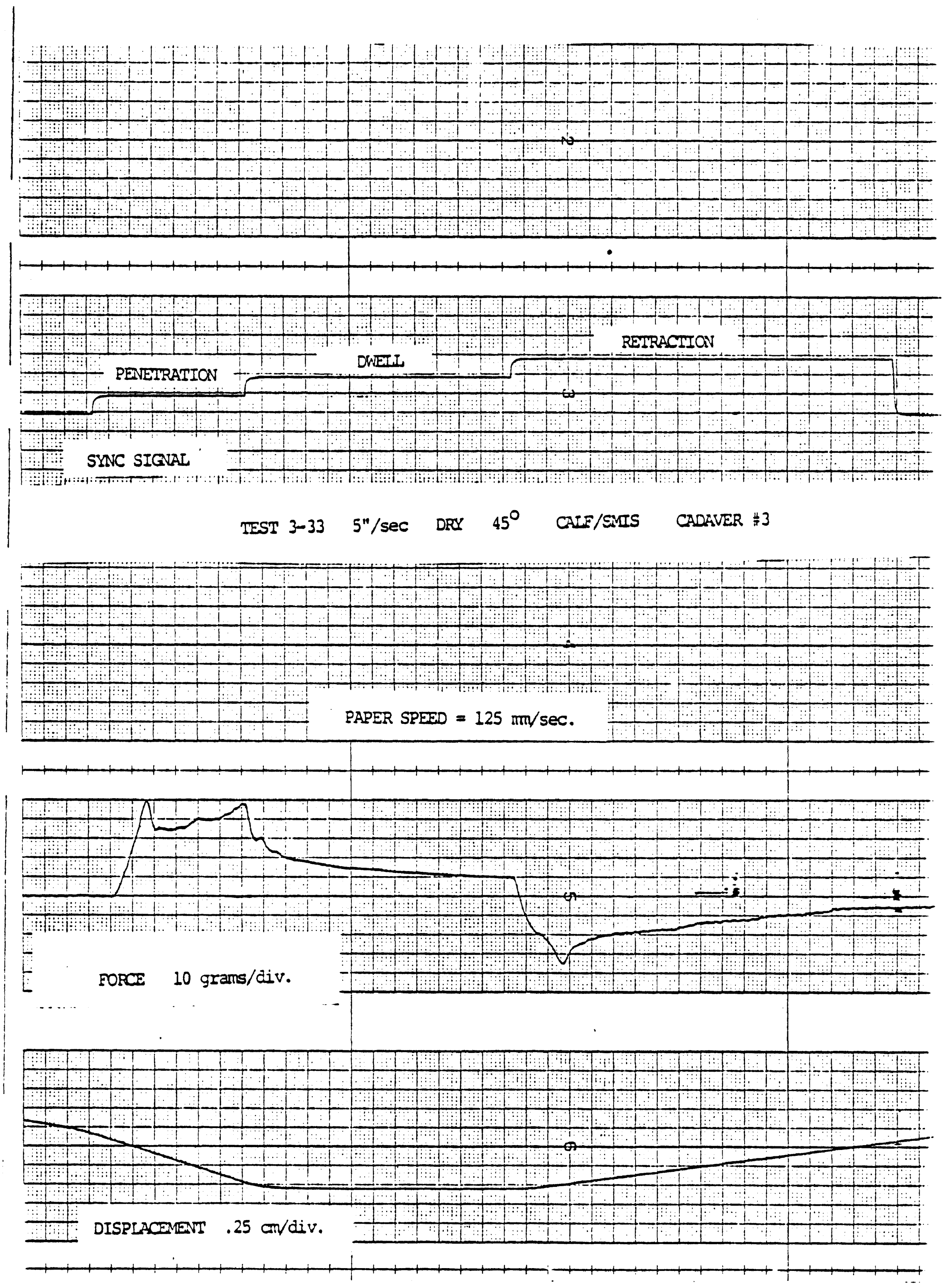



Figure 9 Typical Force, Displacement, and Sync signal Traces for Complete Injection Process

that other characteristics in the force-displacement curve are related to patient acceptance and tissue trauma and should also be considered in evaluating modifications to hypodermic needles.

With this in mind and the general goal of a better understanding of the injection process itself, a more complete characterization of the force-displacement curve was decided upon. A program called "WCAL" was written to perform the analysis of each curve which consisted of the computations illustrated in Figures 10 and 11.

Three force values (F2, F3, F4) and their corresponding distances (or times) from initial skin contact (D2, D3, and D4) are obtained by simple algorithms. F2 is the peak force obtained during the first half of the penetration and is characterized by a substantial decrease in force immediately following. F3 is the force level at which the force curve tends to level out after the peak force. In some tests where the force tends to increase as penetration continues, this corresponds closely to the minimum force value, but in other tests it corresponds to the point where the force-displacement slope shows a sudden decrease or plateau. F4 is taken at 1" past skin contact and therefore D4 is 1 inch or 2.54 centimeters. The ratios F4/F2, F4/F3, F3/F2, D2/D4, and D3/D4 are also computed by WCAL as are the times (T2, T3, T4) corresponding to D2, D3, and D4. The area under the curve from force buildup to point 2 (F2, D2) is computed and called penetration work (PWORK) while the area from 2 to 4 is computed and called drag work (DWORK). This latter area is also divided into the area between points 2 and 3 called first dragwork (DRAGW1) and the area between 3 and 4 called second dragwork (DRAGW2). Total penetration work (TWORK) is equal to PWORK + DWORK . The percentage of PWORK and DWORK are computed (PWORK% and DWORK%) as is the percentage of DRAGW1 of DWORK

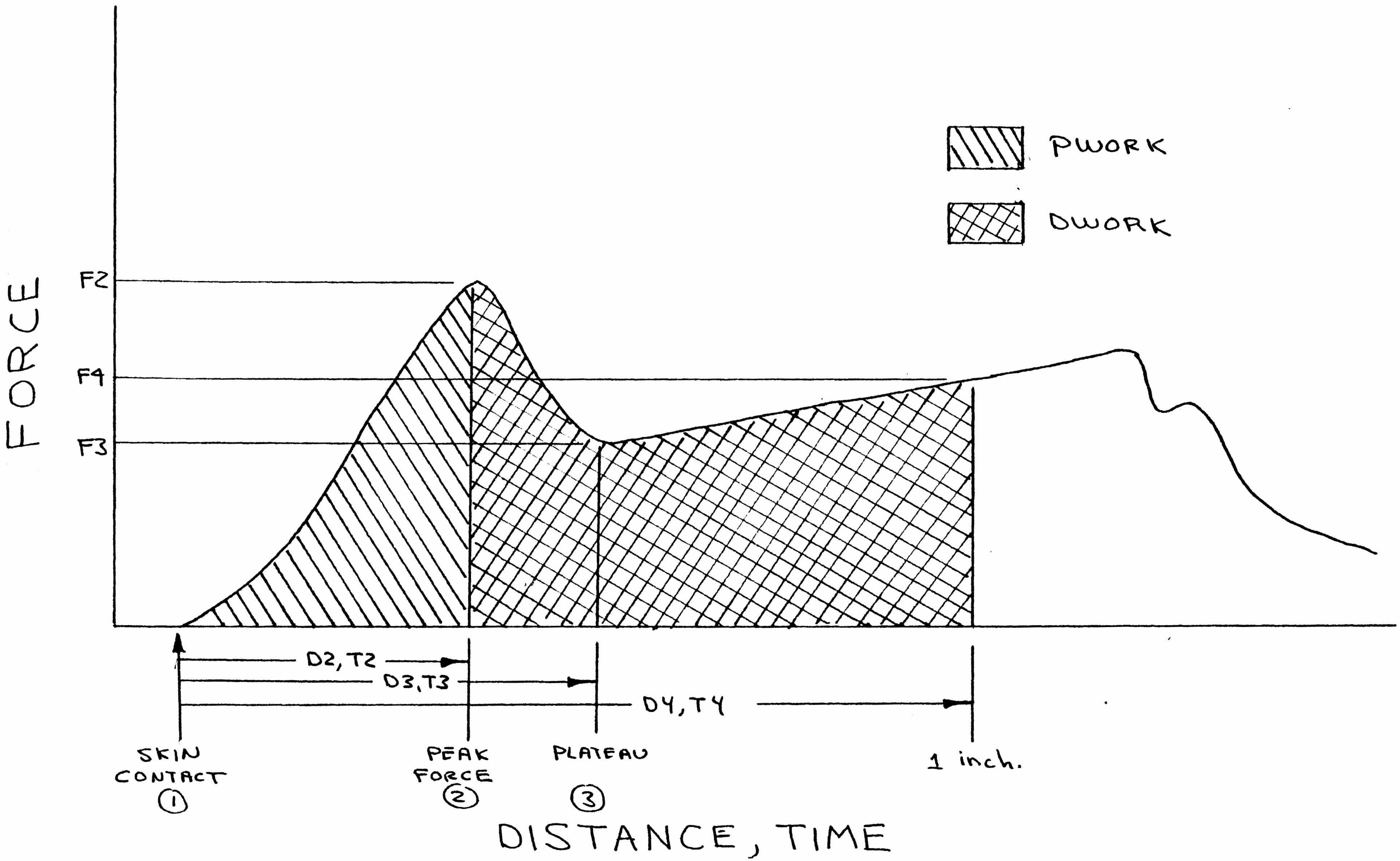



Figure 10 Primary Measurement Variables Calculated from Force/Displacement Curves

[DRWK12% (DRAGW1/DWORK) x 100]. Finally, a normalized dragwork which is really a dragwork per centimeter was computed to remove effects of changes in displacement (D2 and D3) on the measure of dragwork. NDWK is the normalized value of DWORK [NDWK = (DWORK/(D4-D2)] and NDWK2 is the normalized value of DRAGW2 [NDWK2 = DRAGW2/(D4-D3)]. Values of force are reported in Newtons (1N = .221bf = 102gf.), displacement in centimeters (cm), time in milliseconds (msec), work in millijoules, and normalized work in millijoules/centimeter. These calculated variables are summarized in Figure 11.

The program "WCAL" reads in the digitized data from each test, computes values for these parameters and writes the results, along with coded test variables, on a data tape placed on tape unit 0 (program tape is removed).

The lower chart trace in Figure 9 shows the needle position as measured by the LVDT from which the slow start is evident. In an attempt to reduce the force noise due to sudden stopping prior to dwell, the input signal was low pass (approx. 80 Hz cut off) filtered resulting in the rounded corners entering the dwell phase.

2. Statistical Analysis - MTS (MIDAS).

The results from each test analyzed by WCAL are written in binary coded floating point format utilizing one-fourth of a LINC tape block. Since there are 400 blocks available on a tape, results from 1600 tests can be written on a single LINC tape. Data analyzed and stored in this way were copied to a DEC computer tape compatible with the PDP 11/45 computer system installed at HSRI, and then transferred to magnetic tape (800 BPI, fixed block, unlabeled). These results were then read into file at the Michigan Terminal System (MTS) where they could be further analyzed

| VAR. NO. | VARIABLE NAME | DESCRIPTION | UNITS |
|---|---|---|---|
| 11 | F2 | Peak force in 1st half of curve | Newtons |
| 12 | F3 | Force at minimum or plateau following F2 | Newtons |
| 13 | F4 | Force at 1" after skin contact | Newtons |
| 14 | F32 | Ratio of F3 to F2 (F3/F2) | None |
| 15 | F43 | Ratio of F4 to F3 (F4/F3) | None |
| 16 | F42 | Ratio of F4 to F2 (F4/F2) | None |
| 17 | D2 | Distance from skin contact at which F2 occurs | cm. |
| 18 | D3 | Distance from skin contact at which F3 occurs | cm. |
| 19 | D4 | 2.54 cms. (1") past skin contact | cm. |
| 20 | D24 | Ratio of D2 to D4 (D2/D4) | None |
| 21 | D34 | Ratio of D3 to D4 (D3/D4) | None |
| 22 | T2 | Time from skin contact to F2 | msec |
| 23 | T3 | Time from skin contact to F3 | msec |
| 24 | T4 | Time from skin contact to F4 | msec |
| 25 | PWORK | Penetration work-area under force curve from skin contact to F2 | millijoules |
| 26 | DWORK | Drag work-area under force curve from F2 to F4 | millijoules |
| 27 | TWORK | Total work-sum of PWORK and DWORK | millijoules |
| 28 | DRAGW1 | First part of dragwork-area under force curve from F2 to F3 | millijoules |
| 29 | DRAGW2 | 2nd part of dragwork-area under force curve from F3 to F4 | millijoules |
| 30 | PWORK% | Percent of TWORK which is PWORK $(\frac{PWORK}{TWORK} \times 100)$ | % |
| 31 | DWORK% | Percent of TWORK which is DWORK $(\frac{DWORK}{TWORK} \times 100)$ | % |
| 32 | DWORK12% | Percent of DWORK which is DRAGW1 | % |
| 35 | NDWK | Normalized DWORK = DWORK / (D4-D2) | millijoules/cm. |
| 36 | NDWK2 | Normalized DRAGW2 = DRAGW2 / (D4-D3) | millijoules/cm. |

Figure 11 List of Calculated Variables with Descriptions and Units.

by means of a variety of statistical programs in the MIDAS (Michigan Interactive Data Analysis System) package. The statistical results and listings presented in this report were generated using this system.

In order to compare, in a statistical sense, results from different test strata, the Student T-test was used to test for significant differences in mean values. A p value or significance level of .05 was used as the criteria for accepting the null hypothesis that the means of two samples were the same. It is realized that neither of the conditions of independence of test values within a group or between groups was strictly valid since the same cadaver was used for several tests within a group and for several tests between groups. In spite of this lack of adherance to the requirements of the T-test*, it was felt that the results would still provide a reasonable statistical comparison.

* Strictly speaking each test should have been performed on a different cadaver in order to satisfy independence within and between test groups.

SECTION 3

RESULTS

A. GENERAL DESCRIPTION

In total, data from 883 penetration tests of B-D42 hypodermic needles were collected and analyzed for the 48 test conditions. Table 1 shows a breakdown of the sample sizes contained in each block of the test matrix. While a total of 6 cadavers were used in this study, testing on the first two cadavers was primarily for development of experimental protocol and procedures. Test results form these first two cadavers were of small sample size and obtained prior to refinements in the test system and have therefore not been included in the results of this study. Table 2 summarizes the general characteristics and tissue measurements for the four cadavers on which the 883 tests were made. The measurements of fat depth and skin thickness were obtained visually with a linear scale placed next to a cross section of the tissue upon completion of a test series. These measurements are not exact, but rather "eye ball" estimates of the relative tissue thickness to give some idea of the differences between cadavers and body regions (test sites). Table 3 shows a summary of the number of tests conducted on each of these four cadavers for the buttock and calf regions.

B. SKIN TENSION OF EXCISED SKIN

While no attempt was made in this study to measure or recreate a "normal" skin tension, the procedure used in excising the skin was designed to maintain the skin tension as near as possible to that of the intact cadaver skin while maintaining simplicity. The procedure used and described previously (Section D2b of Section 2) worked quite well although as can be seen from Table 2 there was some tissue relaxation as measured by the change

TABLE 1

SAMPLE SIZE BY TEST STRATA

| Test Type | Pen. Angle | Test Site | Dry Velocity ("/Sec) 2.5 | 5 | 10 | 1249 Velocity ("/Sec) 2.5 | 5 | 10 | 360 Velocity ("/Sec) 2.5 | 5 | 10 | Total |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| SMIS | 90° | Butt | 19 | 24 | 25 | 20 | 23 | 27 | 20 | 22 | 29 | 209 |
| | | Calf | 14 | 15 | 12 | 15 | 18 | 12 | 17 | 16 | 13 | 132 |
| | 45° | Butt | | 20 | | | 19 | | | 21 | | 60 |
| | | Calf | | 10 | | | 10 | | | 12 | | 32 |
| SKIN | 90° | Butt | 26 | 27 | 26 | 25 | 25 | 26 | 25 | 25 | 26 | 231 |
| | | Calf | 12 | 12 | 12 | 12 | 12 | 14 | 11 | 13 | 15 | 113 |
| | 45° | Butt | | 29 | | | 27 | | | 26 | | 82 |
| | | Calf | | 8 | | | 8 | | | 8 | | 24 |
| | | Total | 71 | 145 | 75 | 72 | 142 | 79 | 73 | 143 | 83 | 883 |

Table 2

SUMMARY OF CADAVER AND TISSUE INFORMATION

| Cad.# | Age | Sex | Race | Ht(cm) | Wt(kg) | Days Since Death | Cause of Death | Butt Skin Thickness(mm) | Butt Fat Depth(cm) | Calf Skin Thickness( ) | Calf Fat Depth(cm) | % reduction in excised skin grid Butt | Calf |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 3 | 79 | F | C | 149.7 | 59.7 | 5 | Myo. Infarc. | - | - | - | - | - | - |
| 4 | 69 | M | C | 178.5 | 75.0 | 8 | Myo. Infarc. | 3.0 | 2.5 | 1.5 | .1 | 87x95 | - |
| 5 | 39 | F | C | 162.3 | 53.5 | 2 | CVA diabetic | 2.2 | 1.9 | - | .9-1.3 | 88x95 | 97x97 |
| 6 | 55 | F | C | - | 64.0 | 6 | Carc.of Lung | 3.2 | 2.5 | 1.0 | 1.3 | 96x96 | 93x96 |

TABLE 3

SAMPLE SIZE OF TESTS BY CADAVER, BODY REGION, AND TEST TYPE

| CAD. # | SMIS BUTT | SMIS CALF | SKIN BUTT | SKIN CALF | TOTAL PER CADAVER |
|---|---|---|---|---|---|
| 3 | 17 | 20 | 17 | 14 | 68 |
| 4 | 99 | 0 | 73 | 47 | 219 |
| 5 | 78 | 64 | 146 | 0 | 208 |
| 6 | 75 | 80 | 77 | 76 | 308 |
| COLUMN TOTAL | 269 | 164 | 313 | 137 | 883 |

in dimensions of the stamped grid. While no attempt was made to investigate the effect of changes in skin tension on force-displacement characteristics, it was the investigators' sense that changes in skin tension due to excising the skin did not have a significant effect on the results reported here. Evidence in support of this fact will be described later in this section (see comparisons of mean F2 values for SMIS vs SKIN in Section J). Figure 12 illustrates the results of cutting the excised skin tissue preparation after completing the penetration tests. The tension in the skin caused oval shaped openings similar to that resulting from cutting intact skin and supports the conclusion that a "normal" skin tension has been maintained.

C. SAMPLE FORCE-PENETRATION CURVES

Figure 13 shows the penetration portion (and part of dwell) of actual force-time curves at penetration velocities of 2.5, 5, and 10 inches/second. The sync signal level changes denote the beginning of penetration, dwell and retraction phases. For the higher velocities a substantial oscillation is seen to occur at the end of penetration due to the sudden stopping of the needle. This is especially severe at 10 inches/second but, has no effect upon the results of this study since only the first 1" of penetration (1" beyond skin contact) has been analyzed. An algorithum to provide gradual build-up to the desired needle velocity during the first 3/4" of needle travel has been included in the "Call 40" subroutine of BDBAS, but it is seen that some noise still occurs at 10 inches/second prior to skin contact. While the effect of this oscillation in the force signal depends on the relative magnitude of the actual penetration forces, it is not considered to have a significant influence on the analysis of any test results in this study.

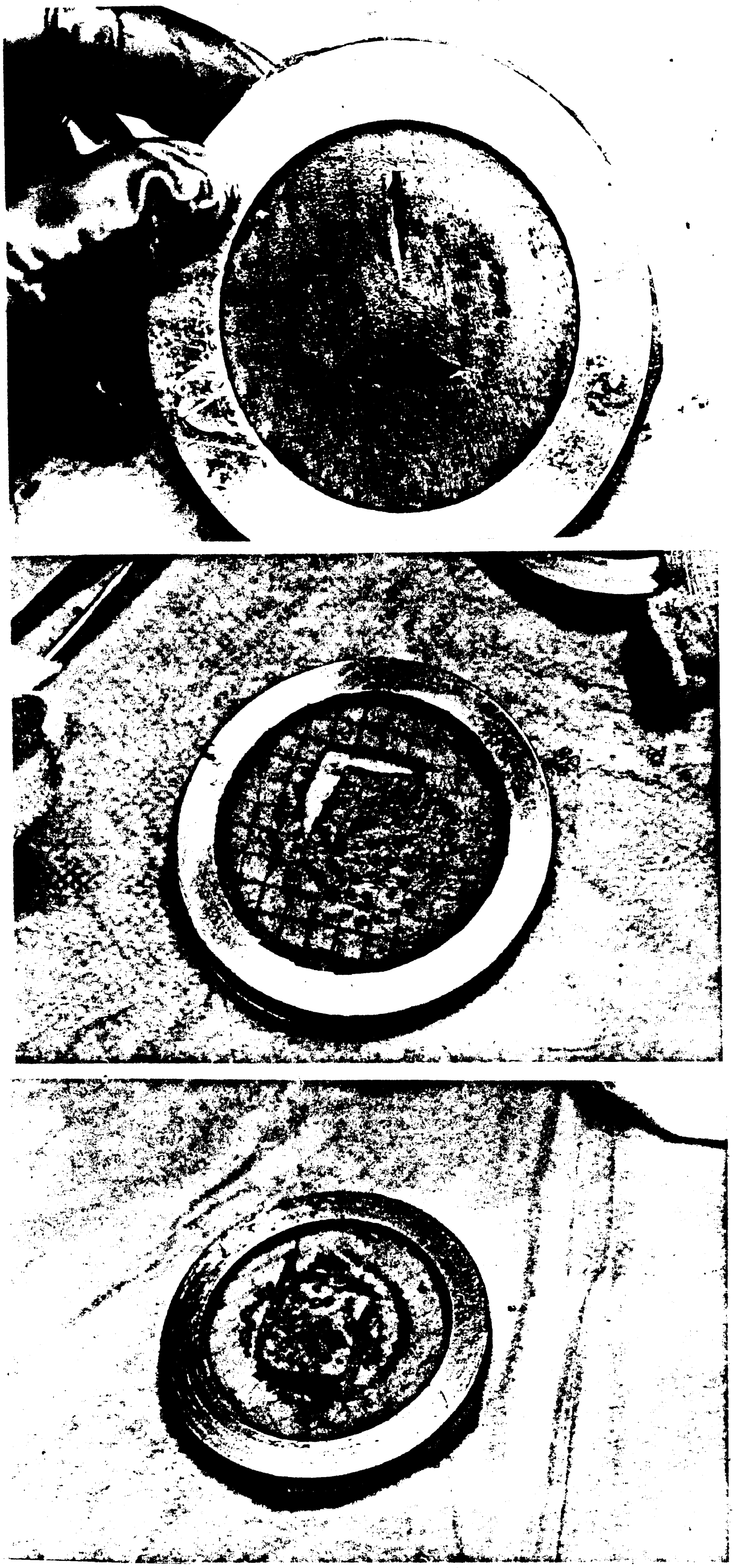


Figure 12 Results of Cutting Excised Skin Tissue Illustrating Similar Response as Normal Intact Skin.

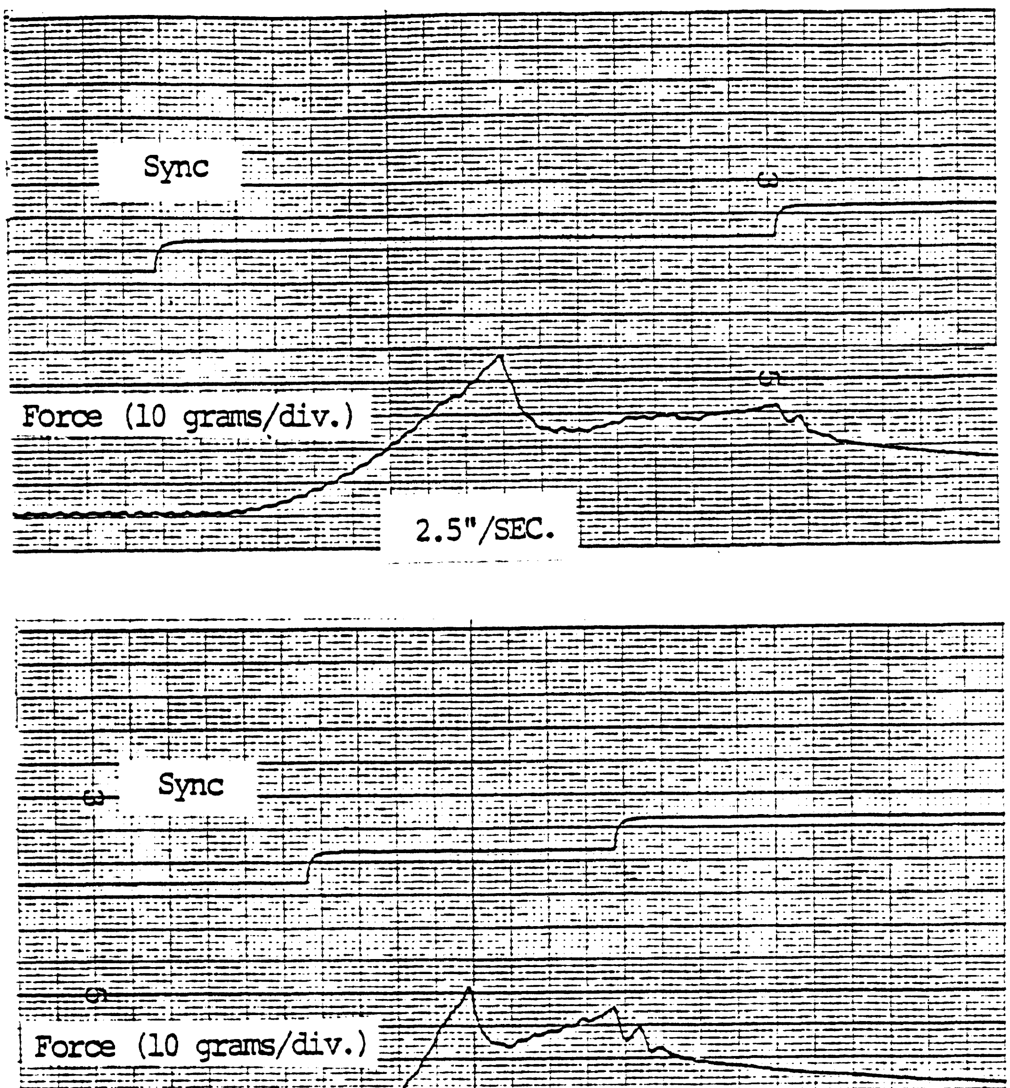



Figure 13 Force and Sync Curves for 2.5 (top), 5.0 (middle), and 10.0 (bottom) inch per second penetration velocities. Paper speed = 125 mm/sec.

The three curves shown in Figure 13 are representative of the type of force response obtained for all 883 tests. The general characteristics of this response are: 1) a sudden and smooth increase in force upon skin contact to a maximum or peak at about .5 to 1.25 centimeters beyond skin contact; 2) an abrupt decrease in force to some new level greater than zero; and 3) a gradual increasing, gradual decreasing, or approximately constant force for the remainder of penetration depending on the particular needle and tissue conditions. In a few cases, for intact calf skin (SMIS/CALF), a second peak was observed in the region after the first peak, but this was not a consistent observation and no attempt was made to quantify it. For purposes of future discussion, the portion of the curve from skin contact to peak force will be referred to as the penetration phase, while the portion from peak force to 1" beyond skin contact is referred to as the drag phase. In accordance with these general features, the response variables described in Section E1 of Section 2 and illustrated in Figure 10 will be used in the remainder of this report for quantifying and comparing the force-displacement characteristics for the different test conditions.

## D. GENERAL DESCRIPTION OF TEST RESULTS

In Appendix F (Computer Sheets) the 24 response variables obtained from each force-displacement curve are listed in groups according to the 48 test strata. Appendix B presents the summary statistics for each of these measurement variables by test group including the sample size, mean, standard deviation, and minimum and maximum values.

In order to visualize and compare these statistics for the various test strata, the mean values of F2, D2, F3, D3, and F4, D4 have been used to reconstruct the "average" force-displacement curves. Figure 14 illustrates this "average" or mean reconstructed force-displacement response for all tests (N=24) in the strata BUTT/SMIS/90/5/DRY.

E. VELOCITY DEPENDENCY

A common characteristic of almost all biological tissues is their visco-elastic nature which implies that their physical properties are rate or velocity dependent. It might be expected, then, to find some kind of velocity dependency of the force-displacement response of hypodermic needles penetrating human tissue. For this reason, the needle injection device and control system developed for this study were designed to provide for constant penetration velocity during each test. While the system can provide any velocity from zero to 14 inches/second in its present configuration, velocities in this study were restricted to 2.5, 5, and 10 inches/second.

Figures 15A through 15L (Appendix A) compare the mean reconstructed response curves for the three penetration velocities in each strata or test condition at a penetration angle of 90°. Table 4 compares the mean values of selected variables for the three velocities. While in a couple of cases (especially CALF/SKIN/DRY) there are differences in the average curves for the three velocities, the overall impression obtained is that velocity has relatively little effect on the force-displacement curve. It should be pointed out that the value of F4 for the 2.5"/second tests in excised skin (SKIN) is erroneously high due to an undetermined source of low frequency noise on the A/D channel. Thus, the greater slopes in the drag portion of the curve for skin tests at 2.5"/second are not true conditions. This is the only error in the analyzed data and affects only the value of F4 (and therefore DWORK) in the 2.5"/second SKIN tests. With this additional fact in mind, the differences between the curves become even less

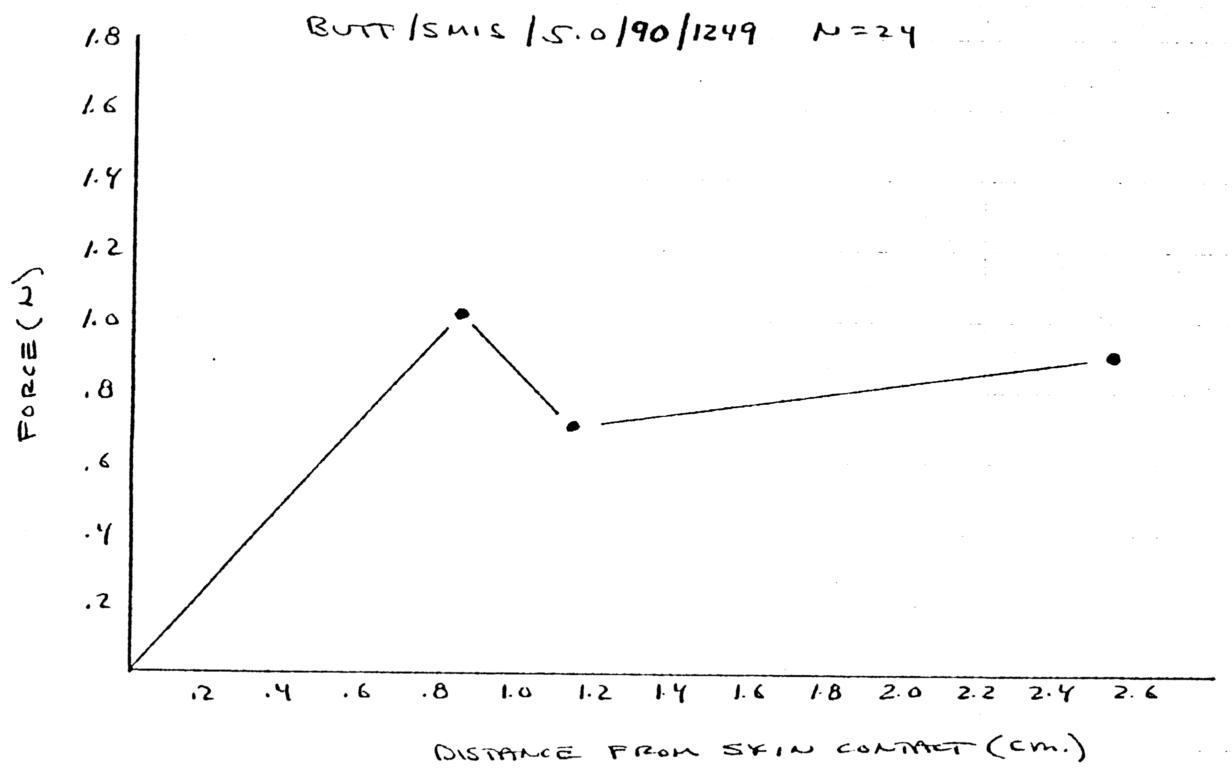



FIGURE 14 Mean Reconstructed Force-Displacement Curve for BUTT/SMIS/5/90/1249 Tests

TABLE 4

COMPARISON OF MEAN VALUES OF SELECTED VARIABLES FOR TESTS AT 2.5, 5.0, and 10.0 INCHES/SECOND

| TEST CONDITIONS | F2 | | | F3 | | | F4 | | | D2 | | | D3 | | | PWORK | | | DWORK | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 2.5 | 5 | 10 | 2.5 | 5 | 10 | 2.5 | 5 | 10 | 2.5 | 5 | 10 | 2.5 | 5 | 10 | 2.5 | 5 | 10 | 2.5 | 5 | 10 |
| DRY/SKIN/90°/BUTT | 1.7 | 1.8 | 1.9 | 1.0 | 1.0 | 1.0 | 1.2 | 1.0 | 1.1 | .9 | .8 | .9 | 1.3 | 1.2 | 1.3 | 6.7 | 6.6 | 7.3 | 18.9 | 19.0 | 19.4 |
| 1249/SKIN/90°/BUTT | 1.0 | 1.2 | 1.1 | .5 | .6 | .6 | .6 | .5 | .6 | .8 | .8 | .9 | 1.2 | 1.2 | 1.3 | 3.7 | 4.1 | 4.7 | 10.4 | 10.9 | 11.3 |
| 360/SKIN/90°/BUTT | 1.1 | 1.1 | 1.2 | .4 | .4 | .4 | .4 | .2 | .4 | .8 | .8 | .8 | 1.2 | 1.3 | 1.2 | 3.6 | 4.1 | 4.0 | 7.1 | 7.0 | 8.6 |
| DRY/SMIS/90°/BUTT | 2.5 | 2.4 | 2.3 | 1.6 | 1.5 | 1.4 | 1.8 | 1.7 | 1.8 | 1.3 | 1.1 | 1.0 | 1.6 | 1.5 | 1.4 | 15.1 | 12.6 | 10.7 | 22.1 | 23.4 | 25.6 |
| 1249/SMIS/90°/BUTT | 1.0 | 1.1 | 1.1 | .6 | .7 | .7 | .8 | .9 | 1.1 | .9 | .8 | .8 | 1.2 | 1.2 | 1.1 | 4.4 | 4.4 | 4.5 | 12.2 | 14.1 | 16.8 |
| 360/SMIS/90°/BUTT | 1.0 | 1.0 | 1.0 | .4 | .5 | .5 | .6 | .7 | .9 | .9 | .9 | .8 | 1.3 | 1.2 | 1.1 | 4.6 | 4.2 | 4.0 | 9.2 | 10.1 | 12.3 |
| DRY/SKIN/90°/CALF | 1.8 | 1.6 | 1.3 | 1.0 | .9 | .8 | 1.3 | .9 | .9 | .9 | .8 | .7 | 1.3 | 1.2 | 1.1 | 7.0 | 5.9 | 4.7 | 20.0 | 16.6 | 17.3 |
| 1249/SKIN/90°/CALF | .7 | .9 | .9 | .4 | .3 | .4 | .5 | .3 | .4 | .7 | .7 | .7 | 1.1 | 1.1 | 1.1 | 2.4 | 3.1 | 3.1 | 8.2 | 7.0 | 9.1 |
| 360/SKIN/90°/CALF | .7 | 1.0 | .9 | .2 | .3 | .3 | .4 | .2 | .3 | .7 | .6 | .7 | 1.1 | 1.0 | 1.2 | 2.4 | 3.0 | 2.8 | 5.4 | 5.2 | 6.6 |
| DRY/SMIS/90°/CALF | 2.0 | 1.9 | 1.9 | 1.4 | 1.4 | 1.4 | 1.8 | 1.9 | 2.2 | .7 | .7 | .6 | .9 | 1.0 | .9 | 6.9 | 7.2 | 6.7 | 30.7 | 31.7 | 34.4 |
| 1249/SMIS/90°/CALF | .7 | .9 | .9 | .5 | .5 | .6 | .8 | 1.0 | 1.0 | .5 | .5 | .6 | .8 | .8 | .9 | 2.0 | 2.7 | 3.2 | 13.7 | 16.4 | 15.8 |
| 360/SMIS/90°/CALF | .7 | .8 | .8 | .3 | .3 | .4 | .6 | .7 | .8 | .6 | .5 | .5 | .8 | .8 | .8 | 2.4 | 2.4 | 2.1 | 9.5 | 11.0 | 12.2 |

Units of F2, F3, F4 = newtons
Units of D2, D3 - centimeters
Units of PWORK, DWORK = millijoules

significant. It will also be noticed that where differences do occur there is usually no trend with velocity which is consistent within a test or more important, between tests. For the SMIS tests, two possible trends of questionable significance can be observed, however. At the calf, the force F4 is consistently higher for higher velocities while there are no clear differences for points 2 and 3. At the buttock this trend in F4 is not observed but the value of D2 seems to be inversely related to velocity. For the excised skin (SKIN), these trends are not apparent.

From a statistical point of view one can also examine this question of velocity dependence. The Student T-test was used to compare mean values of the measurement variables for 2.5"/second tests with 10"/second tests and for 5"/second tests with 10"/second tests. Tables 5 and 6 summarize the results of these comparisons for F2, F3, F4, D2, D3, PWORK, DWORK, TWORK, PWORK%, DWORK%, NDWK, and NDWK2. An X indicates a significant difference in group means at the .05 level of significance. Statistically, it is seen that there are significant differences between variable means at different velocities and that there are more differences between 2.5"/second and 10"/second than between 5"/second and 10"/second. While these tests certainly do not allow the conclusion that penetration velocity has no effect, the randomness of the significant differences together with a comparison of actual mean values from Table 4, support the conclusion that within the range of velocities used here, the velocity dependency is quite small, poorly defined, and of no "practical" significance. Even for the SMIS/CALF tests and SMIS/BUTT tests for which F4 and D2 graphically showed some velocity dependent trends, the differences are seen to be not always significant. In spite of this relative insensitivity to penetration velocity, most of the statistical comparisons which follow will utilize tests at 5"/second only.

TABLE 5

RESULTS OF STUDENT T-TESTS FOR 2.5"/SEC. VS 10"/SEC.
(all tests at 90°)
"X" indicates a significant difference at .05 level

| | | | F2 | F3 | F4 | D2 | D3 | PWORK | DWORK | TWORK | PWORK % | DWORK % | NDWK | NDWK2 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| DRY | SKIN | BUTT | | | | | | | | | | | | |
| | | CALF | X | | X | X | X | X | | | | | | |
| | SMIS | BUTT | | | | X | X | X | | | X | X | | |
| | | CALF | | | X | | | | X | | | | X | X |
| 1249 | SKIN | BUTT | | X | | X | X | X | | X | | | X | X |
| | | CALF | X | | X | | | | | X | | | | |
| | SMIS | BUTT | X | X | X | X | | | X | X | X | X | X | X |
| | | CALF | X | | X | | X | X | X | X | | | X | X |
| 360 | SKIN | BUTT | | | | | | | X | X | | | X | X |
| | | CALF | X | X | X | | | | | | | | | |
| | SMIS | BUTT | | X | X | X | X | | X | X | X | X | X | X |
| | | CALF | | X | X | | | | X | X | X | X | X | X |

TABLE 6

RESULTS OF STUDENT T-TESTS FOR 5.0"/SEC. VS 10"/SEC.
(all tests at 90°)
"X" indicates a significant difference at .05 level

| | | | F2 | F3 | F4 | D2 | D3 | PWORK | DWORK | TWORK | PWORK % | DWORK % | NDWK | NDWK2 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| DRY | SKIN | BUTT | | | | X | X | | | | | | | |
| | | CALF | | | | | | X | | | | | | |
| | SMIS | BUTT | | | | X | | | | | X | X | | |
| | | CALF | | | X | | | | | | | | | |
| 1249 | SKIN | BUTT | | | X | X | X | | | | | | | X |
| | | CALF | | X | X | | | | X | X | | | X | X |
| | SMIS | BUTT | | | X | | | | X | X | X | X | X | X |
| | | CALF | | | | | | | | | | | | |
| 360 | SKIN | BUTT | | X | X | | | | X | | X | X | X | X |
| | | CALF | | | X | | X | | | | | | | X |
| | SMIS | BUTT | | X | X | | | | X | | X | X | X | X |
| | | CALF | | | | | | | | | | | | |

## F. VARIATION OF RESULTS WITHIN TEST STRATA

Aopendix C contains the summary statistics for each test/tissue condition at 90° peentration angle with the results for the three velocities combined. Figures 16 A through 16 L show the reconstructed force-displacement curve envelopes for these groups where the dashed lines correspond to the mean values and the solid lines correspond to the mean plus or minus one standard deviation on the force values. It should be pointed out that these are not true envelopes since they do not incorporate the standard deviations about the distances D2 and D3. These graphs indicate, however, that even within a particular tissue/needle/test strata there can be considerable differences from one injection to another. In the comparisons which follow, these curve envelopes should be kept in mind since only the reconstructed curves for the mean values will be considered.

## G. ANGLE DEPENDENCY

Figures 17A through 17L compare the reconstructed mean force-displacement curves for 90° vs 45° tests for each test strata at 5"/second while Table 7 compares the mean values of selected variables for the two penetration angles. Table 8 summarizes the results of student T-tests comparing the sample means of selected variables at these two angles where an "X" indicates a significant difference in the means at the .05 level.

An overview of these results reveals relatively few and no consistent significant differences in mean values of the measurement variables. In only one case (CALF/SKIN/DRY) is there a significant difference in mean peak force values. Values of D2 are very comparable for the two angles and consequently so are values of penetration work (PWORK). For the buttock tests, the mean values of F3, F4 and consequently DWORK are consistently (but not always significantly ) greater for the 45° tests. This trend is not observed for the calf tests, however. It must be concluded from these results, therefore, that the force-displacement response is relatively insensitive to penetration angles between 45 and 90 degrees to the skin surface.

## H. COMPARISONS BETWEEN NEEDLE LUBRICANTS

Figures 18A through 18D compare the mean reconstructed force-displacement curves for the three needle lubricant conditions (DRY, 1249, 360) for the four tissue conditions of BUTT/SMIS, BUTT/SKIN, CALF/SMIS, CALF/SKIN under the test conditions of 5 inches/second at 90 degrees. Table 9 summarizes and compares mean values of selected variables and Table 10 summarizes the results of Student T-tests between 1249-and 360-lubricant conditions. In all four test strata the dry needle curve stands clearly apart from the two lubricants, the magnitudes of F2, F3, and F4 being significantly greater for the dry needles. In all cases except BUTT/SKIN the

TABLE 7

COMPARISON OF MEAN VALUES OF SELECTED VARIABLES FOR TESTS AT 45 and 90 DEGREES

| TEST CONDITIONS | F2 | | F3 | | F4 | | D2 | | D3 | | PWORK | | DWORK | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 90 | 45 | 90 | 45 | 90 | 45 | 90 | 45 | 90 | 45 | 90 | 45 | 90 | 45 |
| DRY/SKIN/BUTT | 1.8 | 1.9 | 1.0 | 1.3 | 1.0 | 1.4 | .8 | 1.0 | 1.2 | 1.4 | 6.6 | 8.3 | 19.0 | 21.7 |
| 1249/SKIN/BUTT | 1.2 | 1.2 | .6 | .7 | .5 | .7 | .8 | .9 | 1.2 | 1.3 | 4.1 | 4.6 | 10.9 | 13.0 |
| 360/SKIN/BUTT | 1.1 | 1.2 | .4 | .4 | .2 | .4 | .8 | .9 | 1.3 | 1.3 | 4.1 | 4.6 | 7.0 | 8.7 |
| DRY/SMIS/BUTT | 2.4 | 2.3 | 1.5 | 1.6 | 1.7 | 1.6 | 1.1 | 1.1 | 1.5 | 1.5 | 12.6 | 12.3 | 23.4 | 24.6 |
| 1249/SMIS/BUTT | 1.1 | 1.1 | .7 | .8 | .9 | 1.0 | .8 | .8 | 1.2 | 1.1 | 4.4 | 4.4 | 14.1 | 15.7 |
| 360/SMIS/BUTT | 1.0 | 1.1 | .5 | .5 | .7 | .7 | .9 | .8 | 1.2 | 1.2 | 4.2 | 4.2 | 10.1 | 11.5 |
| DRY/SKIN/CALF | 1.6 | 1.3 | .9 | .7 | .9 | 1.0 | .8 | .9 | 1.2 | 1.2 | 5.9 | 4.9 | 16.6 | 15.4 |
| 1249/SKIN/CALF | .9 | .8 | .3 | .4 | .3 | .5 | .7 | .7 | 1.1 | 1.1 | 3.1 | 2.9 | 7.0 | 9.3 |
| 360/SKIN/CALF | 1.0 | 1.0 | .3 | .3 | .2 | .2 | .6 | .8 | 1.0 | 1.1 | 3.0 | 3.4 | 5.2 | 5.4 |
| DRY/SMIS/CALF | 1.9 | 1.6 | 1.4 | 1.2 | 1.9 | 1.6 | .7 | .7 | 1.0 | .9 | 7.2 | 6.0 | 31.7 | 27.7 |
| 1249/SMIS/CALF | .9 | .9 | .5 | .4 | 1.0 | .9 | .5 | .4 | .8 | .8 | 2.7 | 2.0 | 16.4 | 13.9 |
| 360/SMIS/CALF | .8 | .9 | .3 | .4 | .7 | .8 | .5 | .5 | .8 | .8 | 2.4 | 2.6 | 11.0 | 11.2 |

Units of F2, F3, F4 - newtons
Units of D2, D3 = centimeters
Units of PWORK, DWORK - millijoules

TABLE 8

RESULTS OF STUDENT T-TESTS FOR 90° VS 45° TESTS
AT 5.0"/SEC.
"X" indicates a significant difference at the .05 level

| TEST CONDITION | | | F2 | F3 | F4 | D2 | D3 | PWORK | DWORK | TWORK | PWORK % | DWORK % | NDWK | NDWK 2 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| DRY | SKIN | BUTT | | X | X | X | X | X | | X | | | X | X |
| | | CALF | X | | | | | | | | | | | |
| | SMIS | BUTT | | | | | | | | | | | | |
| | | CALF | | | X | | | | X | X | | | X | X |
| 1249 | SKIN | BUTT | | X | X | | | | X | X | | | X | X |
| | | CALF | | | X | | | | X | | | | X | X |
| | SMIS | BUTT | | | | | | | | | | | | |
| | | CALF | | X | | X | | X | | X | | | X | X |
| 360 | SKIN | BUTT | | X | X | | | | X | X | | | X | X |
| | | CALF | | | | X | X | | | | | | | |
| | SMIS | BUTT | | X | | | | | | | | | | |
| | | CALF | | | | X | | | | | | | | |

TABLE 9

COMPARISON OF MEAN VALUES OF SELECTED VARIABLES FOR THE THREE LUBRICANT CONDITIONS-
DRY, 1249, 360, (1 = DRY, 2 = 1249, 3 = 360)

| TEST CONDITIONS | F2 | | | F3 | | | F4 | | | D2 | | | D3 | | | PWORK | | | DWORK | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 1 | 2 | 3 | 1 | 2 | 3 | 1 | 2 | 3 | 1 | 2 | 3 | 1 | 2 | 3 | 1 | 2 | 3 |
| BUTT/SKIN | 1.8 | 1.2 | 1.1 | 1.0 | .6 | .4 | 1.0 | .5 | .2 | .8 | .8 | .8 | 1.2 | 1.2 | 1.3 | 6.6 | 4.1 | 4.1 | 19.0 | 10.9 | 7.0 |
| BUTT/SMIS | 2.4 | 1.1 | 1.0 | 1.5 | .7 | .5 | 1.7 | .9 | .7 | 1.1 | .8 | .9 | 1.5 | 1.2 | 1.2 | 12.6 | 4.4 | 4.2 | 23.4 | 14.1 | 10.1 |
| CALF/SKIN | 1.6 | .9 | 1.0 | .9 | .3 | .3 | .9 | .3 | .2 | .8 | .7 | .6 | 1.2 | 1.1 | 1.0 | 5.9 | 3.1 | 3.0 | 16.6 | 7.0 | 5.2 |
| CALF/SMIS | 1.9 | .9 | .8 | 1.4 | .5 | .3 | 1.9 | 1.0 | .7 | .7 | .5 | .5 | 1.0 | .8 | .8 | 7.2 | 2.7 | 2.4 | 31.7 | 16.4 | 11.0 |

Units of F2, F3, F4 - newtons
Units of D2, D3 - centimeters
Units of PWORK, DWORK = millijoules

value of D2 is significantly greater for the dry needles than the lubricated needles. Table 11 summarizes ratios of D2/D4 for each of the curves from which it is seen that these ratio differences between dry and lubricated needles are most significant for the SMIS (intact tissue) tests. It is also seen from the four graphs that the separation between dry and lubricated needle curves is greater for the intact tissue (SMIS) tests.

Comparing the reconstructed force-displacement curves for the 1249- versus the 360-lubricant condition, it is seen that for all four tissue conditions, the magnitudes of F2 and D2 are nearly identical and therefore the calculated mean values of penetration work (PWORK) for the two lubricants are essentially and statistically the same. The curves differ consistently, however, in the drag portion of the curves, the 1249 lubricant having, in each case, higher values of F3 and F4 and therefore the greater drag work (DWORK, NDWK, and NDWK2).

It is interesting to note that even through the values of F3, F4 and DWORK are significantly different between all three lubricant conditions, the slopes of the mean curves from point 3 to 4 are nearly the same for each tissue condition.

I. BUTTOCK VERSUS CALF

Figures 19A through 19F compare the mean reconstructed force-displacement curves of the buttock and calf regions for the six test strata at 5"/second and 90°. Table 12 compares the mean values of selected variables and Table 13 summarizes the T-test results for buttock versus calf tests. Several observations can be made from these data.

In every case the mean peak force is greater for the BUTT tests than the CALF tests, but in only two cases (both SMIS) is the difference significant. For the intact tissue (SMIS), the peak force also occurs significantly later (i.e., D2 is greater) for the BUTT tests. This relationship

TABLE 10

RESULTS OF STUDENT T-TESTS FOR 1249 VS 360 LUBRICANTS
(all tests at 90° and 5.0"/sec.)

"X" indicates a significant difference at the .05 level

| TEST CONDITION | | F2 | F3 | F4 | D2 | D3 | PWORK | DWORK | TWORK | PWORK % | DWORK % | NDWK | NDWK 2 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| SKIN | BUTT | | X | X | | | | X | X | X | X | X | X |
| SKIN | CALF | | | X | | | | X | | | | X | X |
| SMIS | BUTT | | X | X | | | | X | X | X | X | X | X |
| SMIS | CALF | | X | X | | | | X | X | X | X | X | X |

TABLE 11

D2/D4 RATIOS FOR VARIOUS LUBRICANT AND TEST CONDITIONS

| | DRY | 1249 | 360 |
|---|---|---|---|
| BUTT SKIN | .31 | .31 | .32 |
| BUTT SMIS | .44 | .32 | .33 |
| CALF SKIN | .32 | .28 | .25 |
| CALF SMIS | .28 | .21 | .21 |

TABLE 12

COMPARISON OF MEAN VALUES OF SELECTED VARIABLES FOR BUTTOCK AND CALF TESTS

| TEST CONDITIONS | F2 | | F3 | | F4 | | D2 | | D3 | | PWORK | | DWORK | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | BUTT | CALF | BUTT | CALF | BUTT | CALF | BUTT | CALF | BUTT | CALF | BUTT | CALF | BUTT | CALF |
| DRY/SKIN/90° | 1.8 | 1.6 | 1.0 | .9 | 1.0 | .9 | .8 | .8 | 1.2 | 1.2 | 6.6 | 5.9 | 19.0 | 16.6 |
| 1249/SKIN/90° | 1.2 | .9 | .6 | .3 | .5 | .3 | .8 | .7 | 1.2 | 1.1 | 4.1 | 3.1 | 10.9 | 7.0 |
| 360/SKIN/90° | 1.1 | 1.0 | .4 | .3 | .2 | .2 | .8 | .6 | 1.3 | 1.0 | 4.1 | 3.0 | 7.0 | 5.2 |
| DRY/SMIS/90° | 2.4 | 1.9 | 1.5 | 1.4 | 1.7 | 1.9 | 1.1 | .7 | 1.5 | 1.0 | 12.6 | 7.2 | 23.4 | 31.7 |
| 1249/SMIS/90° | 1.1 | .9 | .7 | .5 | .9 | 1.0 | .8 | .5 | 1.2 | .8 | 4.4 | 2.7 | 14.1 | 16.4 |
| 360/SMIS/90° | 1.0 | .8 | .5 | .3 | .7 | .7 | .9 | .5 | 1.2 | .8 | 4.2 | 2.4 | 10.1 | 11.0 |

Units of F2, F3, F4 = newtons
Units of D2, D3 = centimeters
Units of PWORK, DWORK = millijoules

TABLE 13

RESULTS OF STUDENT T-TESTS FOR BUTT VS CALF
(all tests at 90° and 5.0"/sec.)

"X" indicates a significant difference at the .05 level

| TEST CONDITION | | F2 | F3 | F4 | D2 | D3 | PWORK | DWORK | TWORK | PWORK % | DWORK % | NDWK | NDWK 2 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| DRY | SKIN | | | | | | | | | | | | |
| | SMIS | X | | X | X | X | X | X | | X | X | | |
| 1249 | SKIN | | X | X | | | | X | X | | | X | X |
| | SMIS | X | X | | X | X | X | X | | X | X | | |
| 360 | SKIN | | X | X | X | X | X | X | X | | | X | X |
| | SMIS | | X | | X | X | X | | | X | X | | |

of D2's is also true to a lesser degree for the SKIN tests with lubricated needles and is not true for the case of SKIN/DRY tests. For excised skin, the mean values of F3 and F4 are consistently greater for the BUTT tests. Thus, for excised skin, both the penetration work (PWORK) and drag work (DWORK) are greater on the average for the BUTT tests although these differences were not always statistically significant. For the SMIS tests, even though the peak force, F2, is greater for the BUTT tests, the average value of F4 is consistently smaller for the BUTT tests. This is a consequence of the fact that the slope from point 3 to point 4 is always positive and greater for the SMIS/CALF tests than for the SMIS/BUTT tests. The obvious suggestion is that the muscle tissue in close proximity to the intact calf skin provides a greater drag effect on all three needle conditions than does the fat tissue which comprises the first 1 inch or more of subcutaneous tissue at the buttock. In spite of this observation the differences in normalized drag work (NDWK) were not significant for any lubricant condition for SMIS tests.

