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16. Abstract

In conjunction with a computer-controlled needle injector, cineradiography was used to provide simultaneous measurement of force, skin displacement, and needle tip penetration for different types of needles injected into unembalmed cadaver tissue. The results were analyzed through the use of several parameters which were developed from the data. These parameters were used to correlate penetration characteristics with the physical geometry of the needles.

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A CINERADIOGRAPHIC ANALYSIS OF NEEDLE PENETRATION

Interim Report #5

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INTRODUCTION AND OBJECTIVES

In previous investigations (1, 2) of penetration characteristics of hypodermic needles using an automatic injector, the position of the needle was monitored by an LVDT. The LVDT also is utilized in a feedback control circuit to achieve constant needle velocity during penetration. In conjunction with the force curve which is digitized at the same time, the LVDT further provides a measure of needle displacement at peak force (D2) for comparisons between needle types. In terms of evaluating and comparing the cutting or penetrating ability of needle tips, however, a measure of penetration depth below the skin surface is needed.

In this study we have sought to monitor skin displacement and therefore needle tip penetration (needle displacement minus skin displacement) during automatic injection testing of needles by utilizing a high-speed x-ray cinematography system developed at HSRI. While the study was intended primarily as an exploratory investigation on the use of this high-speed x-ray facility in this application, it was hoped that the results might provide further insight and answers to the following questions:

1) How do factors such as penetration force, skin displacement, and tip penetration differ for needles with different tip geometries? (i.e., how do different tip geometries affect initial cutting).

and, 2) Can the occurrence of peak force (and other force curve characteristics) be correlated with the interaction of point geometry features (i.e., heel, side bevels) with the dermis?

To accomplish these goals, the following set of needles were tested:

Test	Needle and Lubricant	
2	Conical solid	20 g dry
3	Tetrahedral solid	20 g dry
4	42 point solid	20 g dry
5	42 point stock	20 g 1249
6	Side bevel	20 g 360
7	Back bevel	22 g 360
8	A bevel	22 g 360
9	42 point stock	22 g dry

This report describes the procedures used in collecting the data and presents the results obtained. It also discusses these results in terms of the objectives described above and presents the investigators' conclusions, hypotheses, and suggestions formulated from these results.

METHODS

1. Experimental Setup

X-ray movies of needle penetration were made using a high-speed x-ray cinematography system developed at HSRI (3). Figure A illustrates the basic features of this system as it was used in conjunction with the automatic injector. The low level x-ray image formed on the calcium tungstate fluorescent screen by a standard x-ray emission source is optically coupled through a lense and bellows to the input end of a 4-stage magnetically focused image intensifier tube. The intensified image is formed on a 2-inch diameter output phosphor of the image tube and photographed by a high-speed 16mm motion picture camera. A special electronic synchronization circuit gates the image intensifier with the movie camera shutter at the desired film rate.

The HSRI computer-controlled injector was used as in previous work to control needle penetrations in the tissue specimen placed between the x-ray source and fluorescent screen. In these tests the deltoid region of a cadaver arm was used so that the needle and tissue could be placed as close to the fluorescent screen as possible for maximum image sharpness. The needle injector was operated horizontally with the needle parallel to the fluorescent screen and approximately 1-1/4 inches from it. The arm was suspended vertically, hand-up, and was taped in place so that the skin surface at the injection site could be viewed on the phosphor screen throughout the injection. Pieces of fine wire solder taped to the back (outside) side of the tungstate screen provided reference and orientation marks for film analysis.