J. INTACT VERSUS EXCISED TISSUE (SMIS VS SKIN)

Figures 20A through 20F compare the mean reconstructed force-displacement curves of intact (SMIS) versus excised (SKIN) for the six test strata at 5"/second and 90°. Table 14 compares the values of selected variables and Table 15 summarizes the T-test results for SMIS versus SKIN tests.

The most striking difference between the intact and excised skin tests is that the drag work (DWORK, NDWK, NDWK2) is significantly and consistently higher for the intact skin (SMIS). This is as expected, of course, since the needle surface contacts more tissue as it penetrates the intact skin whereas once the needle tip has penetrated through the excised skin, the

TABLE 14

COMPARISON OF MEAN VALUES OF SELECTED VARIABLES FOR SMIS AND SKIN TESTS

| TEST CONDITIONS | F2 | | F3 | | F4 | | D2 | | D3 | | PWORK | | DWORK | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | SKIN | SMIS | SKIN | SMIS | SKIN | SMIS | SKIN | SMIS | SKIN | SMIS | SKIN | SMIS | SKIN | SMIS |
| DRY/BUTT/90° | 1.7 | 2.5 | 1.0 | 1.5 | 1.0 | 1.7 | .8 | 1.1 | 1.2 | 1.5 | 6.6 | 12.6 | 19.0 | 23.4 |
| 1249/BUTT/90° | 1.2 | 1.1 | .6 | .7 | .5 | .9 | .8 | .8 | 1.2 | 1.2 | 4.1 | 4.4 | 10.9 | 14.1 |
| 360/BUTT/90° | 1.1 | 1.0 | .4 | .5 | .2 | .7 | .8 | .9 | 1.3 | 1.2 | 4.1 | 4.2 | 7.0 | 10.1 |
| DRY/CALF/90° | 1.6 | 1.9 | .9 | 1.4 | .9 | 1.9 | .8 | .7 | 1.2 | 1.0 | 5.9 | 7.2 | 16.6 | 31.7 |
| 1249/CALF/90° | .9 | .9 | .3 | .5 | .3 | 1.0 | .7 | .5 | 1.1 | .8 | 3.1 | 2.7 | 7.0 | 16.4 |
| 360/CALF/90° | 1.0 | .8 | .3 | .3 | .2 | .7 | .6 | .5 | 1.0 | .8 | 3.0 | 2.4 | 5.2 | 11.0 |

Units of F2, F3, F4 = newtons
Units of D2, D3 = centimeters
Units of PWORK, DWORK = millijoules

TABLE 15

RESULTS OF STUDENT T-TESTS FOR SMIS VS SKIN TESTS
(all tests at 90° and 5.0"/sec.)
"X" indicates a significant difference at the .05 level

| TEST CONDITION | | F2 | F3 | F4 | D2 | D3 | PWORK | DWORK | TWORK | PWORK % | DWORK % | NDWK | NDWK 2 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| DRY | BUTT | X | X | X | X | X | X | X | X | X | X | X | X |
| DRY | CALF | | X | X | X | X | | X | X | X | X | X | X |
| 1249 | BUTT | | X | X | | | | X | X | X | X | X | X |
| 1249 | CALF | | X | X | X | X | | X | X | X | X | X | X |
| 360 | BUTT | | | X | X | X | | X | X | X | X | X | X |
| 360 | CALF | | X | X | | | | X | X | X | X | X | X |

tissue surface in contact with the needle shaft remains essentially constant. In fact, as shown in Table 16, for all test strata, the force increases from point 3 to point 4 for the intact skin (F4/F3>1) tests whereas in all but the CALF/DRY stratum the force decreases from point 3 to point 4 (F4/F3<1) for the excised skin tests. Also, in every test strata the mean value of F3 and the ratio of F4/F3 is greater for the intact skin tests.

For the DRY needles, the mean value of peak force, F2, is significantly greater for the intact skin while for the lubricated needles, the mean value of F2 for the intact skin is less than and/or about equal to the value for excised skin. A significant observation, however, is that the peak force, F2, occurs sooner (D2 is smaller) for the intact skin than for the excised skin at the calf (SMIS/CALF) and at about the same distance or greater for the intact skin at the buttock. This relative shift in D2 for SMIS versus SKIN is especially obvious for the dry needles where the values of D2 for CALF and BUTT excised skins are approximately the same.

## K. COMPARISONS OF PENETRATION AND DRAG WORK

The measures of penetration work and drag work computed from the force-displacement curves give perhaps the best overall and most meaningful characterization of the injection process since they incorporate all the other measurement variables. While the values of PWORK and DWORK have been included in previous comparisons, this section is presented to summerize the results for these variables. Figures 21A through 21D and 22 A through 22D graphically summarize the results for penetration work (PWORK) and drag work (DWORK) for all test strata. In each graph the mean value

TABLE 16

F4/F3 RATIOS FOR SMIS VERSUS SKIN TESTS

| Test Strata | SMIS | SKIN |
|---|---|---|
| DRY/BUTT | 1.14 | .95 |
| 1249/BUTT | 1.25 | .87 |
| 360/BUTT | 1.41 | .66 |
| DRY/CALF | 1.37 | 1.06 |
| 1249/CALF | 1.85 | .87 |
| 360/CALF | 2.31 | .49 |

for each strata is shown by a symbol and the mean plus and minus one standard deviation is illustrated by brackets. Tables 17 through 20 show the mean values (in millijoules) used for these graphs and include mean values of TWORK, DRAGW1, DRAGW2, and the normalized drag work's NDWK and NDWK2. The normalized work values were computed to give drag work per unit distance (i.e., millijoules/cm) in order to eliminate effects of changes in D2 or D3 on the drag resistance measure.

An overview of these graphs and tables supports the conclusion that the force-displacement response is essentially velocity independent. In only one case, BUTT/SMIS/DRY, is there any clear trend of PWORK (i.e., PWORK decreases with higher velocities) and even here the differences in the means are small in consideration of the spread of the distributions. There is perhaps some indication that DWORK increases with velocity for both CALF and BUTT intact skin, but the dependence is small. It will also be noticed from Table 19 that the velocity dependency of DWORK for BUTT/SMIS/DRY does not exist for the normalized drag works indicating that this apparent relationship is caused by a shift in D2 (and therefore PWORK) with velocity (i.e., PWORK and DWORK as calculated are not independent).

The differences between DRY and lubricated needles are clearly apparent from these data as is the similarity in PWORK and small differences in DWORK (1249 being greater) for the two lubricant conditions. The relative independence of penetration characteristics with penetration angle is also apparent from these graphs and tables.

Comparing PWORK values in these graphs and tables for SMIS and SKIN shows significant differences only for the BUTT/DRY tests, the SMIS values being larger. This of course is due to the increase in D2 with the SMIS tests (see Table 14). A comparison of PWORK values for CALF and BUTT shows the CALF tests to be generally lower than the BUTT tests for all conditions.

TABLE 17

MEAN VALUES OF WORK VARIABLES CALCULATED FOR BUTT/SKIN TESTS

| TEST CONDITION VEL./LUB./ANGLE | PWORK | DWORK | TWORK | DWORK1 | DWORK2 | NDWK | NDWK2 |
|---|---|---|---|---|---|---|---|
| 2.5/DRY/90 | 6.7 | 18.9 | 25.6 | 4.9 | 14.9 | 11.4 | 10.8 |
| 5.0/DRY/90 | 6.5 | 19.0 | 25.5 | 5.3 | 13.6 | 10.9 | 10.0 |
| 10.0/DRY/90 | 7.3 | 19.4 | 26.7 | 6.0 | 13.3 | 11.7 | 10.7 |
| 2.5/1249/90 | 3.6 | 10.4 | 14.1 | 2.8 | 7.6 | 5.9 | 5.5 |
| 5.0/1249/90 | 4.1 | 10.9 | 15.0 | 3.3 | 7.6 | 6.2 | 5.6 |
| 10.0/1249/90 | 4.7 | 11.3 | 16.0 | 3.6 | 7.6 | 7.0 | 6.4 |
| 2.5/360/90 | 3.6 | 7.1 | 10.8 | 2.8 | 4.3 | 4.0 | 3.2 |
| 5.0/360/90 | 4.1 | 7.0 | 11.2 | 3.0 | 4.1 | 4.1 | 3.1 |
| 10.0/360/90 | 4.0 | 8.6 | 12.6 | 3.2 | 5.4 | 4.9 | 4.0 |
| 5.0/DRY/45 | 8.3 | 21.7 | 30.0 | 6.6 | 15.1 | 14.3 | 13.6 |
| 5.0/1249/45 | 4.6 | 13.0 | 17.5 | 4.1 | 8.9 | 7.8 | 7.1 |
| 5.0/360/45 | 4.6 | 8.7 | 13.3 | 3.6 | 5.1 | 5.1 | 4.1 |

Units of PWORK, DWORK, TWORK, DWORK1, DWORK2 = millijoules
Units of NDWK, NDWK2 = millijoules/cm

TABLE 18

MEAN VALUES OF WORK VARIABLES CALCULATED FOR CALF/SKIN TESTS

| TEST CONDITION VEL./LUR./ANGLE | PWORK | DWORK | TWORK | DWORK1 | DWORK2 | NDWK | NDWK2 |
|---|---|---|---|---|---|---|---|
| 2.5/DRY/90 | 7.0 | 19.9 | 26.9 | 5.2 | 14.7 | 11.9 | 11.3 |
| 5.0/DRY/90 | 5.9 | 16.6 | 22.5 | 4.0 | 12.6 | 9.6 | 8.9 |
| 10.0/DRY/90 | 4.7 | 17.3 | 22.0 | 3.9 | 13.4 | 9.3 | 8.9 |
| 2.5/1249/90 | 2.4 | 8.2 | 10.6 | 2.4 | 5.8 | 4.6 | 4.2 |
| 5.0/1249/90 | 3.1 | 7.0 | 10.1 | 2.5 | 4.6 | 4.0 | 3.4 |
| 10.0/1249/90 | 3.1 | 9.1 | 12.3 | 2.7 | 6.4 | 4.9 | 4.4 |
| 2.5/360/90 | 2.4 | 5.4 | 7.8 | 1.7 | 3.8 | 3.0 | 2.6 |
| 5.0/360/90 | 3.0 | 5.2 | 8.2 | 1.9 | 3.3 | 2.7 | 2.1 |
| 10.0/360/90 | 2.8 | 6.6 | 9.4 | 2.6 | 4.0 | 3.6 | 2.9 |
| 5.0/DRY/45 | 4.9 | 15.4 | 20.3 | 3.4 | 12.0 | 9.2 | 9.0 |
| 5.0/1249/45 | 2.9 | 9.3 | 12.2 | 2.2 | 7.1 | 5.2 | 4.9 |
| 5.0/360/45 | 3.4 | 5.4 | 8.8 | 2.0 | 3.3 | 3.0 | 2.4 |

Units of PWORK, DWORK, TWORK, DWORK1, DWORK2 - millijoules
Units of NDWK, NDWK2 - millijoules/cm

TABLE 19

MEAN VALUES OF WORK VARIABLES CALCULATED FOR BUTT/SMIS TESTS

| TEST CONDITION VEL./LUB./ANGLE | PWORK | DWORK | TWORK | DWORK1 | DWORK2 | NDWK | NDWK2 |
|---|---|---|---|---|---|---|---|
| 2.5/DRY/90 | 15.1 | 22.1 | 37.2 | 7.0 | 15.1 | 17.9 | 16.8 |
| 5.0/DRY/90 | 12.7 | 23.4 | 36.0 | 6.2 | 17.1 | 16.5 | 15.7 |
| 10.0/DRY/90 | 10.8 | 25.6 | 36.3 | 7.6 | 18.0 | 16.7 | 15.9 |
| 2.5/1249/90 | 4.4 | 12.2 | 16.6 | 2.4 | 9.8 | 7.4 | 7.2 |
| 5.0/1249/90 | 4.4 | 14.1 | 18.5 | 3.1 | 11.0 | 8.2 | 8.0 |
| 10.0/1249/90 | 4.5 | 16.8 | 21.3 | 3.3 | 13.5 | 9.5 | 9.5 |
| 2.5/360/90 | 4.6 | 9.2 | 13.8 | 2.4 | 6.8 | 5.6 | 5.3 |
| 5.0/360/90 | 4.2 | 10.1 | 14.3 | 2.5 | 7.6 | 5.9 | 5.5 |
| 10.0/360/90 | 4.0 | 12.2 | 16.3 | 2.9 | 9.4 | 7.0 | 6.8 |
| 5.0/DRY/45 | 12.3 | 24.7 | 37.0 | 8.0 | 16.7 | 17.1 | 16.2 |
| 5.0/1249/45 | 4.4 | 15.7 | 20.1 | 3.1 | 12.6 | 9.0 | 8.8 |
| 5.0/360/45 | 4.2 | 11.5 | 15.7 | 3.4 | 8.1 | 6.5 | 6.05 |

Units of PWORK, DWORK, TWORK, DWORK1, DWORK2 - millijoules
Units of NDWK, NDWK2 = millijoules/cm

TABLE 20

MEAN VALUES OF WORK VARIABLES CALCULATED FOR CALF/SMIS TESTS

| TEST CONDITION VEL/LUB./ANGLE | PWORK | DWORK | TWORK | DWORK1 | DWORK2 | NDWK | NDWK2 |
|---|---|---|---|---|---|---|---|
| 2.5/DRY/90 | 6.9 | 30.7 | 37.6 | 4.1 | 26.6 | 16.6 | 16.5 |
| 5.0/DRY/90 | 7.2 | 31.7 | 38.9 | 4.4 | 27.3 | 17.5 | 17.6 |
| 10.0/DRY/90 | 6.7 | 34.5 | 41.1 | 4.9 | 29.6 | 18.2 | 18.4 |
| 2.5/1249/90 | 2.1 | 13.7 | 15.8 | 1.7 | 12.0 | 6.8 | 6.8 |
| 5.0/1249/90 | 2.7 | 16.4 | 19.1 | 2.0 | 14.4 | 8.2 | 8.3 |
| 10.0/1249/90 | 3.2 | 15.8 | 19.0 | 2.4 | 13.4 | 8.4 | 8.6 |
| 2.5/360/90 | 2.4 | 9.5 | 11.9 | 1.4 | 8.2 | 4.8 | 4.8 |
| 5.0/360/90 | 2.4 | 11.0 | 13.4 | 1.6 | 9.4 | 5.5 | 5.5 |
| 10.0/360/90 | 2.1 | 12.2 | 14.3 | 1.8 | 10.5 | 6.0 | 6.0 |
| 5.0/DRY/45 | 5.9 | 27.7 | 33.6 | 3.9 | 23.7 | 14.8 | 14.8 |
| 5.0/1249/45 | 2.0 | 13.9 | 15.9 | 2.1 | 11.8 | 6.6 | 6.6 |
| 5.0/360/45 | 2.6 | 11.2 | 13.8 | 2.1 | 9.1 | 5.4 | 5.3 |

Units of PWORK, DWORK, TWORK, DWORK1, DWORK2 = millijoules
Units of NDWK, NDWK2 = millijoules/cm

The difference is, however, greater for the SMIS tests (intact) than the excised tests.

A comparison of the DWORK values for SMIS and SKIN shows the DWORK to be less in all cases for the excised skin (SKIN). These differences are especially apparent for the CALF. A comparison of the DWORK values for CALF and BUTT shows that for the SKIN tests, DWORK is slightly lower for the CALF. For the SMIS tests DWORK is significantly greater for the CALF with dry needles and essentially the same for the BUTT and CALF for the lubricated needles.

L. VARIATION BETWEEN CADAVERS

Since the 883 tests comprising the results of this study were obtained from four different cadavers, it is logical to examine the data for variation between cadavers in the hope that any consistent observations can be explained by measurable differences in the cadavers themselves, thereby providing additional information on the mechanisms effecting penetration resistance. With this possibility in mind, the basic information and tissue measurements presented in Table 2 were recorded.

Figure 23A through 23L, 24A through 24D, and 25A through 25D present the mean reconstructed force displacement curves, PWORK values and standard deviations, and DWORK values and standard deviations respectively for three of the four cadavers. The sample sizes taken on cadaver #3 were insufficient for these comparisons and so these results were not included. In order to increase the sample sizes for the other three cadavers, results for all three velocities were combined. For the CALF, tests were performed on only two (of these 3) cadavers for the SMIS and SKIN conditions (i.e., no CALF/SMIS tests were done on cadaver #4, and no CALF/SKIN tests were done on cadaver #5). Table 21 summarizes and compares the mean values for selected variables from these three cadavers.

TABLE 21

COMPARISON OF MEAN VALUES OF SELECTED VARIABLES FOR THREE CADAVERS

| TEST CONDITIONS | F2 | | | F3 | | | F4 | | | D2 | | | D3 | | | PWORK | | | DWORK | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 4 | 5 | 6 | 4 | 5 | 6 | 4 | 5 | 6 | 4 | 5 | 6 | 4 | 5 | 6 | 4 | 5 | 6 | 4 | 5 | 6 |
| DRY/SKIN/BUTT | 1.9 | 1.8 | 1.6 | 1.1 | 1.0 | 1.0 | .9 | 1.1 | 1.2 | .9 | .8 | 1.0 | 1.3 | 1.2 | 1.3 | 7.9 | 6.2 | 6.5 | 17.3 | 19.7 | 18.3 |
| 1249/SKIN/BUTT | 1.0 | 1.3 | .8 | .6 | .6 | .5 | .5 | .6 | .5 | 1.0 | .8 | .8 | 1.4 | 1.2 | 1.1 | 5.1 | 4.3 | 3.1 | 9.1 | 12.2 | 9.3 |
| 360/SKIN/BUTT | 1.0 | 1.3 | .9 | .4 | .4 | .3 | .3 | .4 | .3 | .8 | .8 | .8 | 1.2 | 1.2 | 1.3 | 4.0 | 4.3 | 3.0 | 7.7 | 8.1 | 6.2 |
| DRY/SMIS/BUTT | 2.1 | 3.2 | 2.1 | 1.4 | 1.9 | 1.1 | 1.7 | 2.2 | 1.3 | .9 | 1.3 | 1.4 | 1.2 | 1.7 | 1.8 | 8.6 | 18.1 | 13.1 | 26.0 | 27.7 | 15.2 |
| 1249/SMIS/BUTT | 1.1 | 1.2 | .9 | .7 | .8 | .6 | .6 | 1.1 | .8 | .8 | .9 | .8 | 1.1 | 1.3 | 1.2 | 4.4 | 5.2 | 3.8 | 14.8 | 16.5 | 12.2 |
| 360/SMIS/BUTT | 1.0 | 1.1 | .9 | .5 | .6 | .4 | .8 | .9 | .5 | .7 | .9 | 1.0 | 1.0 | 1.2 | 1.4 | 3.7 | 4.3 | 4.8 | 11.4 | 13.2 | 7.2 |
| DRY/SKIN/CALF | 1.7 | – | 1.5 | .7 | – | 1.0 | .7 | – | 1.3 | .9 | – | .7 | 1.4 | – | 1.0 | 6.9 | – | 5.1 | 13.0 | – | 22.5 |
| 1249/SKIN/CALF | 1.0 | – | .8 | .4 | – | .3 | .4 | – | .4 | .9 | – | .6 | 1.3 | – | 1.0 | 3.9 | – | 2.1 | 8.5 | – | 7.9 |
| 360/SKIN/CALF | 1.0 | – | .7 | .4 | – | .2 | .3 | – | .2 | .7 | – | .7 | 1.1 | – | 1.1 | 3.3 | – | 2.3 | 7.4 | – | 4.5 |
| DRY/SMIS/CALF | – | 1.9 | 2.0 | – | 1.3 | 1.5 | – | 2.0 | 1.9 | – | .6 | .8 | – | .9 | 1.1 | – | 5.7 | 8.3 | – | 33.6 | 30.6 |
| 1249/SMIS/CALF | – | .8 | .9 | – | .5 | .5 | – | 1.0 | .9 | – | .6 | .6 | – | .8 | .9 | – | 2.6 | 2.7 | – | 16.4 | 13.9 |
| 360/SMIS/CALF | – | .7 | .8 | – | .3 | .4 | – | .7 | .6 | – | .5 | .5 | – | .8 | .9 | – | 2.1 | 2.5 | – | 11.1 | 10.6 |

Units of F2, F3, F4 = newtons
Units of D2, D3 = centimeters
Units of PWORK, DWORK = millijoules

The first point to be noted from these results is that in many cases there are significant differences from one cadaver to another. For some test strata there is a significant difference in the value of peak force (e.g., BUTT/SMIS/DRY; BUTT/SKIN/1249, BUTT/SMIS/1249, BUTT/SKIN/360) while for others the peak force values are very close (e.g., CALF/SMIS/DRY, CALF/SMIS/1249, BUTT/SMIS/360, CALF/SMIS/360). For some strata there is a significant change in D2 between two or more cadavers (e.g., BUTT/SMIS/DRY, BUTT/SKIN/1249, CALF/SKIN/1249, BUTT/SMIS/360) while for others the differences are insignificant (e.g., CALF/SMIS/1249, BUTT/SKIN/360, CALF/SKIN/360, CALF/SMIS/360). Also in some strata there are significant differences in the values of PWORK (BUTT/SMIS/DRY), DWORK (e.g., BUTT/SMIS/DRY), and in the force ratio F43 (e.g., BUTT/SKIN/DRY, CALF/SKIN/DRY).

Upon closer examination of these results, one begins to get the impression that these cadaver differences are not very consistent or explainable in terms of measured cadaver and tissue parameters. This, indeed, may be the case to some extent since all possibly important parameters were not measured or controlled (e.g., actual skin tension, contact pressure on intact skin). In spite of this, the graphs in Figures 26 through 29 were constructed in an attempt to visualize more clearly any consistent differences between cadavers. From these figures a number of trends can be observed:

F2

| | | |
|---|---|---|
| a) | For SMIS/BUTT | Cad. #5 > Cad. #4; Cad. #5 > Cad. #6 |
| b) | For SKIN/BUTT | Cad. #4 > Cad. #6; Cad. #5 > Cad. #6 |
| c) | For SMIS/CALF | Cad. #6 > Cad. #5 |
| d) | For SKIN/CALF | Cad. #4 > Cad. #6 |

D2

a) For SMIS/BUTT — Cad. #4 < Cad. #5 < Cad. #6

b) For SKIN/BUTT — Cad. #4 > Cad. #5; Cad. #5 < Cad. #6

c) For SMIS/CALF — Cad. #5 < Cad. #6

d) For SKIN/CALF — Cad. #4 > Cad. #6

PWORK

a) For SMIS/BUTT — Cad. #5 > Cad. #4

b) For SKIN/BUTT — Cad. #4 > Cad. #6

c) For SMIS/CALF — Cad. #5 < Cad. #6

d) For SKIN/CALF — Cad. #4 > Cad. #6

DWORK

a) For SMIS/BUTT — Cad. #5 > Cad. #4 > Cad. #6

b) For SKIN/BUTT — Cad. #5 > Cad. #4; Cad. #5 > Cad. #6

c) For SMIS/CALF — Cad. #5 > Cad. #6

d) For SKIN/CALF/LUB. — Cad. #4 > Cad. #6
SKIN/CALF/DRY — Cad. #4 < Cad. #6

From these relationships the following statements can be made:

1) Peak force and PWORK for cadaver #5 are consistently higher than for cadaver #6 for BUTT tests but consistently lower for SMIS/CALF tests.

2) Peak force and PWORK for cadaver #4 are greater than for cadaver #6 for SKIN/BUTT and SKIN/CALF.

3) D2 for cadaver #4 is consistently smaller than for cadaver #5 for SMIS/BUTT.

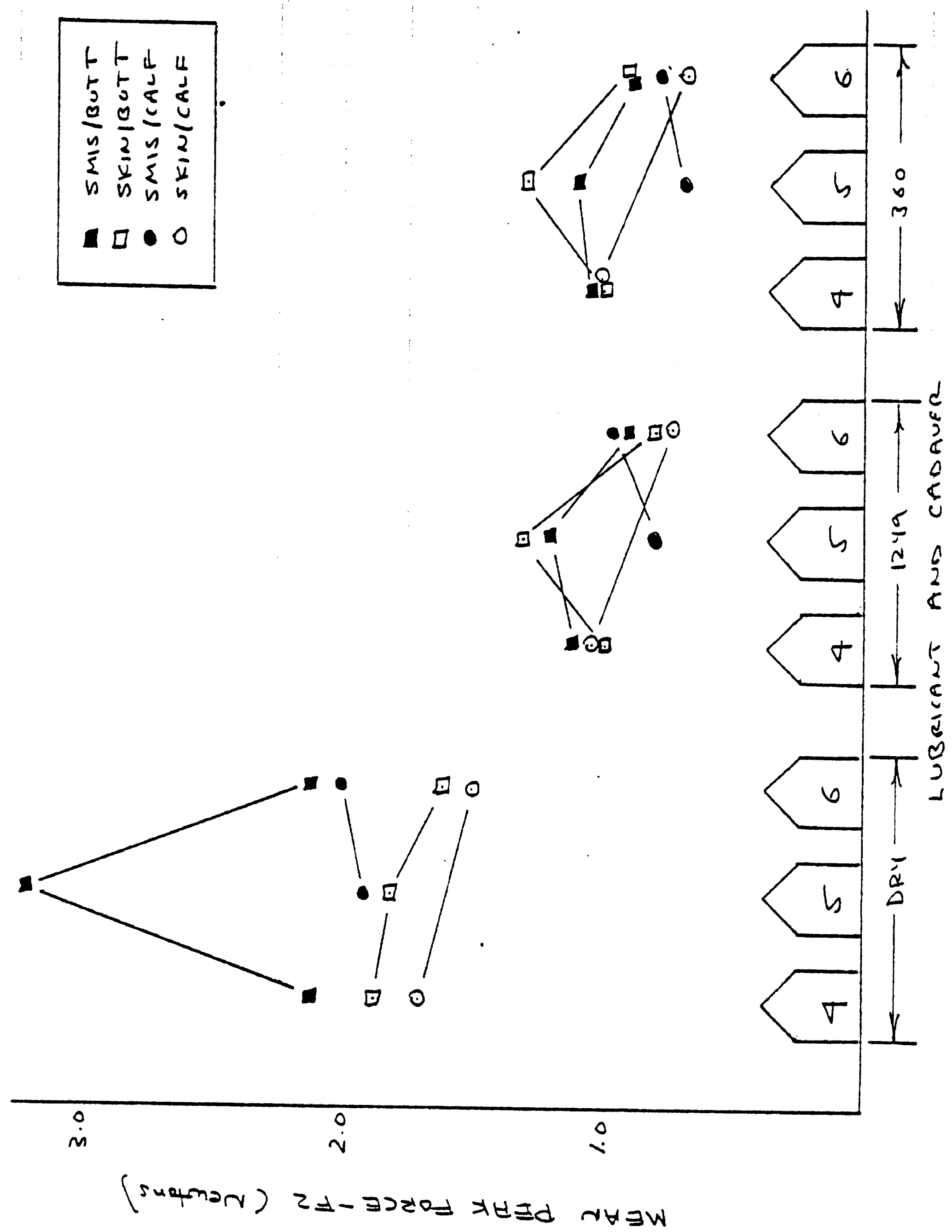



FIGURE 26 Comparison of Peak force Values from Cadavers 4, 5, and 6.

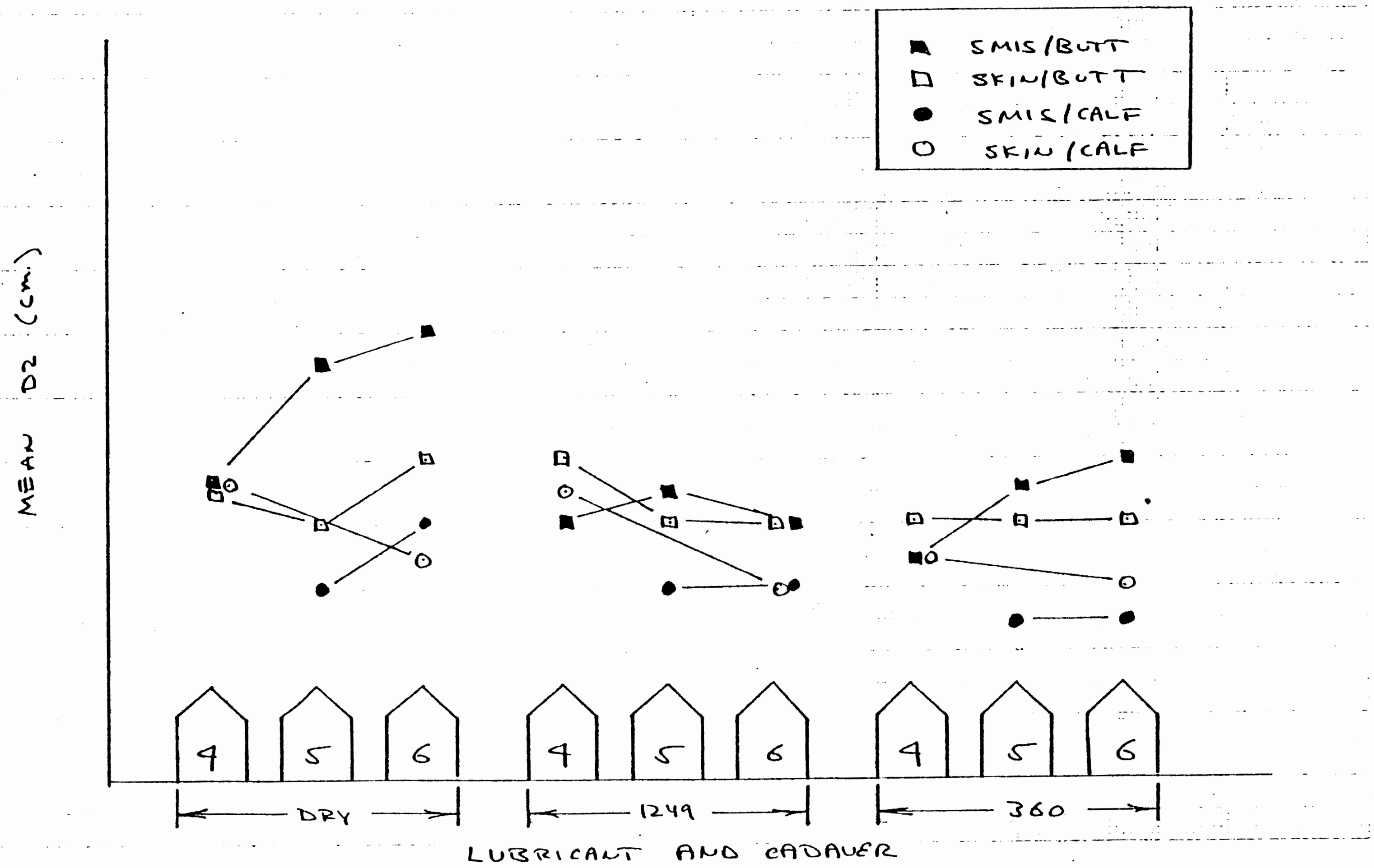



FIGURE 27 Comparison of D2 Values from Cadavers 4, 5, and 6

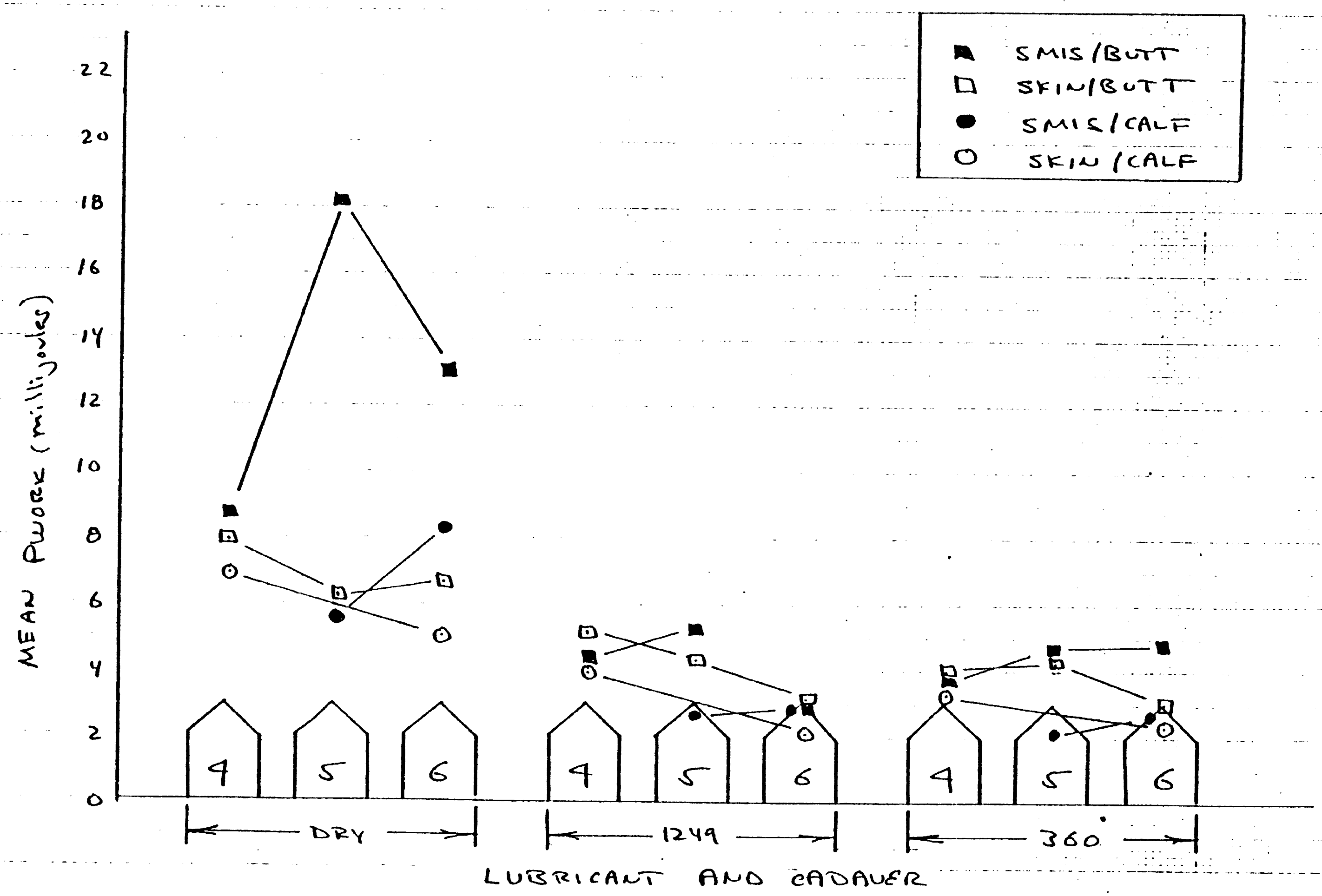



FIGURE 28 Comparison of PWORK Values from Cadavers 4, 5, and 6

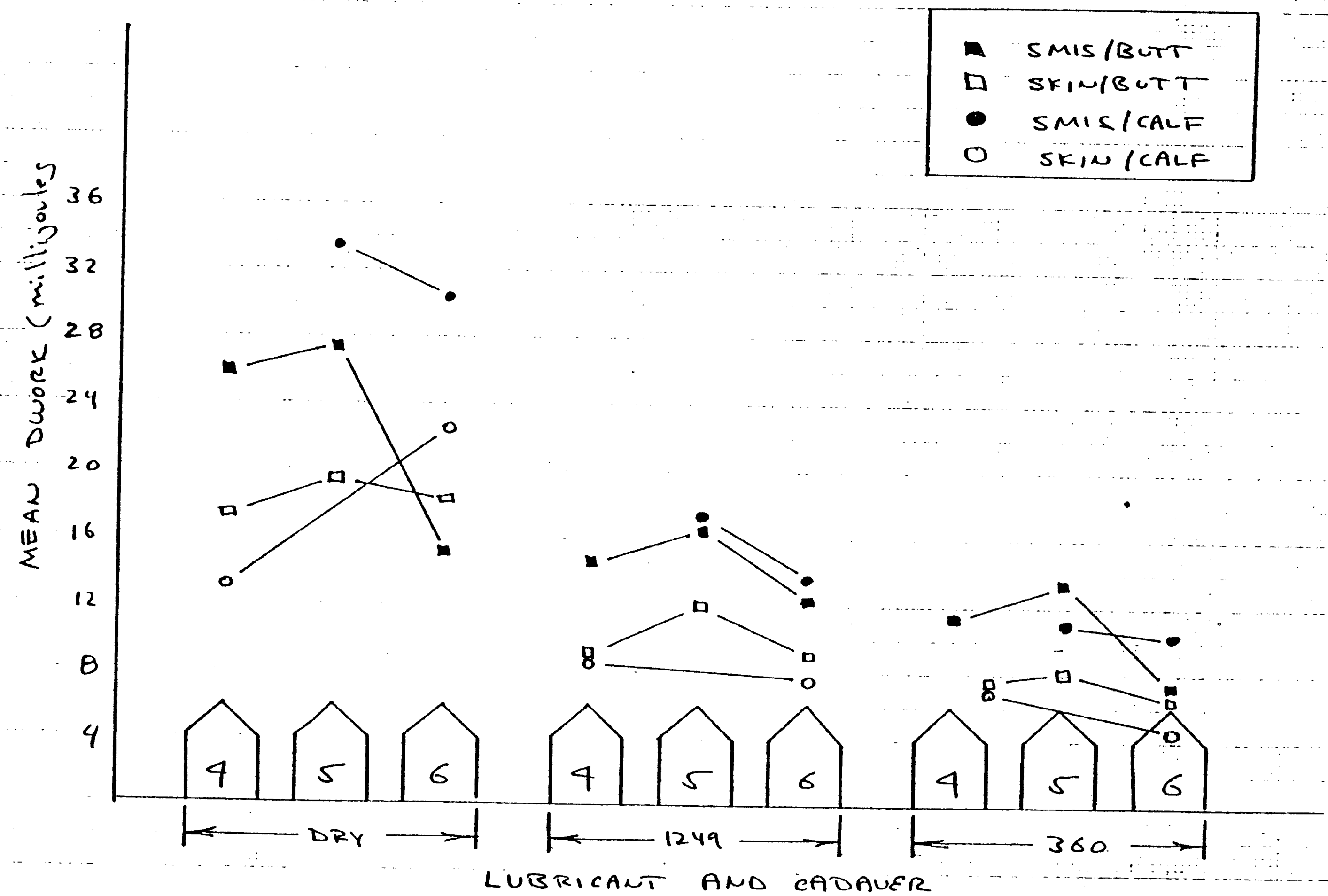



FIGURE 29 Comparison of DWORK Values from Cadavers 4, 5, and 6.

4) D2 for cadaver #4 is consistently greater than for cadaver #6 for SKIN/CALF.

5) DWORK for cadaver #5 is consistently higher than for cadaver #4 or cadaver #6.

6) DWORK for cadaver #4 is greater than for cadaver #6 for lubricated needles in SKIN/CALF and less for dry needles in SKIN/CALF.

Examining now the data in Table 2 with regard to these observations the following comments can be made:

Peak force in cadaver #5 was higher than for cadaver #6 for BUTT tests even though the measured BUTT skin thickness was less (2.2 mm vs 3.2 mm). There is, however, a large difference in the age of the cadavers (39 vs 55) and in the time since death (2 vs 6 days) which could account for these differences. Intuitively one might have expected the peak force to be smaller for cadaver #5 than for cadaver #6 for SMIS/BUTT due to a thinner skin and less subcutaneous fat. At the time of testing it was observed, however, that the buttock tissue of cadaver #5 was quite easily depressed (i.e., soft) in relation to other cadavers. This is further evidenced by the fact that D2 was greater for cadaver #5 than for cadaver #4 (statement 3 above) for SMIS/BUTT even though the fat was thicker on cadaver #4. It appears that the condition of the skin and underlying tissue due to age and possibly time since death, may be more important factors in penetration resistance than the tissue thickness measurements themselves. The reason for the reversal in the relationship of peak forces from SMIS/BUTT to SMIS/CALF for these two cadavers is not obvious from the data of Table 2.

Statement 4 above, that D2 is greater for cadaver #4 than cadaver #6 for SKIN/CALF could be a result of different SKIN tensions, cadaver #4 being considerably older than cadaver #6. These tension differences would not necessarily be indicated by the grid relaxation factors shown in Table 2 unless the differences were a result of the excising process itself.

The high values of DWORK measured on cadaver #5 are also not clearly explained by the data of Table 12 but again could be due to age and tissue condition differences previously noted. The reason for the reversal in the relationship of DWORK's for cadavers #4 and 6 for lubricated versus dry needles in skin calf (statement 6) is also not explainable from these data but clearly points out the fact that distinctly different mechanisms are operating in the lubricated and dry conditions during the drag portion of penetration.

A more detailed examination of all the measurement variables and their variations between cadavers in terms of the cadaver information in Table 2 is beyond the scope of this study and perhaps premature with the small number of cadavers and limited measurements on each. It would seem, however, based on the comparisons of this section, that a more thorough and careful quantification of cadaver tissue should be a part of any future testing and could provide useful information on the mechanism of the injection process.

## SECTION 4

## CONCLUSIONS, DISCUSSION, AND SUGGESTIONS

### A. DISCUSSION AND CONCLUSIONS

#### 1. Velocity Dependency

Within the velocity range of 2.5 to 10.0 inches/second the resistance to penetration is relatively insensitive to penetration velocity. Peak force values and PWORK values are comparable for all three velocities tested although there appears to be some tendency for D2 and PWORK to decrease with increasing velocity, especially for SMIS/BUTT and SKIN/CALF/DRY conditions. For SMIS tests, the values of F4 and DWORK (and to a lesser extent, F3) tend to increase with higher velocities as does the ratio of F4 to F3. In a statistical sense, a significant difference in mean values can be found at the .05 level for a number of selected measurement variables using the Student T-test to compare mean values for the velocity strata. There is, however, no pattern to these results which would suggest a consistent and clear velocity dependency. From a practical viewpoint, in terms of patient acceptance and tissue trauma, it is doubtful that any of the observed velocity differences would be of importance.

#### 2. Angle Dependency

For injection angles between 45 and 90 degrees to the skin surface, the penetration resistance and force-displacement characteristics are virtually independent of penetration angle. The only consistently observable difference (which was not always statistically significant) was a tendency for D2 to be smaller at 45° for the SMIS tests. This is no doubt due to the fact that the needle does not directly compress the skin and subcutaneous tissue as in the 90 degree tests and so there is less tissue deformation at peak force during the 45 degree tests. If peak force is, in fact, correlated with some point on the needle tip (e.g., heel) exiting from the dermis, one would expect that D2 would be greater for 45 degree tests, other factors being equal. The material deformation effect, however, could and probably does mask any such observation.

3. Lubricant Comparisons

In general, the mean values of peak force, F2, and penetration work, PWORK, for DRY needles were 1 1/2 to 3 times greater than for the 1249 and 360 lubricated needles which were very comparable to each other. Mean values of DWORK for DRY needles were 2 to 3 times greater than for 360 lubricated needles and 1.5 to 2.3 times greater than for 1249 lubricated needles. The primary difference between the 1249 and 360 lubricated needles was in the values of DWORK, the 1249 values being about 1 1/2 times greater on the average. It was also observed that the mean values of D2 were greater for the DRY needles, especially for the SMIS tests and that the overall differences between DRY and lubricated needles were most notable for SMIS tests. There was virtually no significant difference in peak force or PWORK values between the two lubricated conditions for any test strata. The largest ratio for D2/D4 (i.e., the greatest D2 value) occurred for BUTT/SMIS tests while the smallest ratio was for CALF/SMIS tests for all lubricant conditions, although these differences were greatest for DRY needles.

4. Buttock vs. Calf

A consistent finding in comparing BUTT and CALF tests was a greater mean value of peak force (F2) and PWORK for the BUTT tests. For skin tests the mean values of F2 and PWORK were about 1.1 to 1.4 times greater for BUTT tests while for SMIS tests the mean values of F2 and PWORK were 1.2 and 1.7 times greater, respectively, for BUTT tests. For SMIS tests, the mean value of D2 was also significantly greater for the BUTT tests, reflecting the thick layer of subcutaneous relatively compressible fat in the buttock region in comparison to the predominance of the stiffer muscle tissue at the calf.

For excised skin, DWORK is consistently higher for the BUTT than CALF. For intact skin (SMIS tests) the value of F4 and the ratio F4 to F3 is consistently greater for CALF tests although a T-test does not always show a significant difference in normalized dragwork since the mean value of F3 tends to be smaller for CALF tests.

The differences between CALF and BUTT tests for excised skin (greater F2, PWORK, and DWORK for BUTT) are probably due to differences in skin thickness and possibly skin tension at the two sites, while differences for SMIS tests (greater F2, D2, and PWORK for BUTT and greater F4 and F4/F3 for CALF) are clearly a result of the properties of the subcutaneous tissue.

5. SKIN vs. SMIS

A distinct advantage of using cadaver tissue as opposed to living tissue is that the injection process can be studied on the skin or dermis itself without the effects of the underlying tissues. In comparing the results for intact versus excised skin tissue, the distinct difference is in the drag portion of the force-displacement curve. As would be expected, DWORK, NDWK, NDWK2, and F4 are consistently greater for the SMIS tests. In fact, for all SMIS tests the ratio of F4 to F3 is greater than 1.0 while for all but one case the ratio of F4 to F3 is less than 1.0 for SKIN tests.

Concerning peak force, F2, it is interesting and significant that in only one case (BUTT/DRY) was there a statistically significant difference between intact and excised tissue. Thus there is little question that the peak force is directly attributable to the interaction of the needle (probably some point on the tip) with the dermis itself. The importance of the subcutaneous tissue in modifying the penetration phase of the force-displacement curve is most clearly seen, however, in the position of the peak force, or D2. For the CALF tests, the peak force occurs substantially sooner for SMIS than SKIN tests, while for the BUTT tests, it occurs slightly later or at about the same distance for SMIS tests compared to skin tests.

6. Intra-strata Variation

In Section F of Chapter 3 it was noted that within each test strata there could be considerable variance in the force-displacement curves. This is not so surprising to anyone who has worked with biological systems and simply points out the complexity and non-homogeneity of biological tissues, the difficulty of attempting to quantify and understand this behavior, and the necessity of using a tissue simulant in any standard test.

7. Inter-cadaver Variation

A substantial amount of inter-cadaver variation was found, some of which was consistent between test strata and explainable on the basis of measured cadaver parameters. Other variations were not so consistent or understandable in terms of measured tissue properties.

On the one hand this variation between cadavers is somewhat disturbing. It is likely, however, that these variations reflect the response variation which is to be found on living subjects due to age, body composition, tissue condition, and other factors and in this sense are a necessary part of the total picture. If this is the case, important information for understanding the injection process should be obtained from a series of carefully controlled experiments on a number of cadavers. This would involve the development of a set of tests for precise quantification of cadaver tissue and condition, including such factors as skin tension and tissue compressibility, and establishment of a single test protocol for the comparisons.

8. Cadaver vs. Living Tissue

Two advantages of using cadaver tissue were mentioned in Section 1 - a) the ability to obtain large sample sizes for statistical comparisons, and b) the ability to study the tissue response in a number of ways not possible on living subjects (e.g., excised skin). The question of the similarity of the responses of cadaver tissue and living tissue to the injection process is an important one, however, and must be considered. As outlined in Section 1, a comparison of living and dead tissue was made by Stathopulos, et al. in the early stages of this project. Injection equipment used on living subjects was brought to HSRI and used in performing tests on one cadaver. While the analysis of the resulting data has not been completed at this time, initial indications are that the living and dead tissue results are quite comparable (5).

Upon reviewing the literature on skin properties and skin testing, no evidence could be found that any major changes occur to the properties of the skin within several days of death as long as the tissue is refrigerated. Nahum, et al. (1973) in performing puncture tests on cadaver tissue noted that for unembalmed tissues from 36 hours to several days old

> .....There was no evidence of initial stiffening of the tissues when the earliest tests were performed, and no change was noted over the several days of testing, during which the material was refrigerated except when under actual test. To the touch, the tissues at all times felt very life-like.

For the tests performed in this study it could also be said that the cadaver skin tissue felt very "normal" and (except for temperature) could not be distinquished from living skin. With regard to the effects of temperature it should be noted that Gadd, et al. (1965), found no effects of temperature on penetration resistance of skin over a range down through the freezing point of the tissues.

Probably the greatest difference in living and dead tissue is not due to changes in the skin, but rather to changes in the subcutaneous tissue. Two types of effects could be important. One is related to the natural turgor of the tissue due to vascular pressures and cellular pressures. Thus living tissue probably has a greater tendency to "bounce back" after being depressed than cadaver tissue. The second effect concerns the differences between living and dead muscle tissue and would probably be significant only in those body regions where the layer of fat is relatively thin (e.g., arms and legs). Two differences exist. First, muscle has undergone some chemical changes (protein coagulation) in passing through the state of rigor mortis.[1] Second, dead muscle, even if it were biochemically the same, cannot undergo active tension likely to occur in living subjects.

From the results of this study, comparing buttock and calf penetration responses, it is clear that the properties of the underlying tissue can have a significant effect on parameters of the force-displacement curve. From this, one may infer that changes in the subcutaneous tissue due to loss of fluid pressure and/or changes in muscle could cause changes in the force-displacement response. Some insight into the magnitude and significance of any such changes may be provided by the report in preparation by Stathopulos, et al. (5).

---

[1] It should be noted that rigor mortis has passed within 24 hours of death and does not exist at the time of testing.

It should also be pointed out, however, that the ability of muscle to contract in living subjects could be a significant factor increasing the variability of the measured response. Tests examining the difference between injection responses in relaxed and tensed muscle (possibly using EMG's as an indicator) tissues should be performed and the effects of muscle tension considered and perhaps controlled in future testing of living subjects.

9. Effects of Subject Age and Sex

It is well known and documented ( 3 ) that the composition and mechanical properties of skin change with age and so it might be expected that penetration resistance might change as well. While some significant variations in penetration parameters exist between the four cadavers (aged 39 to 79) used in this study, no correlations with subject age or sex are apparent. In addition to the small sample size which makes any meaningful correlation difficult, two other explanations seem plausable. First, it may be that changes and differences in dermal and subcutaneous tissue with age do not significantly influence the tissue resistance to punctures of the size of 22 gauge hypodermic needles. Second, it may be that other factors which affect skin and tissue characteristics such as subjects health and physical condition are more significant and therefore mask any correlations with age or sex.

10. Skin Tension

In this study, the intact tissue tests were performed with the skin surface compressed somewhat by a plexiglass plate, but with otherwise normal skin tension as it exists on the cadaver. Tension of excised skin was maintained as near normal as possible by gluing an aluminum ring to the intact skin before excising. No attempt was made, however, to measure or vary the skin tension to determine its importance. It may be, for example, that variations in the skin tension between cadavers could account for some of the variance between cadavers. The results of this study indicate that, at least to the extent that skin tension affects the deformability of the skin during needle penetration, it will probably affect some of the penetration parameters. This would also suggest that skin tension may be a more important consideration where the subcutaneous tissue is primarily fat and more easily deformed.

### 11. Recommended Characteristics of a Standard Skin Simulant and Test Protocol

Perhaps the most significant result of this study in terms of choosing a standard skin simulant and test protocol is that observable differences exist between (1) excised and intact skin and (2) intact skin at different body regions. In other words, the measured parameters of the force-displacement curve on needle penetration can be significantly affected by the characteristics of the subcutaneous tissue. Differences may result not only in values of peak force (BUTT vs. CALF) but also in the needle position at peak force and in the drag phase of the penetration process.

The extent to which these differences in force-displacement characteristics must be considered in the measurement and comparison of needle and lubricant modifications depends ultimately on their correlation with patient reaction and tissue trauma. It would seem at this time, however, that to use a single piece of thin synthetic material as a skin simulant may be inadequate (or at least less than the best possible situation). Rather, a composite of two materials may be necessary to simulate completely the force-displacement response characteristics of the injection process. The outer material would be relatively thin and would represent the dermis. The inner material would be relatively thick for representing the fat and muscle and, in fact, two or three different materials could be used interchangeably to encompass the range of tissue characteristics demonstrated by variation of fat/muscle thicknesses and muscle tensions.

Beyond these considerations, the material(s) should demonstrate the general force-displacement characteristics of real tissue consisting of the rise to a peak force at .5 to 1.5 centimeters (depending on conditions) and a sharp decrease to a lower and gradually increasing (with penetration depth) drag force. It would also be desirable that the force values be similar to those reported in this study for the various lubricant conditions, but it is more important that the relationships of the force values and work quantities be similar within and between test conditions. That is, the synthetic material should demonstrate proportionately lower work and force values for the lubricated needles than dry needles and lower drag work values for the 360 lubricant than for the 1249 lubricant, etc.

With regard to velocity and penetration angle dependency, the results here suggest that the force-displacement characteristics need not and probably should not be velocity or angle dependent within the ranges tested.

With these considerations in mind, a recommended standard test protocol would consist of the following:

1. Use of a dual layered synthetic material, approximately 8" in diameter, the upper layer of which is thin and, when tested alone, simulates the force-displacement characteristics of excised skin. The lower layer should be 1 1/2 - 2" thick and simulate the compressibility and drag characteristics of fat/muscle combinations. This composite of material should probably be supported on the bottom and sides by a rigid container.

2. Penetration of the above material using a constant penetration velocity of 5"/second to a depth of 1.5 inch.

3. Penetration angle of 90° to the surface of the skin simulant.

4. Computerized control of the experiemnt and on-line digitization of the data is desirable, although not essential, for fast and accurate data collection and analysis.

## B. SUGGESTIONS FOR FUTURE WORK

In this study an injection device and data collection and analysis system were developed for obtaining penetration data of hypodermic needles in cadaver tissue. A general data base of force-displacement curves during needle penetration was established for a wide range of needle, tissue, and test conditions and, in addition, a series of tests were performed on some potential skin simulants and the results compared (4) with the results in human tissue. From each penetration response curve, a number of measurements were computed in an attempt to quantify and compare results from different test strata. This report has been an attempt to describe and summarize this work and the results. Because of the volume of data, it has not been possible to examine every relationship and measurement variable as completely as may be desirable. Thus, it is not intended that this report represent the end of the data analysis of the 883 cadaver tests performed for this study or that the findings presented in the preceding pages represent final answers or conclusions. To be sure, this study should be regarded as only a preliminary and basic step toward obtaining a complete understanding of the injection process, and the mechanisms involved in generating the penetration resistance response characteristics, and toward determining and designing a standard tissue simulant and test protocol.

The following paragraphs list and discuss (not in any priority order) a number of tasks which are worthy of consideration for future work.

1. Develop a series of tests for quantifying tissue compressibility (softness) for comparing penetration results between body regions and subjects (living or dead).