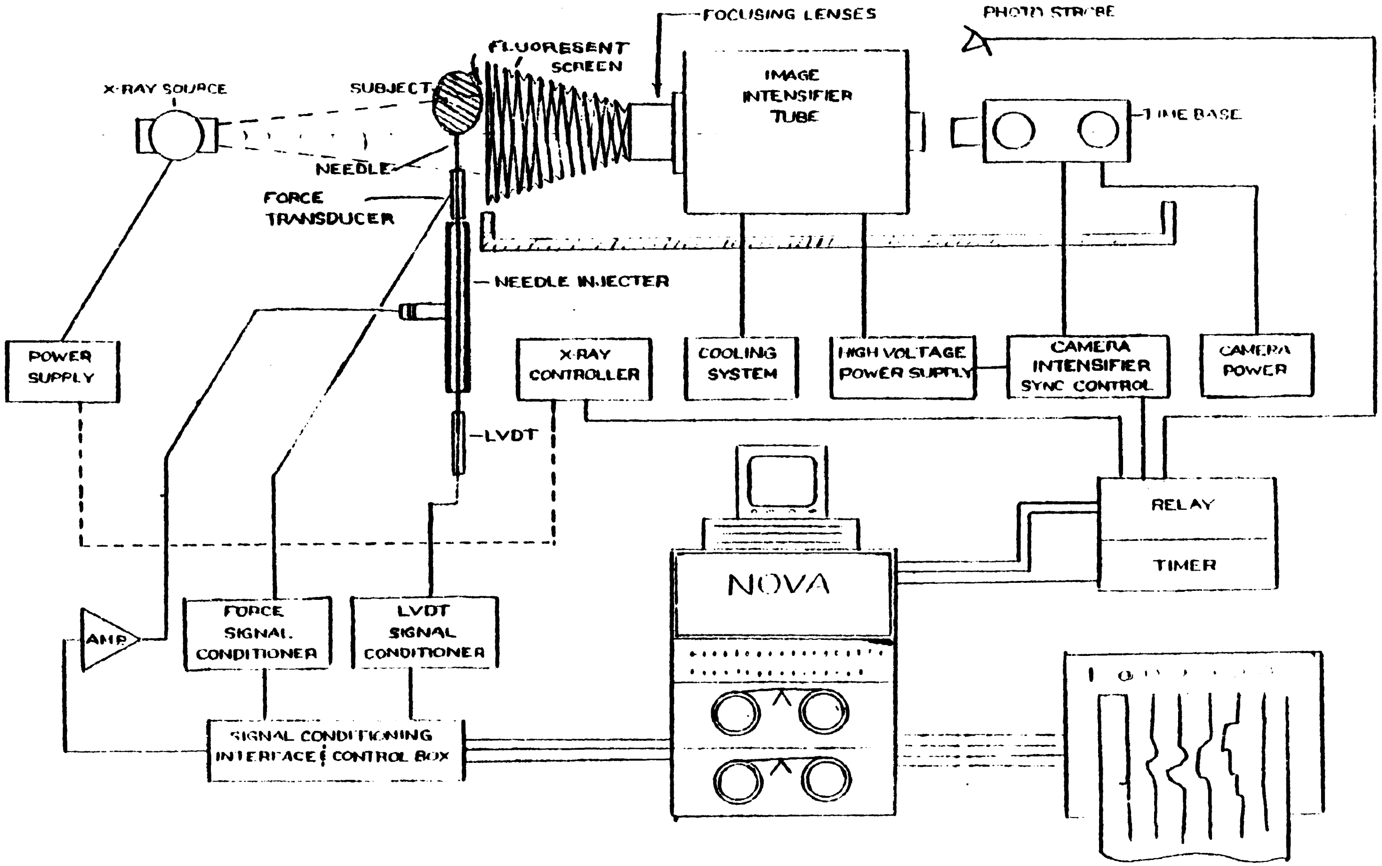

FIGURE A - A schematic diagram of the HSRI high speed x-ray cineradiographic hypodermic needle injection system.

Modifications were made to both the computer software and hardware so that the computer controlled the x-ray and high-speed camera equipment through a TTL controlled interface and thereby synchronized them with needle movement. A modified photographic strobe flash unit was used to synchronize the film and force recordings by simultaneously overexposing a film frame and providing a voltage spike to the chart recorder. The strobe was triggered just prior to needle/skin contact by closing the strobe switch through two copper leaf contacts attached to the injector frame and moving shaft. Figure B illustrates the timing of these computer, timer, and relay sync signals in relation to needle displacement, force, and strobe signals. Since it was necessary to output the computer signal controlling x-ray exposure* prior to entering the subroutine to begin needle movement (Basic Subroutine Call 40), the computer signal for turning the x-ray on was input to a timer with a 125 msec delay. The output of this timer then triggered the relay switch and turned on the x-ray exposure just prior to skin contact.

Using GE silastic as a binder a thin line of lead dust was placed on the arm in the plane of the needle immediately prior to testing. This provided a radiopaque surface of the epidermis which could be seen as the skin was deflected behind other tissue. Figure C shows a polaroid photograph and drawing of the needle partially injected into the arm and shows the solder reference lines, needle and hub, tissue specimen and lead line denoting the deflected epidermis.

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*Activating the x-ray source requires first turning on the x-ray power supply (standby) and after a second or two turning on the x-ray source itself (exposure). See Figure B.

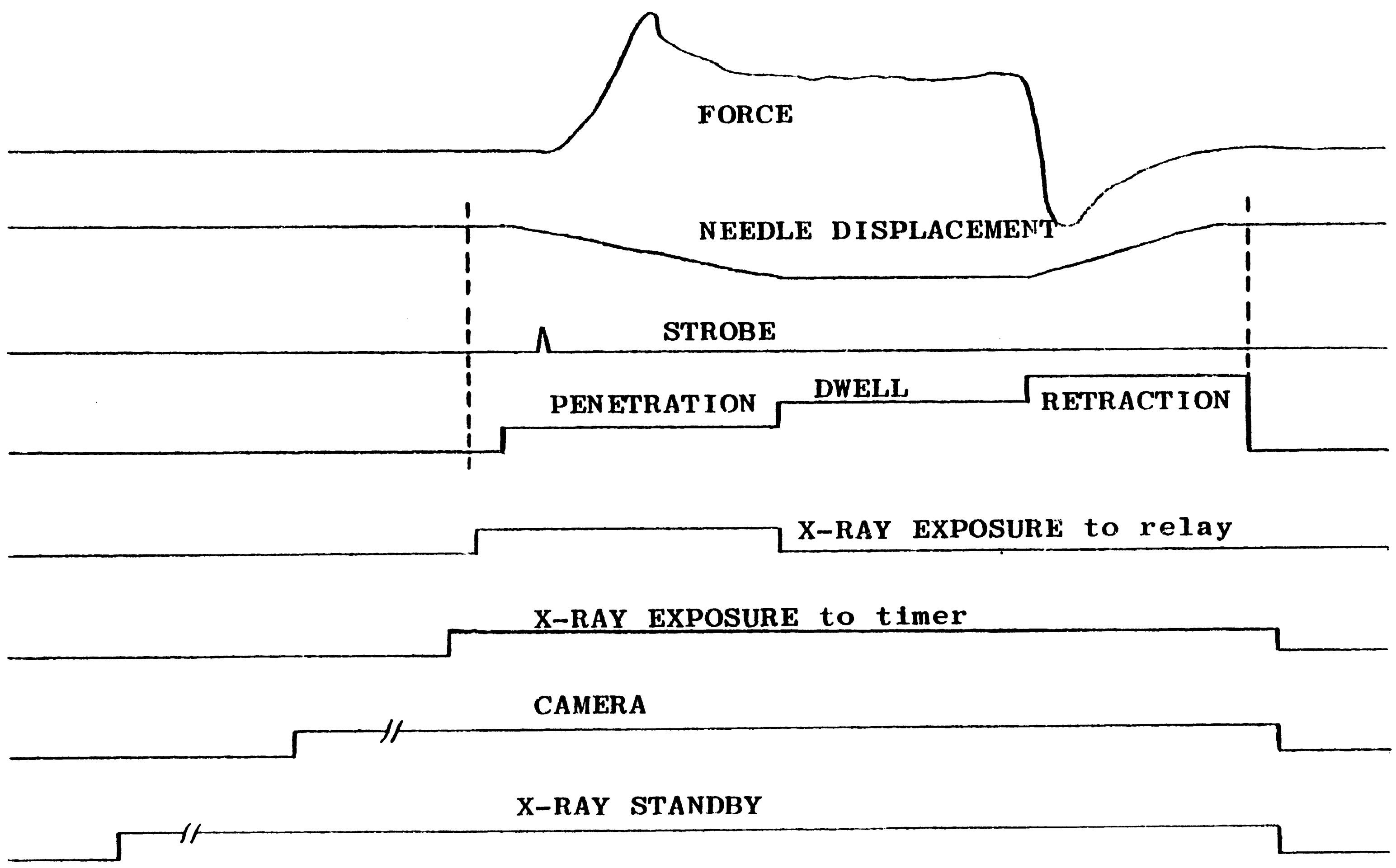
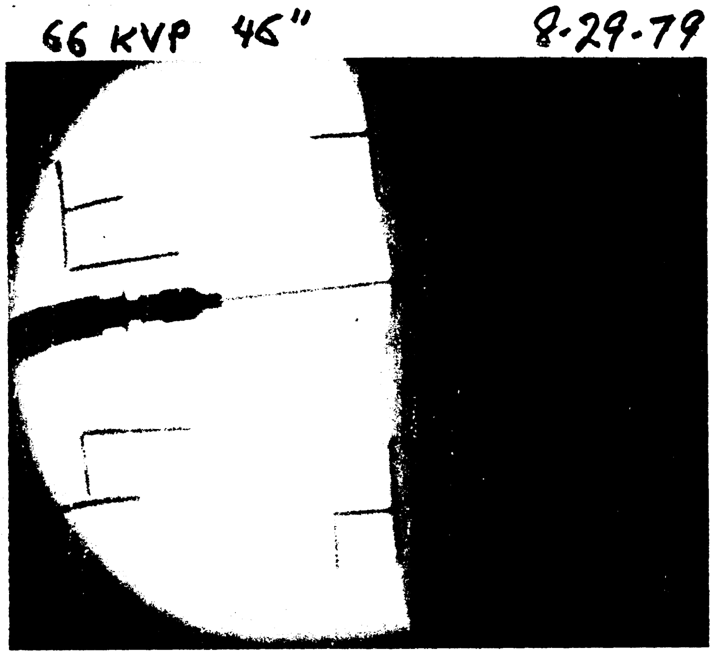