2. Develop a device for measuring and modifying cadaver excised skin tension in order to determine its effects on penetration force-displacement characteristics and compare results between cadavers.

3. Modify and improve the needle injection device to:
   a) reduce its size and weight
   b) increase its velocity range
   c) improve its velocity control features
   d) reduce noise at penetration/dwell and dwell/retraction transition points.

4. Conduct additional cadaver tissue tests using new and better procedures (including 1 and 2 when available) to describe and quantify tissue differences. A variety of new tissue conditions could be used such as penetrating intact fat or intact muscle with skin removed in order to study the characteristics and contribution of each tissue separately. Also, the performance of lubricants

should be tested after pre-penetration through a rubber membrane as occurs prior to actual use.

5. Develop a technique for monitoring the depth of needle penetration into tissue in order to correlate force values with needle geometry and tissue anatomy. The present series of tests monitored needle position but due to tissue depression, this does not describe needle position in the tissue. It is only through measuring actual needle depth in the tissue that the observed features of the force curve can ultimately be explained in terms of needle geometry, tissue characteristics, etc. If, for example, peak force is due to the heel of the needle tip exiting the dermis, then the peak force should correlate closely with skin thickness for similar needles, regardless of the subcutaneous tissue characteristics.

   The ultimate goal would be to develop a technique which could be easily and reliably used to monitor needle depth in the tissue of both cadaver and living subjects. Prior to such a device, however, it may be of interest and value to use existing techniques such as high speed films and high speed x-rays (recently developed at HSRI) on a limited number of intact and excised tissue cadaver tests in order to correlate needle depth with force data.

6. Continue search for and testing of potential skin and subcutaneous tissue simulants.

7. Begin to investigate procedures for measuring patient acceptance (e.g., pain) and tissue trauma for eventual correlation with force-displacement data.

8. Perform testing of new needle designs and new lubricants.

9. Expand injection testing and quantification to include characteristics of dwell and retraction phases of the injection process.

10. Perform injection tests with other types of needles and test set-up conditions (e.g., IV needles injected at low angles into pressurized veins).

11. Continue collecting data on living subjects examining effects of muscle contraction on the force-displacement curves.

REFERENCES CITED

1) Gadd, C.W., Peterson, F.J., Lange, W.A. Strength of Skin and Its Measurement with Special Application to Trauma. In Biomechanics Monograph. ASME, New York, pp. 184-191 (1967).

2) Nahum, A.M., Gadd, C.W., Schneider, D.C. and Madeira, R.C., Tolerances of Superficial Soft Tissues to Injury. Journal of Trauma, 12(12): 1044-1052 (1973).

3) Ridge, M.D. and Wright, V. Mechanical Properties of Skin: A Bio-engineering Study of Skin Structure. J. Applied Physiol. 21(5): 1602-1606 (1965).

4) Schneider, L.W., Peck, L.S., Melvin, J.M. Penetration Characteristics of Hypodermic Needles in Selected Skin Simulants. (In preparation).

5) Stathopulos, R., Berger, H. Choma , P.
Preliminary Study of Hypodermic Needle Puncture in Live and Cadaveric Human Flesh to Examine Influence of Lubricant Systems, Injection Angle, and Injection Velocity on Penetration Resistance of Flesh Medium. BD reports 78-008, 78-009, and 78-11 (In preparation).

# APPENDIX A

## FIGURES 15 THROUGH 25

The figures contained in this appendix compare the measurement results for the different test strata using mean reconstructed force-displacement curves and plots of PWORK and DWORK. Due to the number of graphs in each figure they have been separated from the main text for ease of reading.

FIGURE 15 (A-L)

Graphical Comparisons of Mean Reconstructed Force-Displacement Curves for the Three Penetration Velocities at Different Test Strata

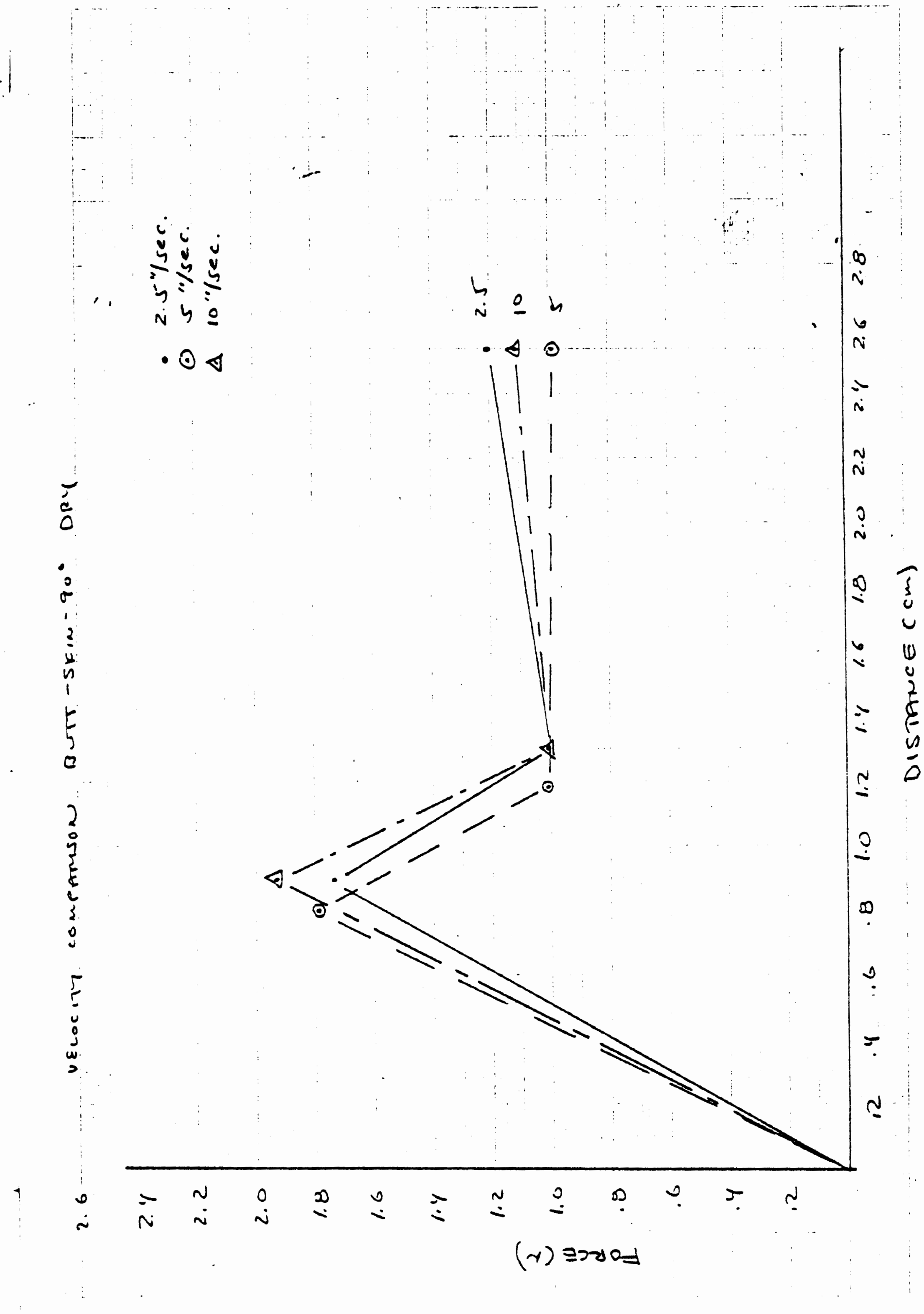

VELOCITY COMPARISON BUTT-SKIN-90° DRY
• 2.5"/sec.
⊙ 5"/sec.
Δ 10"/sec.
2.5
10
5
FORCE (N)
DISTANCE (cm)
.2 .4 .6 .8 1.0 1.2 1.4 1.6 1.8 2.0 2.2 2.4 2.6 2.8
.2 .4 .6 .8 1.0 1.2 1.4 1.6 1.8 2.0 2.2 2.4 2.6

FIGURE 15 A

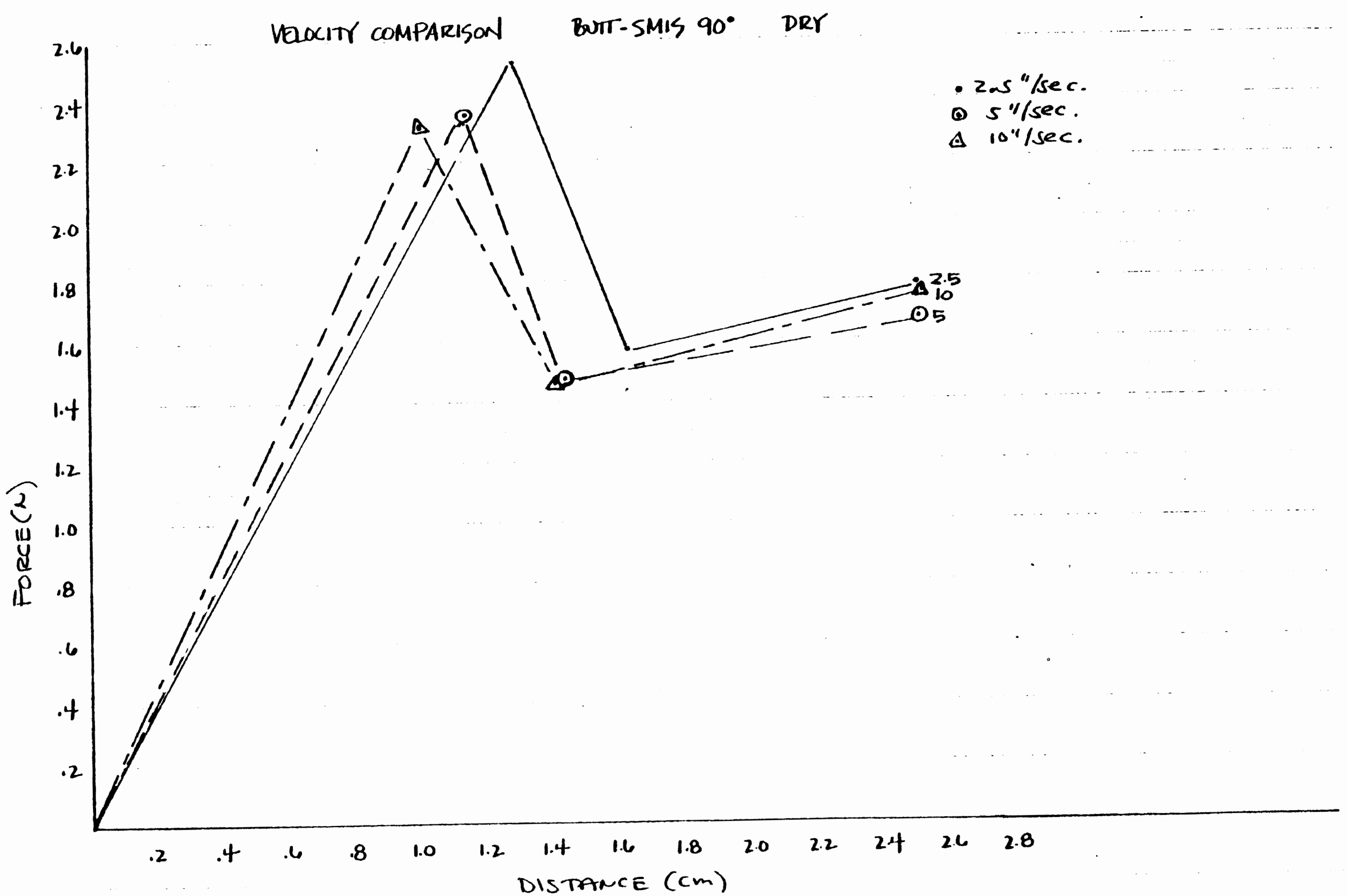
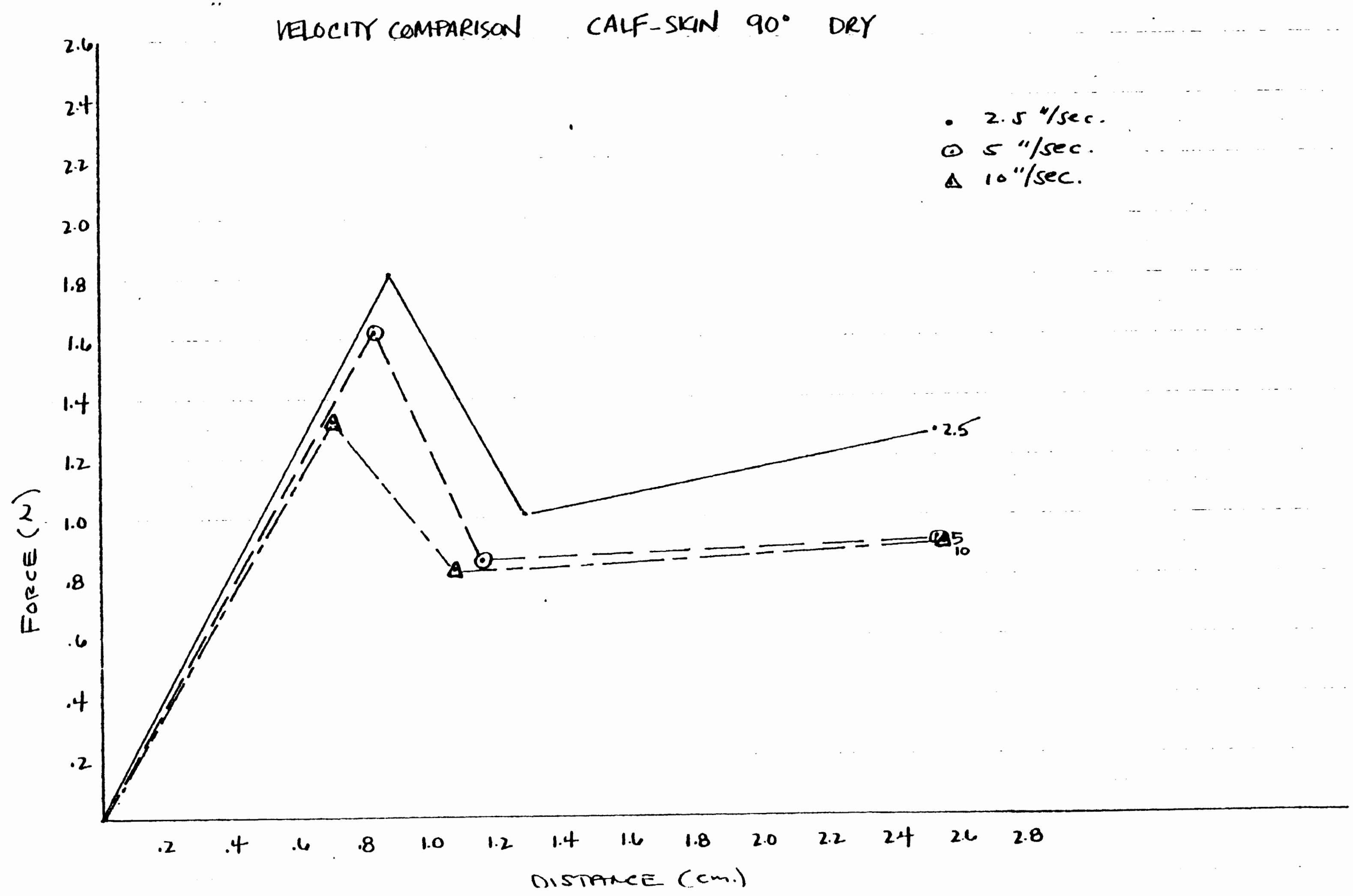

VELOCITY COMPARISON
BUTT-SMIS 90°
DRY
• 2.5 "/sec.
⊙ 5 "/sec.
△ 10"/sec.
2.5
10
5
FORCE (λ)
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
.2
.4
.6
.8
1.0
1.2
1.4
1.6
1.8
2.0
2.2
2.4
2.6
2.8
DISTANCE (cm)

FIGURE 15B



VELOCITY COMPARISON CALF-SKIN 90° DRY
• 2.5 "/sec.
⊙ 5 "/sec.
Δ 10"/sec.
FORCE (2)
DISTANCE (cm.)
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
.2 .4 .6 .8 1.0 1.2 1.4 1.6 1.8 2.0 2.2 2.4 2.6 2.8
2.5
5
10


FIGURE 15C

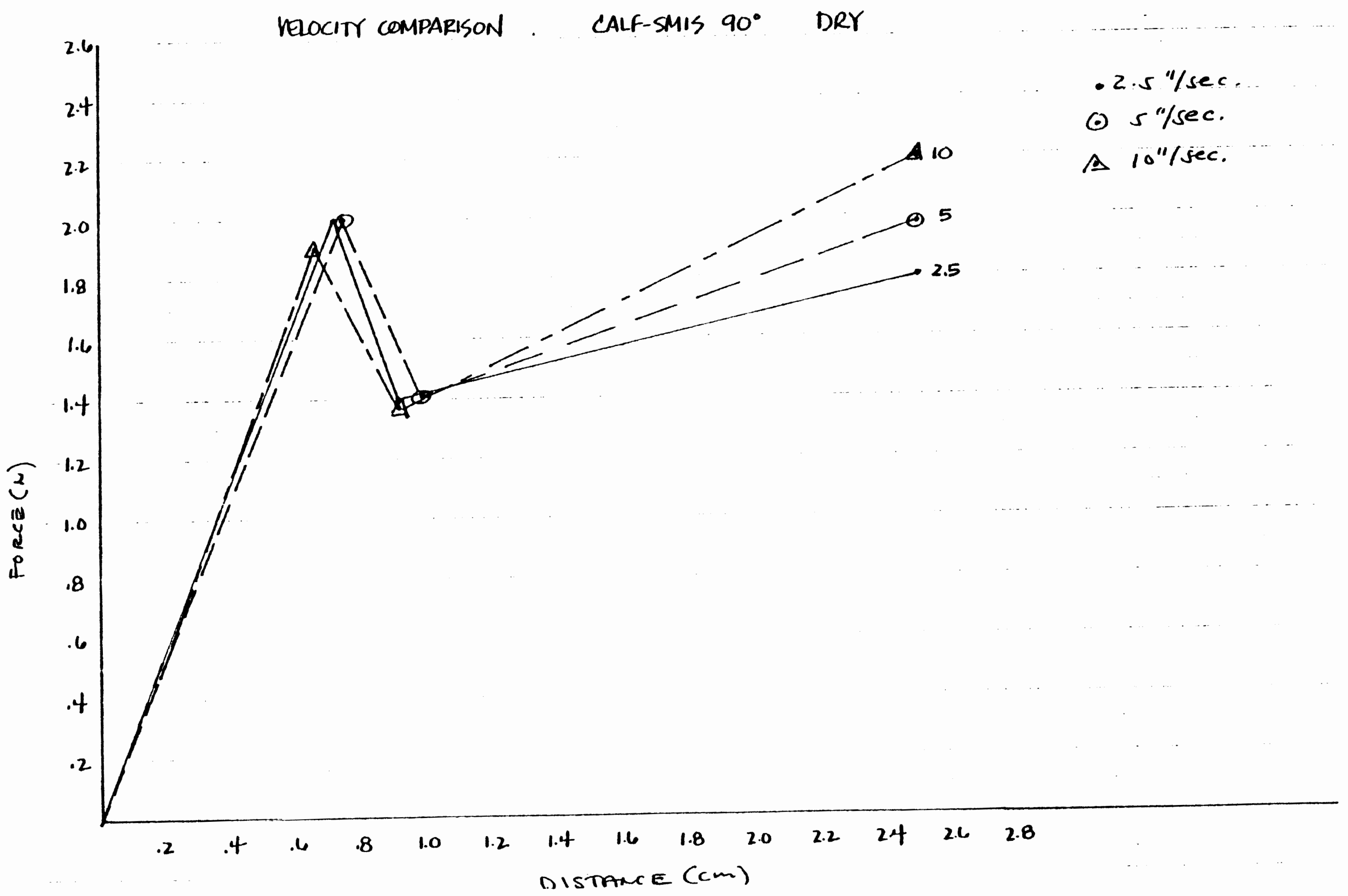

VELOCITY COMPARISON
CALF-SMIS 90°
DRY
• 2.5 "/sec.
⊙ 5 "/sec.
△ 10"/sec.
10
5
2.5
FORCE (lb)
DISTANCE (cm)
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
.2
.4
.6
.8
1.0
1.2
1.4
1.6
1.8
2.0
2.2
2.4
2.6
2.8

FIGURE 15 D

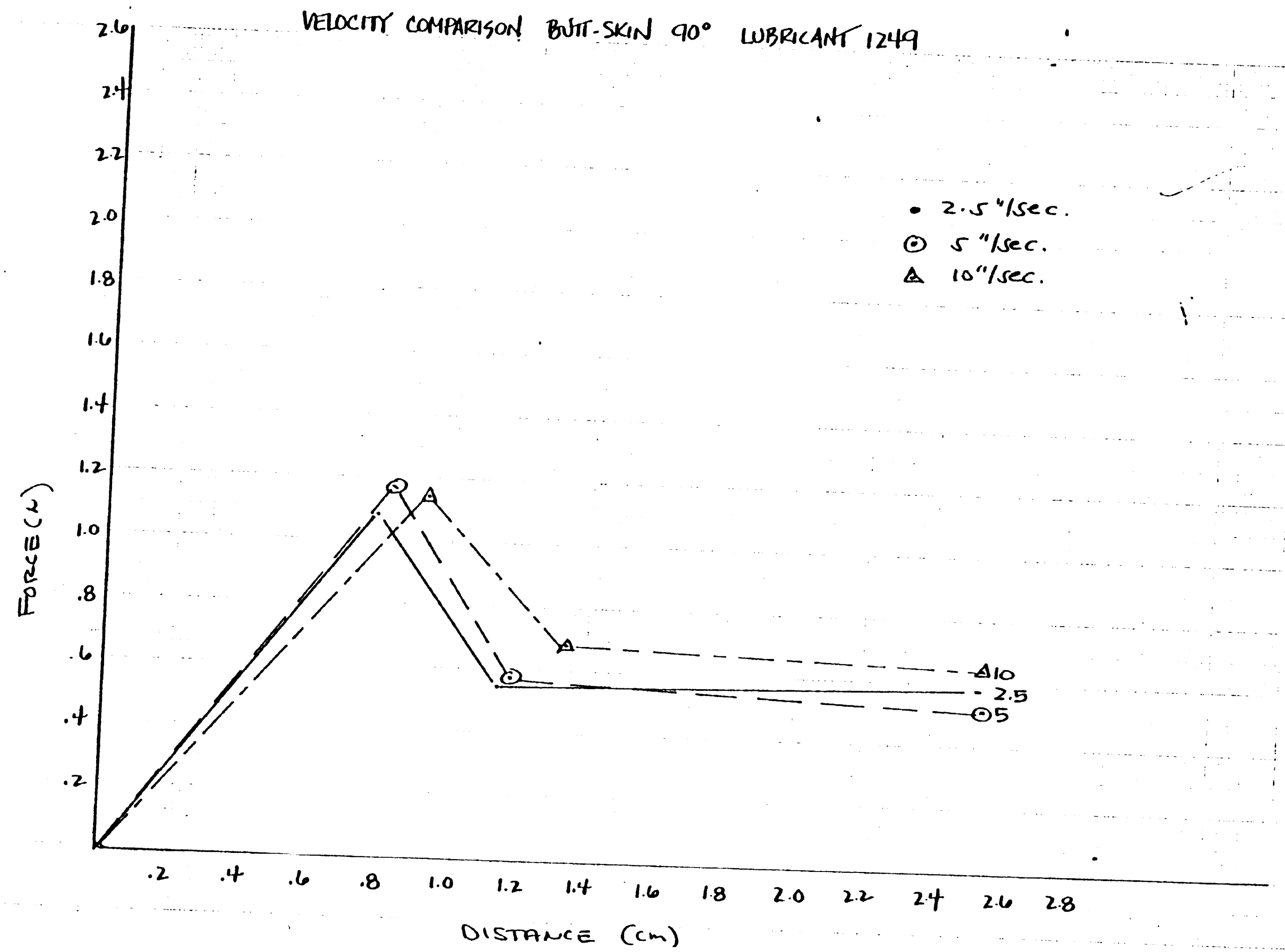

VELOCITY COMPARISON BUTT-SKIN 90° LUBRICANT 1249
• 2.5 "/sec.
⊙ 5 "/sec.
△ 10"/sec.
△10
• 2.5
⊙5
FORCE (N)
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
.2
.4
.6
.8
1.0
1.2
1.4
1.6
1.8
2.0
2.2
2.4
2.6
2.8
DISTANCE (cm)

FIGURE 15 E

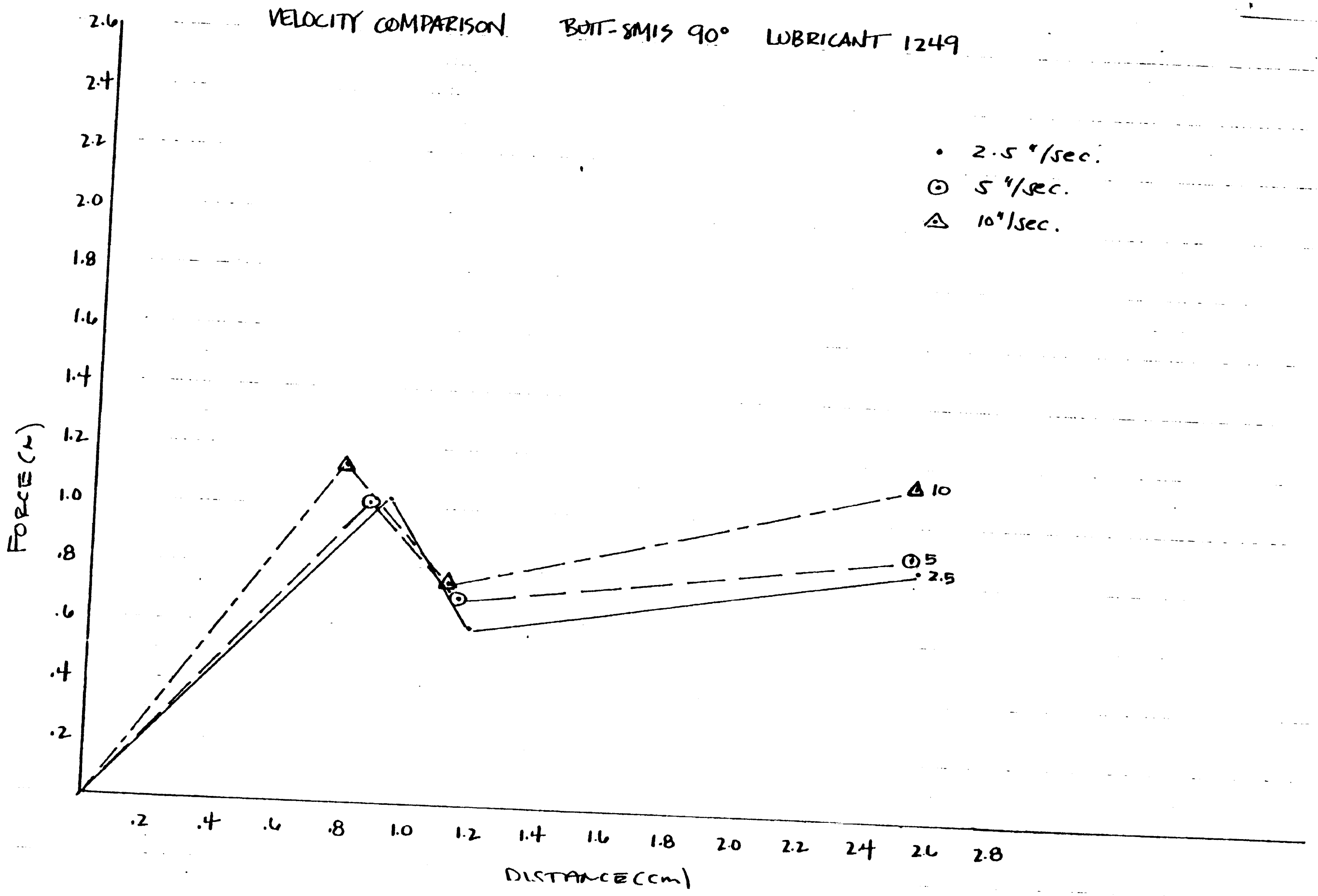

VELOCITY COMPARISON   BUTT-SMIS 90°   LUBRICANT 1249
• 2.5 "/sec.
⊙ 5 "/sec.
△ 10"/sec.
△ 10
⊙ 5
• 2.5
FORCE (lb)
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
.2 .4 .6 .8 1.0 1.2 1.4 1.6 1.8 2.0 2.2 2.4 2.6 2.8
DISTANCE (cm)

FIGURE 15 F

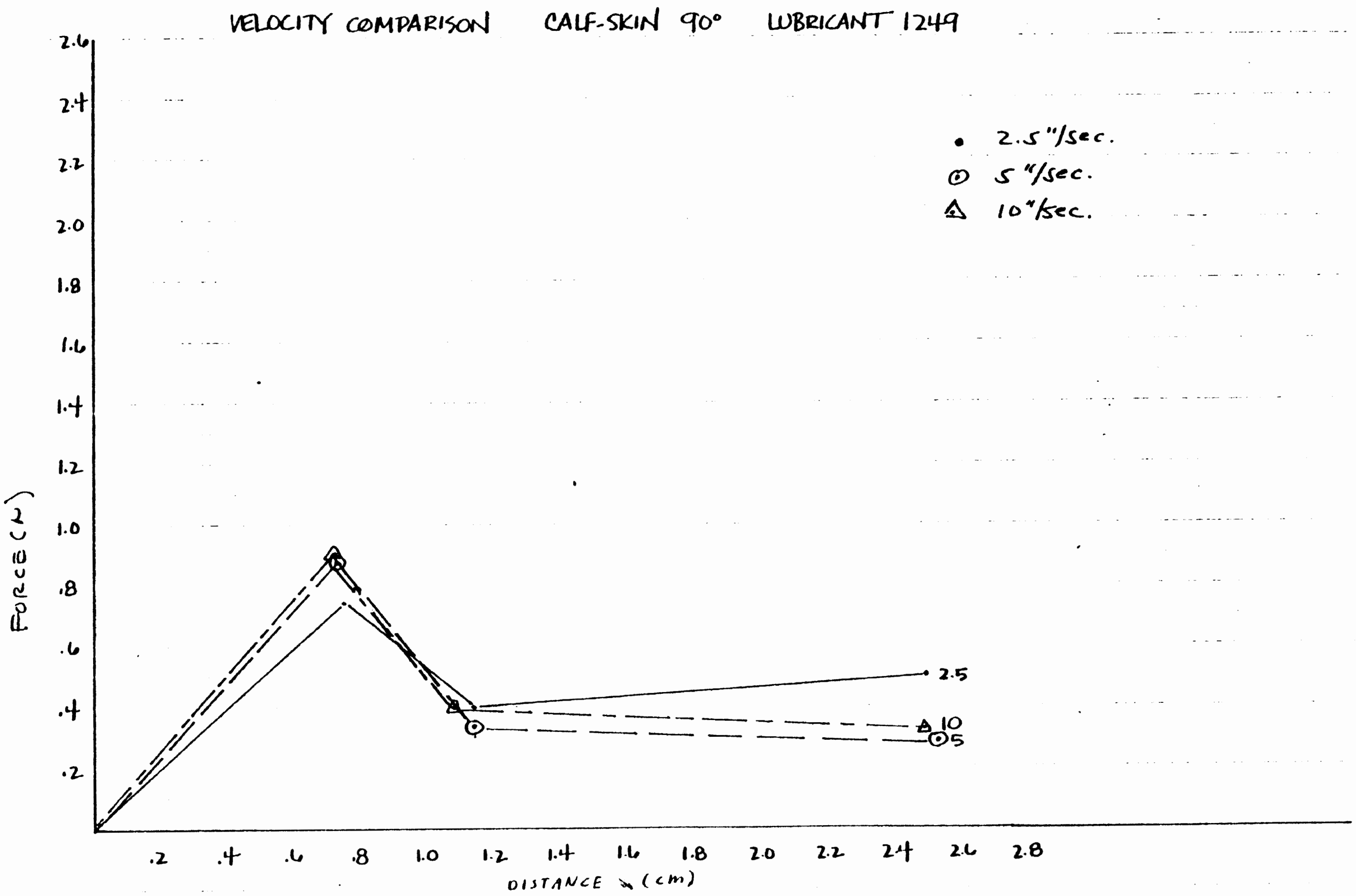

VELOCITY COMPARISON CALF-SKIN 90° LUBRICANT 1249
• 2.5"/sec.
⊙ 5"/sec.
△ 10"/sec.
2.5
10
5
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
FORCE (N)
.2 .4 .6 .8 1.0 1.2 1.4 1.6 1.8 2.0 2.2 2.4 2.6 2.8
DISTANCE x (cm)

FIGURE 15 G

VELOCITY COMPARISON CALF-SMIS 90° LUBRICANT 1249

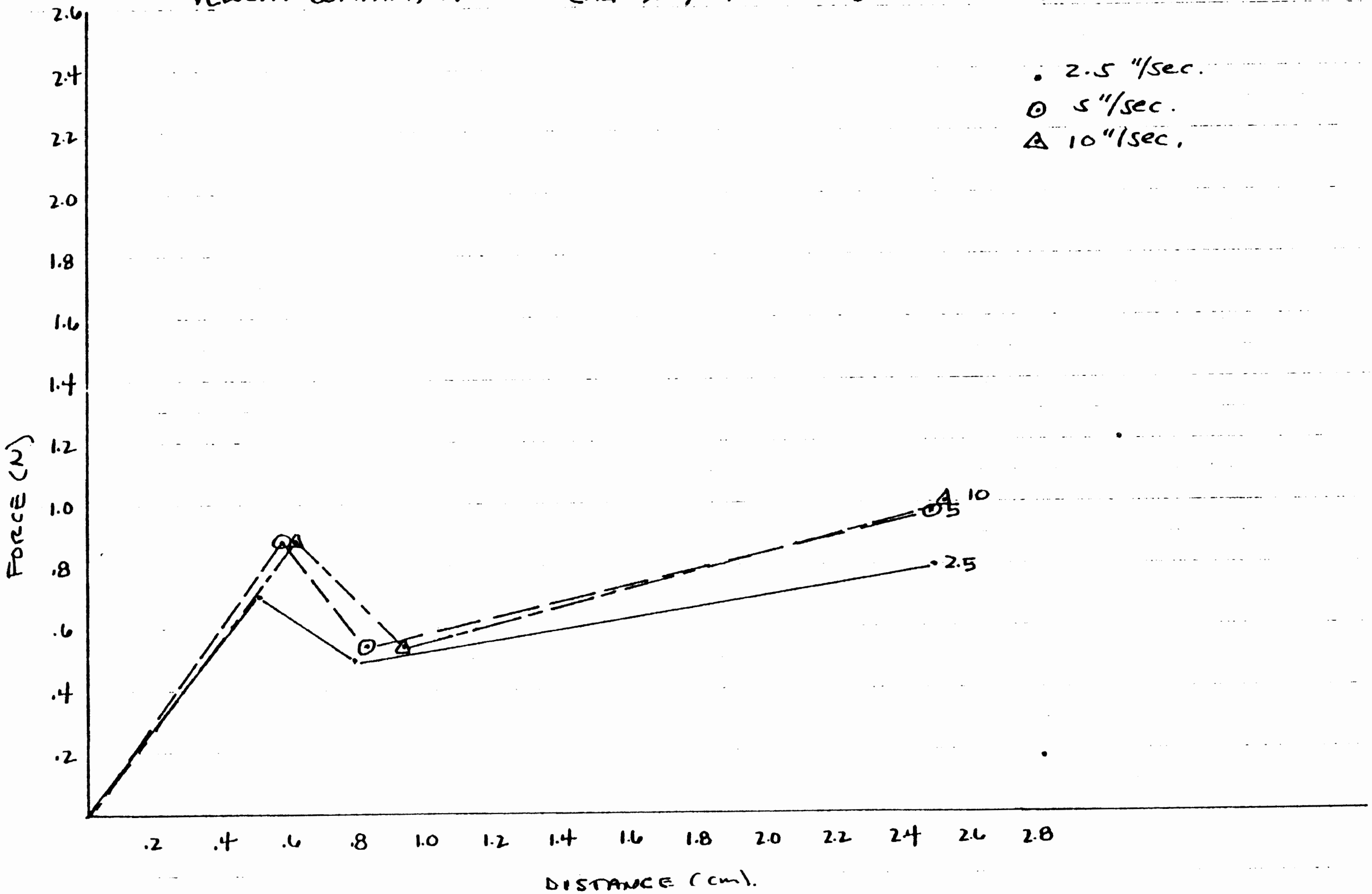



FIGURE 15 H

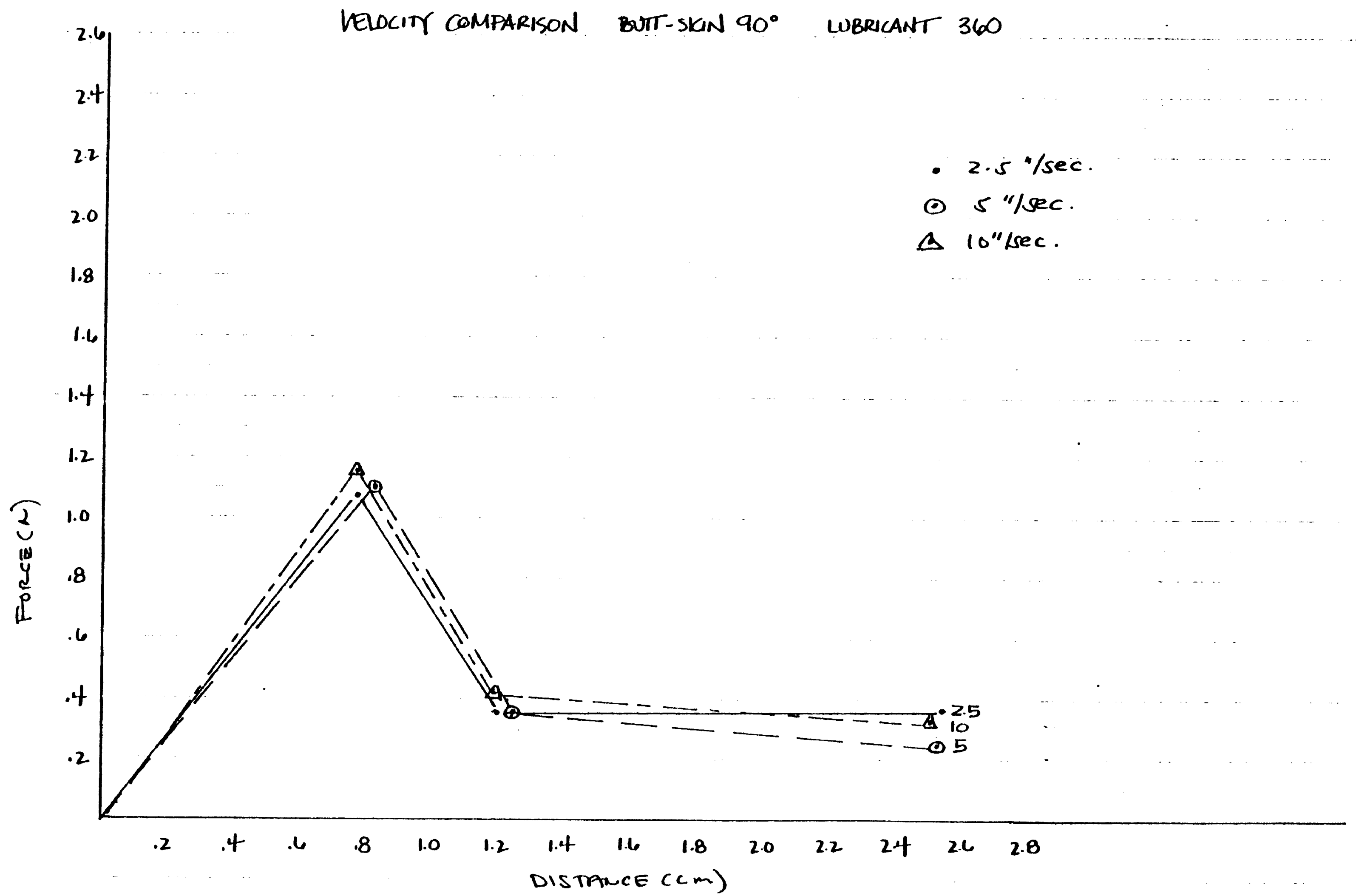

VELOCITY COMPARISON BUTT-SKIN 90° LUBRICANT 360
• 2.5 "/sec.
⊙ 5 "/sec.
△ 10"/sec.
2.5
10
5
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
FORCE (N)
.2 .4 .6 .8 1.0 1.2 1.4 1.6 1.8 2.0 2.2 2.4 2.6 2.8
DISTANCE (cm)

FIGURE 15 I

VELOCITY COMPARISON BUTT-8MIS 90° LUBRICANT 360

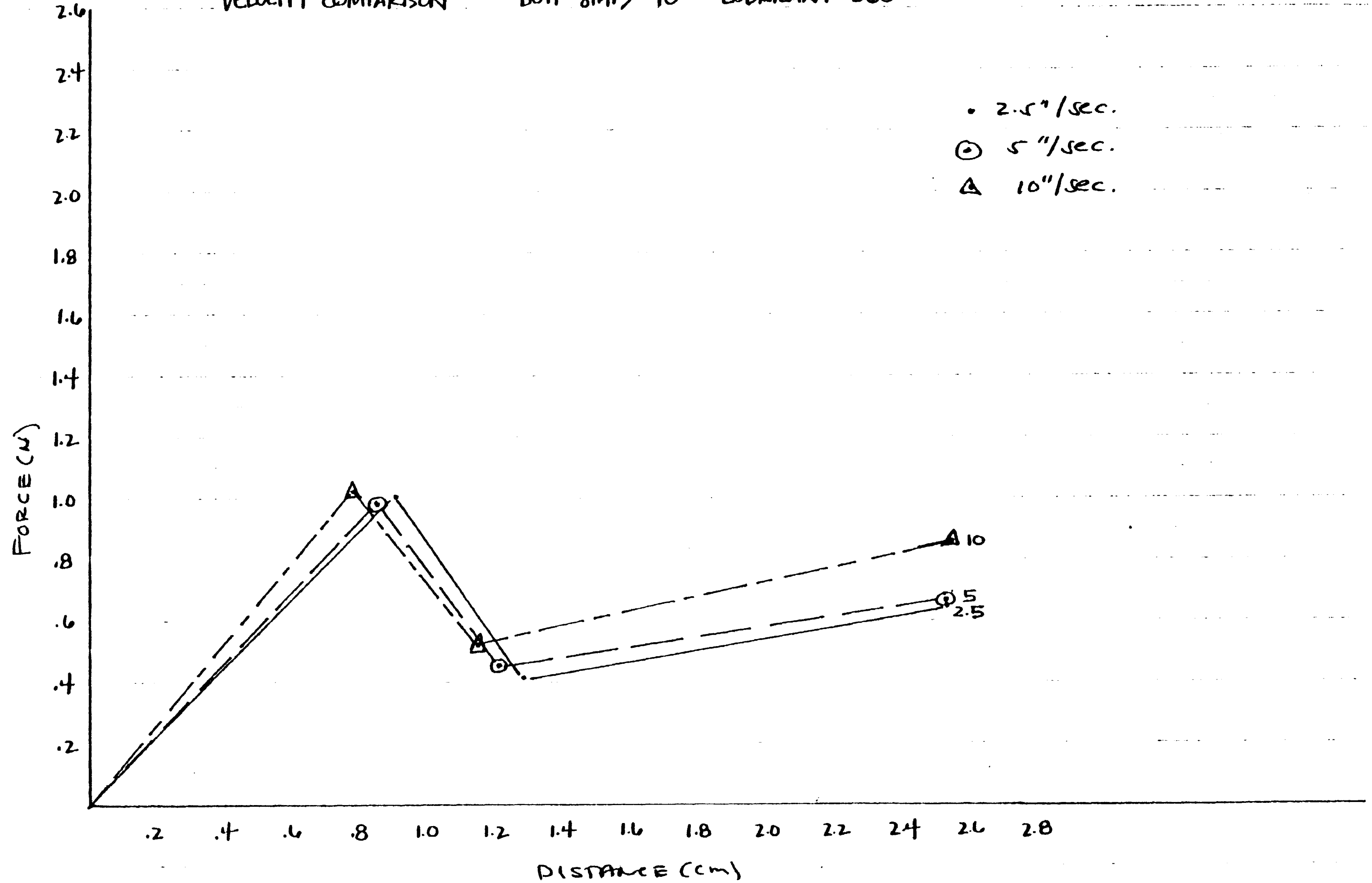



FIGURE 15 J

VELOCITY COMPARISON CALF-SKIN 90° LUBRICANT 360

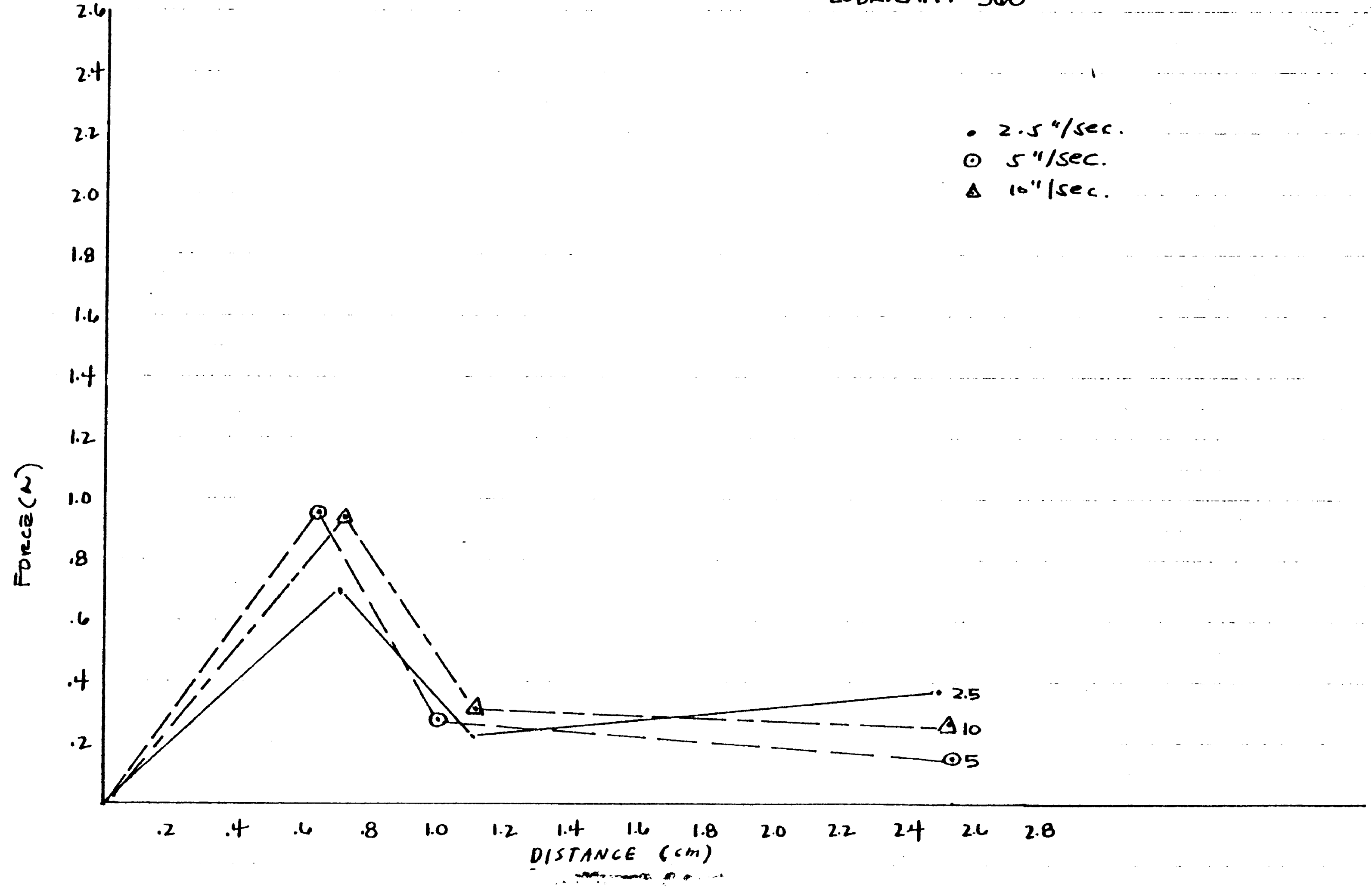



FIGURE 15 K

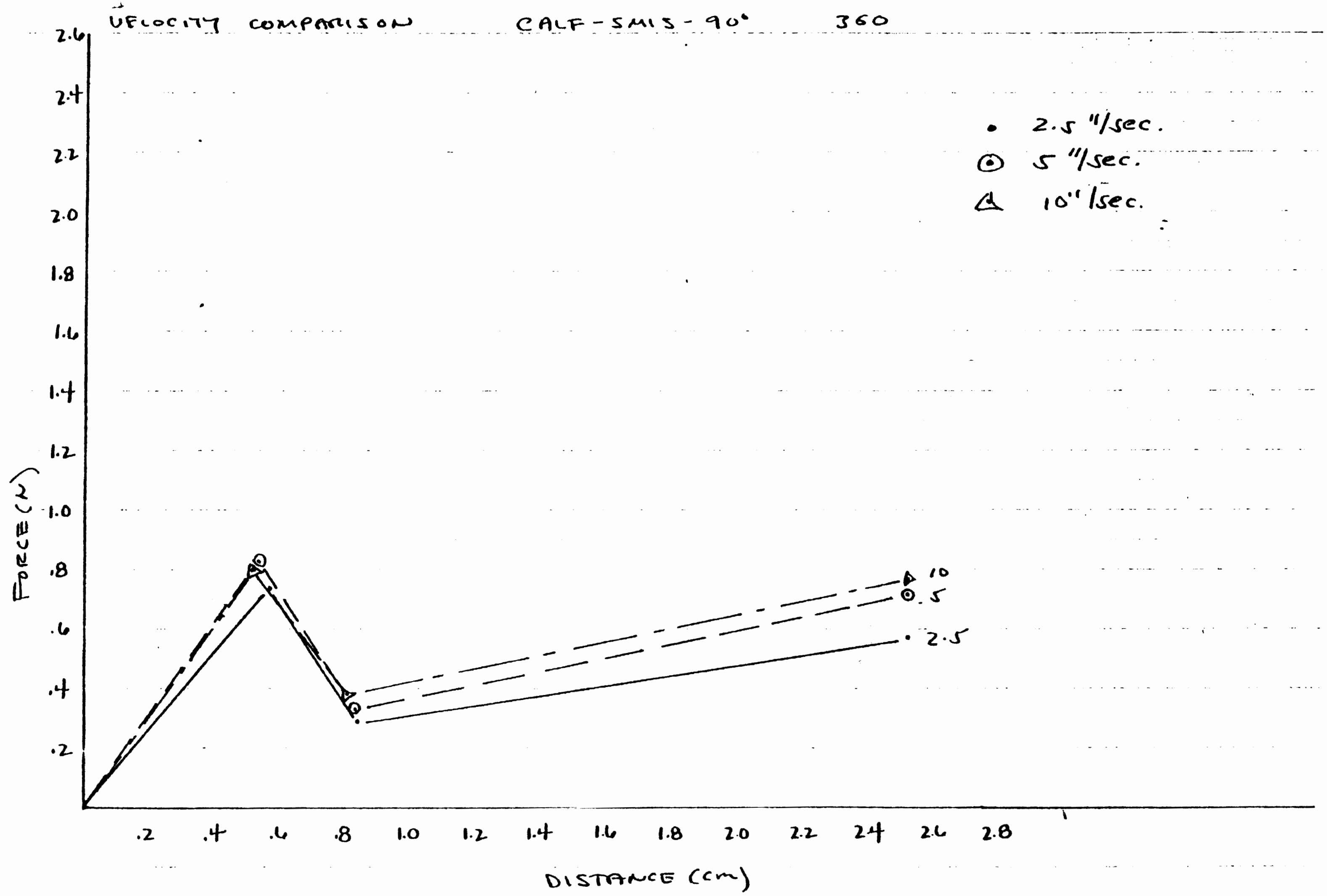
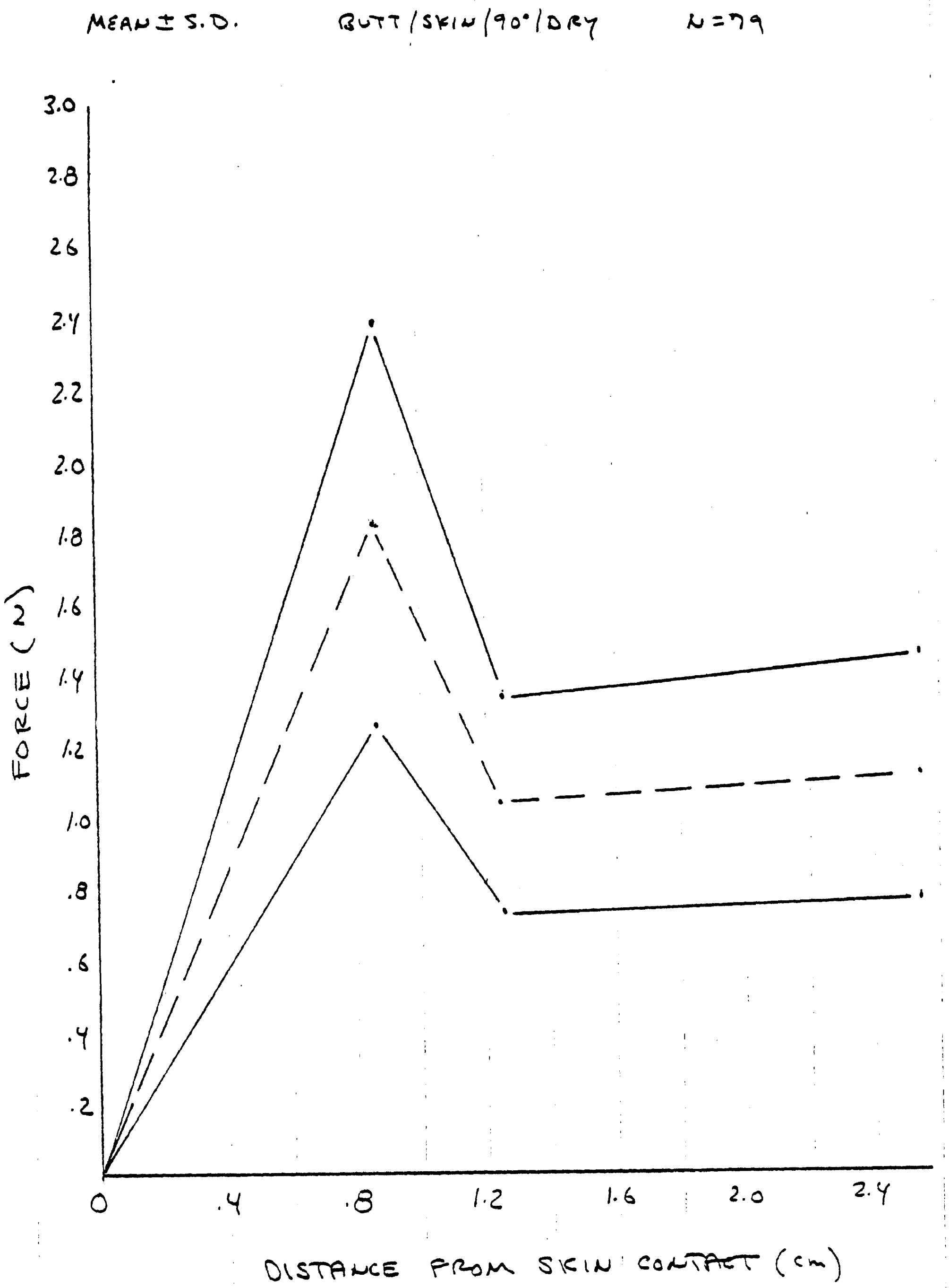