FIGURE B - Timing diagram illustrating the temporal sequencing of events during a cineradiographic test.



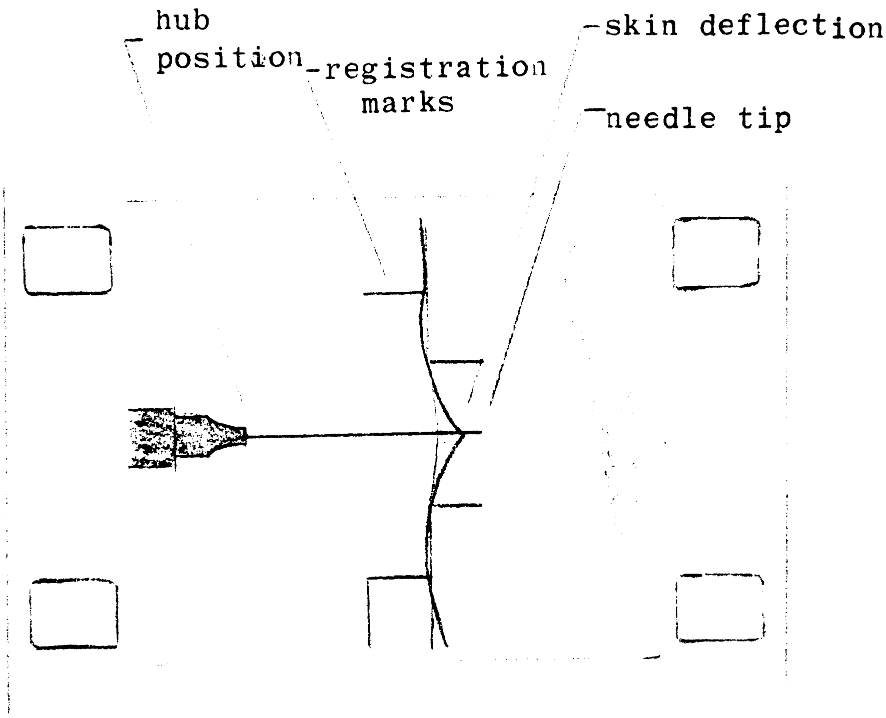


Figure C

Photograph of intensified x-ray image on the intensifier tube and illustration of how image appears on a movie film frame.

Injections were performed at a velocity of 2 inches/second to a depth of 1.5 inches beyond skin contact at 90 degrees to the skin surface. The frame rate of the camera varied from 700 to 950 frames/second.

2. Data Analysis

Data analysis consisted primarily of digitizing needle position and skin deflection relative to initial skin position from the film data. This was accomplished using a Numonic Corporation digitizer, and remotely controlled single step film projector. Needle tip penetration was computed for each digitized frame (approximately every 10th frame) by subtracting skin deflection from needle tip position. Actual distances were computed from these digitized results by using the measure of needle length as a magnification factor. These displacement curves were synchronized and matched to the digitized force values using the strobe pulse and computed film frame rate. Because it was difficult to locate the actual needle tip (especially after penetration), the position of the needle hub was digitized and the needle tip position was computed by adding the digitized value of needle length. The solder reference marks were used to zero the digitizer at a common point in all film so that the initial skin position remained the same between frames.

RESULTS

1. General

Accompanying this report is a 16mm x-ray film of tests 2 through 9. The results presented in this section were produced from data taken from this film and digitized as described in the Methods section.

The results of the tests are given in Figures 1 through 13 and Tables 1 and 2. Figures 1 through 8 are plots of the force, skin deflection and tip penetration for each of the eight needles. These graphs provide a comparison of the time relationship between these variables. Figures 9 and 10 show force versus skin deflection and tip penetration for all tests. Figures 11 and 12 show tip penetration at breakthrough plotted versus heel length and cutting slope. Figure 13 is a composite of peak force, peak skin deflection, tip penetration at breakthrough and cutting slope for all needles. Table 1 is a listing of needle type and the measured tip to side bevel and tip to heel lengths. Table 2 presents the needle injection parameters that were determined for each needle in this study. Copies of the original force tracings are presented in the Appendix of this report.

2. Comparison of Force, Skin Deflection and Tip Penetration for Each Needle

a) Test #2 - Conical Solid 20g Dry Needle (Figure 1). This needle is characterized by an extremely high peak force (890 grams). The concavity of the force curve indicates that a greater and greater force is required to deflect the skin a given distance, reflecting the non-linear compression characteristics of the tissue. After peak force, the force falls off 66 percent. Skin deflection rises linearly to a peak of 14.1mm. The times of peak deflection and peak force correspond very closely. Tip penetration appears to begin immediately after skin contact and continues at a relatively slow and constant rate to a value of 2.6mm at peak force (and peak skin deflection) at which time it shows a sudden increase as "break through" occurs.

b) Test #3 - Tetrahedral Solid 20g Dry (Figure 2). The general characteristics of this needle are similar to those of the conical needle although the peak force of 350 grams is considerably lower. Force again falls off about 66 percent after its peak and skin deflection rises linearly to a peak value of 11.6mm. The times of peak deflection and peak force correspond exactly. Although early increases in tip penetration are somewhat obscured by noise, it appears that tip penetration begins immediately with force build-up, reashes a depth of almost 2mm at peak force, and then shows a well defined increase as break-through occurs.

c) Test #4 - 42 Point Solid 20g Dry (Figure 3). Due to equipment difficulties the x-ray source shut off early in this test and data on skin deflection and tip penetration could only be taken out to 400 milliseconds. Force in Figure 3 is therefore plotted out to 400 milliseconds also. The appendix includes the original chart recording of the entire force curve from which it is seen that the force does not exhibit the typical characteristics of a distinct peak followed by a sudden drop in value. Rather, the force rises linearly to a plateau at about 147 grams and then continues with a low and fluctuating slope to a maximum of 200 g near 720 milliseconds. Because skin deflection appears to plateau after 147 grams of force it can be assumed that puncture occurred and that "peak" force should be somewhere near this value. Tip penetration starts immediately and increases linearly to a value of 3.5mm at peak force.

d) Test #5 - 42 Point Stock 20g 1249 (Figure 4). For this needle, the rising edge of the force curve is slightly convex and reaches a peak of 113 grams at which point the force falls off 22 percent. The rising edge of the skin deflection curve is also somewhat convex and after peak force there is almost no recoil* of the skin. Tip penetration begins immediately and reaches a peak of 4.4mm at peak force. Because of this relatively large amount of penetration there is only a slight slope change in tip penetration at peak force.

e) Test #6 - Side Bevel 20g 360 (Figure 5). The peak force of 86 grams for this needle was the lowest seen for all the needles tested. There was a 30 percent drop in force following the peak. The rising force curve tends to be convex except for a concave portion just before peak force. Skin deflection reaches a broad peak at 3mm and there is only a slight amount of skin recoil after peak force. As with the previous tests, tip penetration starts immediately. Penetration is 4.1mm at peak force and the change in slope at this point is quite small.

f) Test #7 - Back Bevel 22g 360 (Figure 6). Force rises linearly to a sharp peak of 148 grams. The drop in force after peak was about 63 percent. Skin deflection also rises linearly to a peak of 4.8mm, coinciding with the time of peak force. There is a greater amount of skin recoil than observed for the needles in tests 5 and 6. Tip penetration again appears to start at skin contact, reaches a value of 2mm

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*Recoil will be defined as a drop in skin deflection after puncture of the skin; this term is appropriate because the skin and underlying tissue represent a compressed elastic element that may release suddenly after puncture.

at peak force, and then increases in slope with a more pronounced inflection than observed in tests 5 and 6.

g) Test #8 - A Bevel 22g 360 (Figure 7). The force for this needle has a very linear rise to a peak of 113 grams and drops off 39 percent after the peak. Skin deflection reaches a maximum value of 4.2mm coincident with the time of peak force. There is a small amount of skin recoil following peak deflection. Again, tip penetration starts very early. There is a penetration of about 2.7mm at peak force and a fairly well defined increase in slope at this point.

h) Test #9 - 42 Point 22g Dry (Figure 8). Force reaches a peak value of 98 grams. The drop in force after peak was 23 percent. Skin deflection reaches a peak value of 3.6mm coincident with the time of peak force. There is very little skin recoil after peak deflection.

As in the other tests, tip penetration appears to start immediately. At peak force there is a penetration of 4.1mm. There is a discernable increase in the slope of tip penetration but it appears to start somewhat before peak force and is more gradual than that observed in the other tests.

By several criteria (see discussion section) this needle appears to have desirable injection characteristics. This finding is not expected considering that this needle is unlubricated. However, with a sample of one, the variability between needles or differences in tissue sites might account for the discrepancy between the observed and the expected results.

3. Force vs. Skin Deflection

Figure 9 illustrates the relationship between force and skin deflection for all needles plotted from zero to their peak values. Tests 2 and 3 are only plotted over part of their range due to the extremely high values of force and skin deflection.

It is seen from this graph that the relationship is quite linear over the range of 0 to 4mm of deflection and 0 to 150 grams of force for all needles. The most interesting and significant observation, however, is that the average slopes of the curves for the various needles are practically identical. In view of widely differing tip geometries and lubrications, this constancy of the force-deflection slope is somewhat unexpected. The implications of this will be covered in the discussion section.