VELOCITY COMPARISON
CALF-SMIS-90°
360
2.5 "/sec.
5 "/sec.
10"/sec.
10
5
2.5
FORCE (N)
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
.2
.4
.6
.8
1.0
1.2
1.4
1.6
1.8
2.0
2.2
2.4
2.6
2.8
DISTANCE (cm)

FIGURE 15 L

FIGURE 16 (A-L)

Reconstructed Force-Displacement Curves for Different Test Strata Illustrating the Variance (± one standard deviation) on Force Values



MEAN ± S.D.
BUTT/SKIN/90°/DRY
N=79
3.0
2.8
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
FORCE (N)
0
.4
.8
1.2
1.6
2.0
2.4
DISTANCE FROM SKIN CONTACT (cm)


FIGURE 16 A

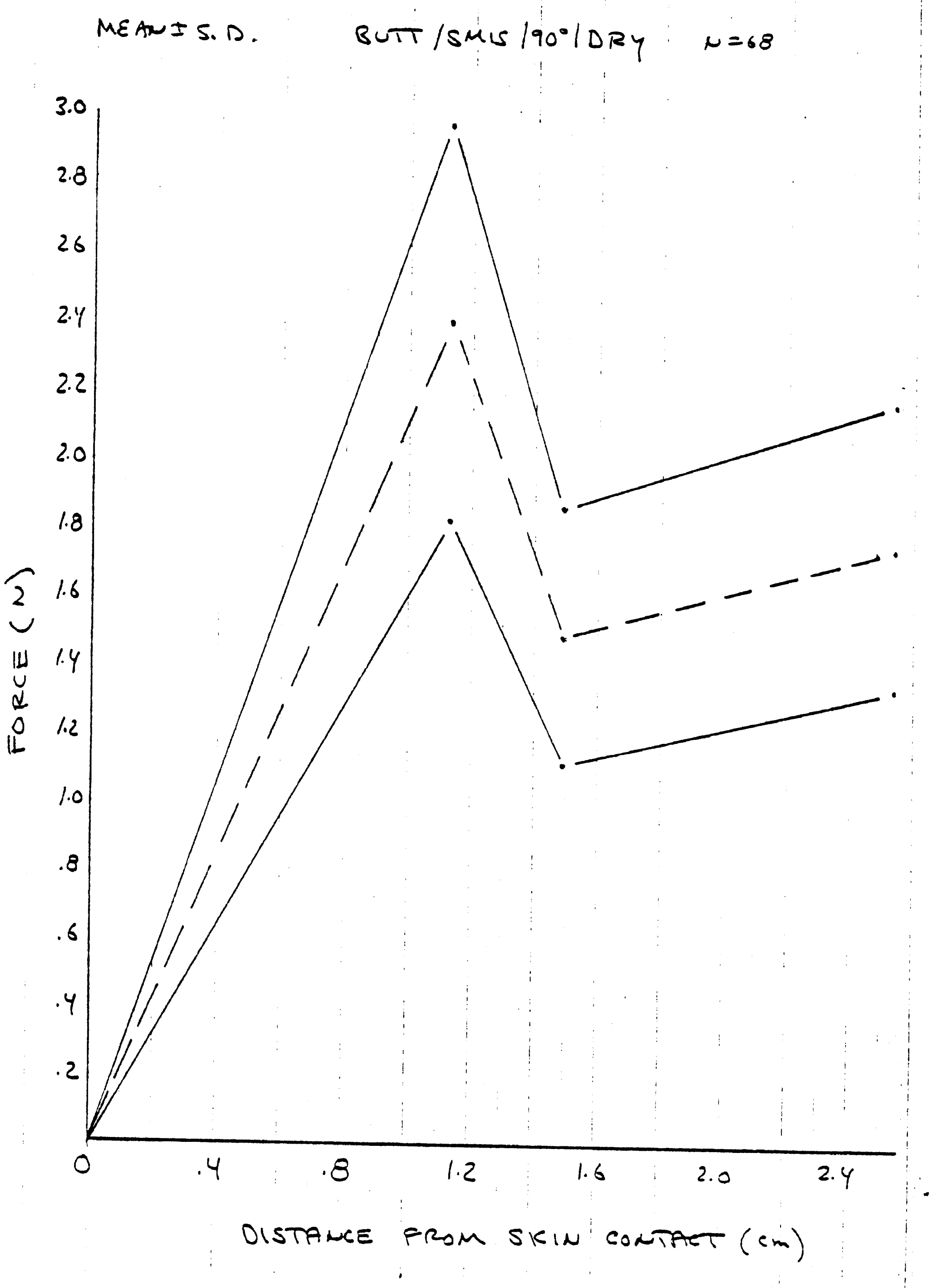

MEAN ± S.D.
BUTT / SMLS / 90° / DRY
N = 68
3.0
2.8
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
FORCE (N)
0
.4
.8
1.2
1.6
2.0
2.4
DISTANCE FROM SKIN CONTACT (cm)

FIGURE 16 B

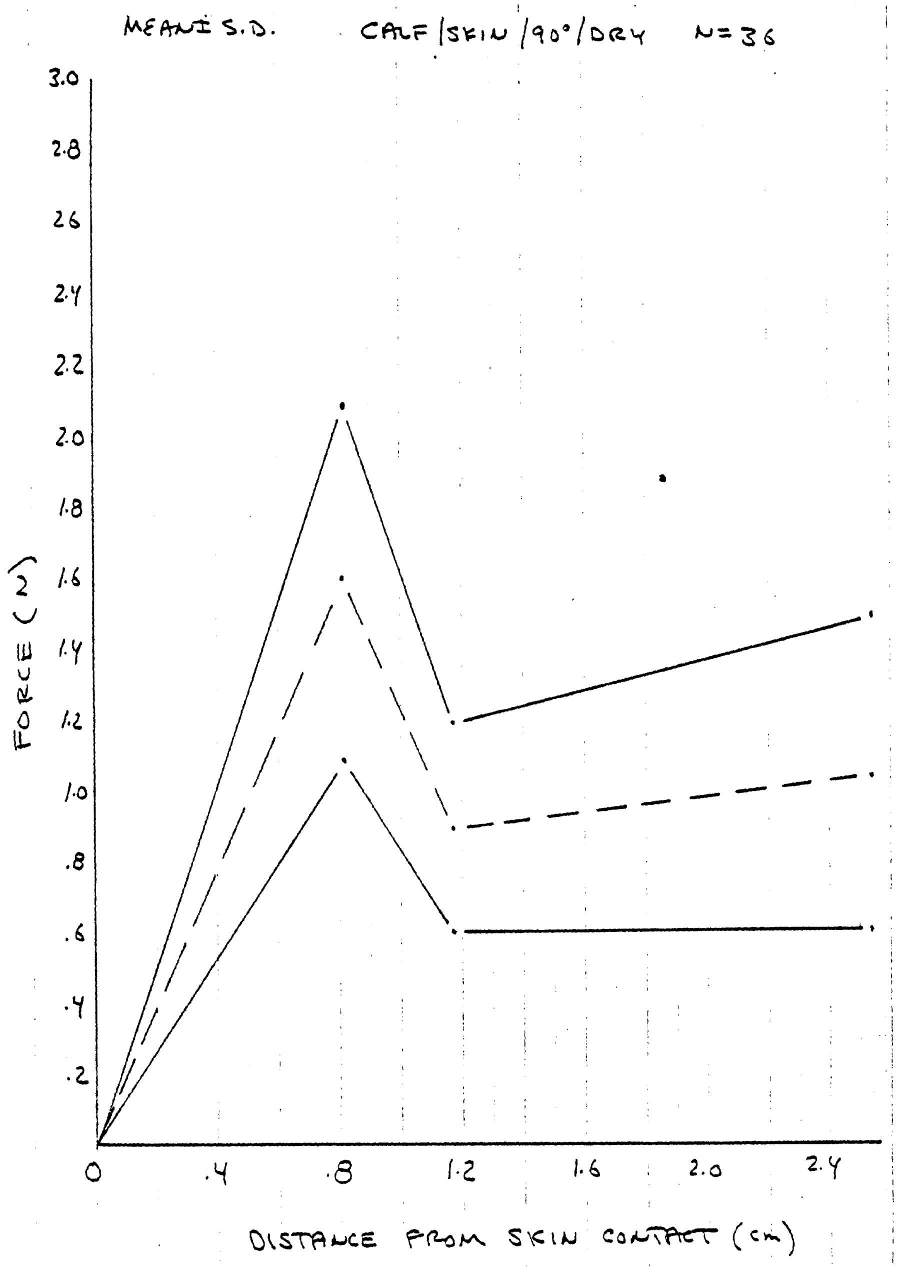

MEAN ± S.D.
CALF / SKIN / 90° / DRY
N = 36
3.0
2.8
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
FORCE (N)
0
.4
.8
1.2
1.6
2.0
2.4
DISTANCE FROM SKIN CONTACT (cm)

FIGURE 16C

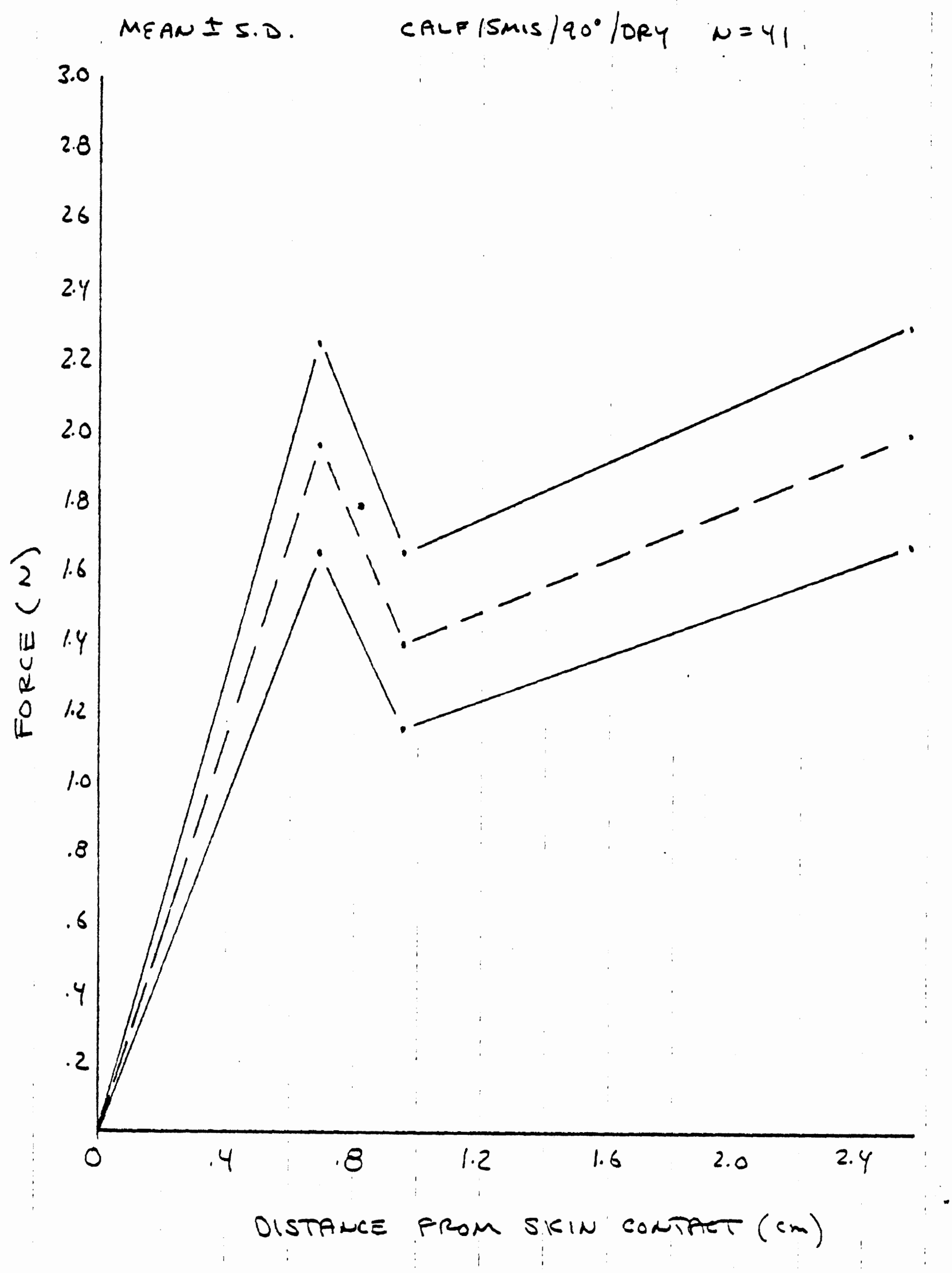
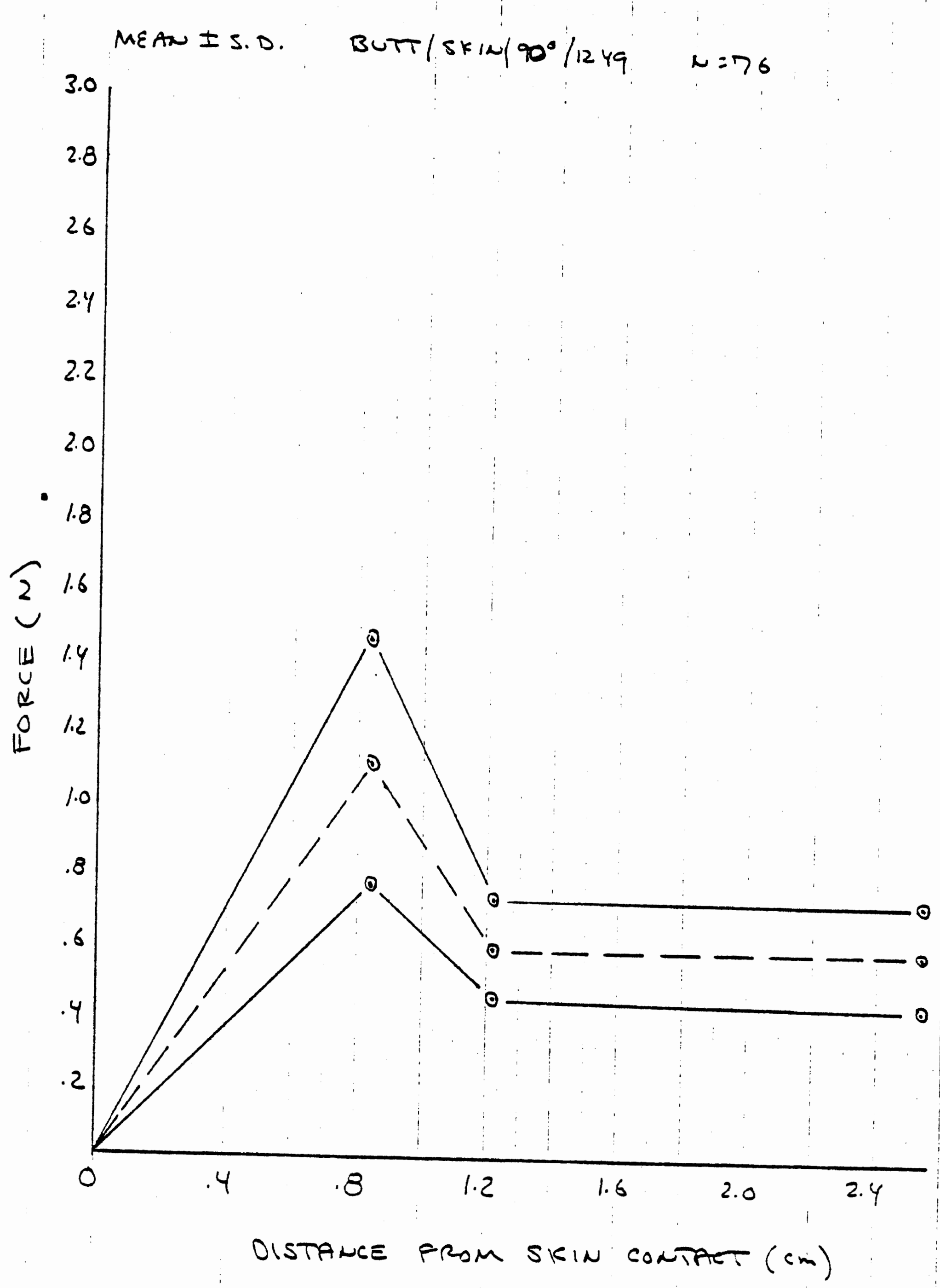

MEAN ± S.D.
CALF/SMIS/90°/DRY N=41
3.0
2.8
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
FORCE (N)
0
.4
.8
1.2
1.6
2.0
2.4
DISTANCE FROM SKIN CONTACT (cm)

FIGURE 16 D



MEAN ± S.D.
BUTT/SKIN/90°/1249
N=76
3.0
2.8
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
FORCE (N)
0
.4
.8
1.2
1.6
2.0
2.4
DISTANCE FROM SKIN CONTACT (cm)


FIGURE 16 E

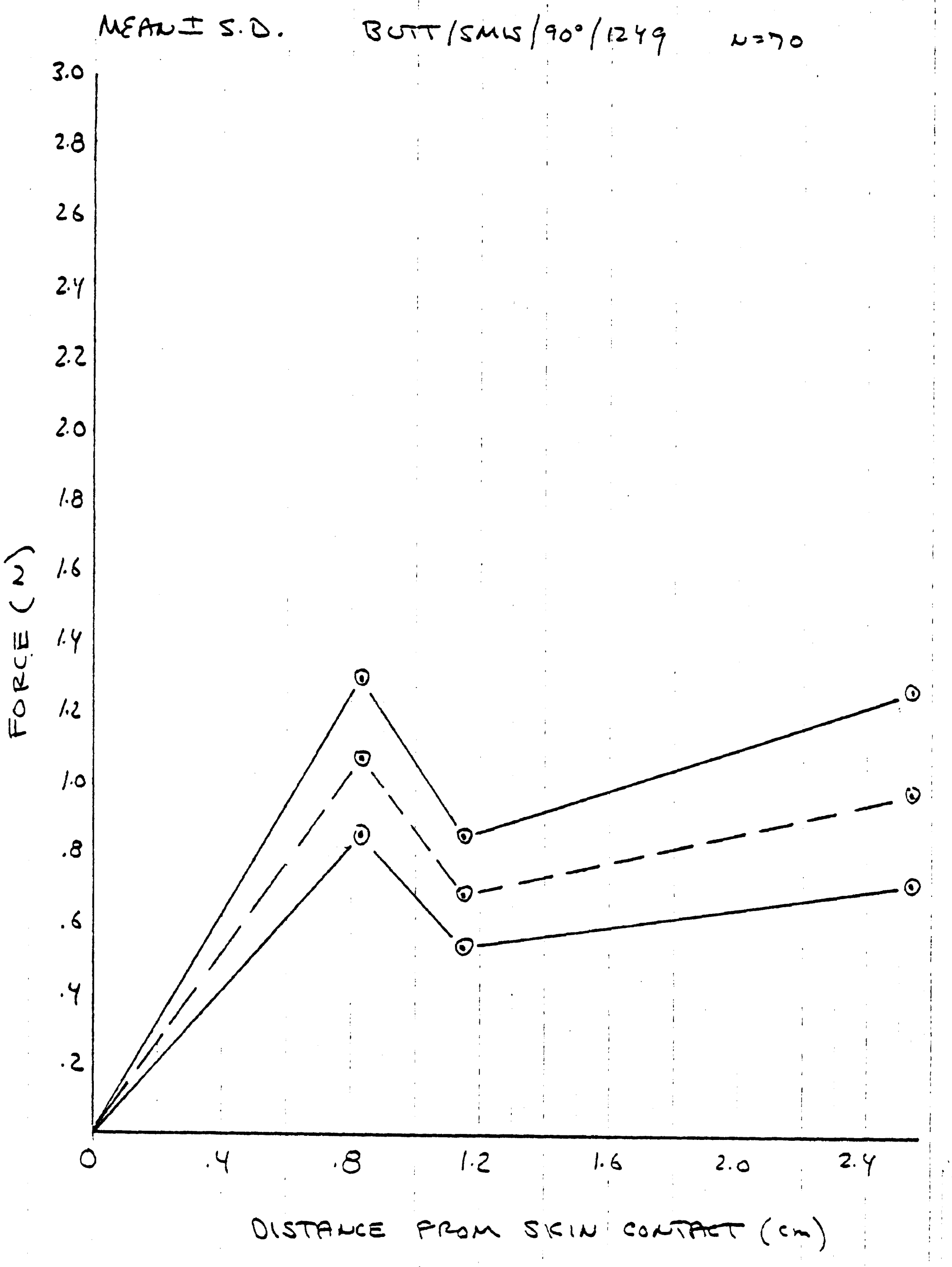

MEAN ± S.D.
BUTT/SMLS/90°/1249
N=70
FORCE (N)
3.0
2.8
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
0
.4
.8
1.2
1.6
2.0
2.4
DISTANCE FROM SKIN CONTACT (cm)

FIGURE 16 F

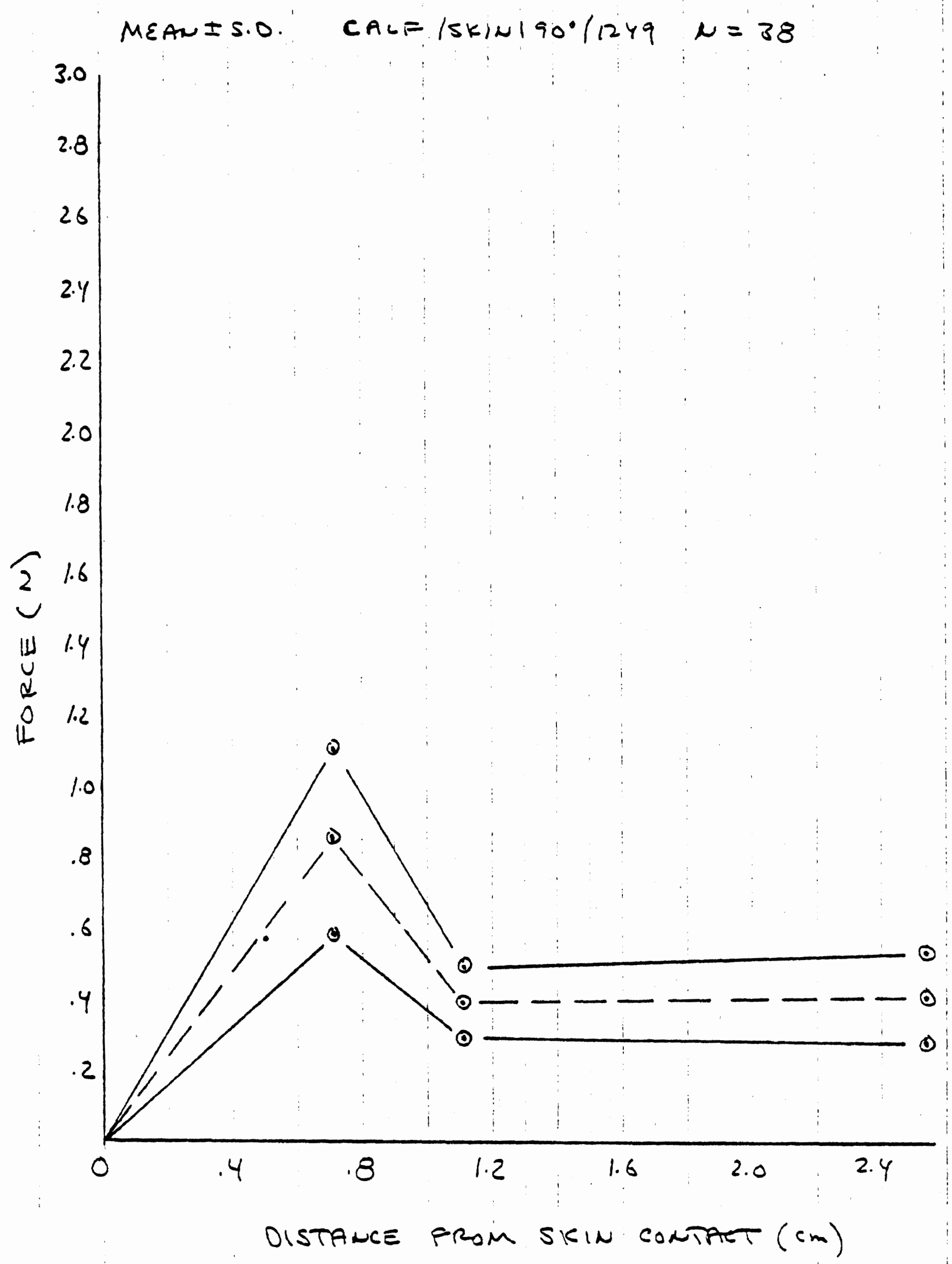

MEAN ± S.D.
CALF /SKIN / 90° / 1249
N = 38
3.0
2.8
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
FORCE (N)
0
.4
.8
1.2
1.6
2.0
2.4
DISTANCE FROM SKIN CONTACT (cm)

FIGURE 16 G

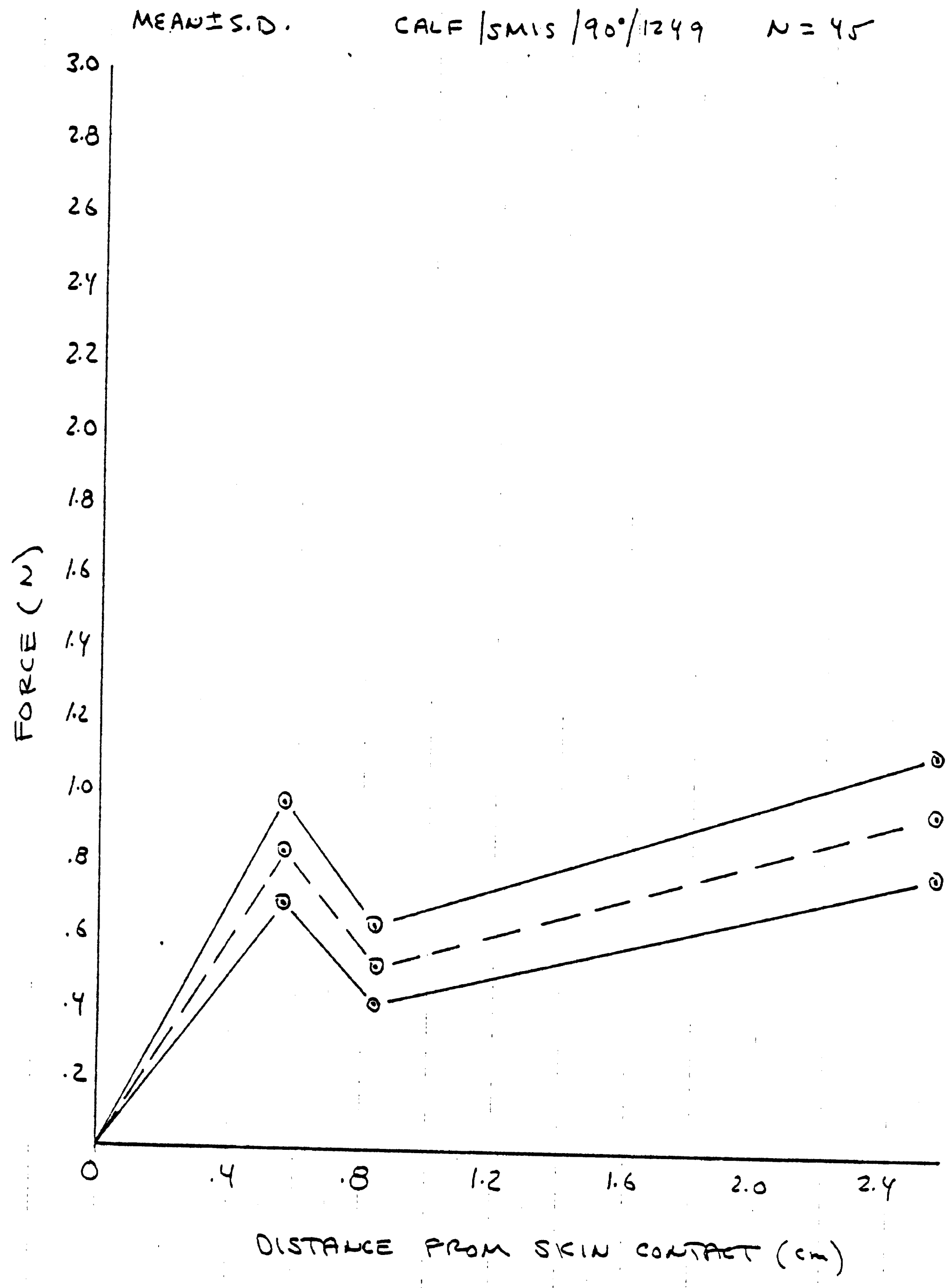
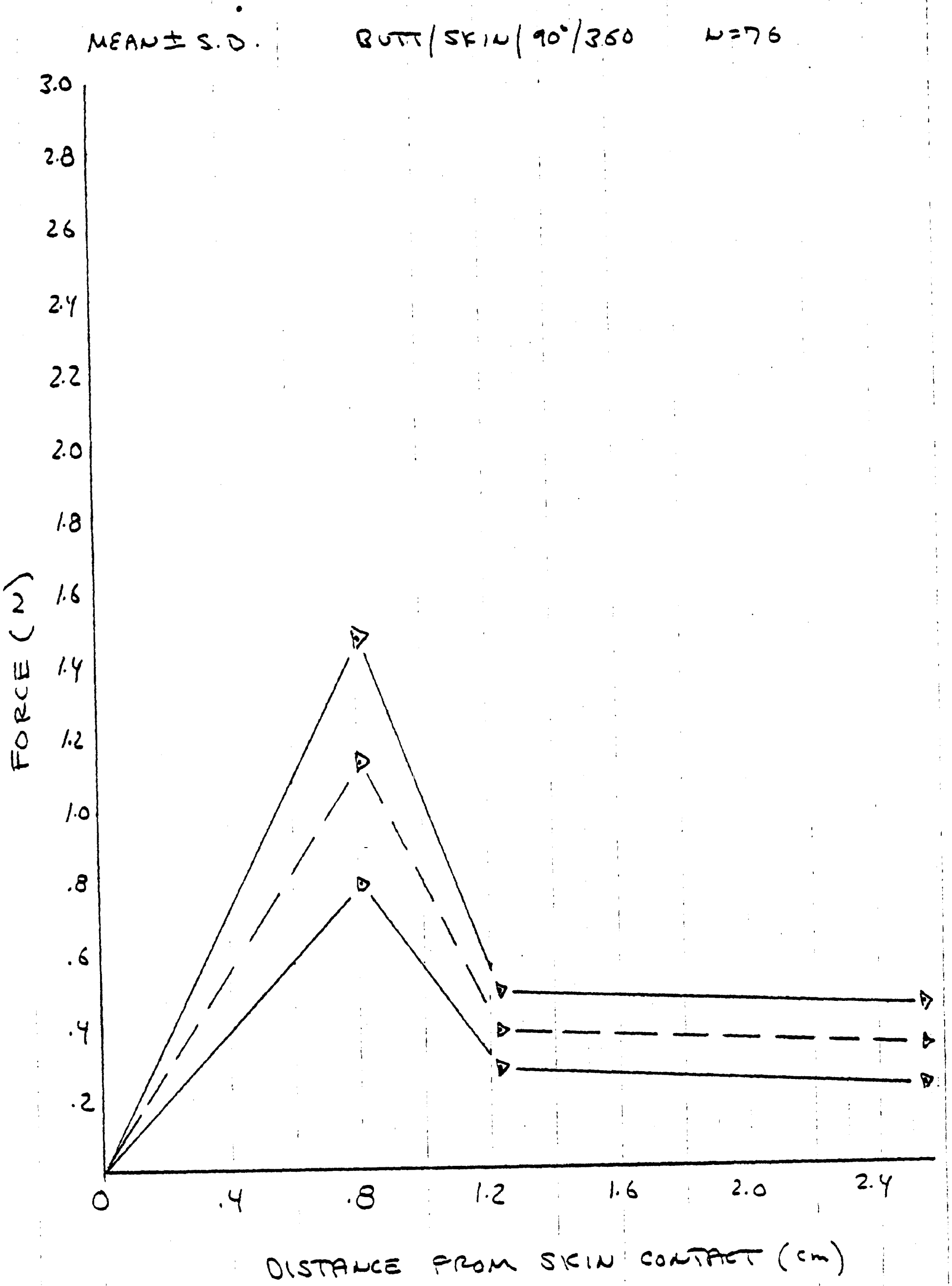

MEAN ± S.D.
CALF / SMIS / 90° / 1249
N = 45
3.0
2.8
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
FORCE (N)
0
.4
.8
1.2
1.6
2.0
2.4
DISTANCE FROM SKIN CONTACT (cm)

FIGURE 16 H



MEAN ± S.D.
BUTT/SKIN/90°/360
N=76
3.0
2.8
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
FORCE (N)
0
.4
.8
1.2
1.6
2.0
2.4
DISTANCE FROM SKIN CONTACT (cm)


FIGURE 16 I

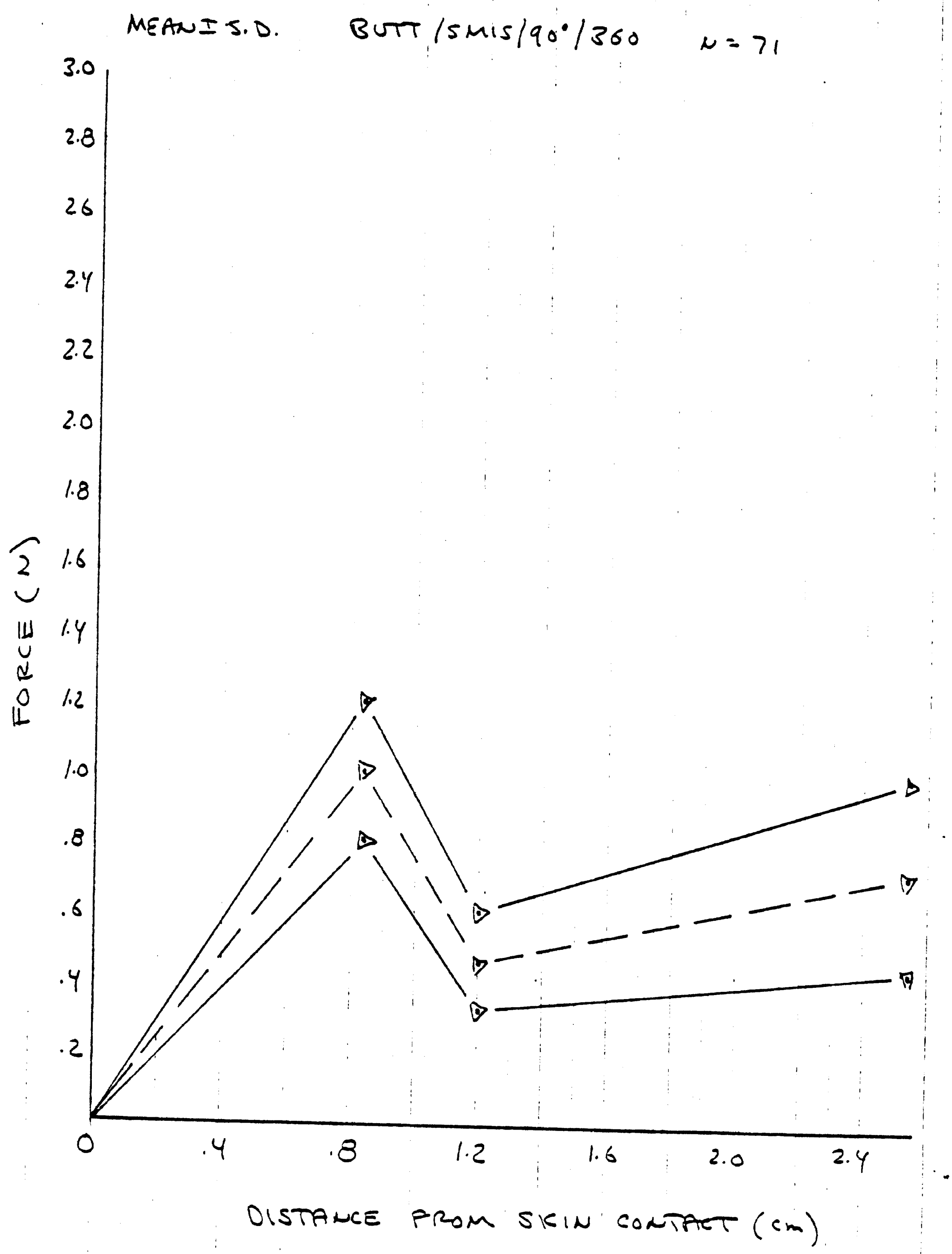

MEAN ± S.D.
BUTT/SMIS/90°/360
N = 71
3.0
2.8
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
FORCE (N)
0
.4
.8
1.2
1.6
2.0
2.4
DISTANCE FROM SKIN CONTACT (cm)

FIGURE J

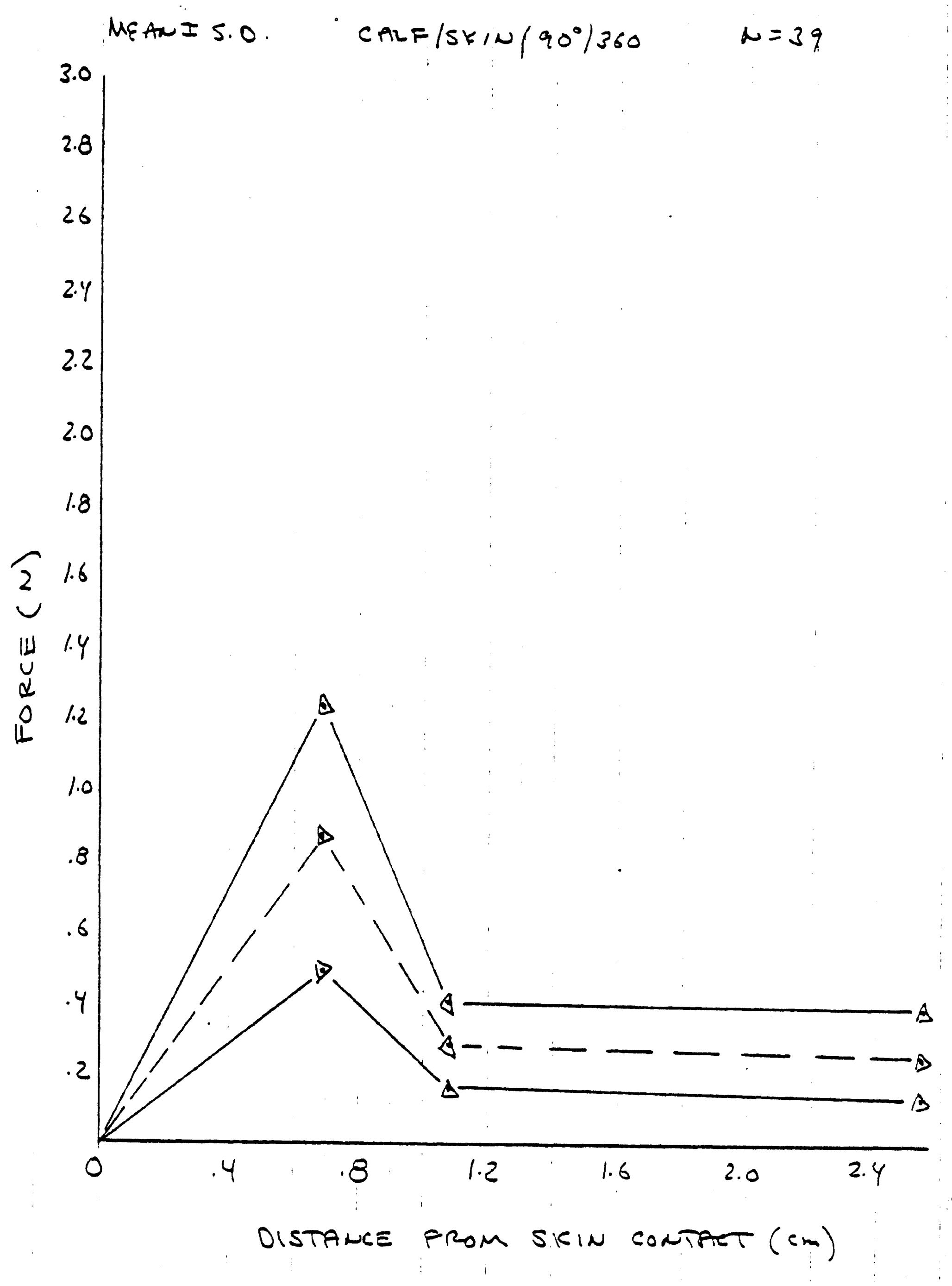
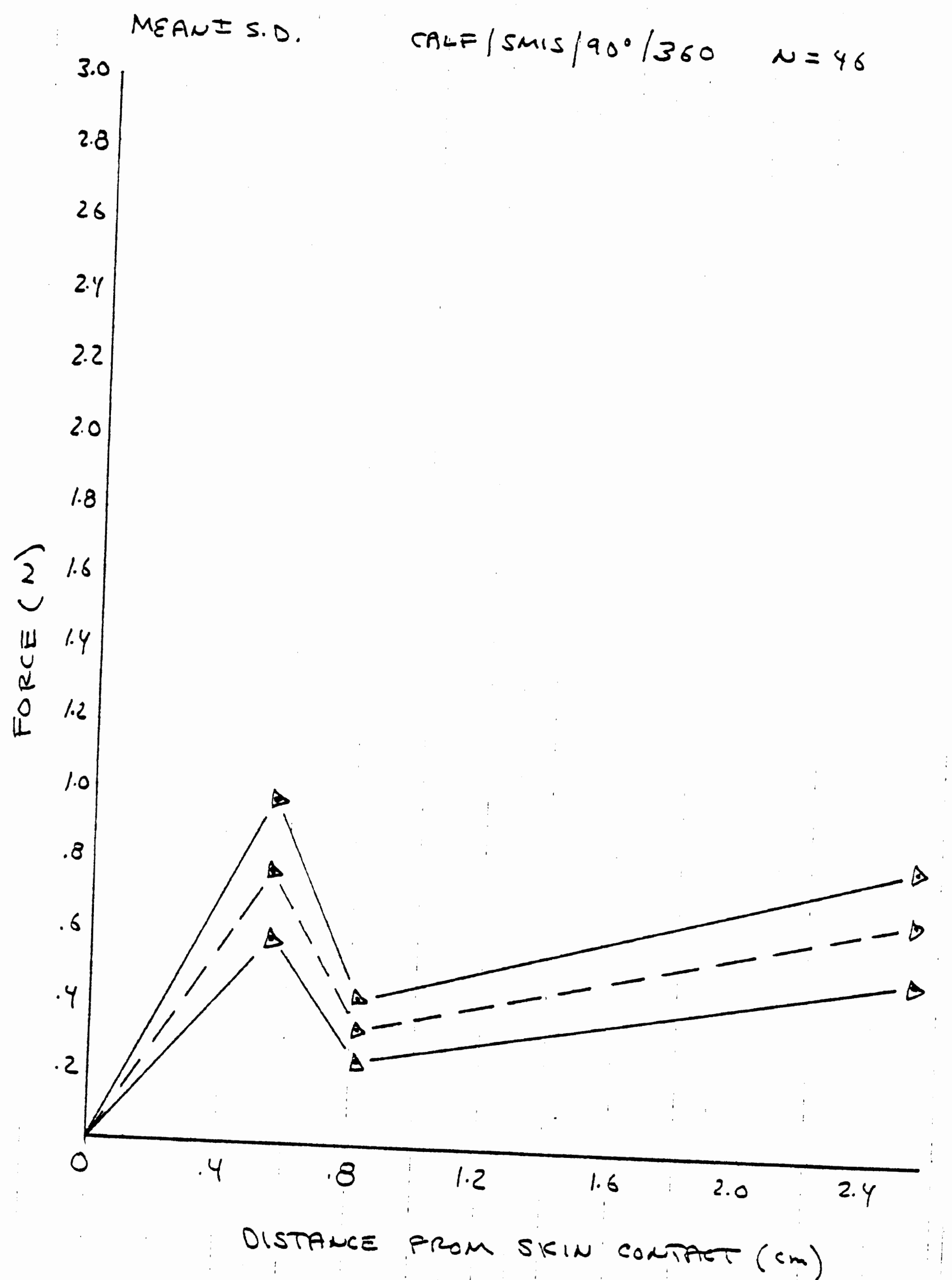

MEAN ± S.D.
CALF/SKIN/(90°)/360
N=39
3.0
2.8
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
FORCE (N)
0
.4
.8
1.2
1.6
2.0
2.4
DISTANCE FROM SKIN CONTACT (cm)

FIGURE 16 K



MEAN ± S.D.
CALF / SMIS / 90° / 360
N = 46
3.0
2.8
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
FORCE (N)
0
.4
.8
1.2
1.6
2.0
2.4
DISTANCE FROM SKIN CONTACT (cm)


FIGURE 16 L

FIGURE 17 (A-L)

Graphical Comparisons of Mean Reconstructed Force-Displacement Curves for 90 and 45 Degree Tests at 5"/second

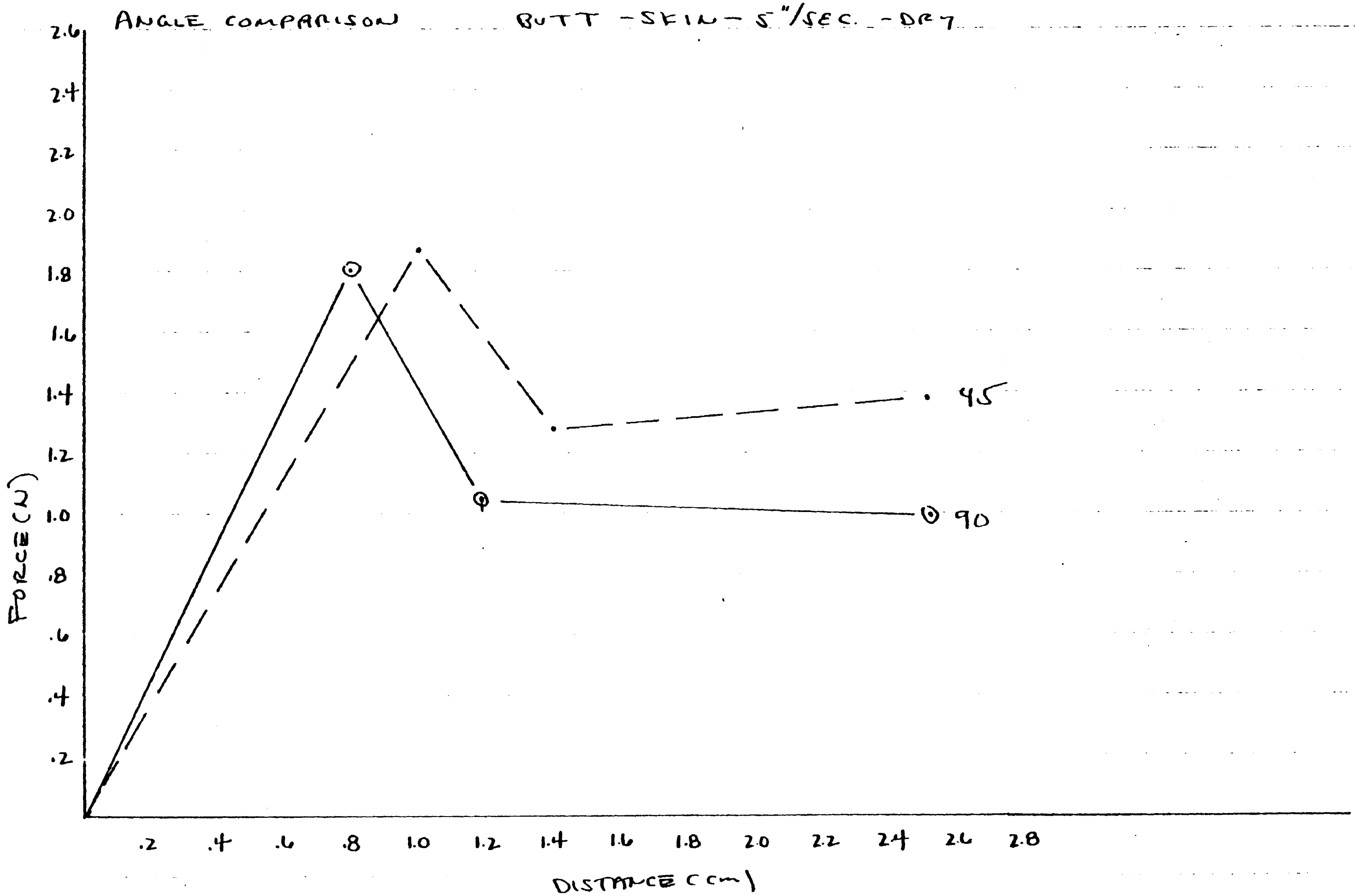

ANGLE COMPARISON
BUTT - SKIN - 5"/SEC. - DRY
FORCE (N)
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
.2
.4
.6
.8
1.0
1.2
1.4
1.6
1.8
2.0
2.2
2.4
2.6
2.8
DISTANCE (cm)
45
90

FIGURE 17 A

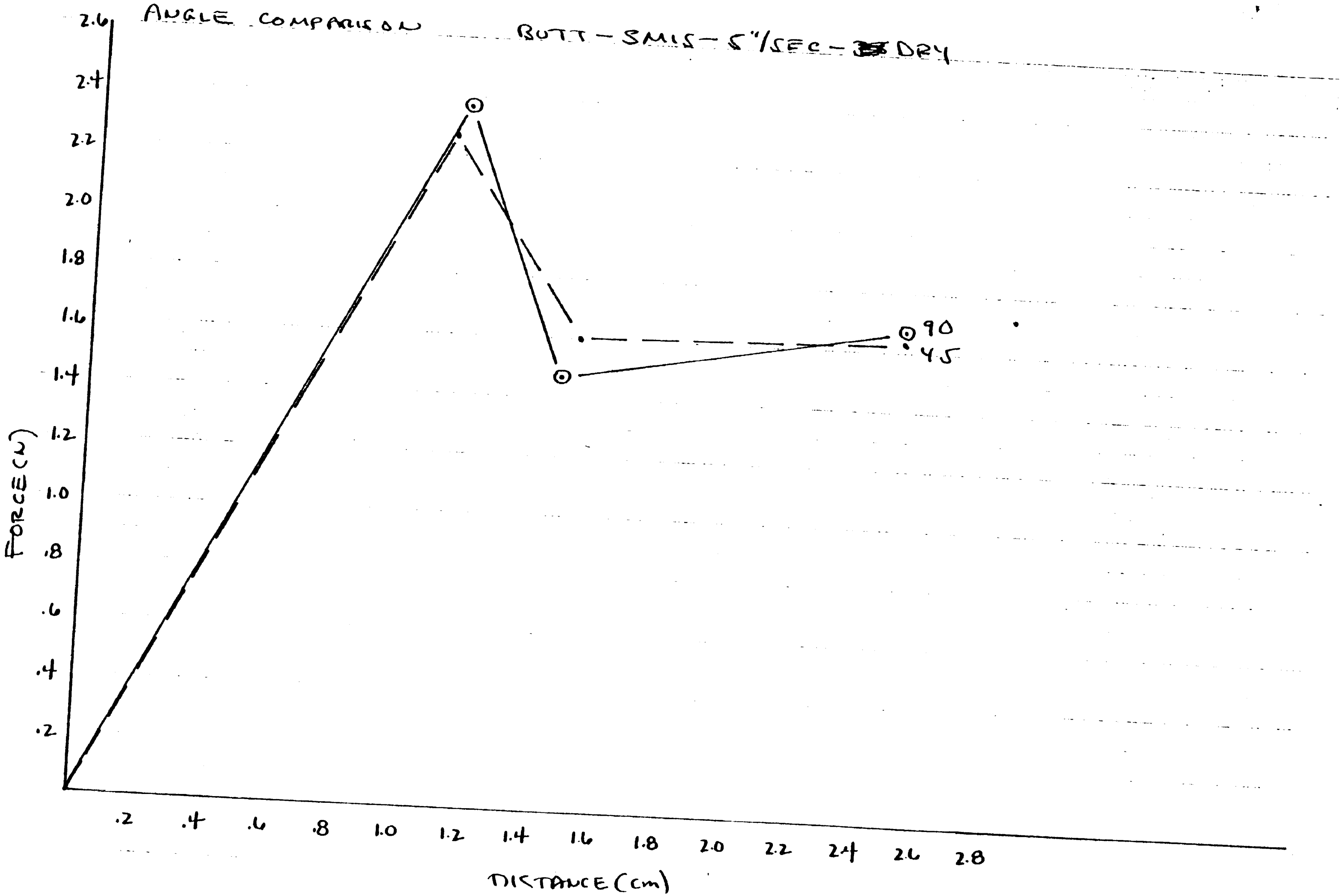

ANGLE COMPARISON
BUTT - SMIS - 5"/SEC - DRY
FORCE (N)
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
⊙ 90
• 45
.2
.4
.6
.8
1.0
1.2
1.4
1.6
1.8
2.0
2.2
2.4
2.6
2.8
DISTANCE (cm)

FIGURE 17B

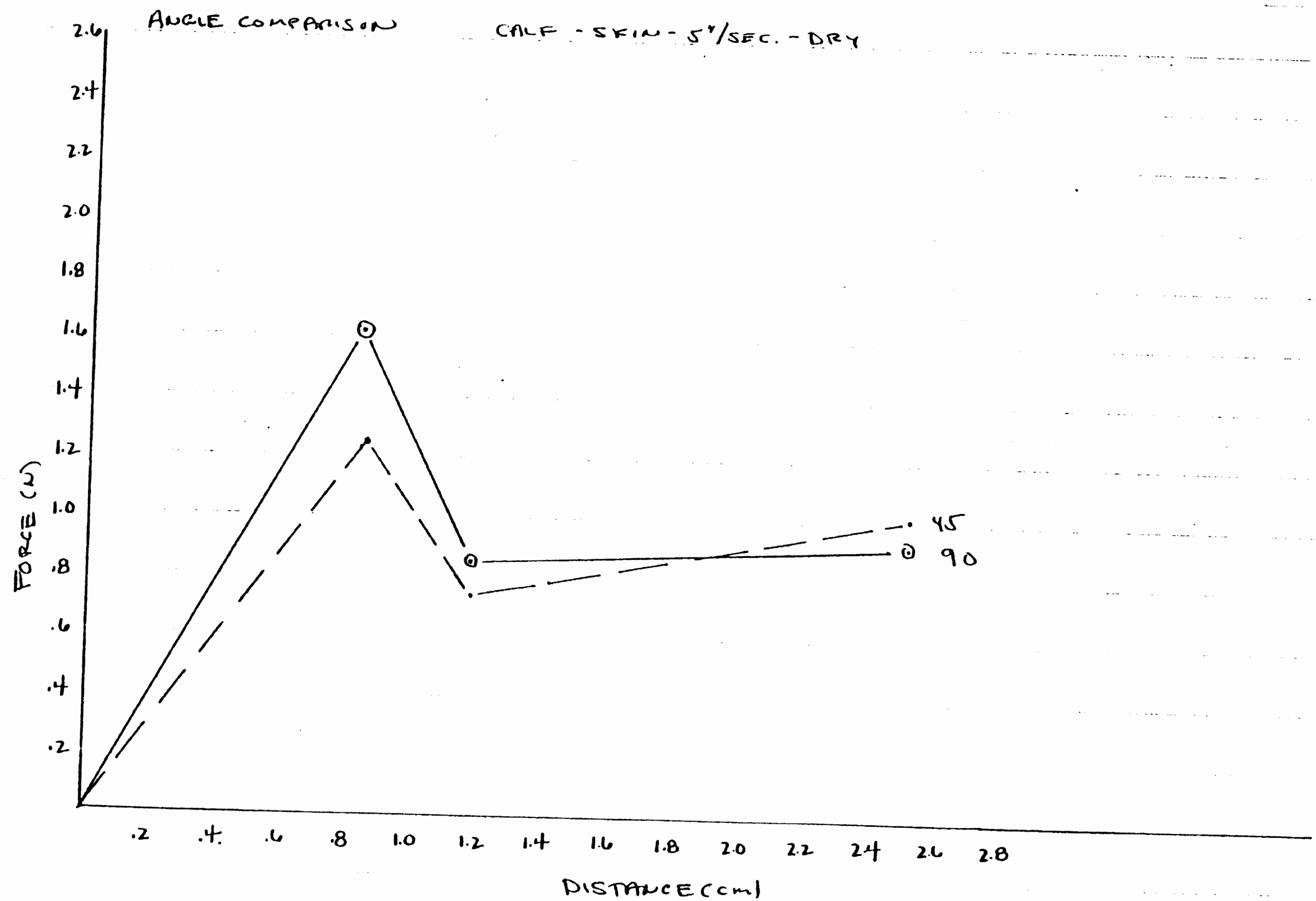
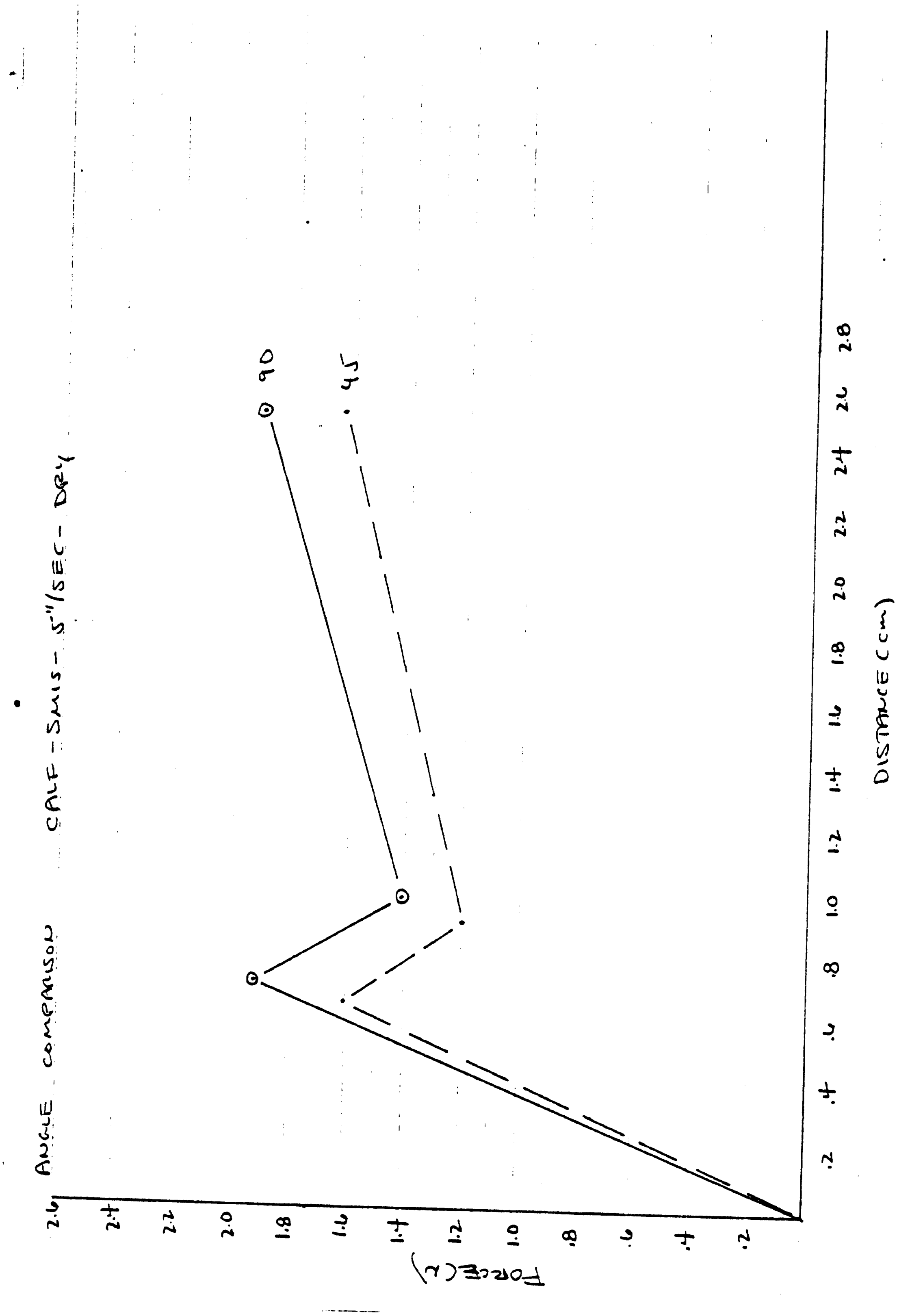

ANGLE COMPARISON
CALF - SKIN - 5"/SEC. - DRY
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
FORCE (N)
45
90
.2
.4
.6
.8
1.0
1.2
1.4
1.6
1.8
2.0
2.2
2.4
2.6
2.8
DISTANCE (cm)

FIGURE 17 C



ANGLE COMPARISON
CALF - SMIS - 5"/SEC - DRY
90
45
FORCE
DISTANCE (cm)
.2 .4 .6 .8 1.0 1.2 1.4 1.6 1.8 2.0 2.2 2.4 2.6 2.8
.2 .4 .6 .8 1.0 1.2 1.4 1.6 1.8 2.0 2.2 2.4 2.6


FIGURE 17 D

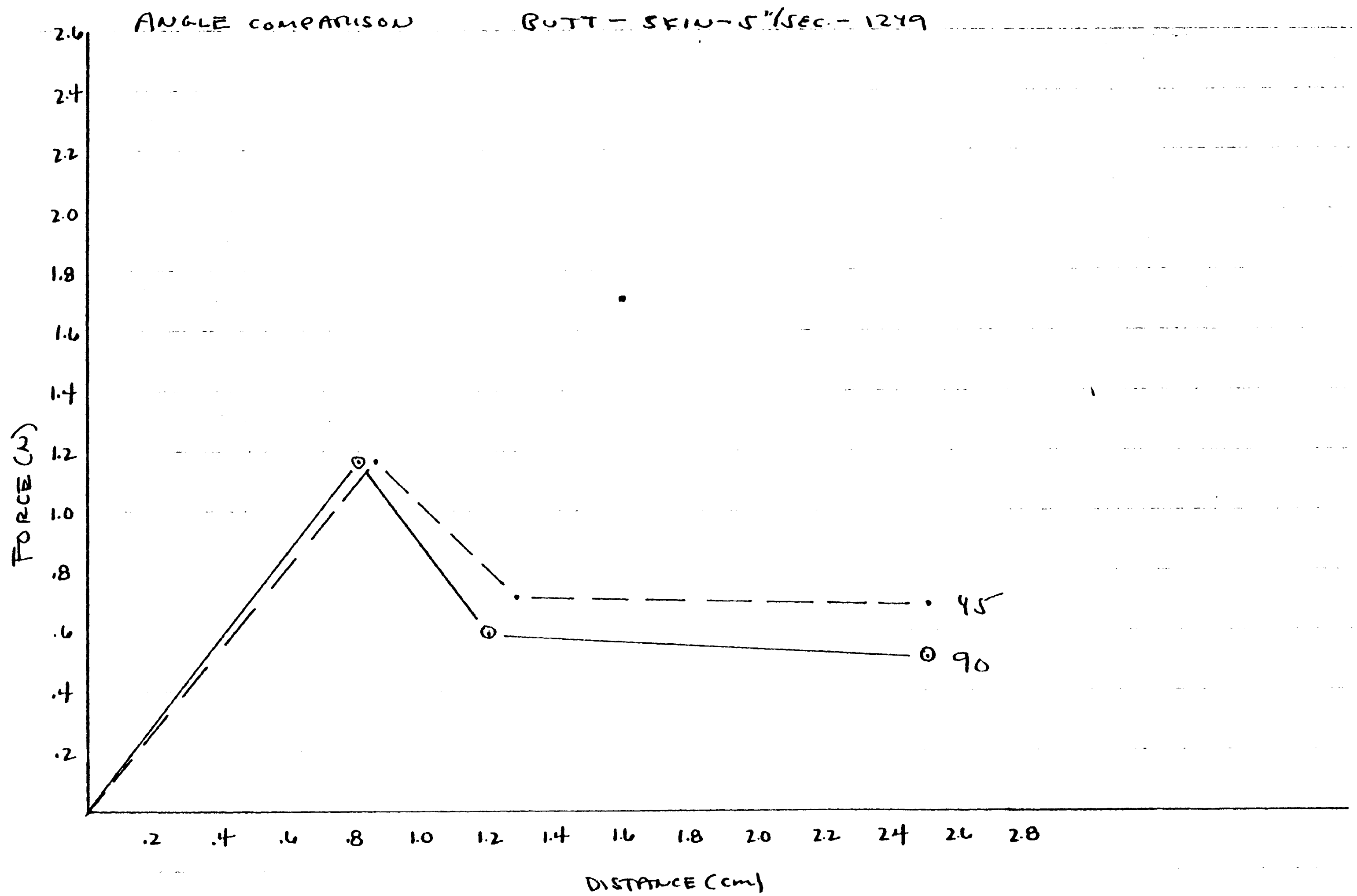
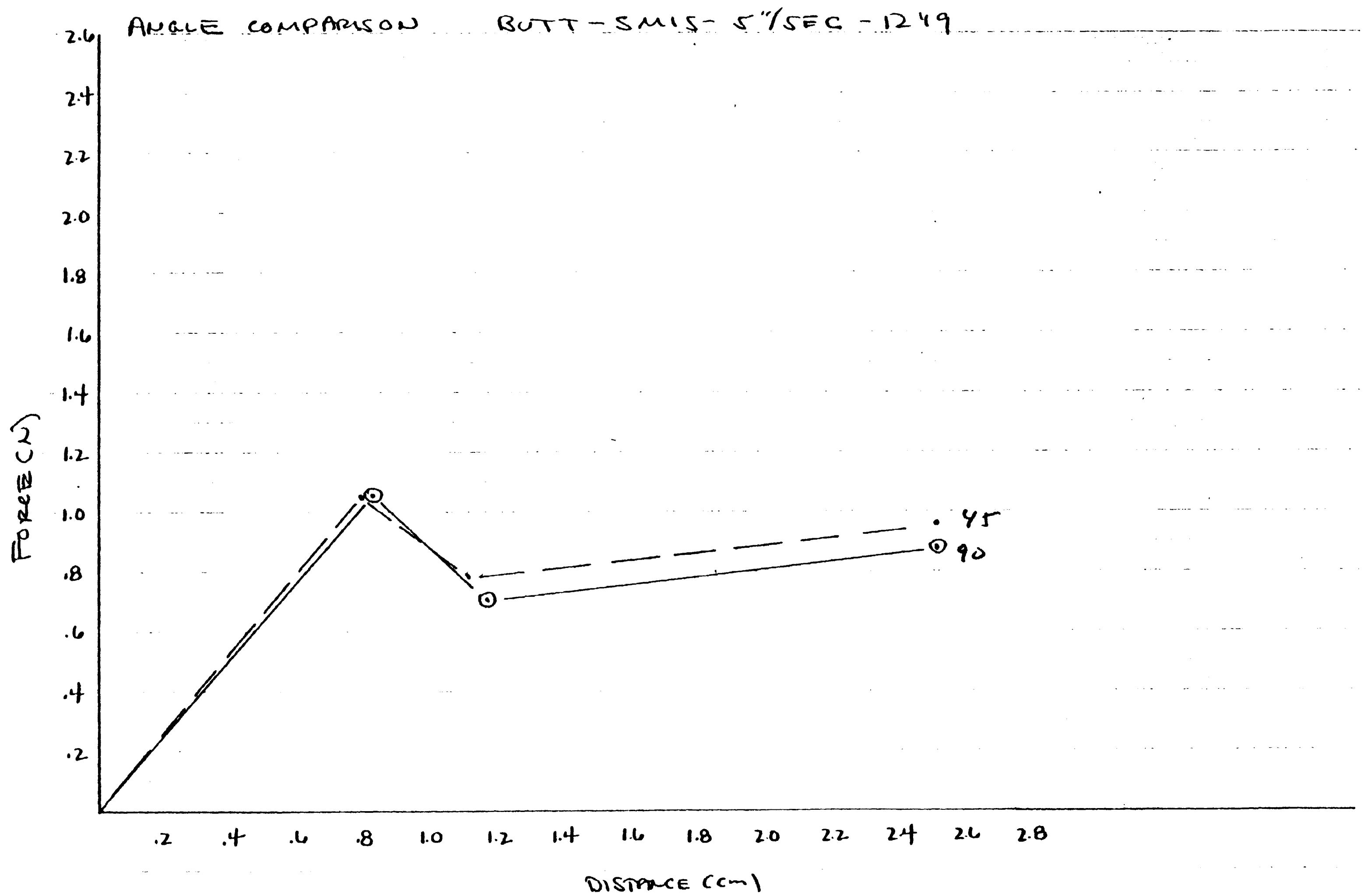

ANGLE COMPARISON
BUTT - SKIN - 5"/SEC - 1249
FORCE (N)
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
45
90
.2
.4
.6
.8
1.0
1.2
1.4
1.6
1.8
2.0
2.2
24
2.6
2.8
DISTANCE (cm)

FIGURE 17 E



ANGLE COMPARISON
BUTT-SMIS- 5"/SEC -1249
FORCE (N)
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
.2
.4
.6
.8
1.0
1.2
1.4
1.6
1.8
2.0
2.2
2.4
2.6
2.8
DISTANCE (cm)
45
90


FIGURE 17 F

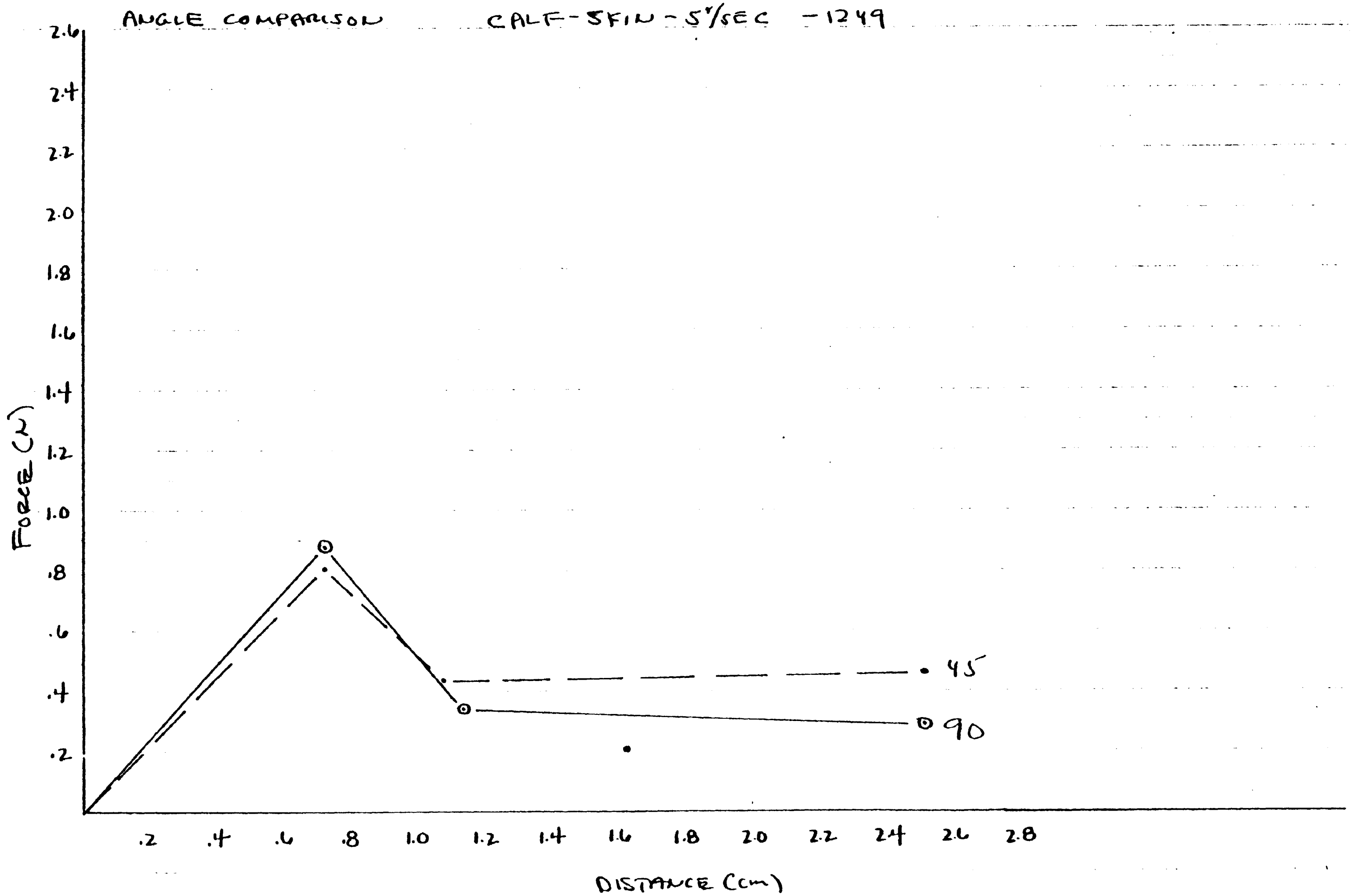

ANGLE COMPARISON
CALF-5FIN-5'/SEC -1249
FORCE (N)
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
.2
.4
.6
.8
1.0
1.2
1.4
1.6
1.8
2.0
2.2
2.4
2.6
2.8
45
90
DISTANCE (cm)

FIGURE 17 G

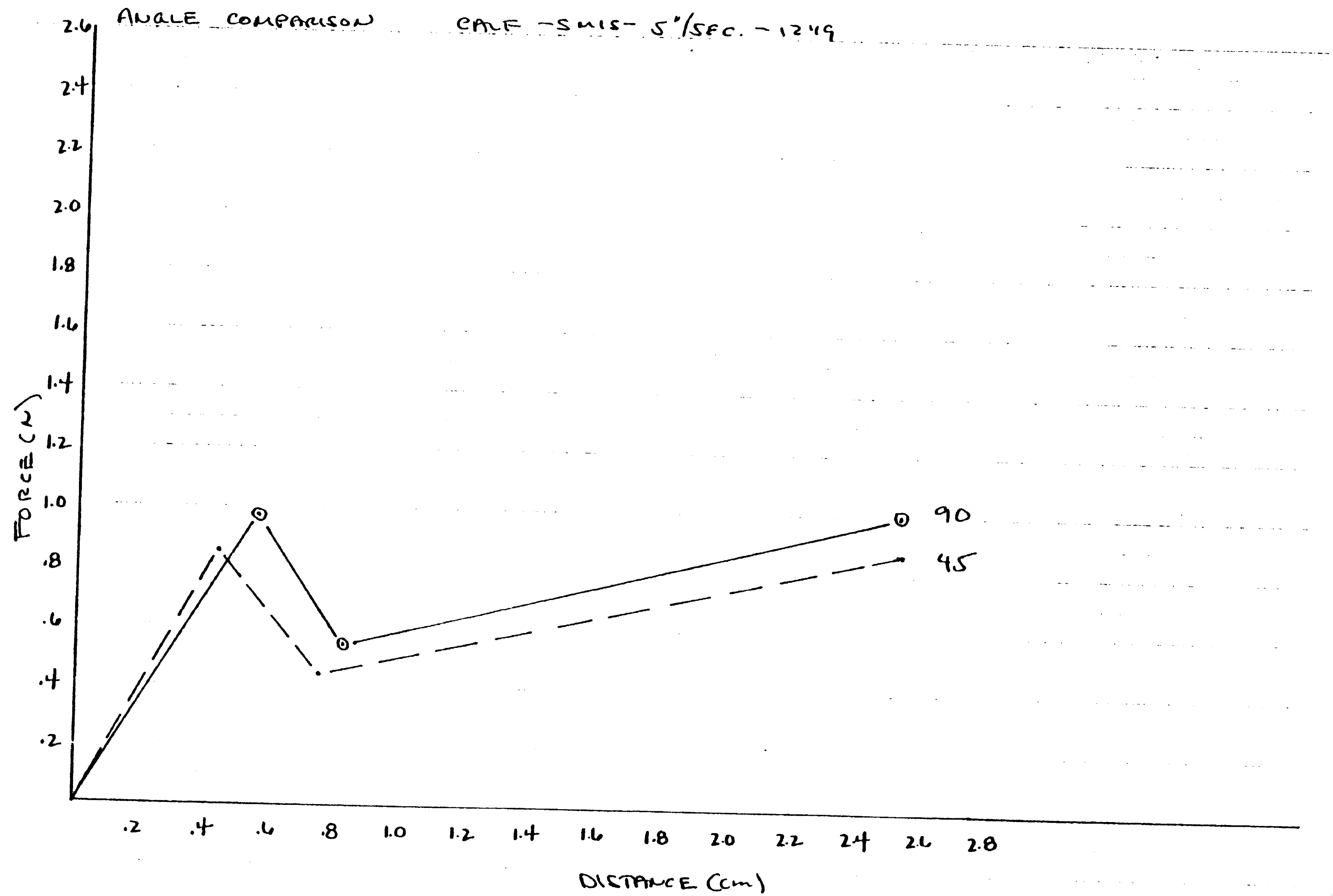
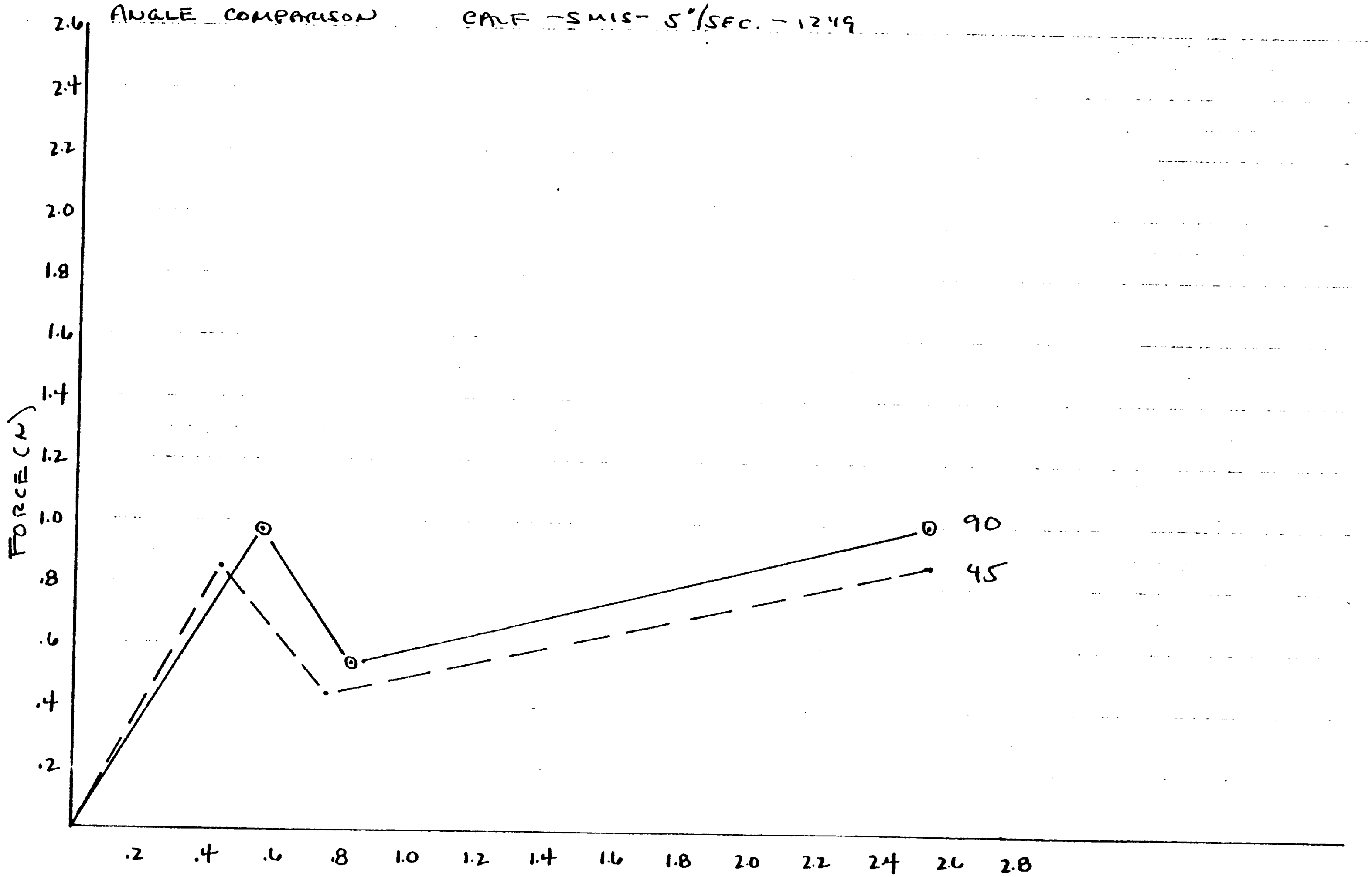

ANGLE COMPARISON
CALF -SMIS- 5"/SEC. - 1249
FORCE (N)
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
.2
.4
.6
.8
1.0
1.2
1.4
1.6
1.8
2.0
2.2
2.4
2.6
2.8
90
45
DISTANCE (cm)

FIGURE 17 H




DISTANCE (cm)

FIGURE 17 I

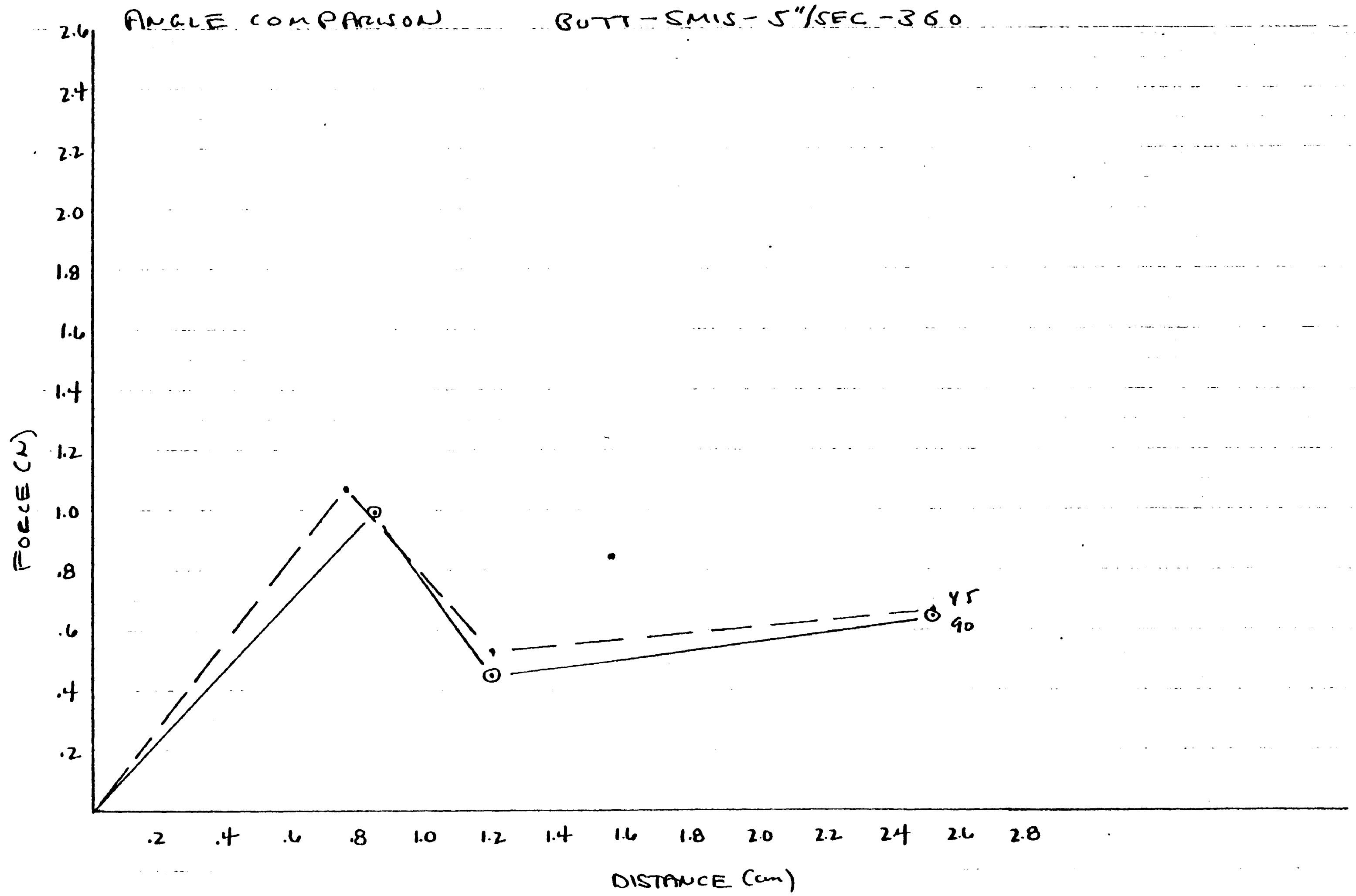

ANGLE COMPARISON
BUTT-SMIS-5"/SEC-360
FORCE (N)
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
45
90
.2
.4
.6
.8
1.0
1.2
1.4
1.6
1.8
2.0
2.2
2.4
2.6
2.8
DISTANCE (cm)

FIGURE 17 J

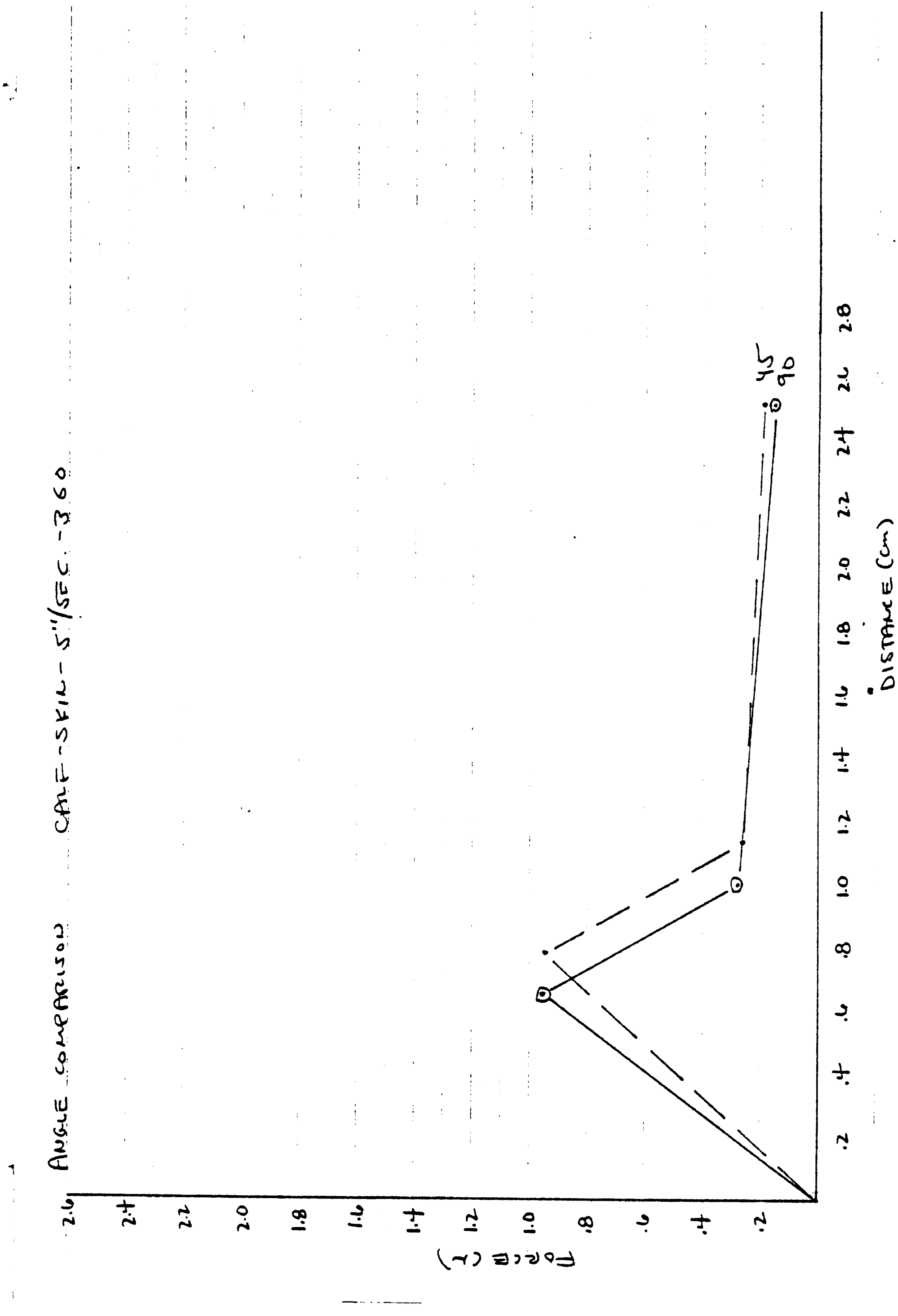

ANGLE COMPARISON
CALF-SKIN-5"/SEC.-360
FORCE (1)
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
.2
.4
.6
.8
1.0
1.2
1.4
1.6
1.8
2.0
2.2
2.4
2.6
2.8
DISTANCE (cm)
45
90

FIGURE 17K

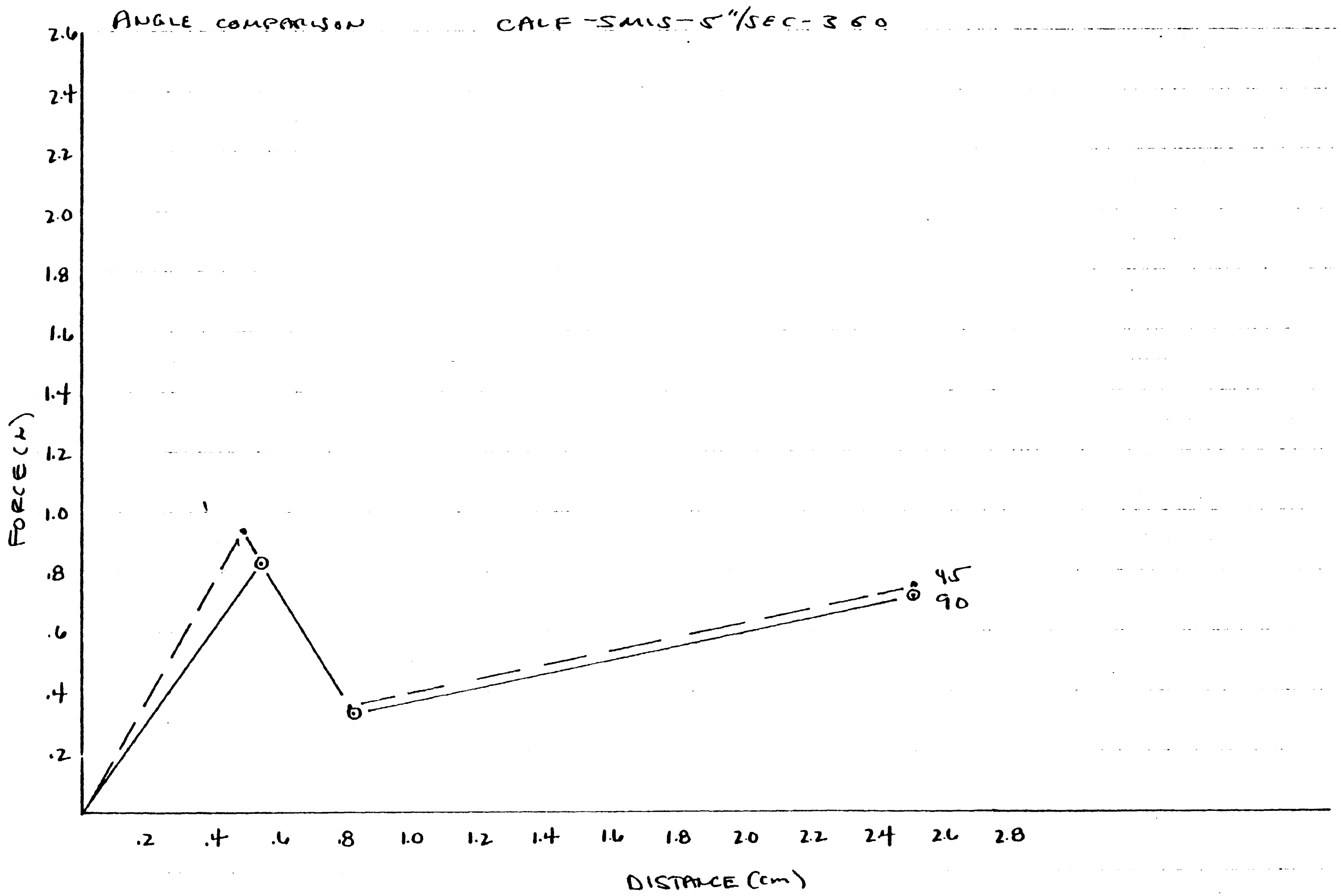

ANGLE COMPARISON
CALF-SMIS-5"/SEC-360
FORCE (2)
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
.2
.4
.6
.8
1.0
1.2
1.4
1.6
1.8
2.0
2.2
2.4
2.6
2.8
DISTANCE (cm)
45
90

FIGURE 17 L

FIGURE 18 (A-D)

Graphical Comparisons of Mean Reconstructed Force-Displacement Curves for the Three Lubricant Conditions - DRY, 1249, and 360.

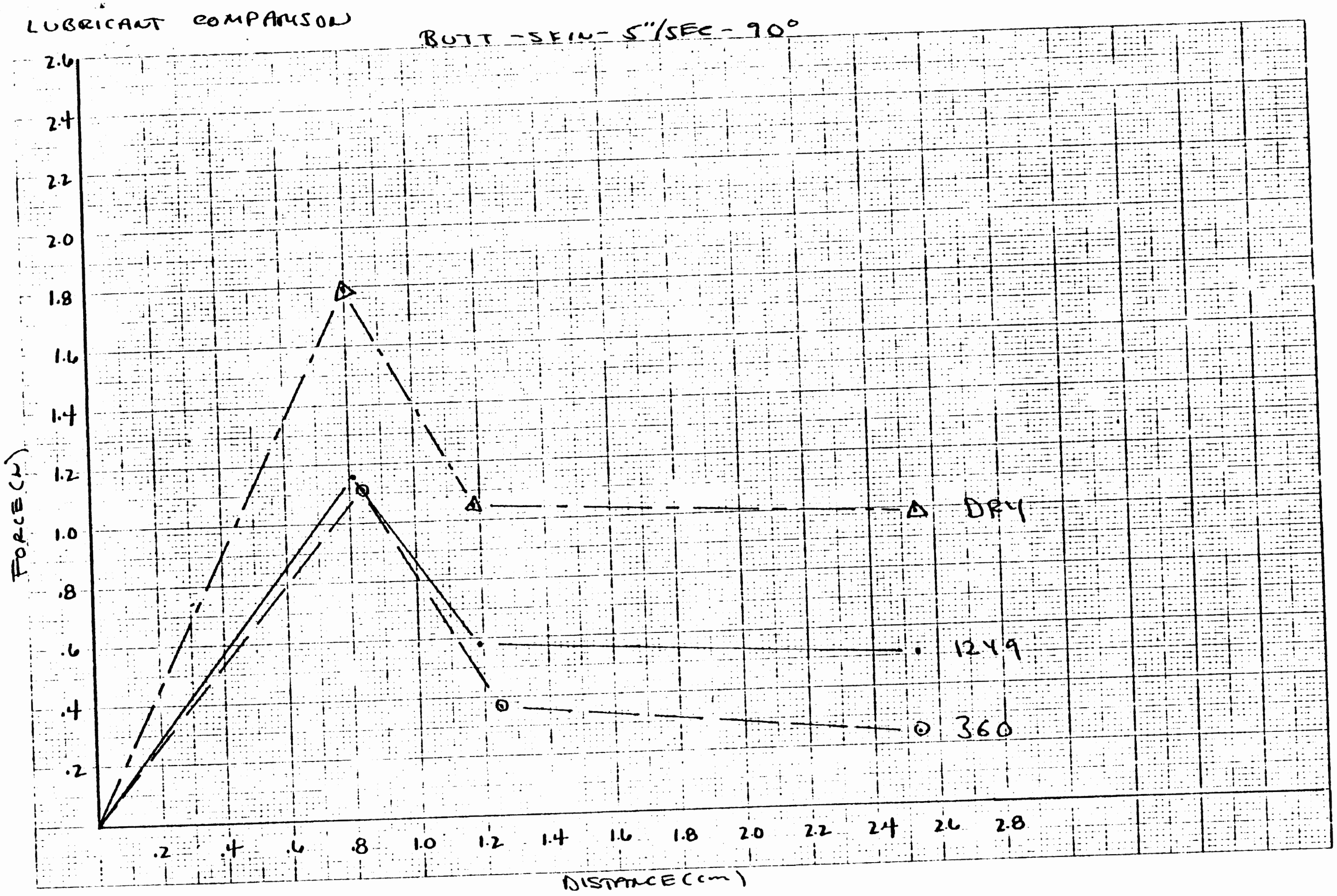
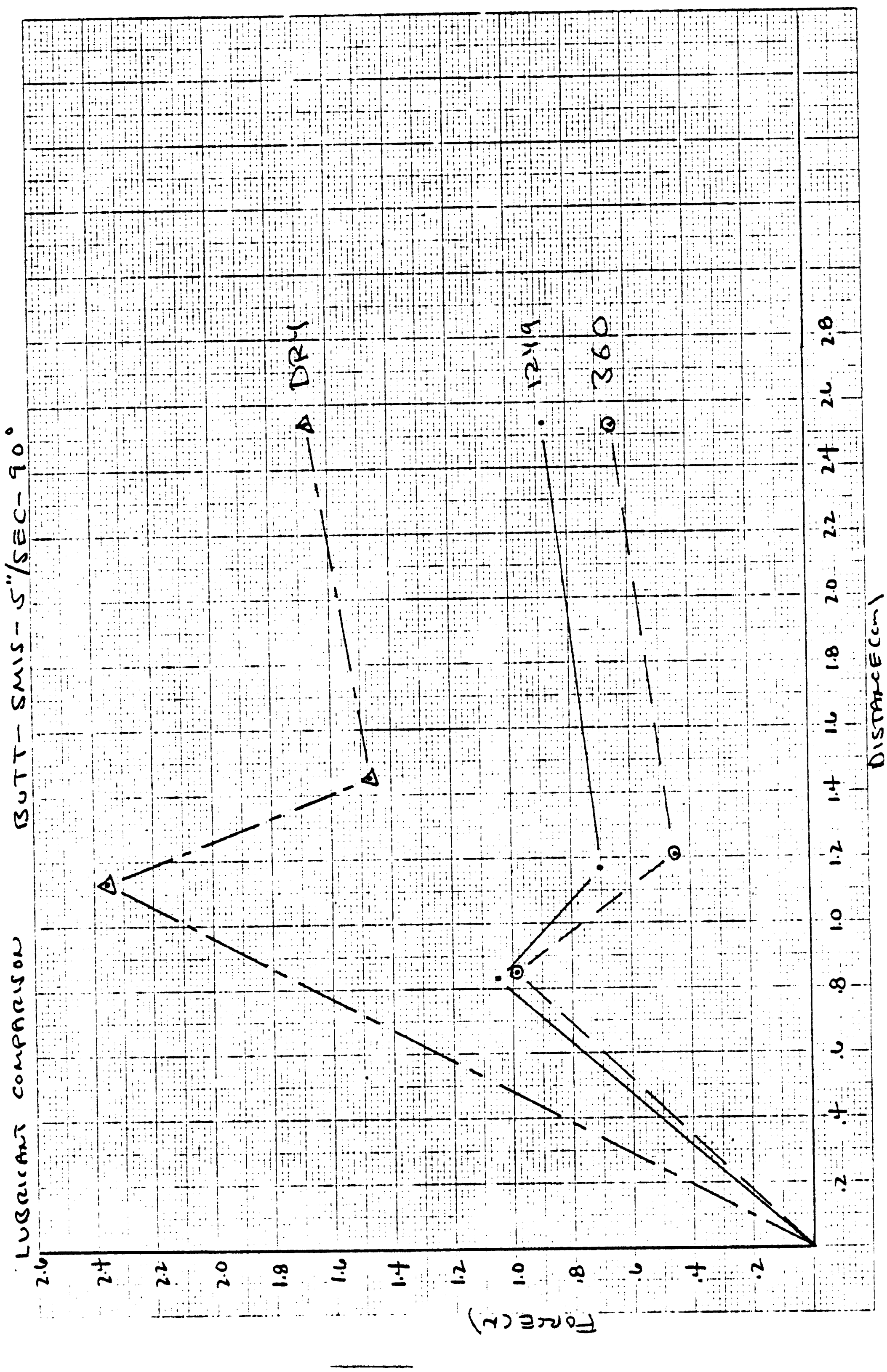

LUBRICANT COMPARISON
BUTT - SKIN - 5"/SEC - 90°
DRY
1249
360
DISTANCE (cm)
.2
.4
.6
.8
1.0
1.2
1.4
1.6
1.8
2.0
2.2
2.4
2.6
2.8
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2

FIGURE 18 A



LUBRICANT COMPARISON BUTT-SMIS-5"/SEC-90°
DRY
1219
360
FORCE (z)
DISTANCE (cm)
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
.2
.4
.6
.8
1.0
1.2
1.4
1.6
1.8
2.0
2.2
2.4
2.6
2.8


FIGURE 18B

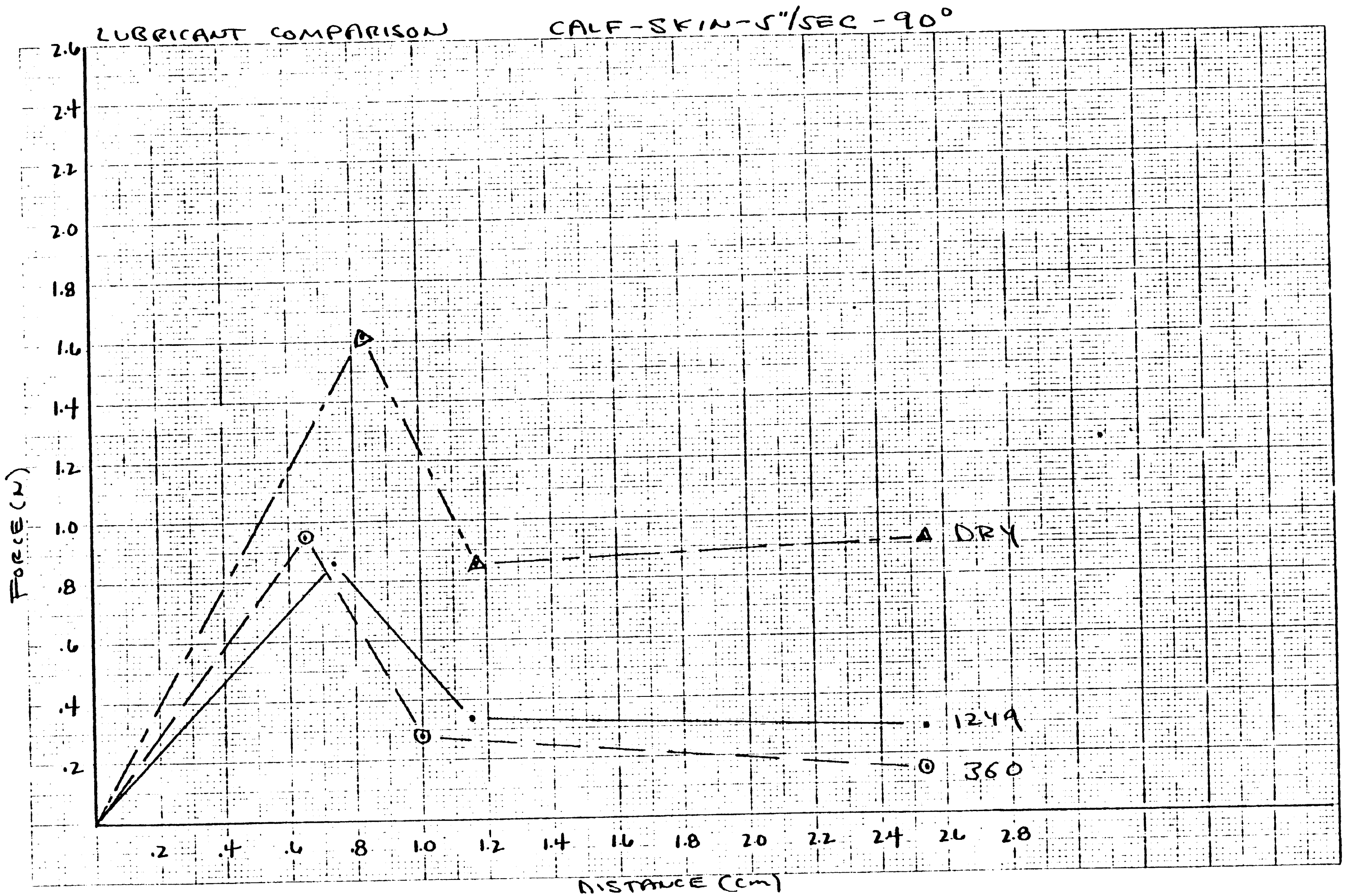

LUBRICANT COMPARISON
CALF-SKIN-5"/SEC -90°
FORCE (N)
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
.2
.4
.6
.8
1.0
1.2
1.4
1.6
1.8
2.0
2.2
2.4
2.6
2.8
DISTANCE (cm)
DRY
1249
360

FIGURE 18C

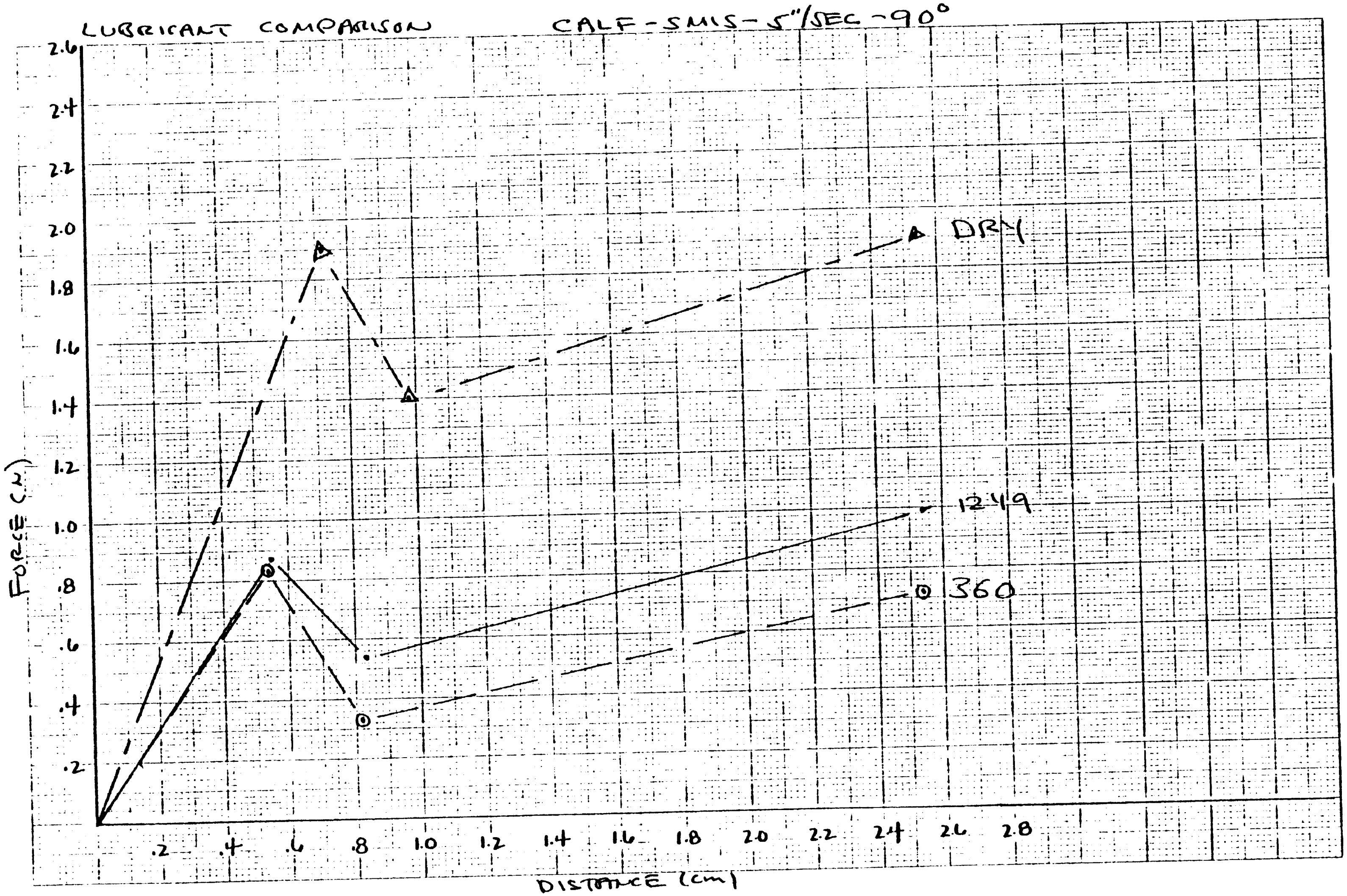

LUBRICANT COMPARISON
CALF-SMIS-5"/SEC-90°
FORCE (N)
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
DISTANCE (cm)
.2
.4
.6
.8
1.0
1.2
1.4
1.6
1.8
2.0
2.2
2.4
2.6
2.8
DRY
1249
360

FIGURE 18D

FIGURE 19 (A-F)

Graphical Comparisons of Mean Reconstructed Force-Displacement Curves for BUTT and CALF Tests

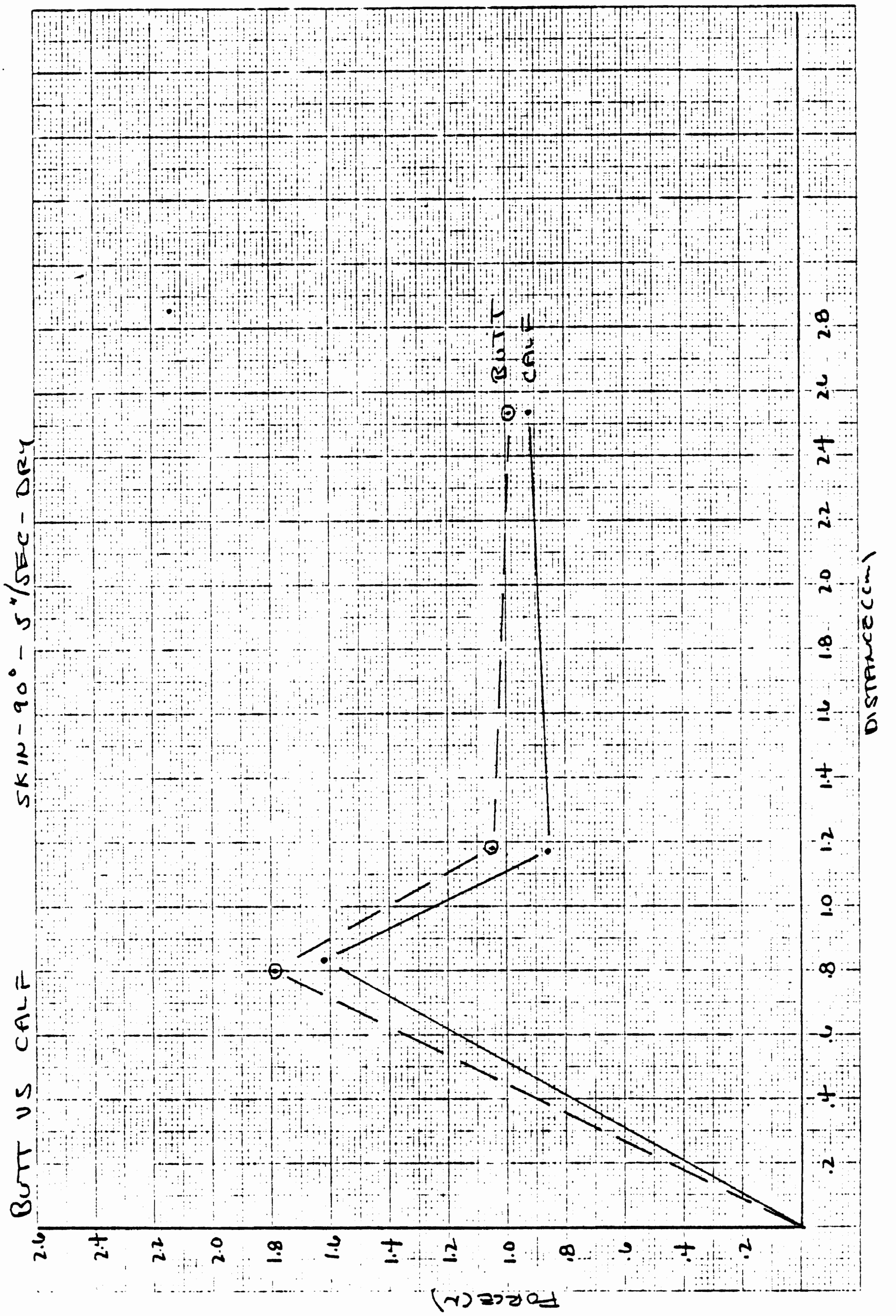

BUTT VS CALF SKIN - 90° - 5"/SEC - DRY
BUTT
CALF
FORCE (N)
DISTANCE (cm)
.2 .4 .6 .8 1.0 1.2 1.4 1.6 1.8 2.0 2.2 2.4 2.6 2.8
.2 .4 .6 .8 1.0 1.2 1.4 1.6 1.8 2.0 2.2 2.4 2.6

FIGURE 19 A

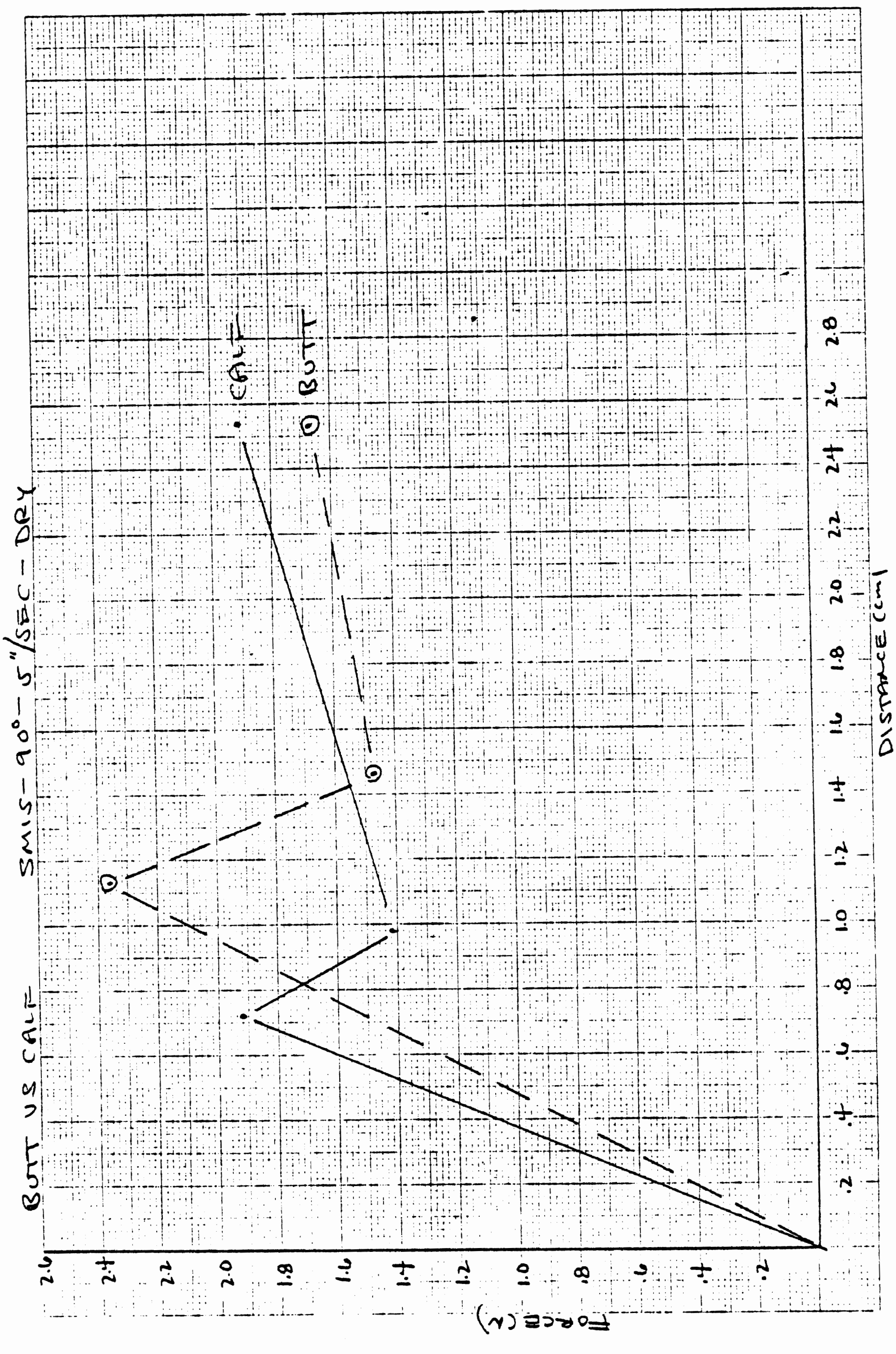

BUTT VS CALF
SMIS – 90° – 5"/SEC – DRY
CALF
BUTT
DISTANCE (cm)
.2 .4 .6 .8 1.0 1.2 1.4 1.6 1.8 2.0 2.2 2.4 2.6 2.8
2.6 2.4 2.2 2.0 1.8 1.6 1.4 1.2 1.0 .8 .6 .4 .2

FIGURE 19B

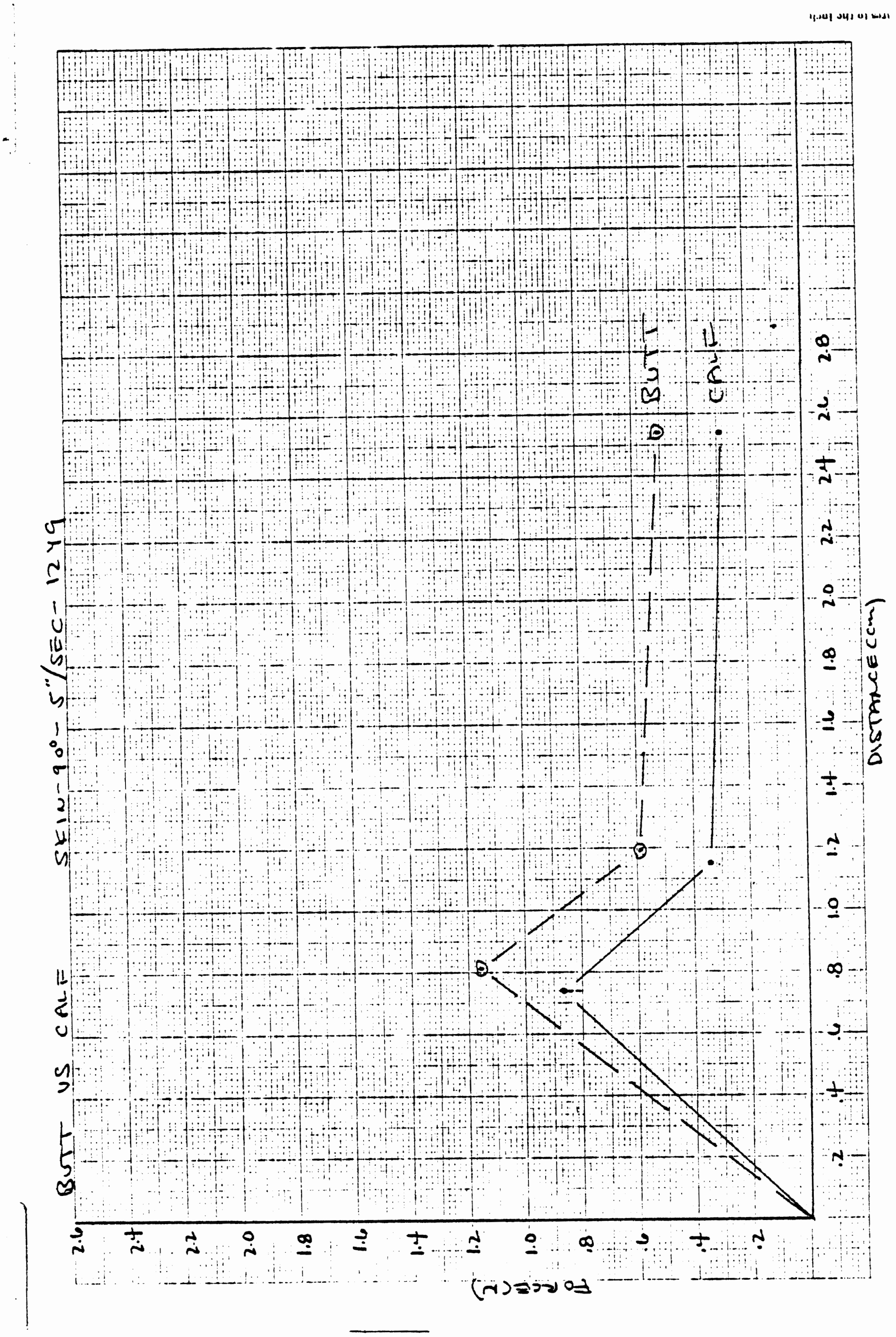

BUTT VS CALF
SKIN-90°-5"/SEC-1249
BUTT
CALF
DISTANCE (cm)
.2
.4
.6
.8
1.0
1.2
1.4
1.6
1.8
2.0
2.2
2.4
2.6
2.8

FIGURE 19C

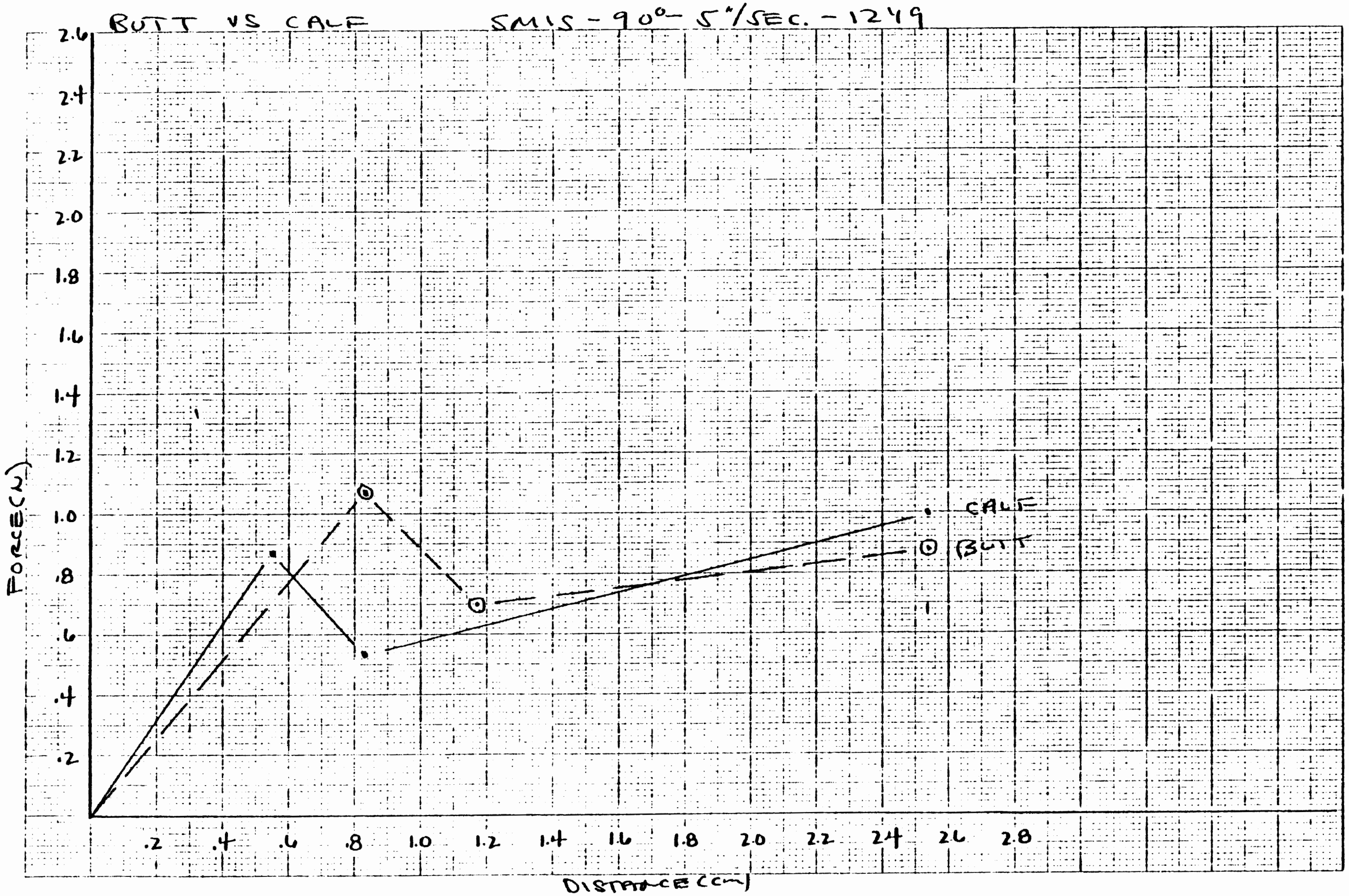

BUTT VS CALF
SMIS - 90° - 5"/SEC. - 1249
FORCE(N)
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
.2
.4
.6
.8
1.0
1.2
1.4
1.6
1.8
2.0
2.2
2.4
2.6
2.8
DISTANCE(cm)
CALF
BUTT

FIGURE 19D

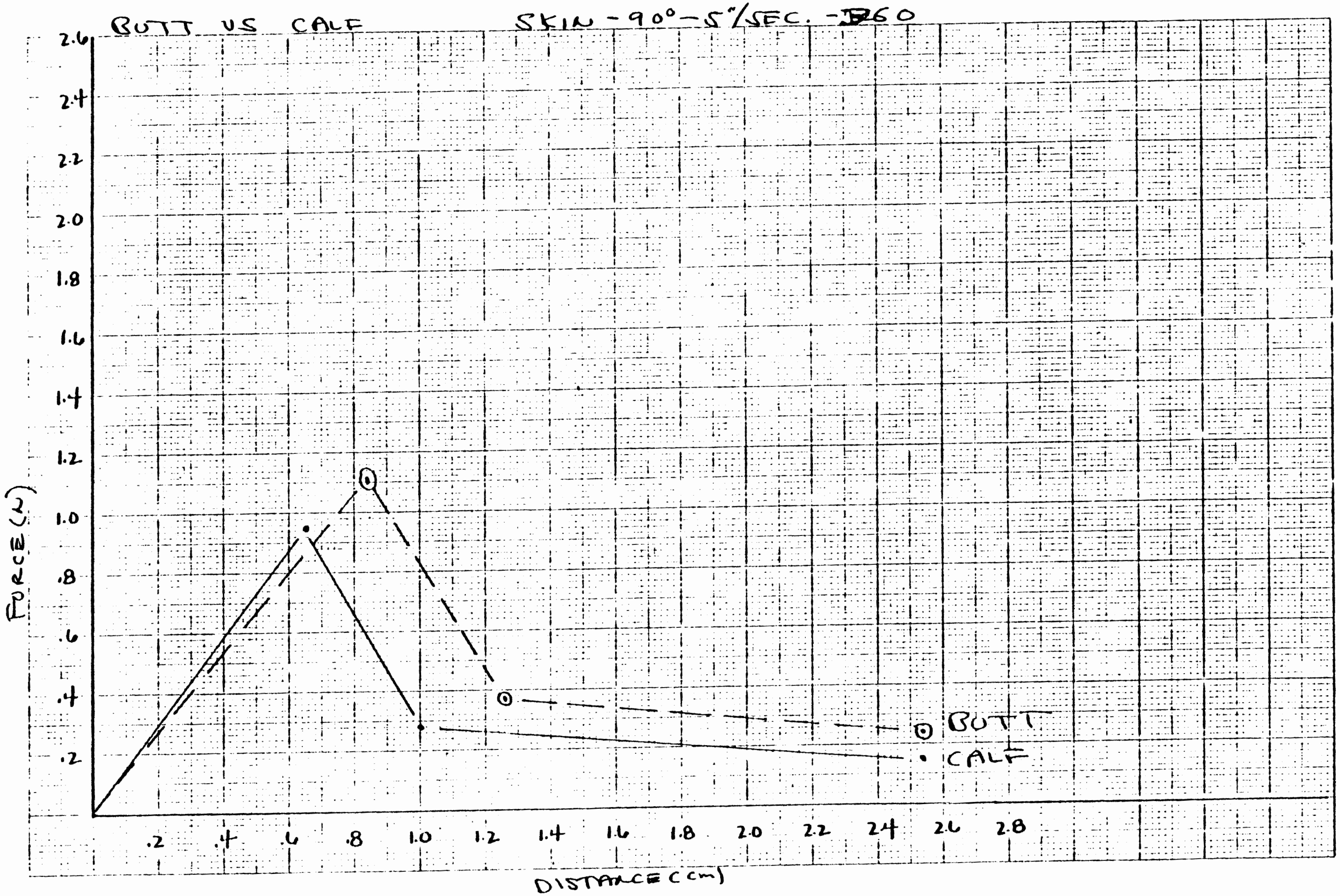

BUTT VS CALF
SKIN-90°-5"/SEC.-360
FORCE (#)
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
.2
.4
.6
.8
1.0
1.2
1.4
1.6
1.8
2.0
2.2
2.4
2.6
2.8
DISTANCE (cm)
BUTT
CALF

FIGURE 19E

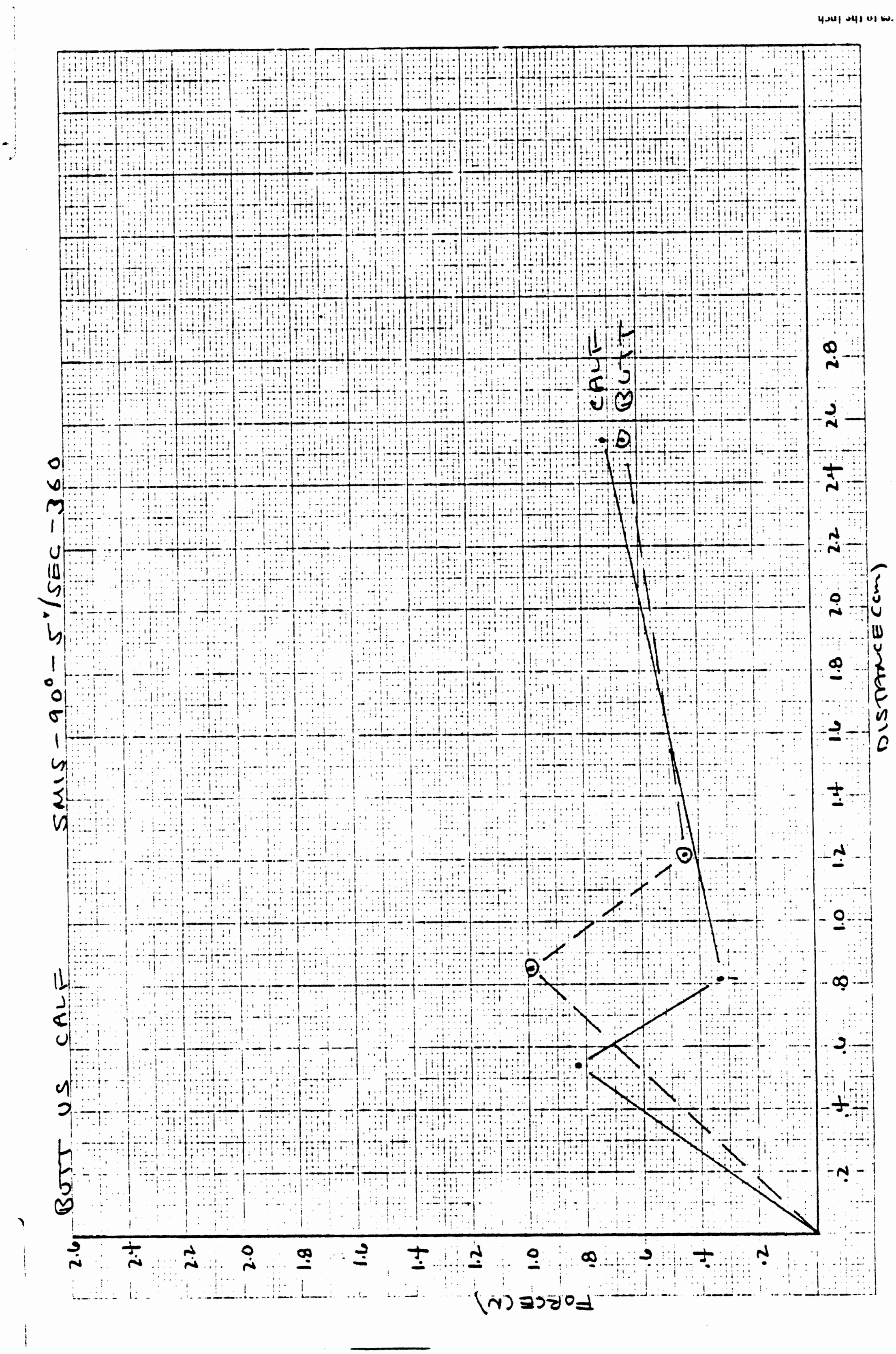

BUTT VS CALF
SMIS-90°-5'/SEC-360
CALF
BUTT
DISTANCE (cm)
FORCE
.2
.4
.6
.8
1.0
1.2
1.4
1.6
1.8
2.0
2.2
2.4
2.6
2.8

FIGURE 19F

FIGURE 20 (A-F)

Graphical Comparisons of Mean Reconstructed Force-Displacement Curves for SMIS vs. SKIN Tests.

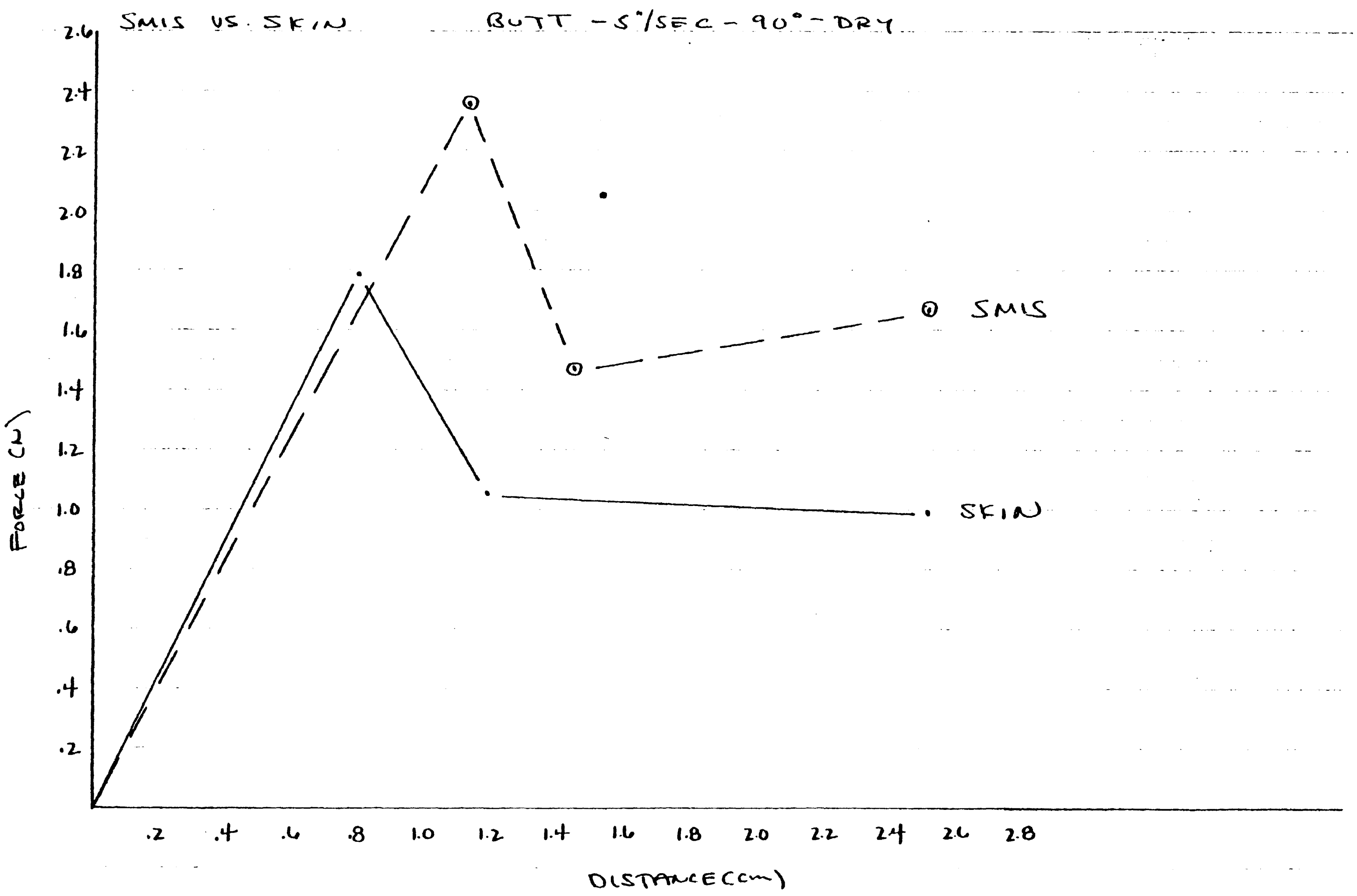

SMIS VS. SKIN
BUTT - 5"/SEC - 90° - DRY
SMIS
SKIN
FORCE (N)
DISTANCE (cm)
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
.2
.4
.6
.8
1.0
1.2
1.4
1.6
1.8
2.0
2.2
2.4
2.6
2.8

FIGURE 20 A

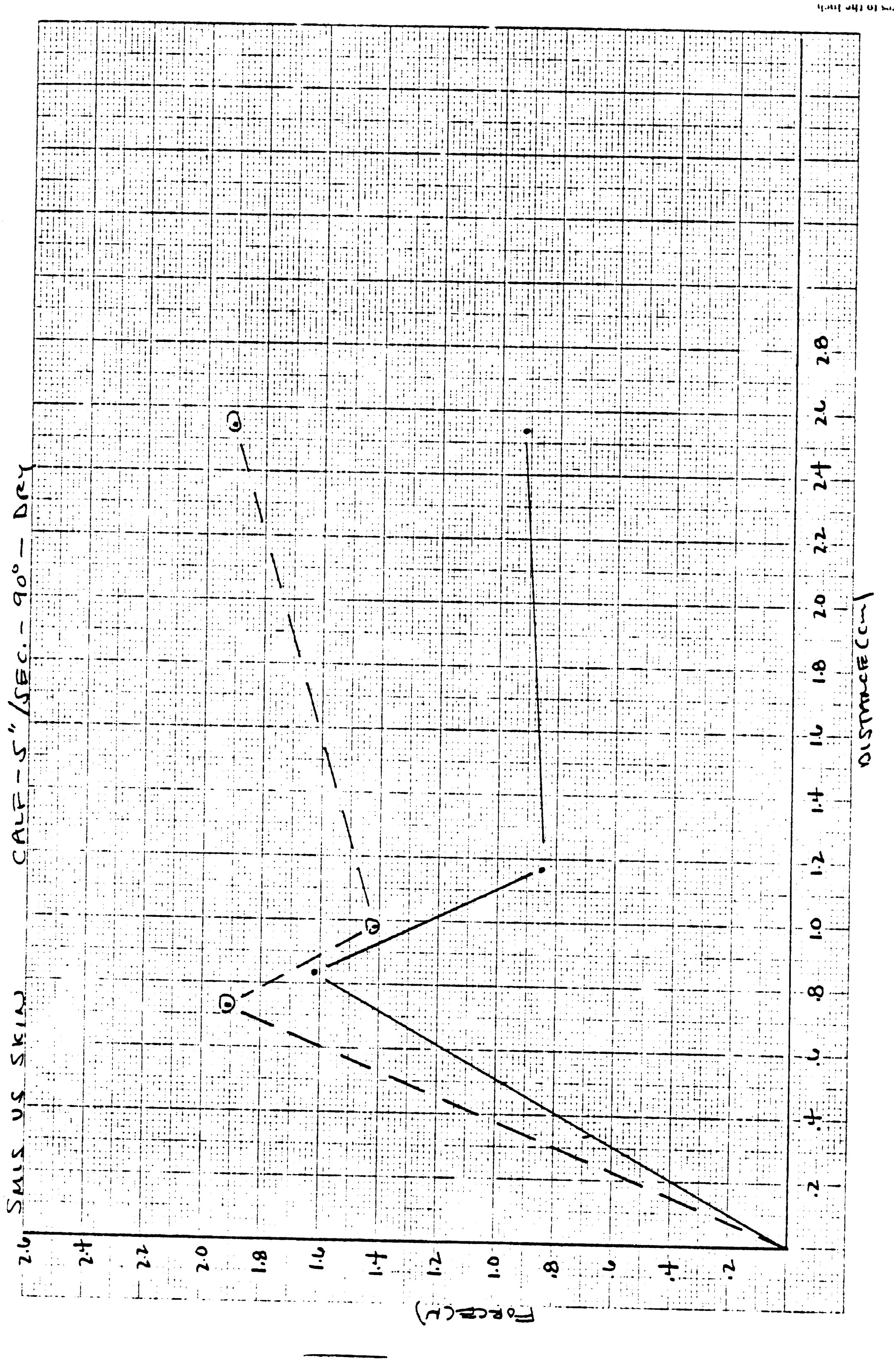

SKIS VS SKIN CALF-5"/SEC.-90°-DRY
FORCE (lb)
DISTANCE (cm)
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
2.8

FIGURE 20B

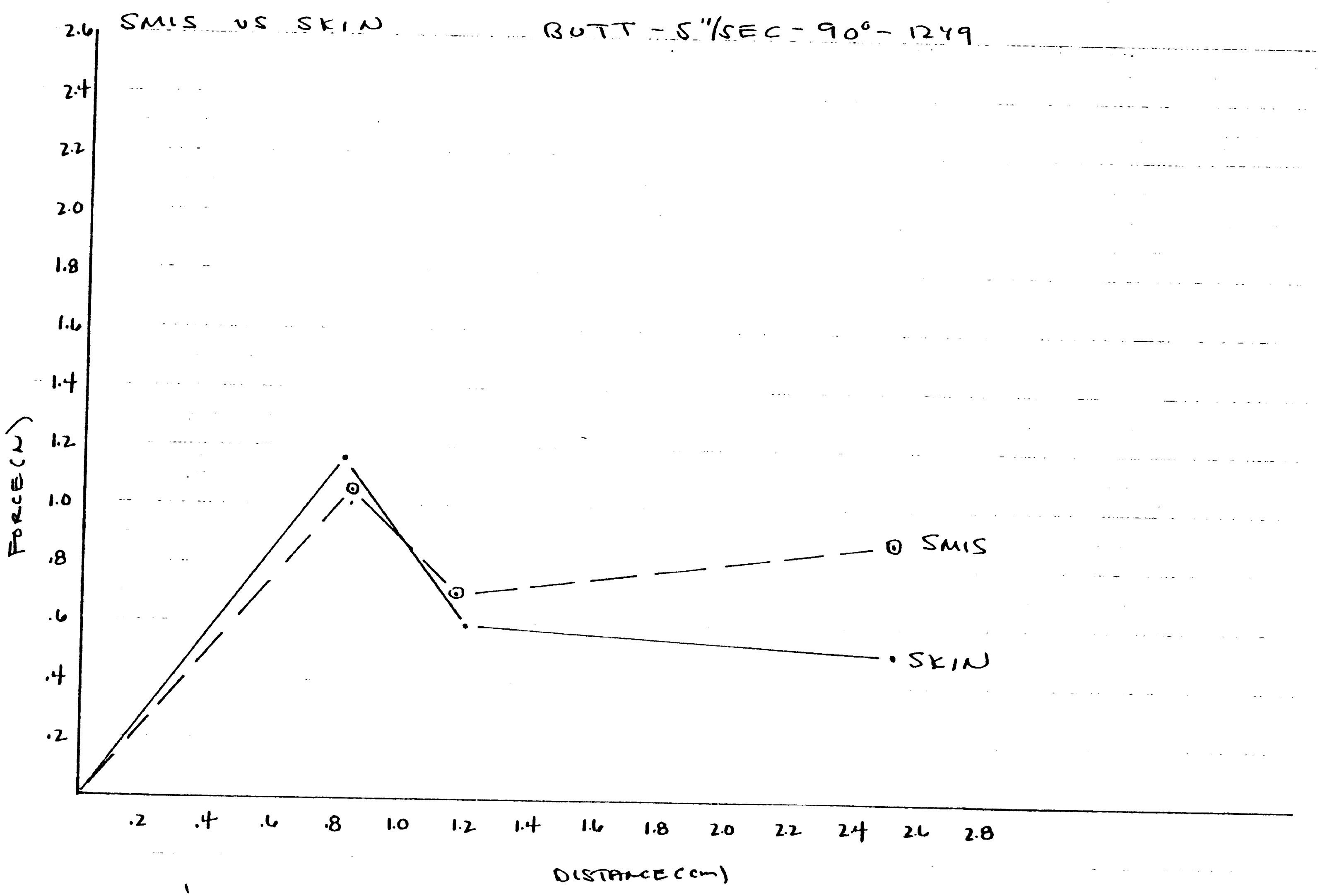

SMIS vs SKIN
BUTT - 5"/SEC - 90° - 1249
FORCE (N)
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
.2
.4
.6
.8
1.0
1.2
1.4
1.6
1.8
2.0
2.2
2.4
2.6
2.8
DISTANCE (cm)
SMIS
SKIN

FIGURE 20C

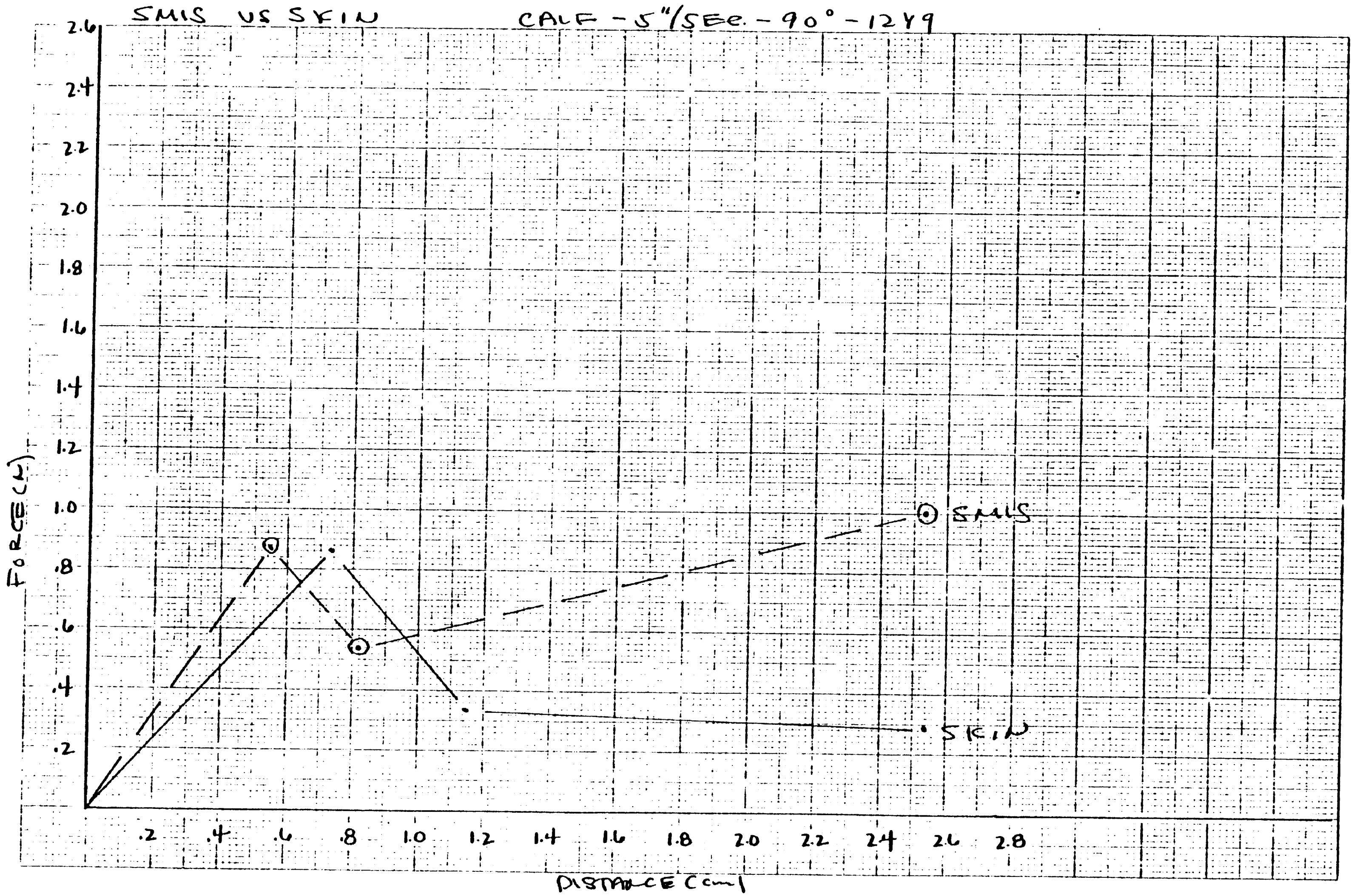

SMIS VS SKIN
CALF - 5"/SEC. - 90° - 1249
FORCE (N)
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
.2
.4
.6
.8
1.0
1.2
1.4
1.6
1.8
2.0
2.2
2.4
2.6
2.8
DISTANCE (cm)
SMIS
SKIN

FIGURE 20D

SMIS VS SKIN BUTT - 5"/SEC - 90° - 360

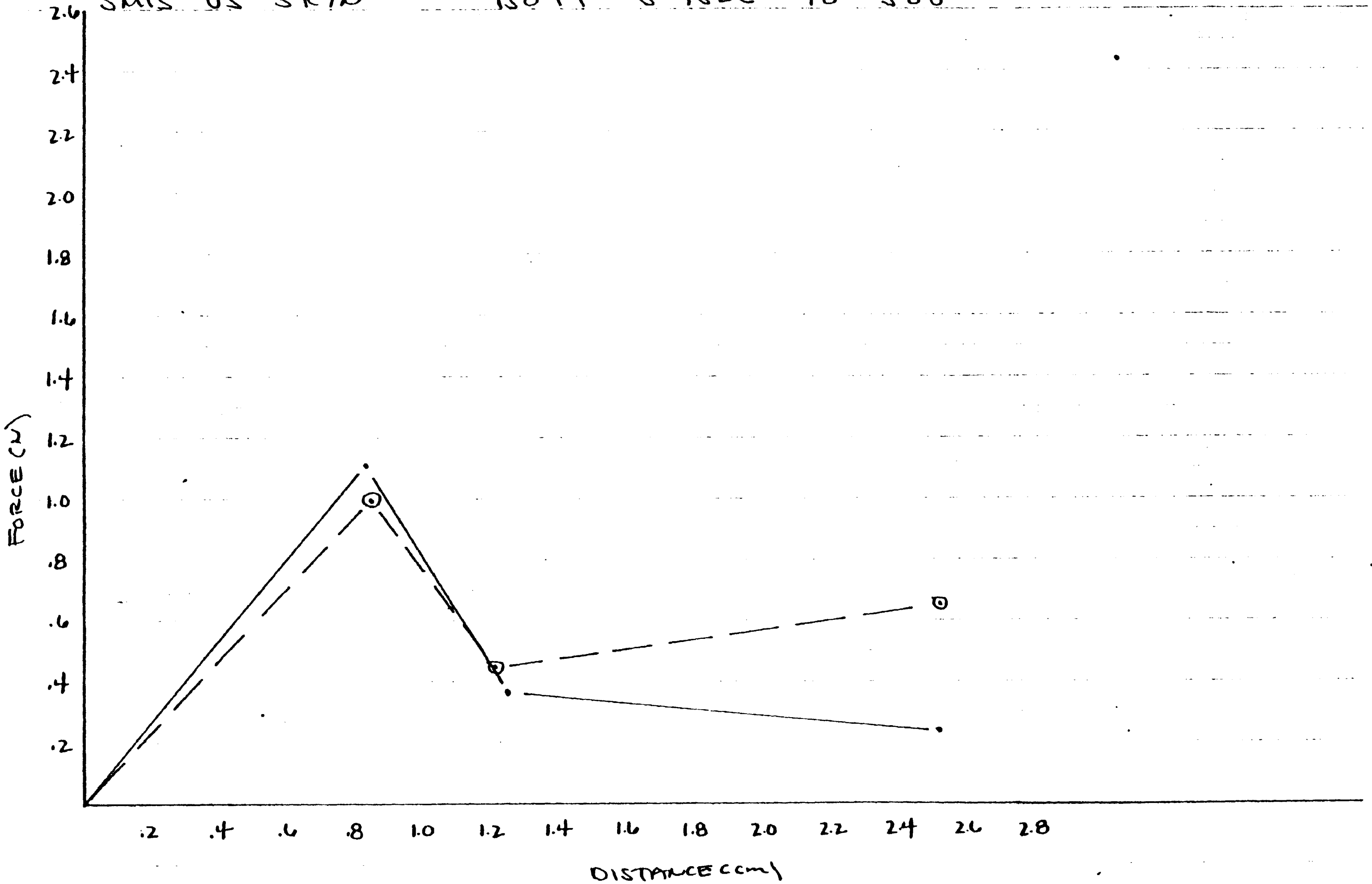



FIGURE 20E

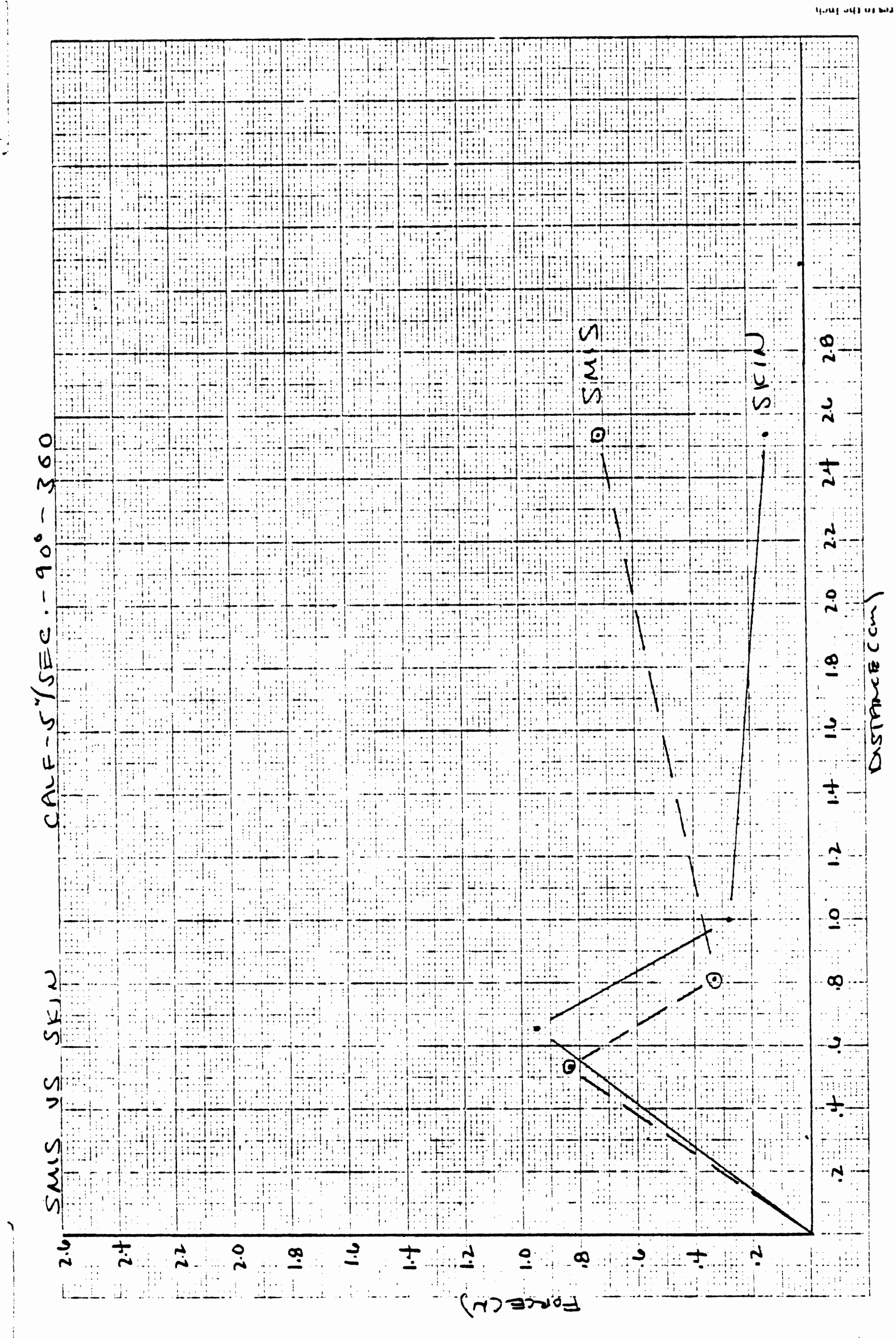



FIGURE 20F

FIGURE 21 (A-D)

Graphical Comparisons of PWORK Values

PWORK FOR BUTT-SKIN

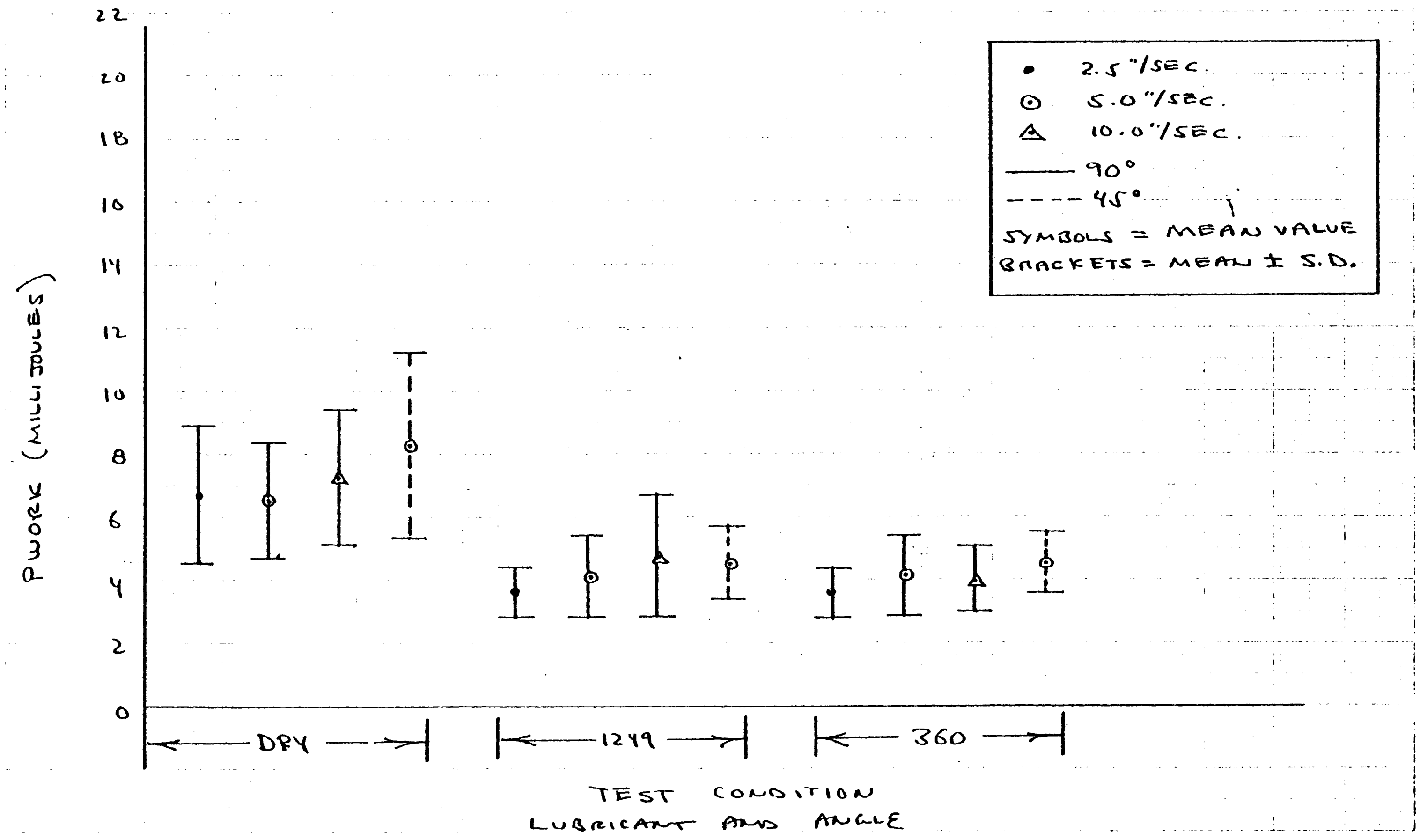



FIGURE 21 A

PWORK FOR BUTT-SMLS

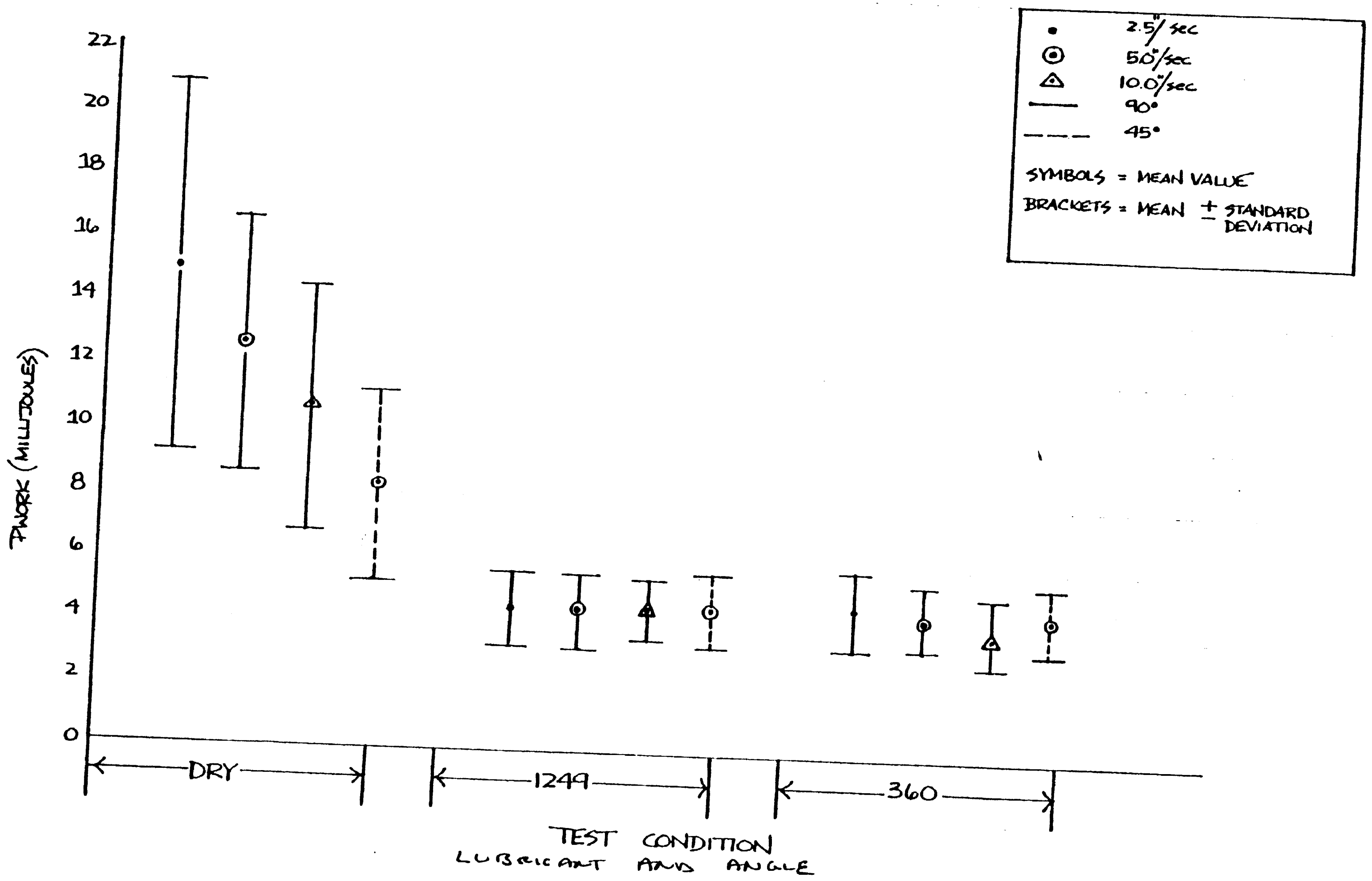



FIGURE 21B

PWORK FOR CALF-SKIN

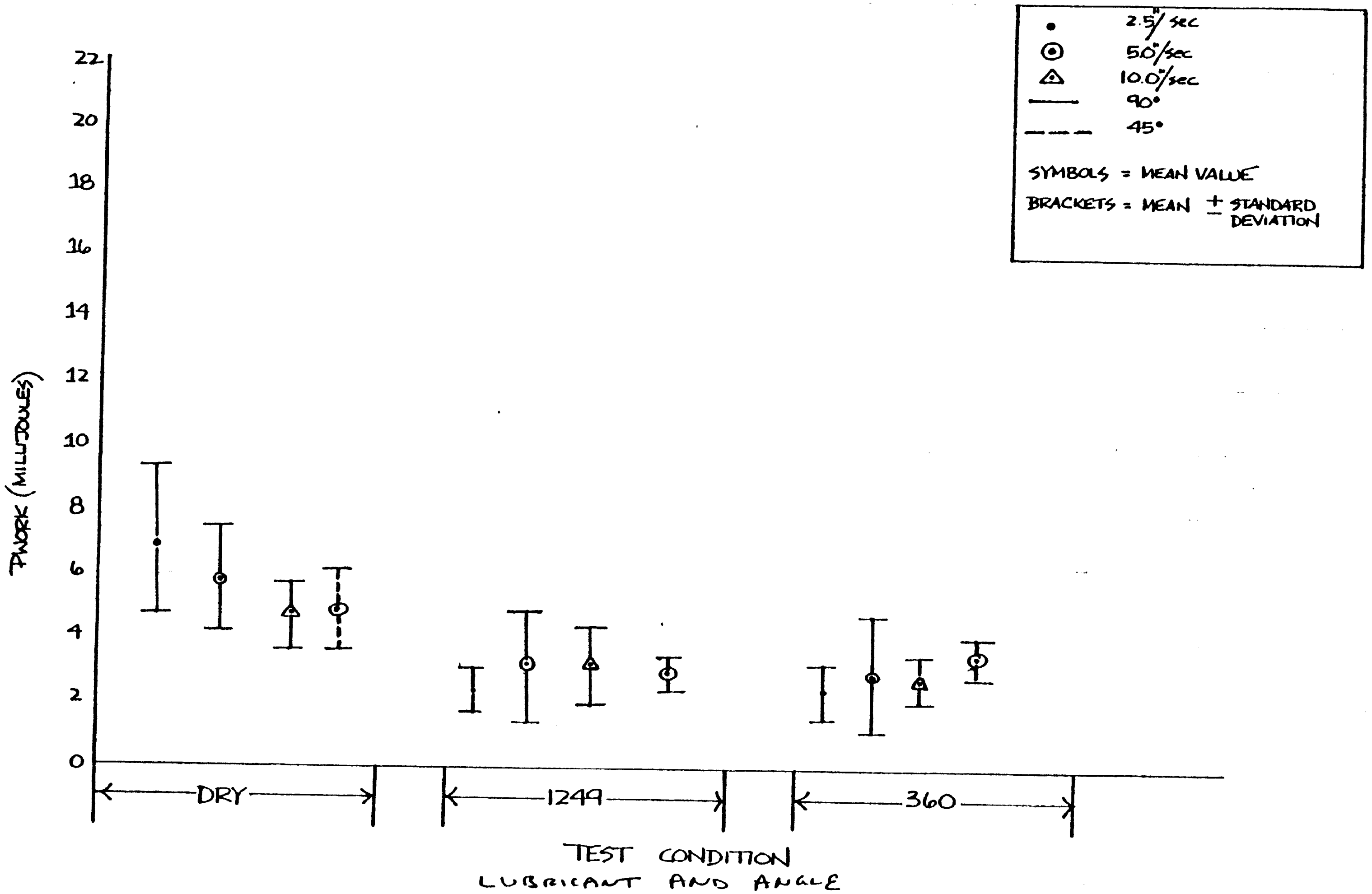
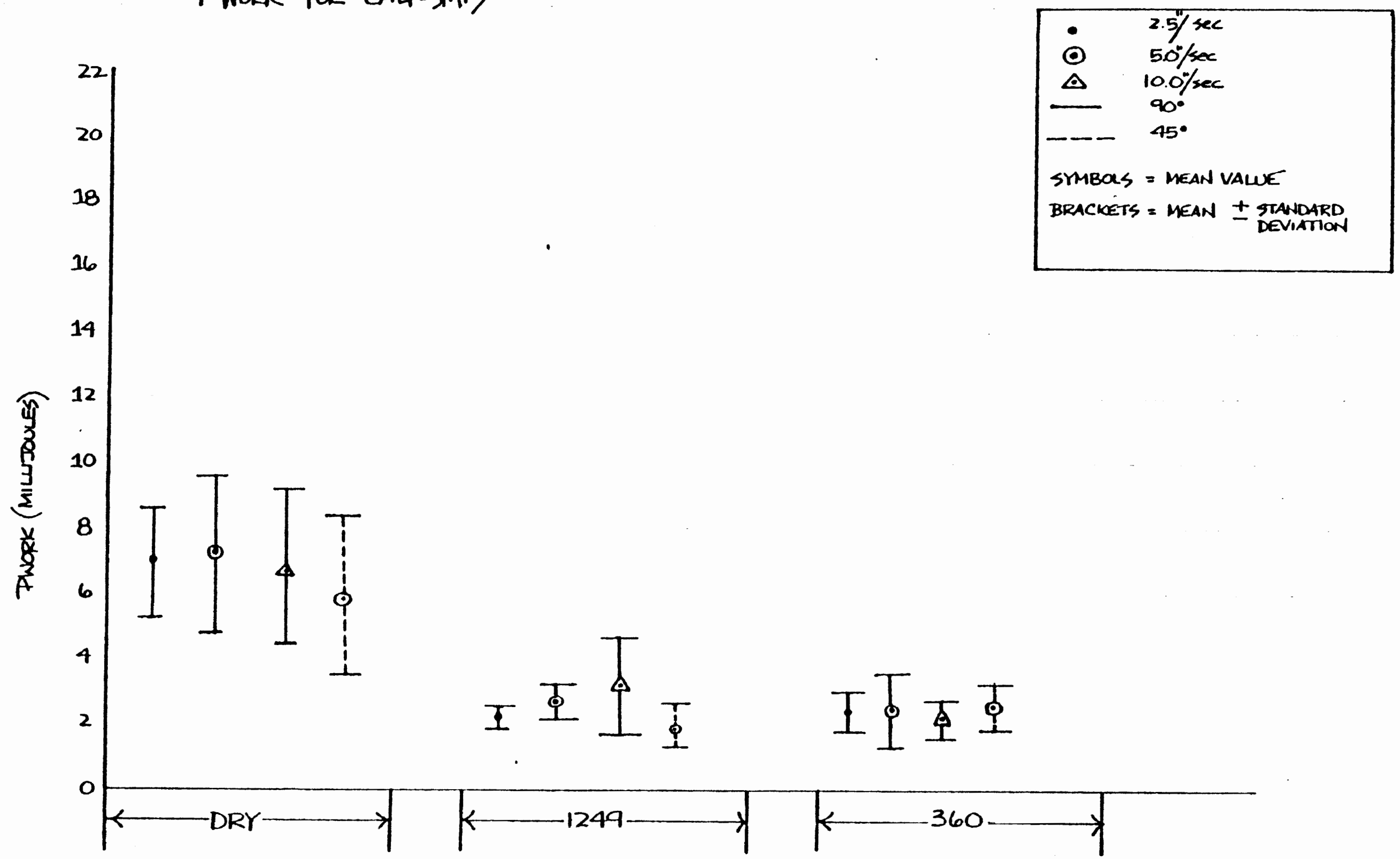



FIGURE 21C

PWORK FOR CALF-SMIS




TEST CONDITION
LUBRICANT AND ANGLE

FIGURE 21D

FIGURE 22 (A-D)

Graphical Comparisons of DWORK Values

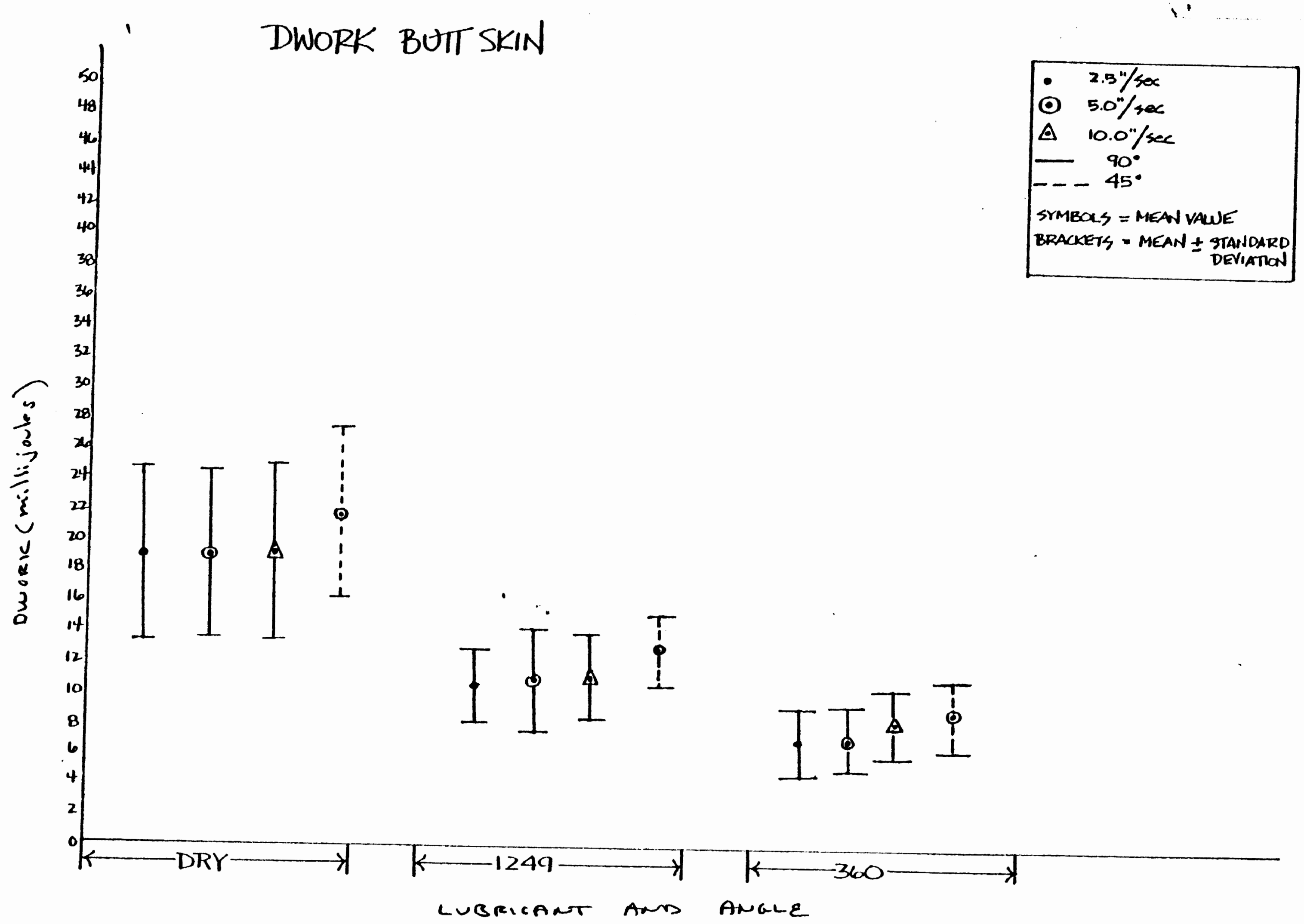

DWORK BUTT SKIN
DWORK (millijoules)
50
48
46
44
42
40
38
36
34
32
30
28
26
24
22
20
18
16
14
12
10
8
6
4
2
0
DRY
1249
360
LUBRICANT AND ANGLE
2.5"/sec
5.0"/sec
10.0"/sec
90°
45°
SYMBOLS = MEAN VALUE
BRACKETS = MEAN ± STANDARD DEVIATION

FIGURE 22 A

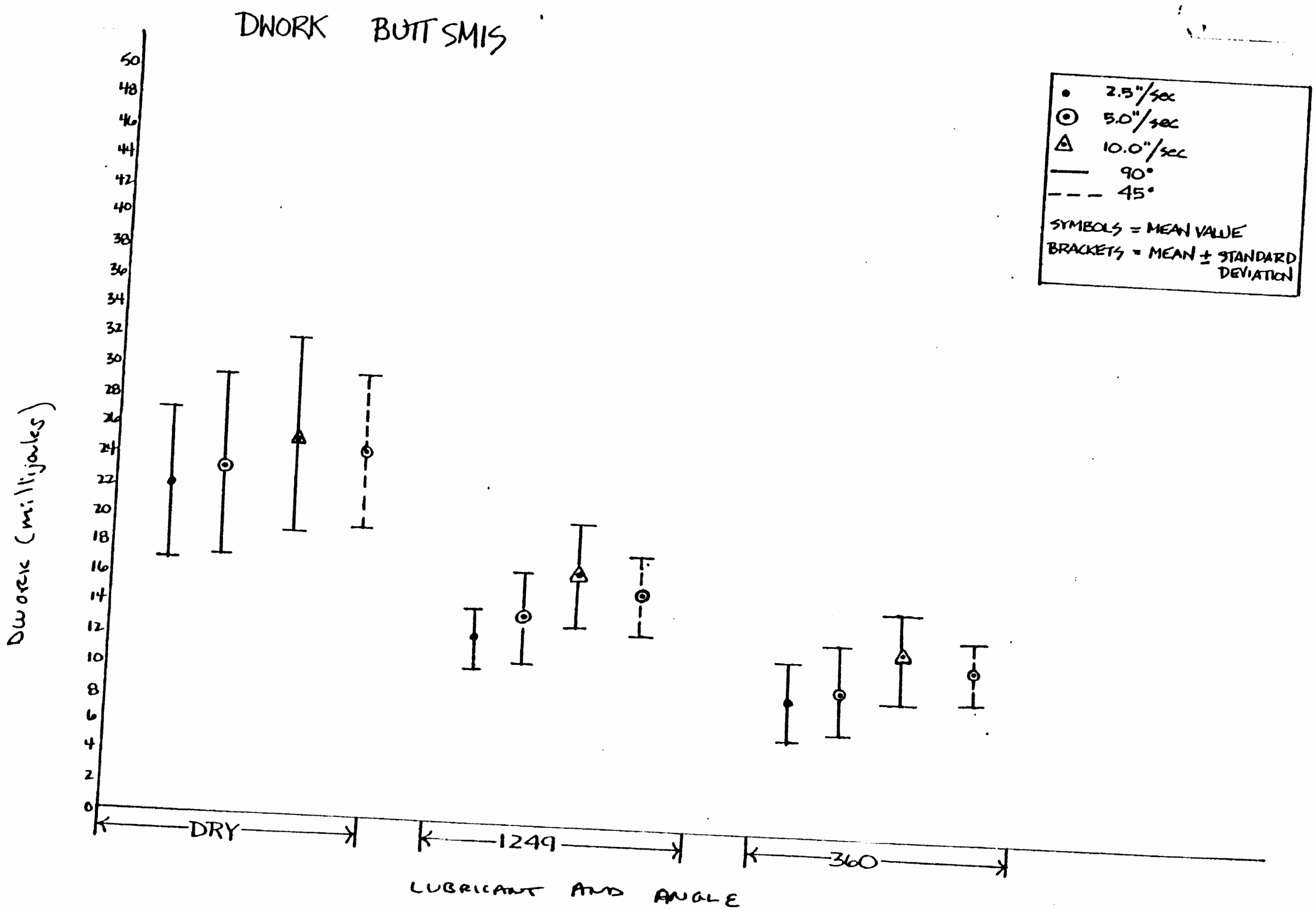

DWORK BUTT SMIS
2.5"/sec
5.0"/sec
10.0"/sec
90°
45°
SYMBOLS = MEAN VALUE
BRACKETS = MEAN ± STANDARD DEVIATION
50
48
46
44
42
40
38
36
34
32
30
28
26
24
22
20
18
16
14
12
10
8
6
4
2
0
DWORK (millijoules)
DRY
1249
360
LUBRICANT AND ANGLE

FIGURE 22B

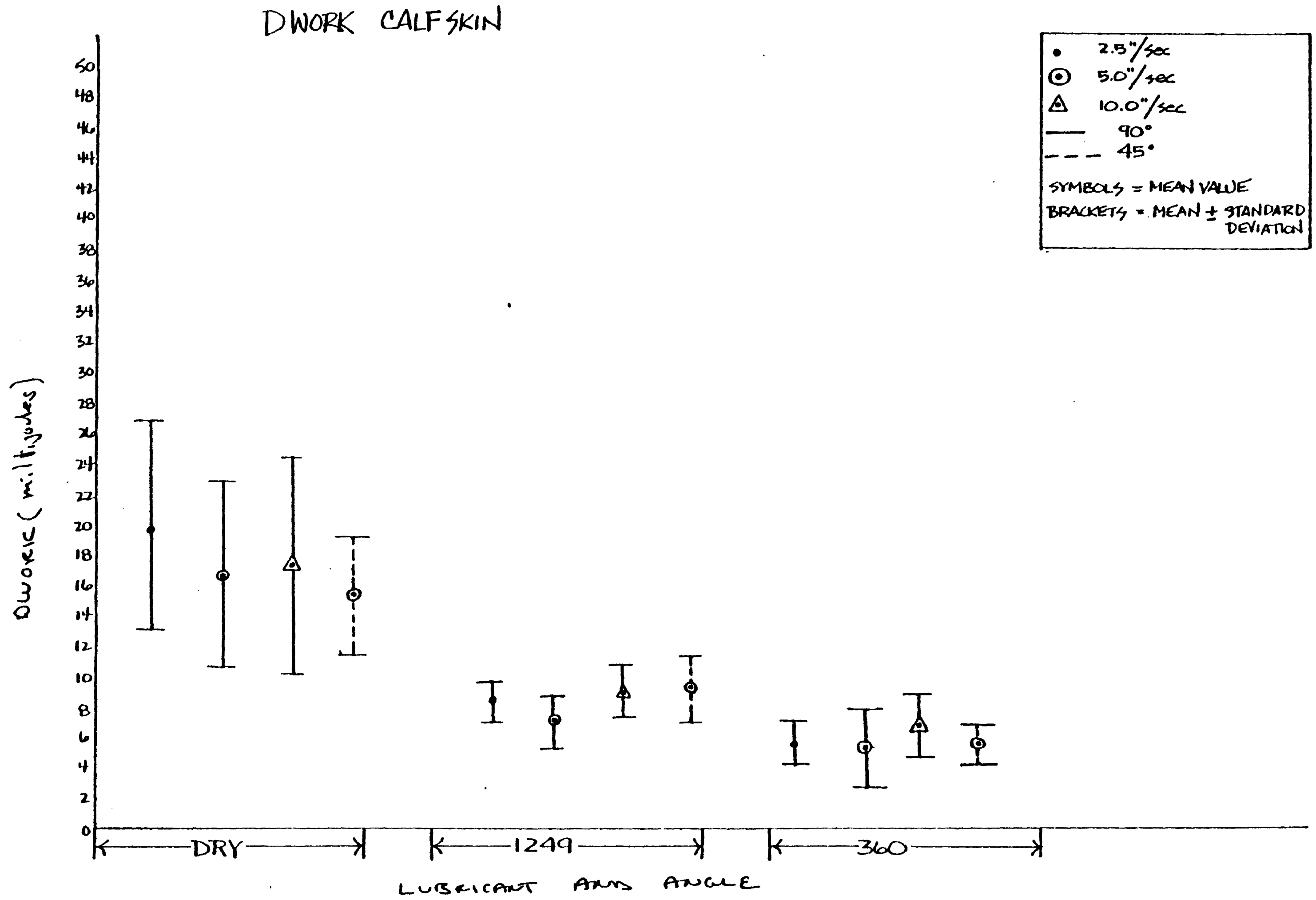

DWORK CALFSKIN
DWORK ( millijoules)
50
48
46
44
42
40
38
36
34
32
30
28
26
24
22
20
18
16
14
12
10
8
6
4
2
0
DRY
1249
360
LUBRICANT AND ANGLE
2.5"/sec
5.0"/sec
10.0"/sec
90°
45°
SYMBOLS = MEAN VALUE
BRACKETS = MEAN ± STANDARD DEVIATION

FIGURE 22C

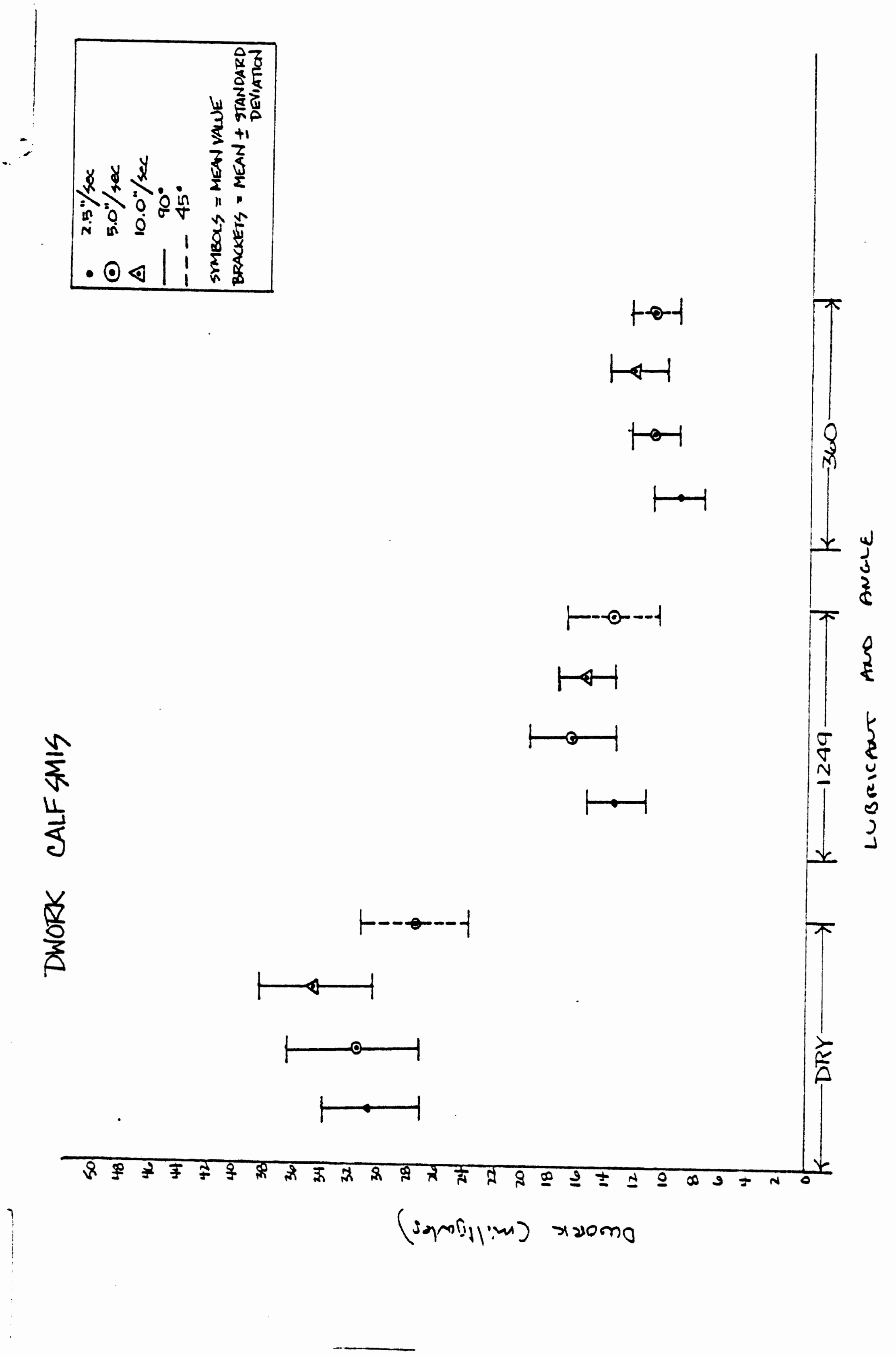

DWORK CALF SMIS
• 2.5"/sec
⊙ 5.0"/sec
△ 10.0"/sec
—— 90°
- - - 45°
SYMBOLS = MEAN VALUE
BRACKETS = MEAN ± STANDARD DEVIATION
DWORK (millijoules)
0
2
4
6
8
10
12
14
16
18
20
22
24
26
28
30
32
34
36
38
40
42
44
46
48
50
DRY
1249
360
LUBRICANT AND ANGLE

FIGURE 22D

FIGURE 23 (A-L)

Graphical Comparisons of Mean Reconstructed Force-Displacement Curves for Cadavers 4, 5, and 6

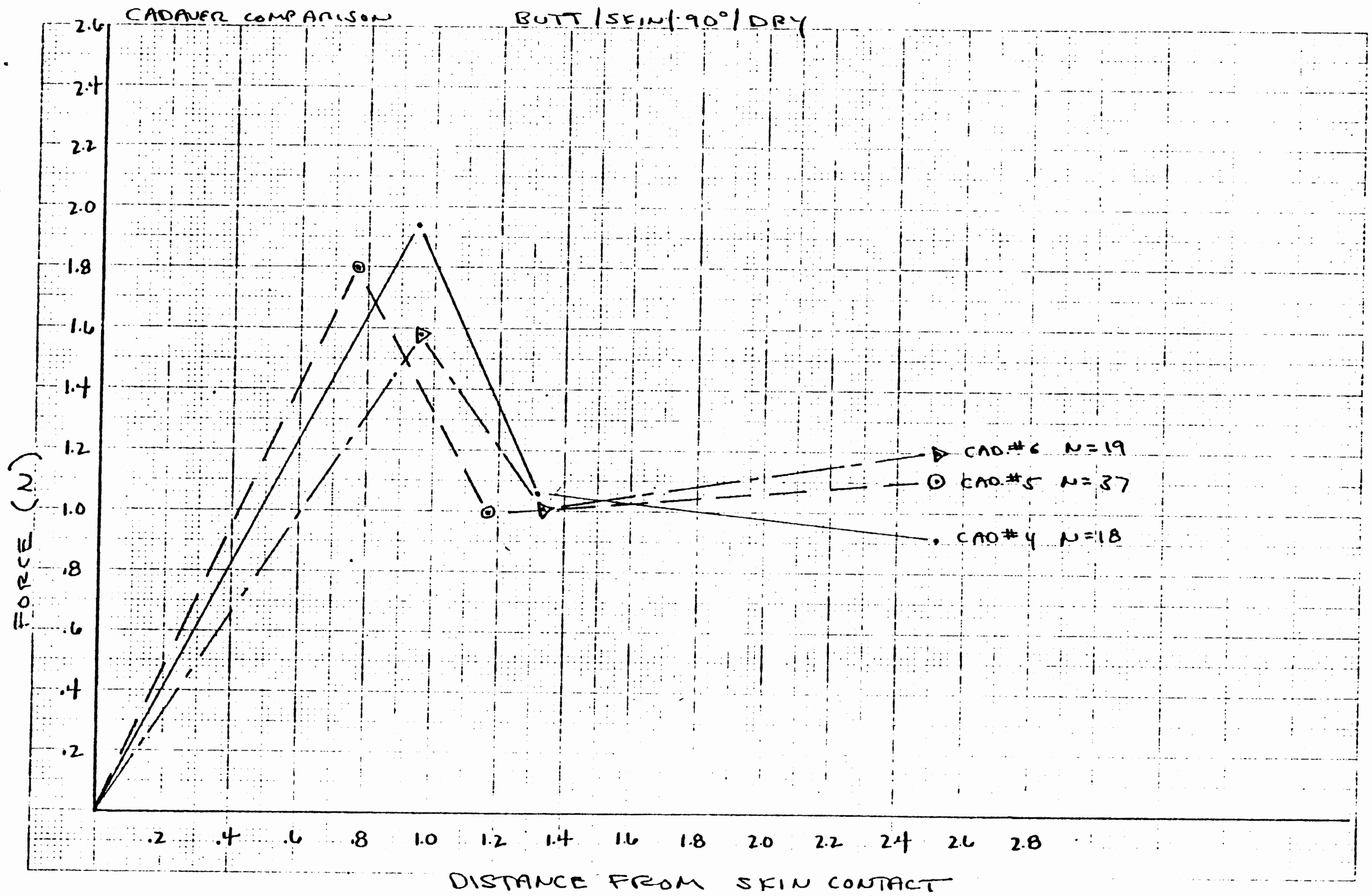

CADAVER COMPARISON
BUTT / SKIN / 90° / DRY
FORCE (N)
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
.2
.4
.6
.8
1.0
1.2
1.4
1.6
1.8
2.0
2.2
2.4
2.6
2.8
CAD #6 N=19
CAD #5 N=37
CAD #4 N=18
DISTANCE FROM SKIN CONTACT

FIGURE 23A

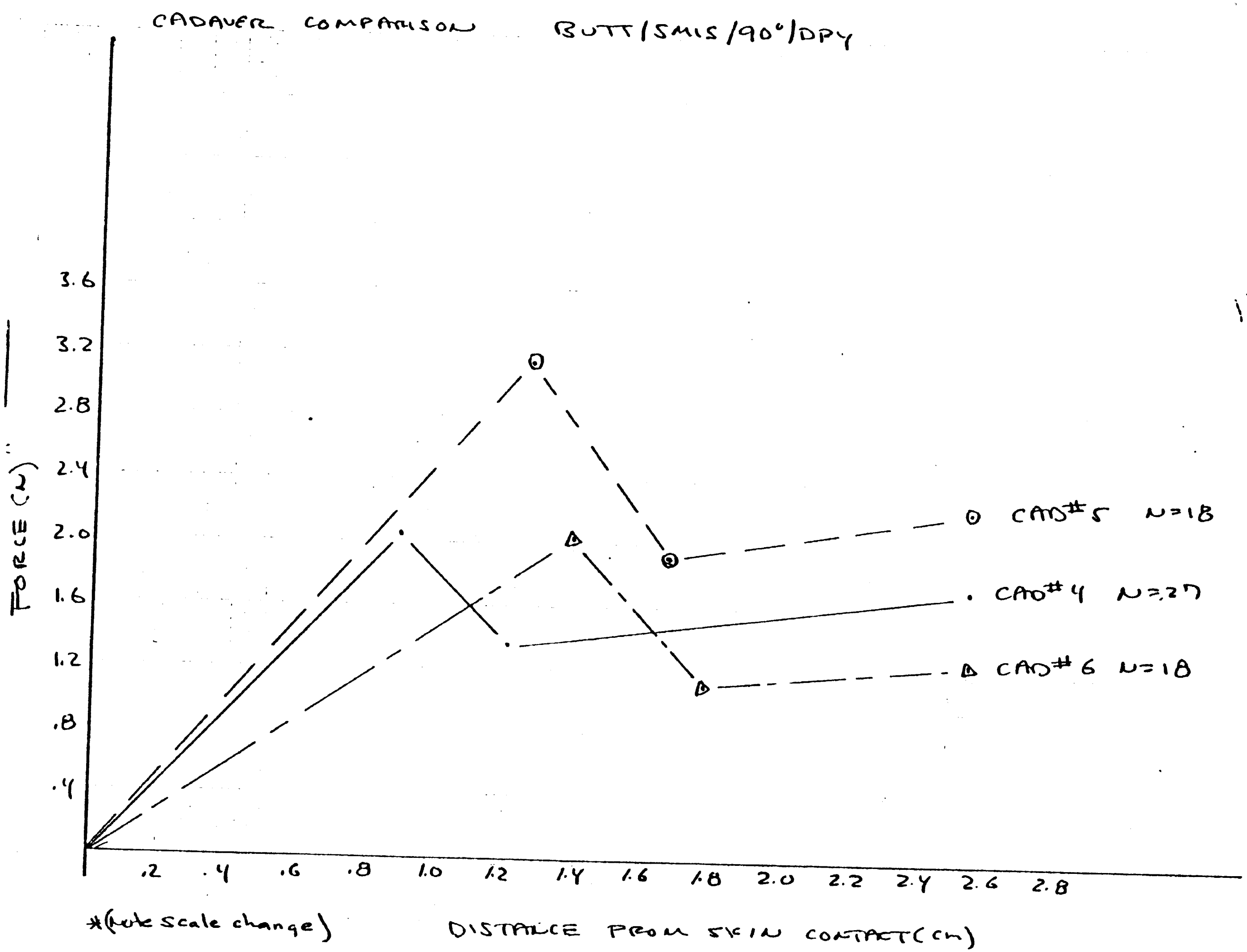
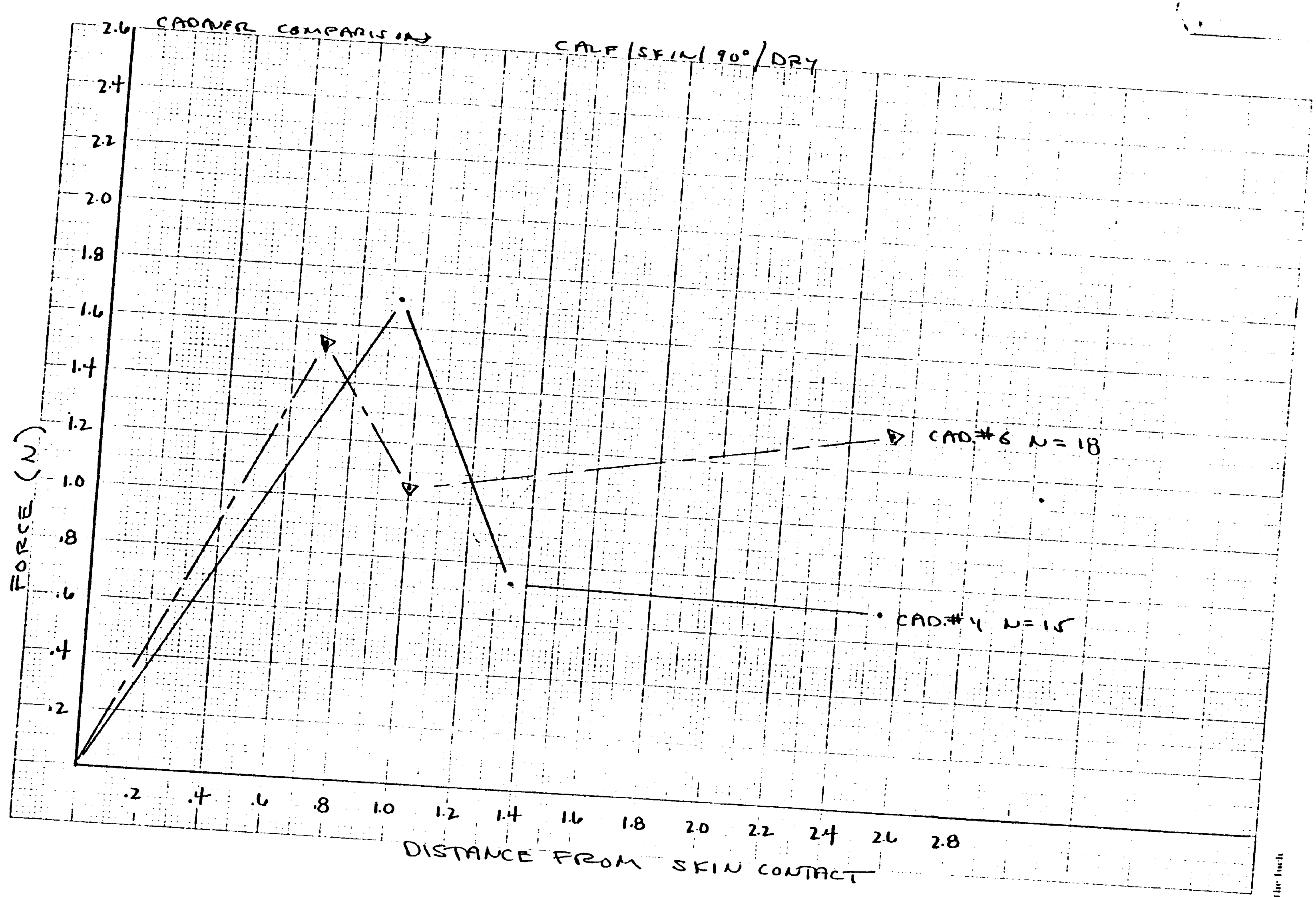

CADAVER COMPARISON BUTT/SMIS/90°/DPY
FORCE (N)
3.6
3.2
2.8
2.4
2.0
1.6
1.2
.8
.4
.2 .4 .6 .8 1.0 1.2 1.4 1.6 1.8 2.0 2.2 2.4 2.6 2.8
*(note scale change)
DISTANCE FROM SKIN CONTACT (cm)
CAD#5 N=18
CAD#4 N=27
CAD#6 N=18

FIGURE 23B



CADAVER COMPARISON
CALF/SKIN/90°/DRY
FORCE (N)
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
.2
.4
.6
.8
1.0
1.2
1.4
1.6
1.8
2.0
2.2
2.4
2.6
2.8
CAD#6 N=18
CAD#4 N=15
DISTANCE FROM SKIN CONTACT


FIGURE 23C

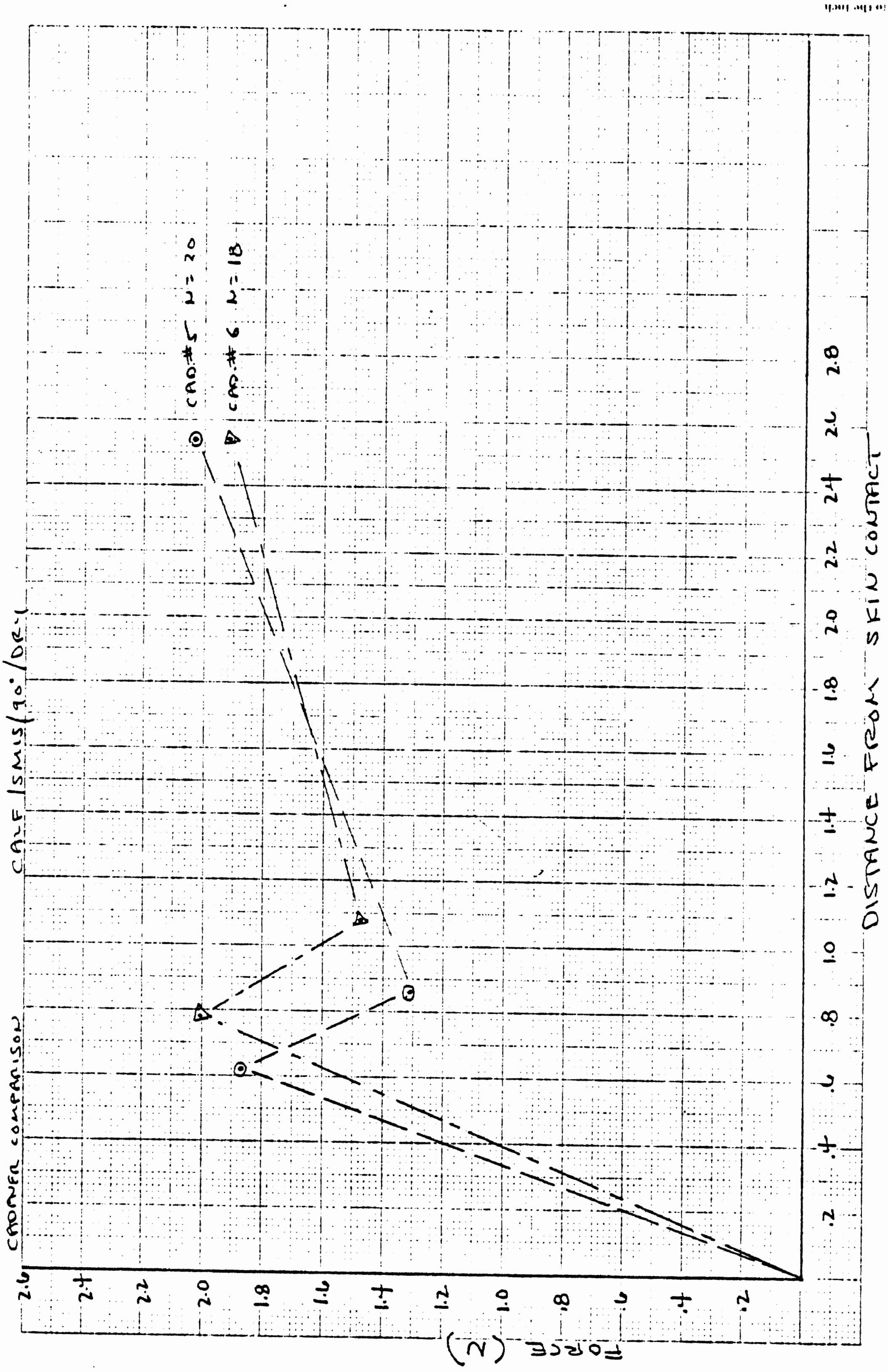

CROWER COMPARISON
CALF/SMIS/90°/DR-1
⊙ CAD #5 N=20
▽ CAD #6 N=18
FORCE (N)
DISTANCE FROM SKIN CONTACT
.2 .4 .6 .8 1.0 1.2 1.4 1.6 1.8 2.0 2.2 2.4 2.6 2.8
.2 .4 .6 .8 1.0 1.2 1.4 1.6 1.8 2.0 2.2 2.4 2.6

FIGURE 23D

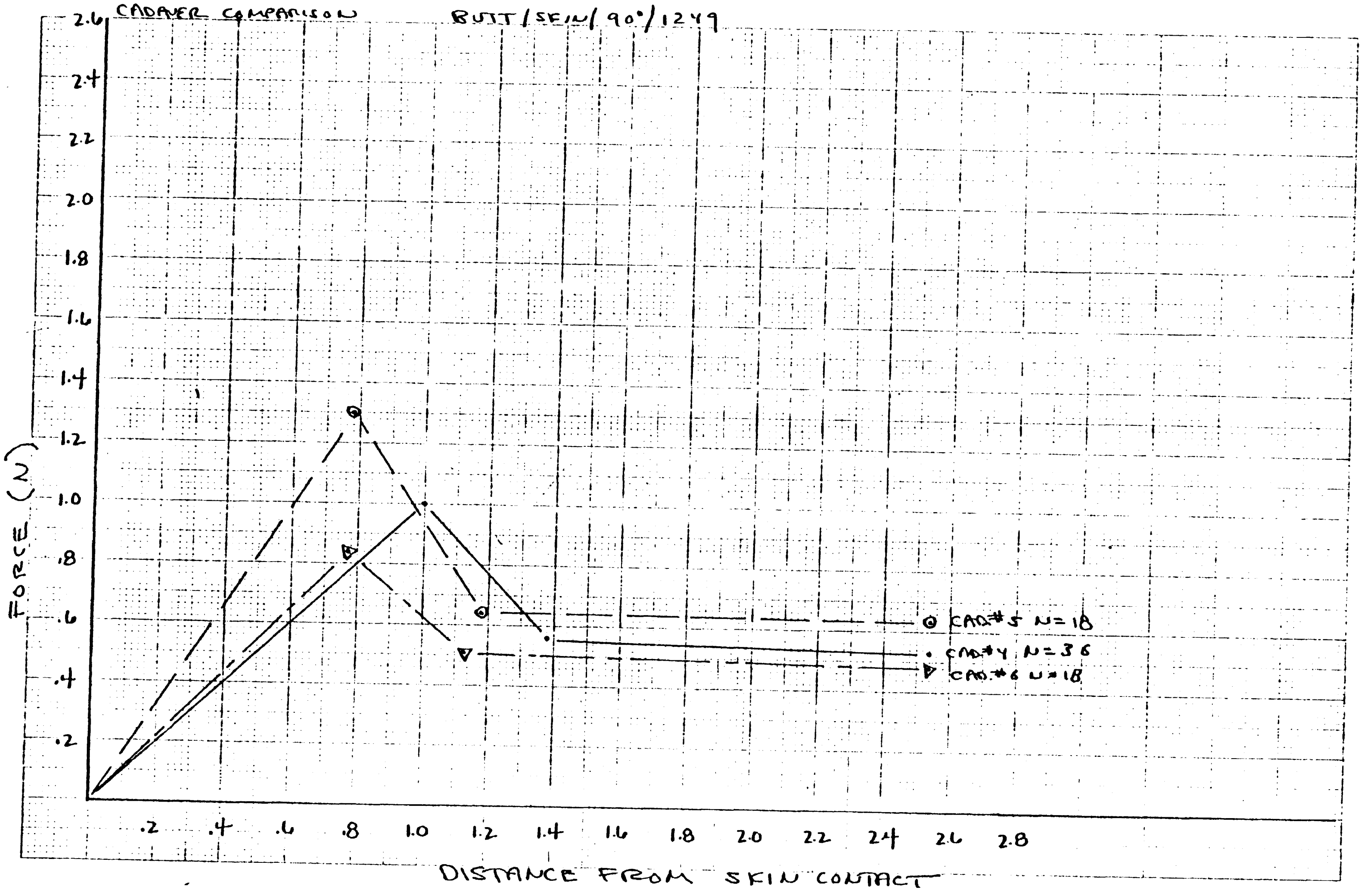

CADAVER COMPARISON
BUTT/SKIN/90°/1249
FORCE (N)
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
.2
.4
.6
.8
1.0
1.2
1.4
1.6
1.8
2.0
2.2
2.4
2.6
2.8
DISTANCE FROM SKIN CONTACT
CAD#5 N=18
CAD#4 N=36
CAD#6 N=18

FIGURE 23E

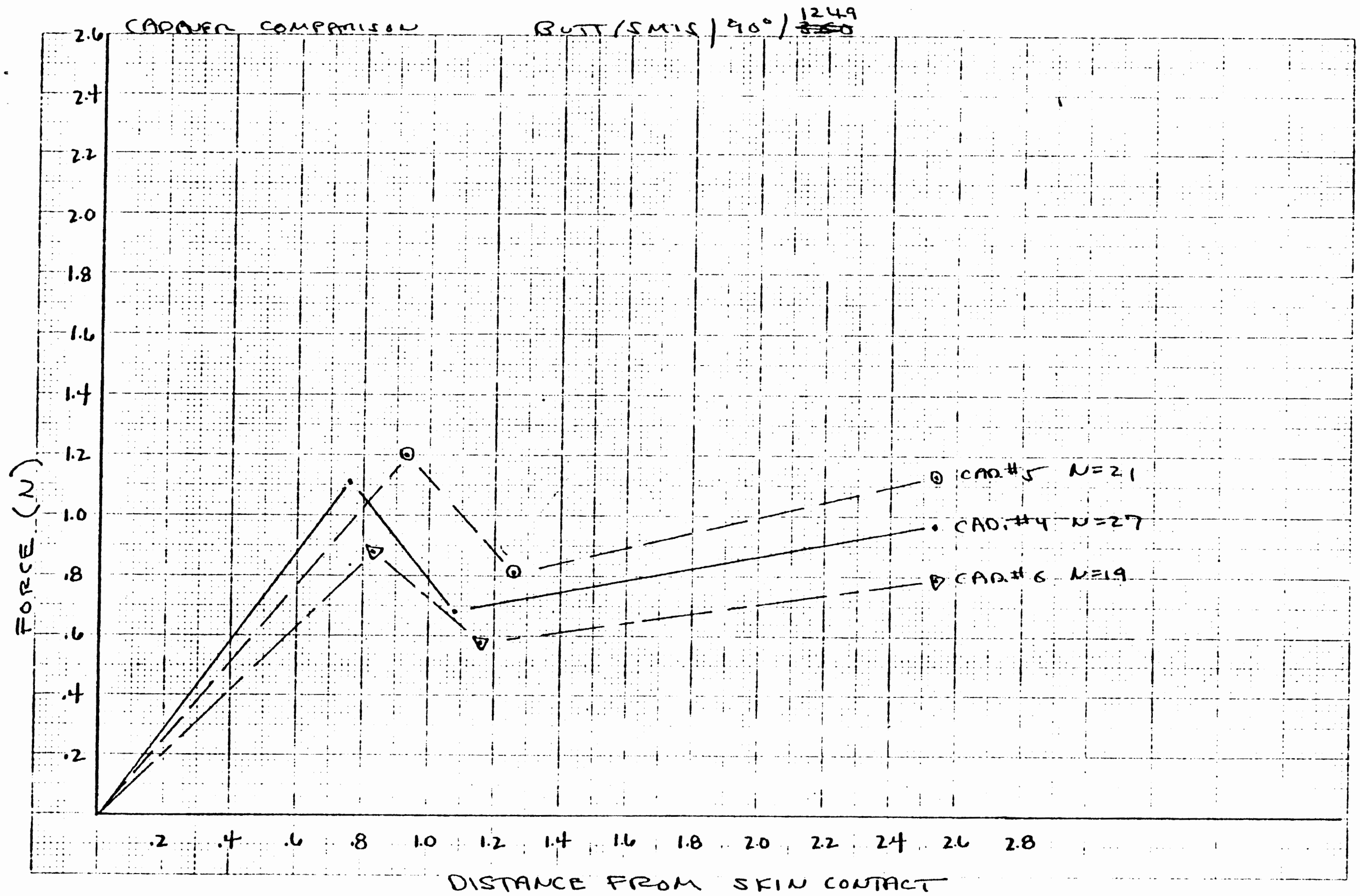

CADAVER COMPARISON
BUTT (SMIS) 90° / 1249
FORCE (N)
DISTANCE FROM SKIN CONTACT
CAD #5 N=21
CAD #4 N=27
CAD #6 N=19

FIGURE 23F

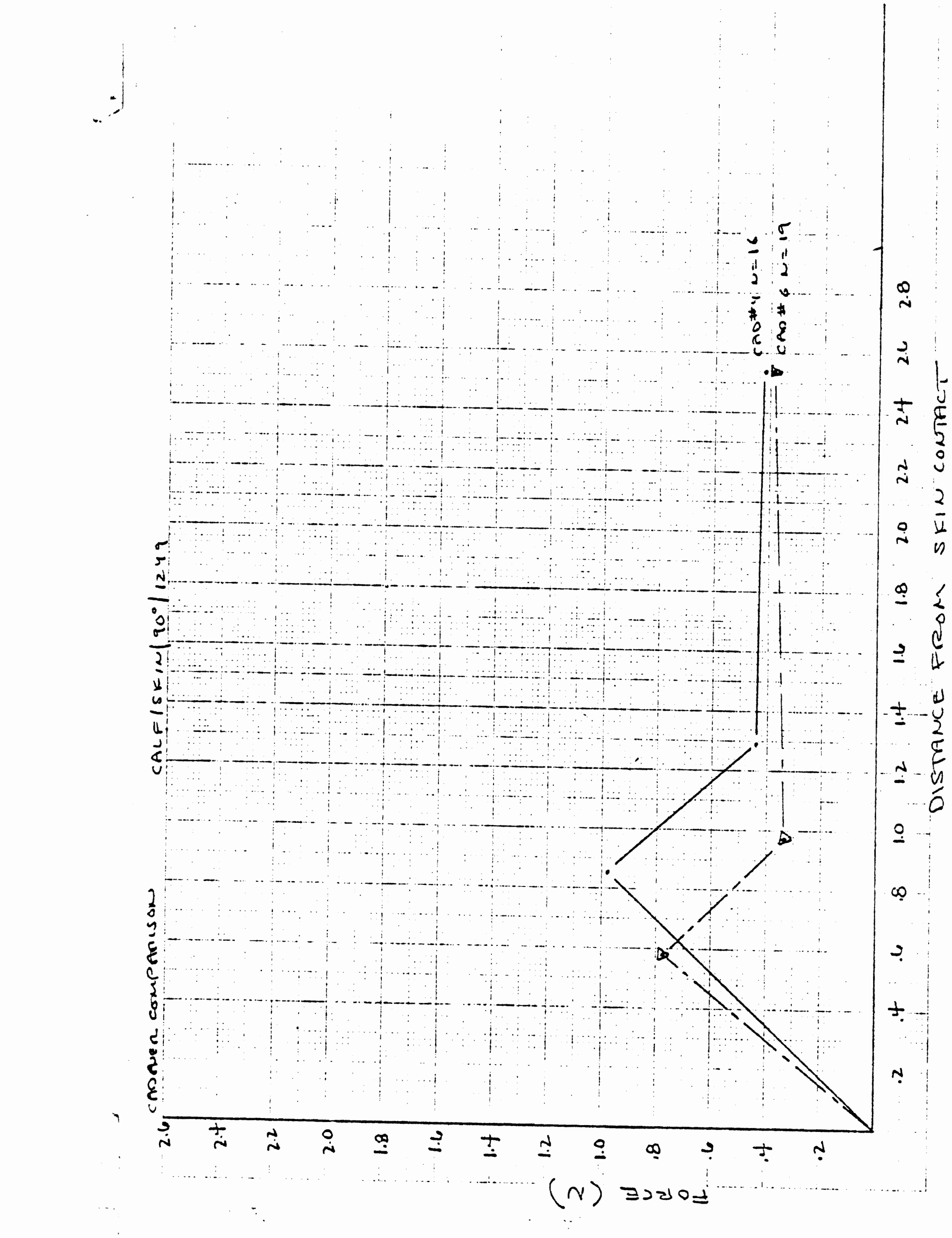

CADAVER COMPARISON
CALFSKIN/90°/1249
CAD#4 N=16
CAD#6 N=19
DISTANCE FROM SKIN CONTACT
FORCE
.2 .4 .6 .8 1.0 1.2 1.4 1.6 1.8 2.0 2.2 2.4 2.6 2.8
.2 .4 .6 .8 1.0 1.2 1.4 1.6 1.8 2.0 2.2 2.4 2.6

FIGURE 23 G

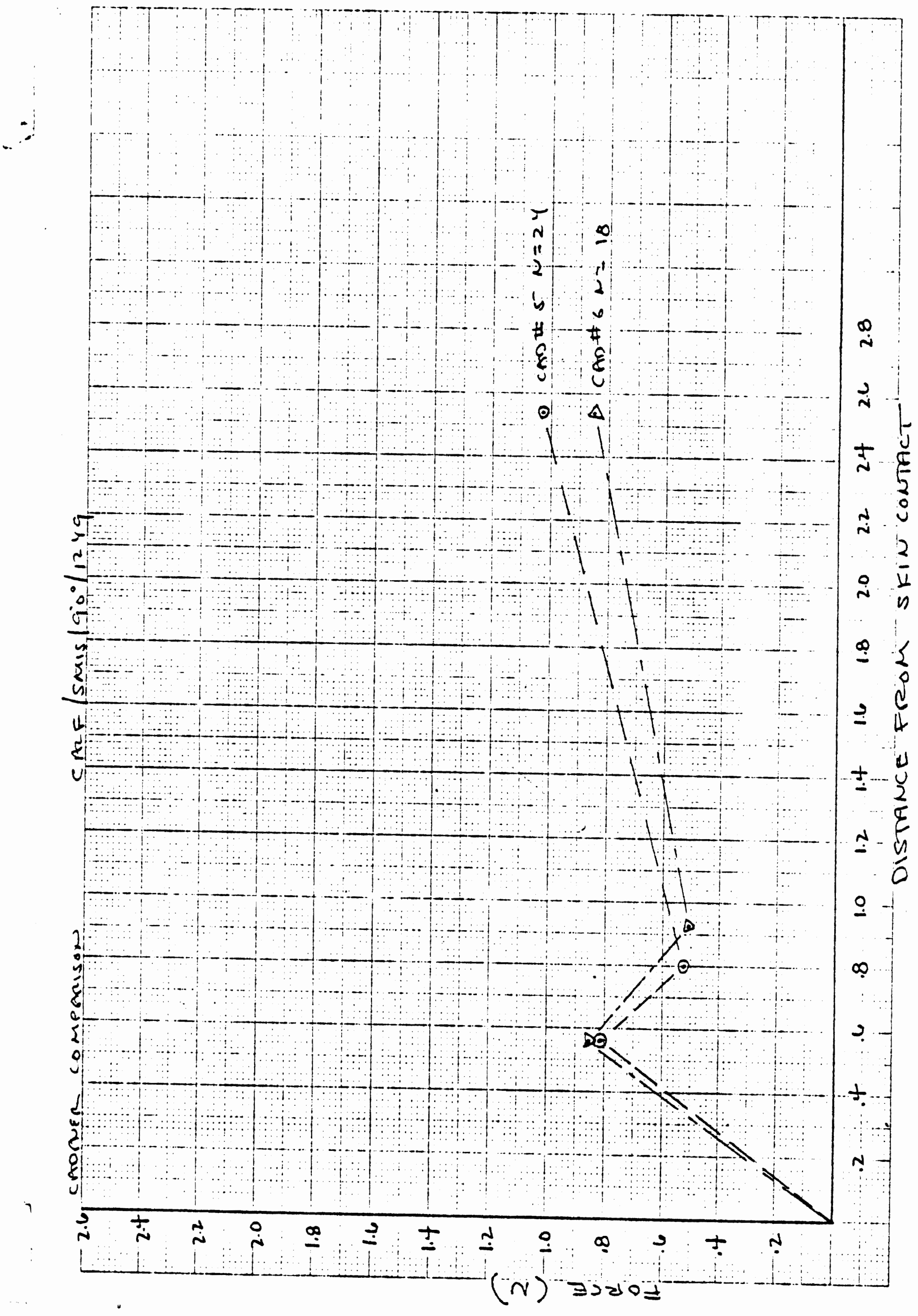
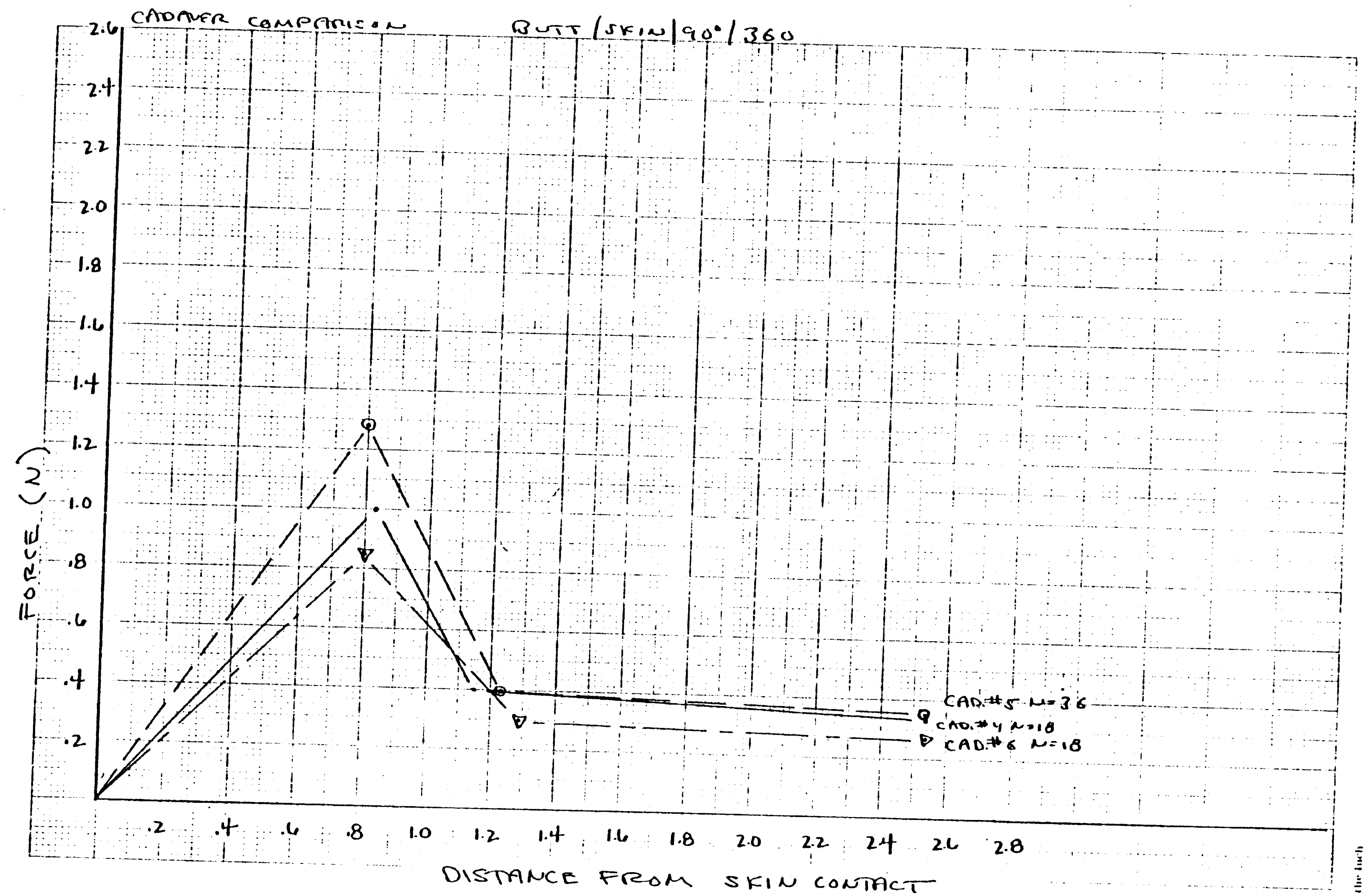

CORNER COMPARISON
CALF/SMIS/90°/1249
⊙ CAD#5 N=24
△ CAD#6 N=18
DISTANCE FROM SKIN CONTACT
.2 .4 .6 .8 1.0 1.2 1.4 1.6 1.8 2.0 2.2 2.4 2.6 2.8
FORCE (N)
.2 .4 .6 .8 1.0 1.2 1.4 1.6 1.8 2.0 2.2 2.4 2.6

FIGURE 23 H



CADAVER COMPARISON
BUTT / SKIN / 90° / 360
FORCE (N)
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
CAD. #5 N=36
CAD. #4 N=18
CAD. #6 N=18
.2
.4
.6
.8
1.0
1.2
1.4
1.6
1.8
2.0
2.2
2.4
2.6
2.8
DISTANCE FROM SKIN CONTACT


FIGURE 23 I

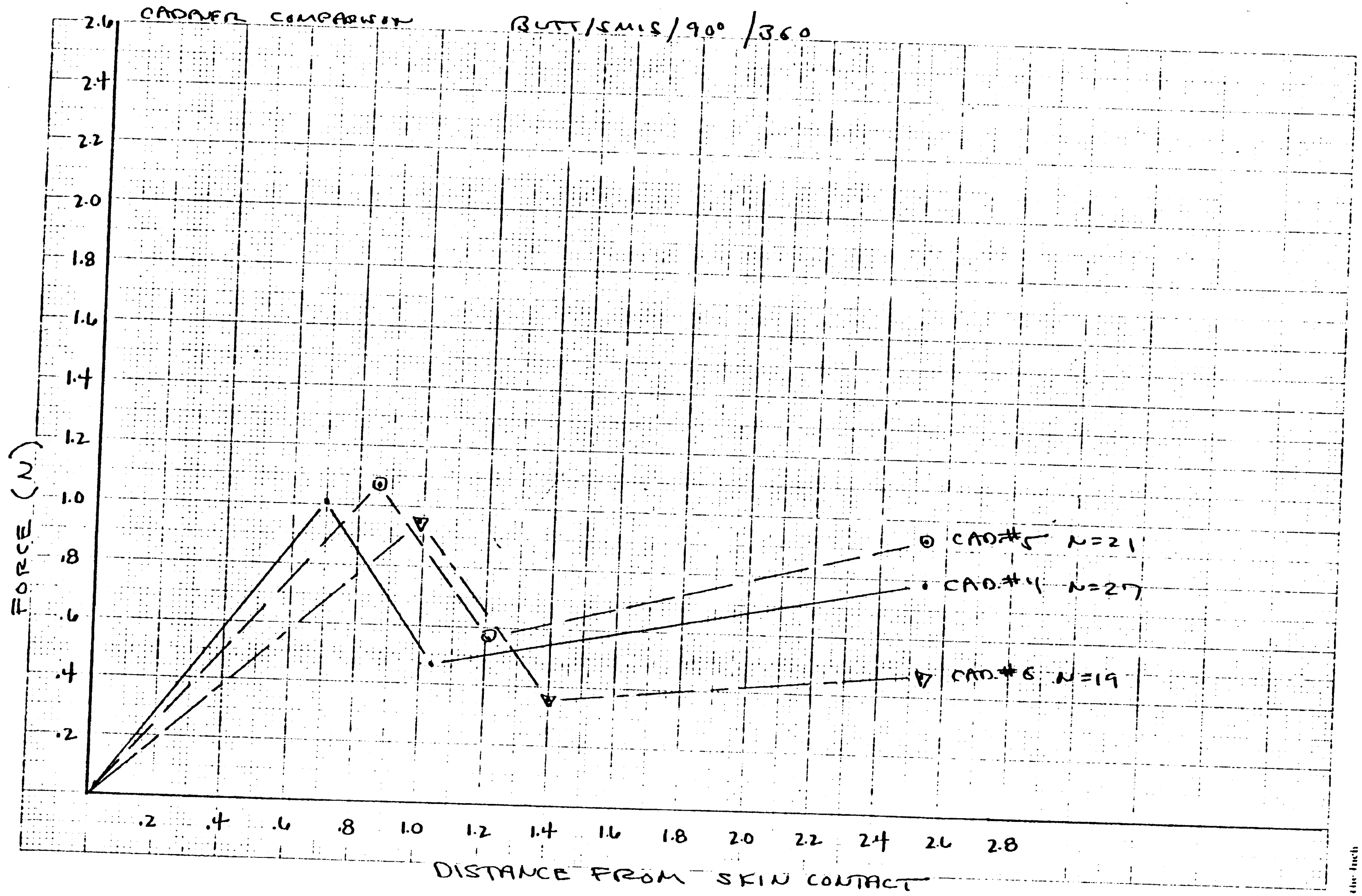

CADAVER COMPARISON
BUTT/SMIS/90°/360
FORCE (N)
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
.2
.4
.6
.8
1.0
1.2
1.4
1.6
1.8
2.0
2.2
2.4
2.6
2.8
DISTANCE FROM SKIN CONTACT
CAD#5 N=21
CAD#4 N=27
CAD#6 N=19

FIGURE 23 J

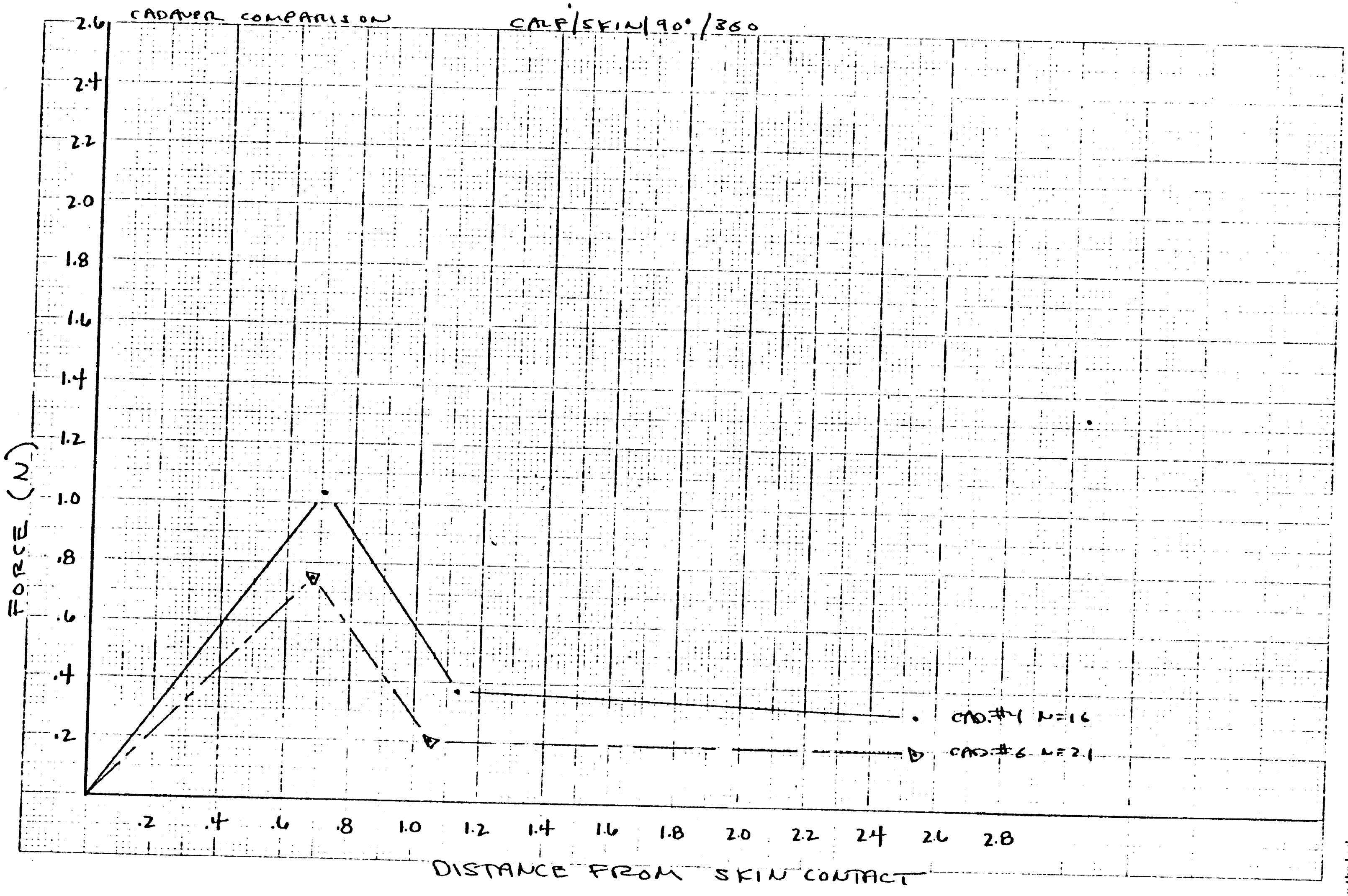

CADAVER COMPARISON
CALF/SKIN/90°/360
FORCE (N)
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
.2
.4
.6
.8
1.0
1.2
1.4
1.6
1.8
2.0
2.2
2.4
2.6
2.8
DISTANCE FROM SKIN CONTACT
CAD.#4 N=16
CAD.#6 N=21

FIGURE 23 K

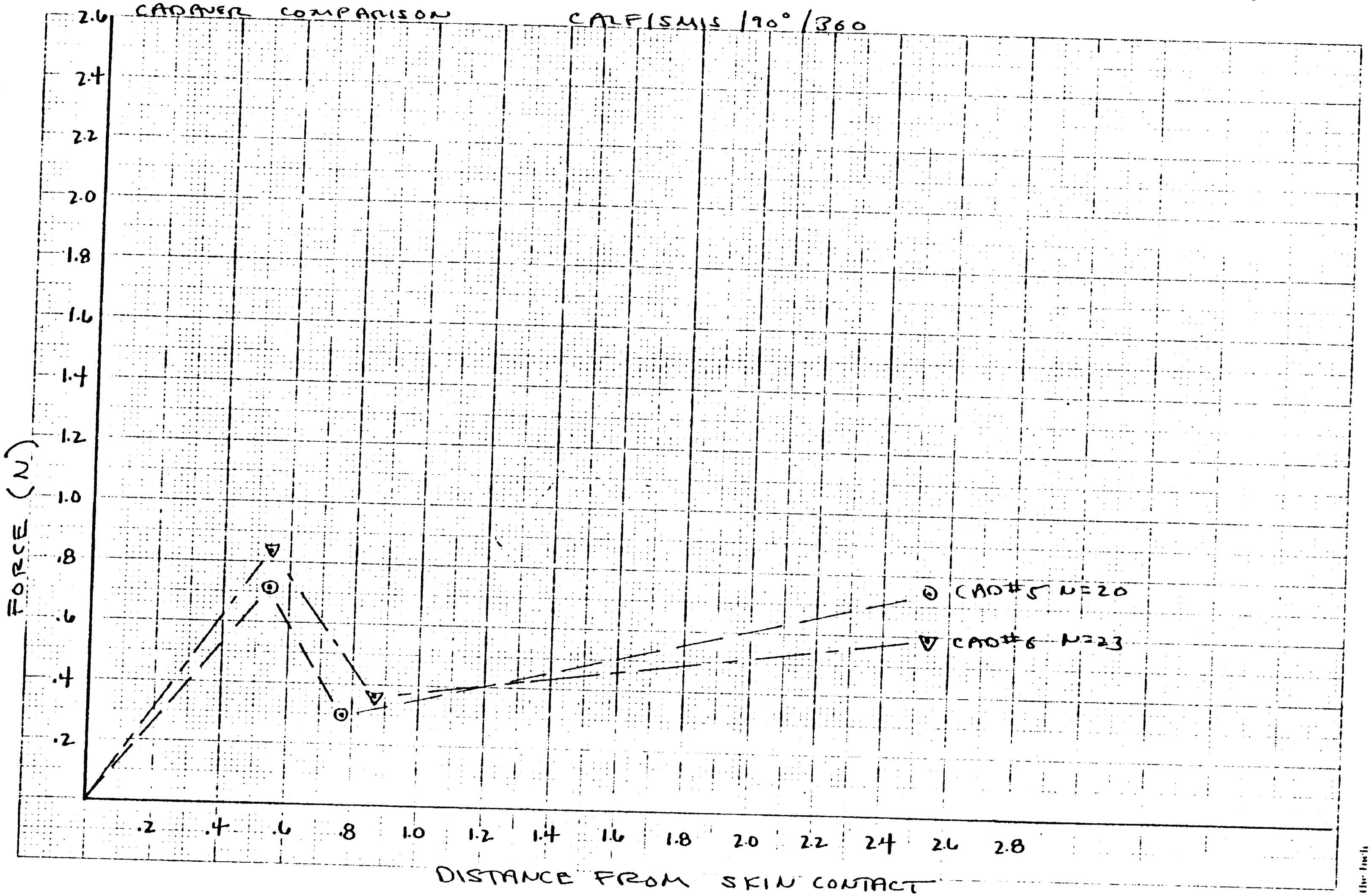

CADAVER COMPARISON
CALF(SMIS /90° /360
FORCE (N)
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
.8
.6
.4
.2
.2 .4 .6 .8 1.0 1.2 1.4 1.6 1.8 2.0 2.2 2.4 2.6 2.8
DISTANCE FROM SKIN CONTACT
⊙ CAD#5 N=20
▽ CAD#6 N=23

FIGURE 23 L

FIGURE 24 (A-D)

Graphical Comparisons of PWORK Values for Cadavers 4, 5, and 6

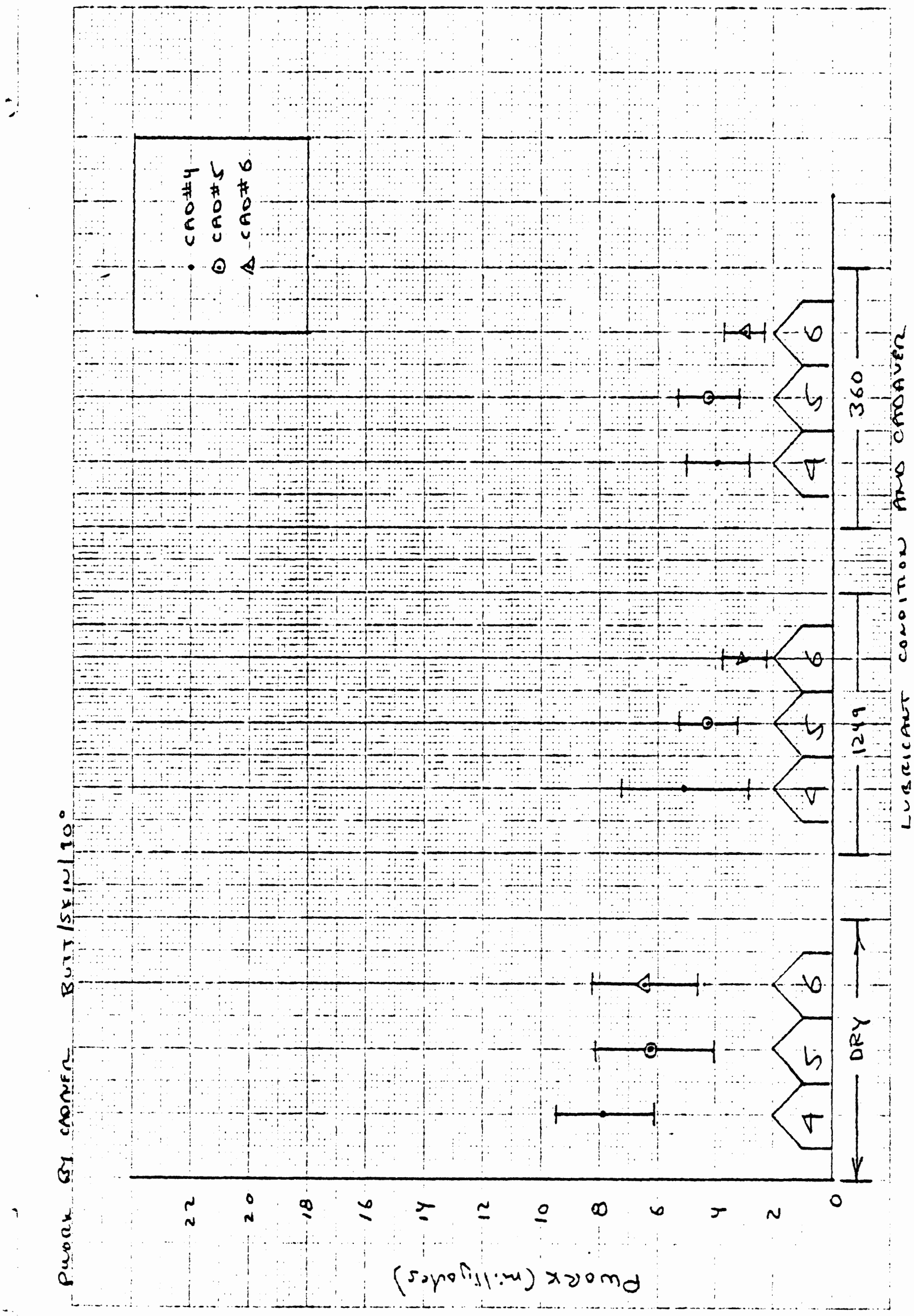

PWORK BY CADAVER BUTT/SKIN/10°
PWORK (millijoules)
0
2
4
6
8
10
12
14
16
18
20
22
• CAD#4
⊙ CAD#5
△ CAD#6
4
5
6
DRY
1249
360
LUBRICANT CONDITION AND CADAVER

FIGURE 24A

PWORK BY CADAVER BUTT/SMIS/10°

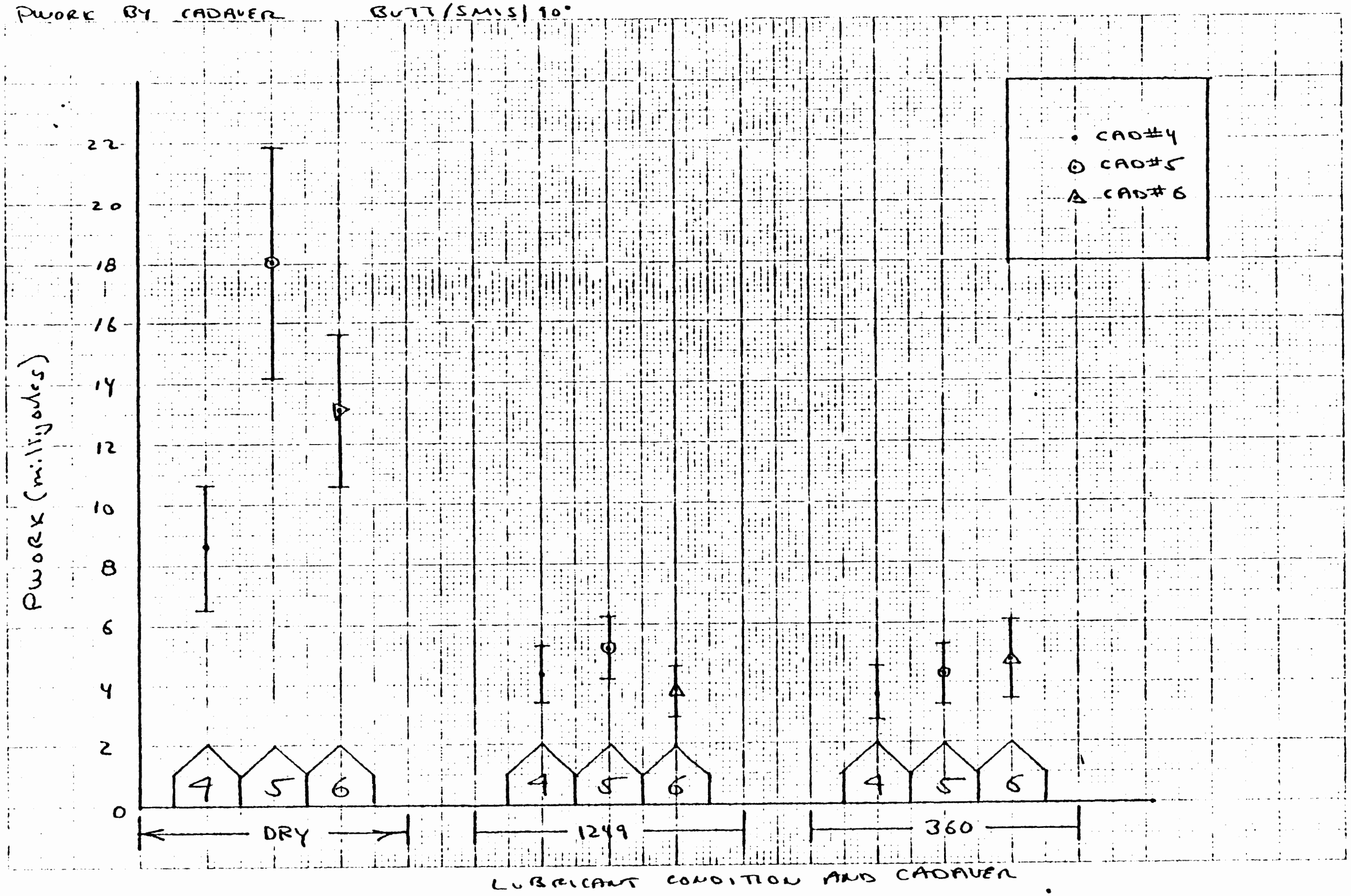
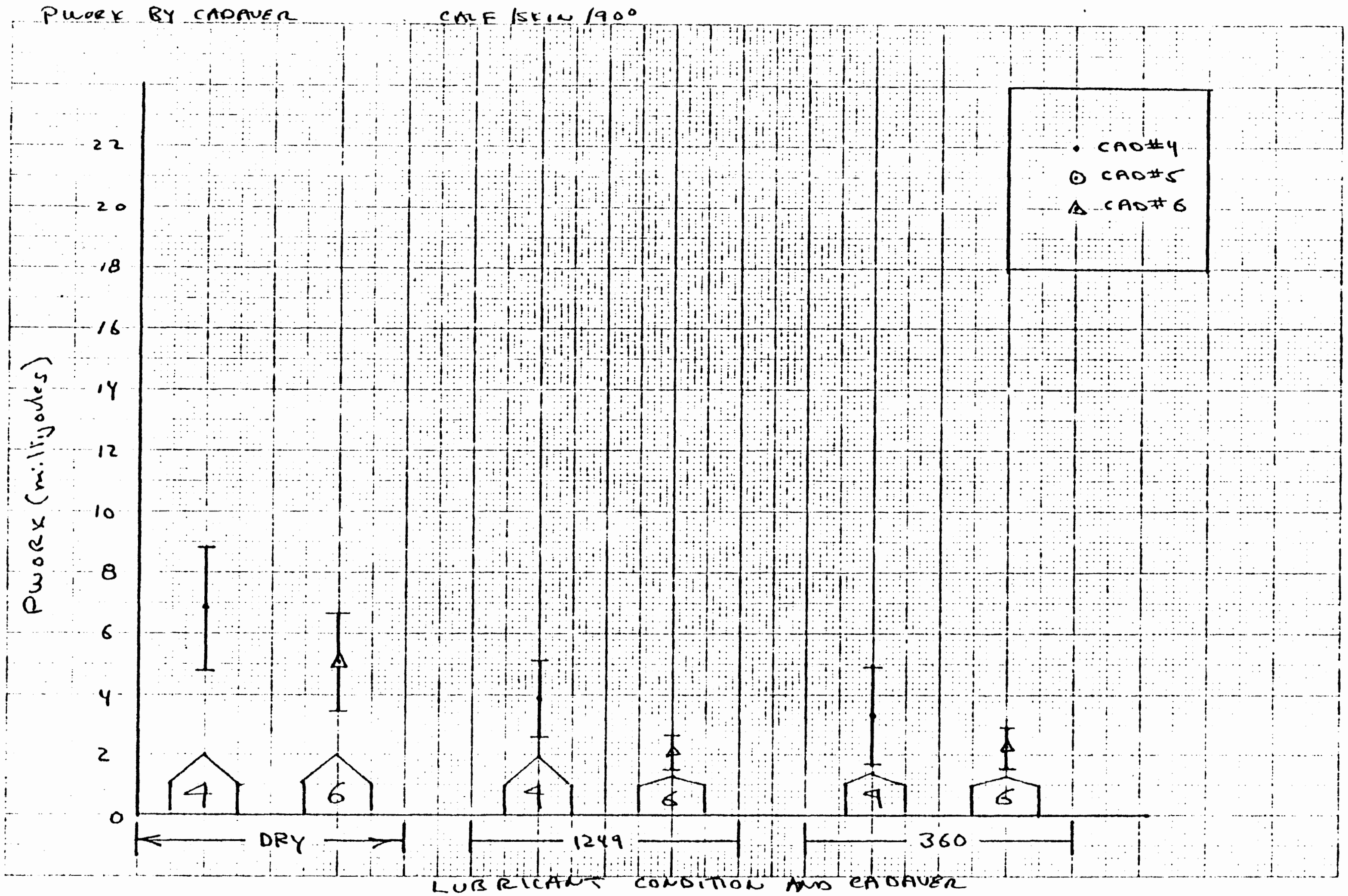



FIGURE 24B



PWORK BY CADAVER
CALF SKIN /90°
PWORK (millijoules)
22
20
18
16
14
12
10
8
6
4
2
0
• CAD#4
⊙ CAD#5
Δ CAD#6
4
6
4
6
4
6
DRY
1249
360
LUBRICANT CONDITION AND CADAVER


FIGURE . 24C

PWORK BY CADAVER CALF/SMIS/90°

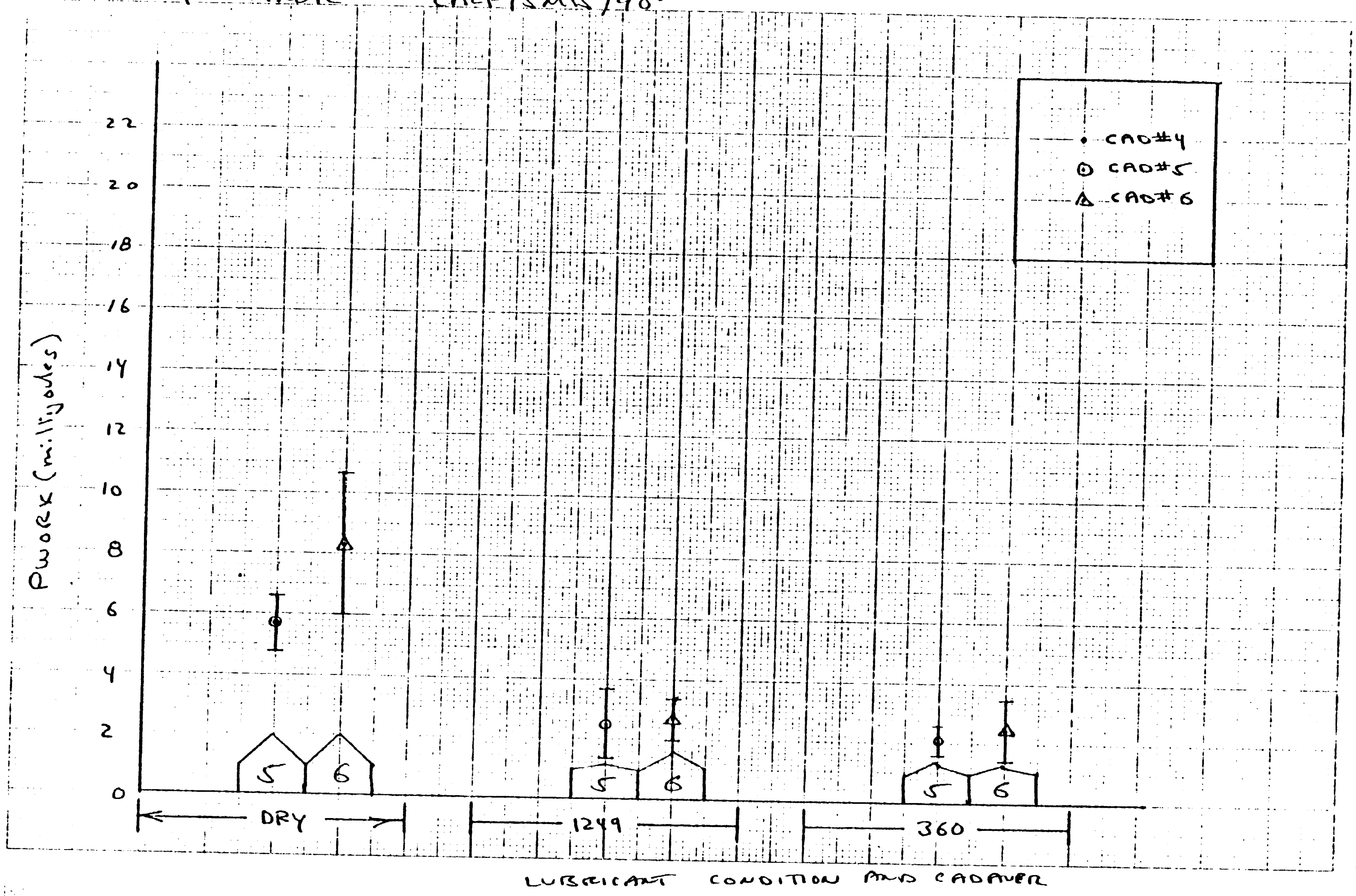



FIGURE 24D

FIGURE 25 (A-D)

Graphical Comparisons of DWORK Values for Cadavers 4, 5, and 6

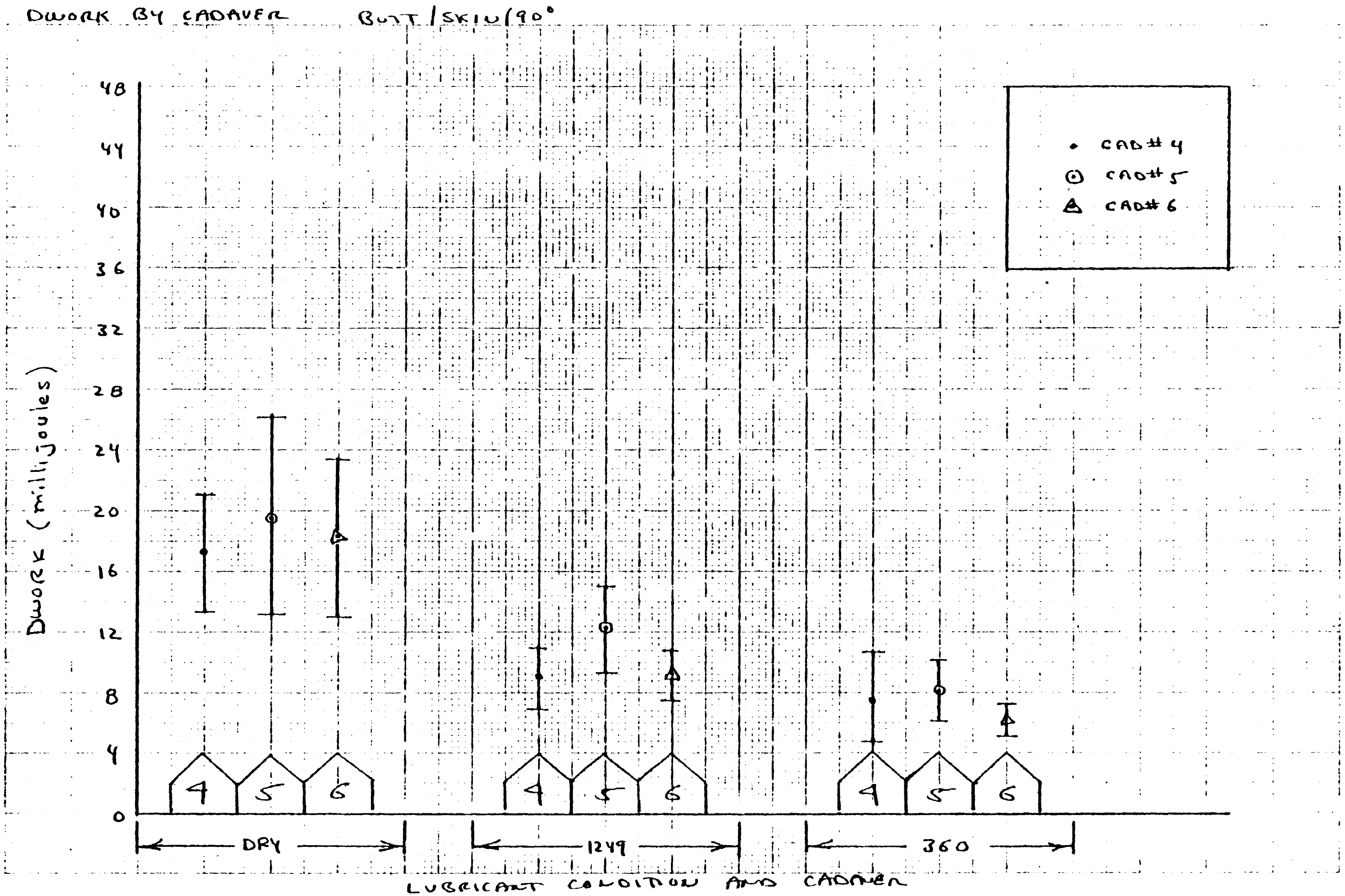
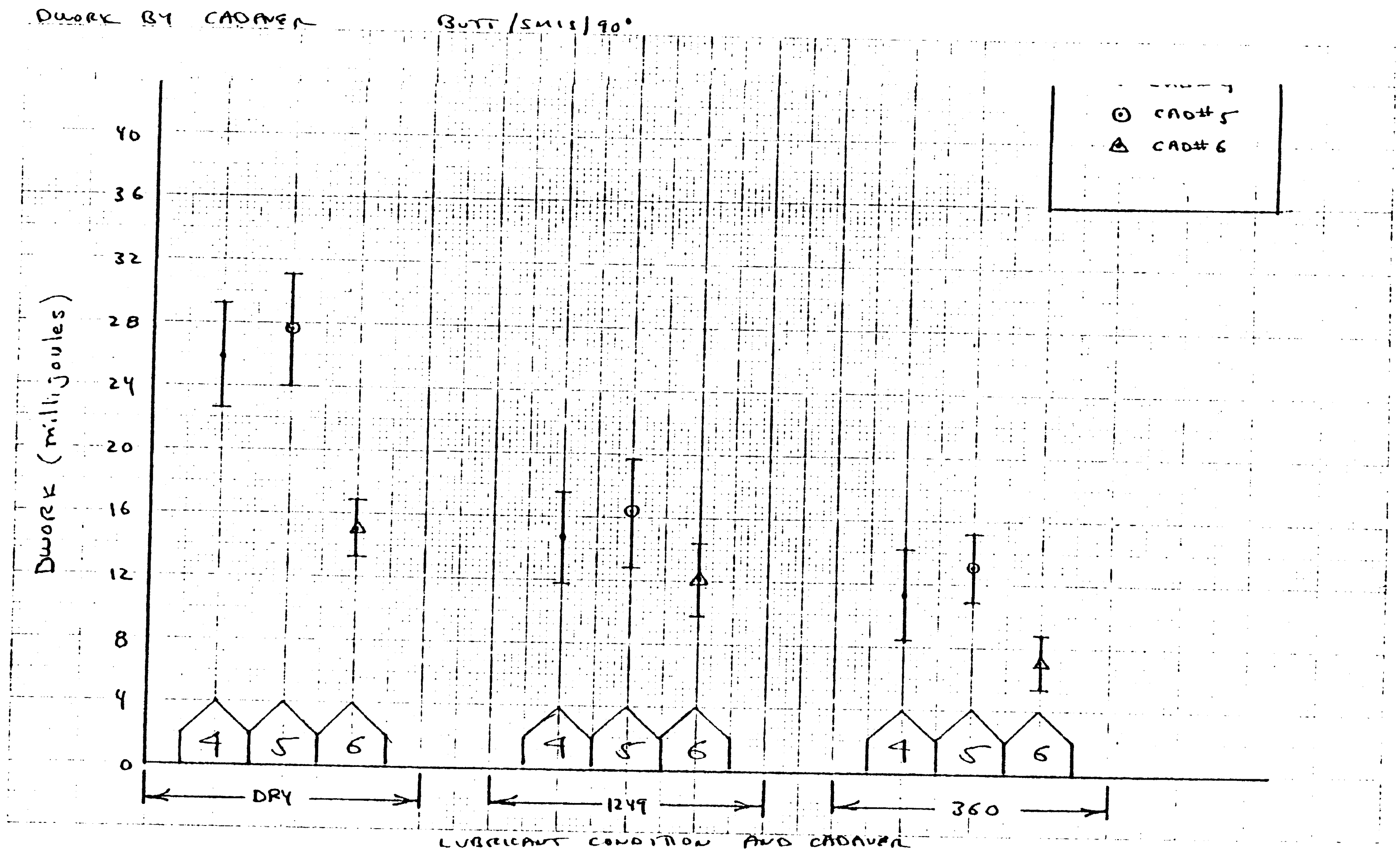

DWORK BY CADAVER BUTT/SKIN/90°
48
44
40
36
32
28
24
20
16
12
8
4
0
DWORK (millijoules)
CAD#4
CAD#5
CAD#6
4
5
6
DRY
1249
360
LUBRICANT CONDITION AND CADAVER

FIGURE 25A



DWORK BY CADAVER
BUTT /SM1S/ 90°
CAD#5
CAD#6
DWORK (millijoules)
40
36
32
28
24
20
16
12
8
4
0
4
5
6
DRY
1249
360
LUBRICANT CONDITION AND CADAVER


FIGURE 25B

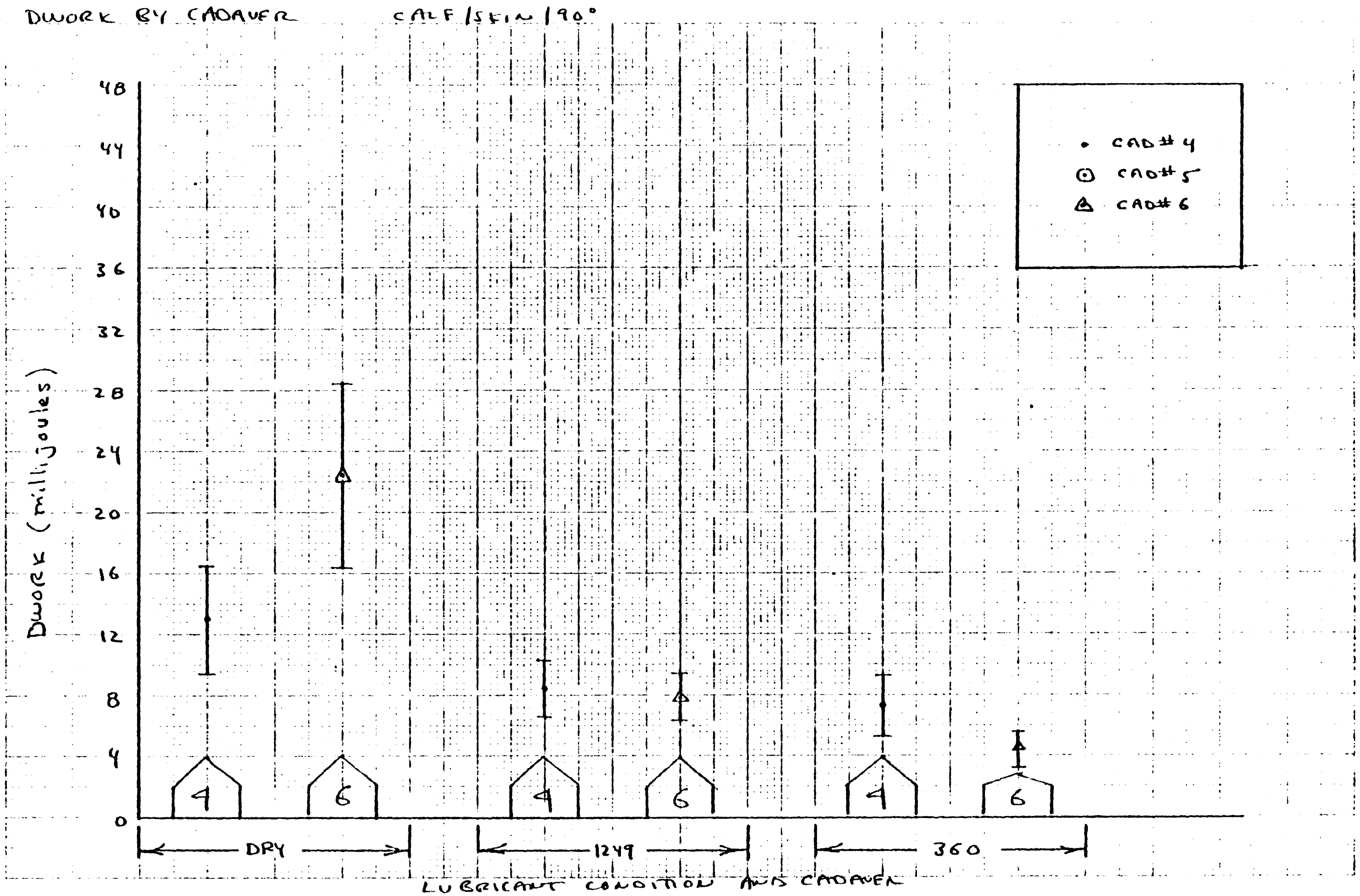

DWORK BY CADAVER
CALF/SKIN/90°
48
44
40
36
32
28
24
20
16
12
8
4
0
DWORK (millijoules)
• CAD#4
⊙ CAD#5
△ CAD#6
4
6
4
6
4
6
DRY
1249
360
LUBRICANT CONDITION AND CADAVER

FIGURE. 25C

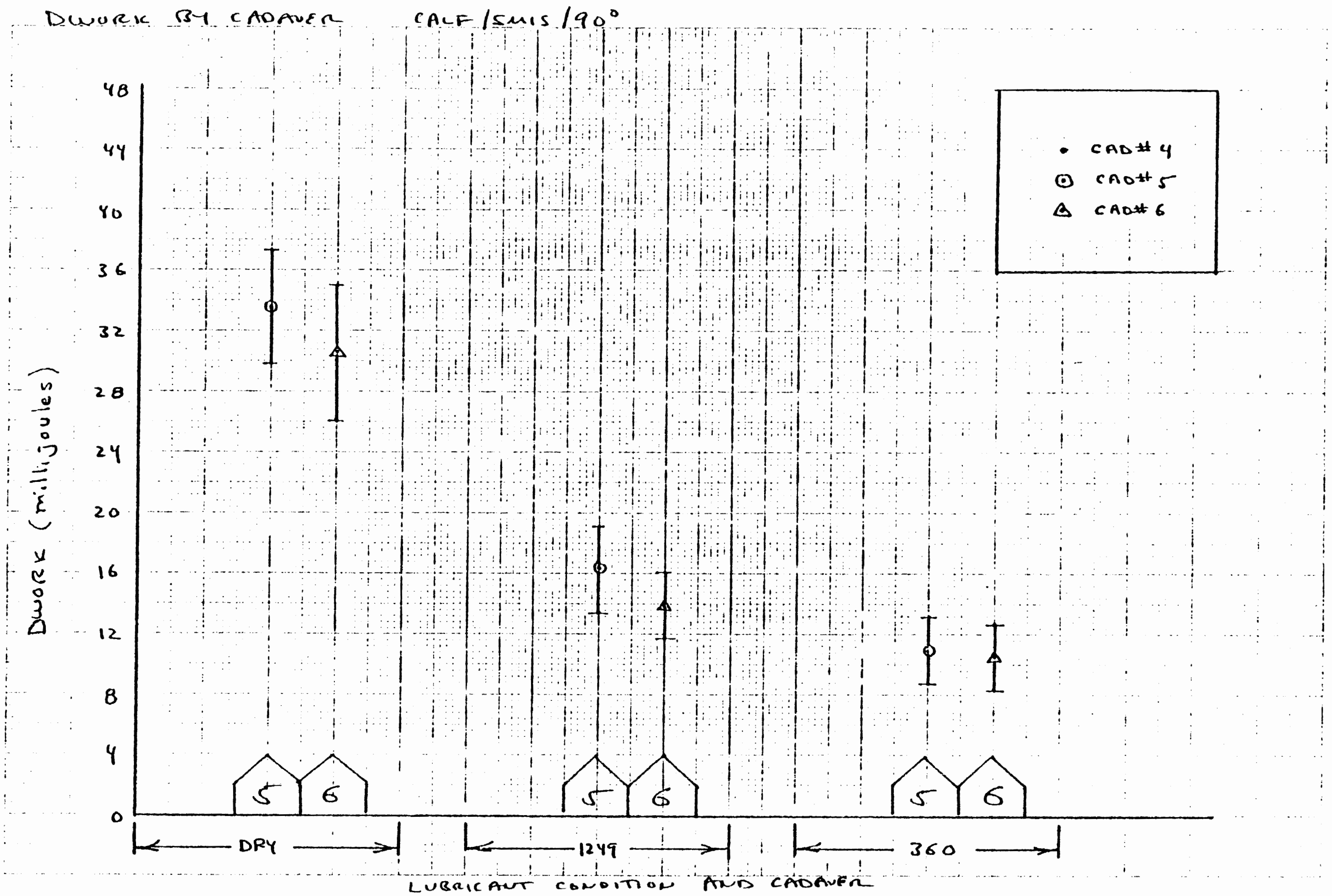

DWORK BY CADAVER
CALF/SMIS/90°
48
44
40
36
32
28
24
20
16
12
8
4
0
DWORK (millijoules)
• CAD#4
⊙ CAD#5
△ CAD#6
5
6
DRY
1249
360
LUBRICANT CONDITION AND CADAVER

FIGURE 25D