4. Force vs. Tip Penetration

Figure 10 illustrates the relationship between force and tip penetration. Unlike the force vs. deflection curves, the tip penetration curves show large slope differences for different needles. The non-cutting conical and tetrahedral needles have very large slopes, almost vertically upward. This means that very large increases in force are required to produce only slight amounts of tip penetration. The side bevel 20g 360 needle used in test #6 and the 42 point stock 20g 1249 needle of test #5 have the lowest slopes. When compared to the non-cutting needles, these needles require a much smaller force increase to produce a given increase in tip penetration. When combined with other parameters, the slope of the force vs. tip penetration curve may be very useful to describe the skin cutting properties of the needle tip.

5. Tip Penetration at Peak Force Versus Tip to Heel Length

Table 1 presents the tip to heel and tip to side bevel lengths taken by a dial caliper along with tip penetration measures for the needles tested. Figure 11 illustrates the relationship between tip penetration at peak force and tip to heel length for each of these needles. If peak force represented the heel of the needle puncturing the dermis, one would expect a good correlation between tip penetration and heel length. It is clear from Figure 11 that there is a poor correlation between these parameters especially if the non-cutting conical and tetrahedral needles with the two lowest values in tip to heel length (2.03 and 2.41,, respectively) are excluded. The discussion section will elaborate on this finding.

6. Tip Penetration at Peak Force Versus Slope of Penetration-Force Curve

Table 2 summarizes computed penetration parameters for the needles tested and provides definition of the terms used. Figure 12 shows a plot of tip penetration at peak force and the cutting slope, SL_{PF} for the 8 needles tested. It can be seen that there is a good correlation ($r = .92$) between these parameters indicating that better cutting needle tips (higher SL_{PF}, lower SL_{FP}) achieve a greater tip penetration at peak force than poorer cutting tips.

7. Summary of Computed Penetration Characteristics

Figure 13 is a composite presentation which summarizes and compares four of the measured penetration parameters for the needles tested. These include: peak force, peak skin deflection, tip penetration at peak force and cutting slope (SL_{PF}).

TABLE 1

NEEDLE TIP DIMENSIONS* AND PENETRATION MEASURES

Test No.	Needle and Lubricant	Heel Length	Side Bevel Length	TP_p-1mm	TP_p-2mm
2	Con.Sel. 20g Dry	2.03		1.6	.6
3	Tet.Sol. 20g Dry	2.41		1.0	0
4	42 point sol. 20g Dry	4.24	1.40	2.5	1.5
5	42 point stock 20g 1249	3.76	1.57	3.5	2.5
6	Side bevel 22 g 360	3.35	1.41	3.1	2.1
7	B bevel 20g 360	3.73	.89	1.0	0
8	A bevel 22g 360	3.43	1.27	1.7	.7
9	42 point stock 22g Dry	3.84	1.07	3.1	2.1

*All dimensions in mm.

TABLE 2

SUMMARY OF COMPUTED PENETRATION PARAMETERS

Test No.	Needle	Test	F_2	SD_p	TP_p	F_d	SL_{fd}	SL_{fp}	SL_{pf}
2	Con.Sol. 20g Dry	2	890	14.1	2.6	66	29	220	.005
3	Tet.Sol. 20g Dry	3	351	11.6	2.0	66	25	260	.004
4	42 Point Sol. 20g Dry	4	147	5.6	3.5	-	27	45	.022
5	42 Point Stock 20g 1249	5	113	4.3	4.5	22	30	26	.039
6	Side Bevel 20g 360	6	86	3.1	4.1	30	29	24	.042
7	Back Bevel 22g 360	7	148	4.8	2.0	61	33	91	.011
8	A Bevel 22g 360	8	115	4.2	2.7	39	28	45	.022
9	42 Point Stock 22g Dry	9	98	3.6	4.1	23	26	30	.033

Parameters	Units	Description
F_2	grams	Peak force
SD_p	millimeters	Skin deflection at peak force
TP_p	millimeters	Tip penetration at peak force
F_d	%	Percent drop in force after peak
SL_{fd}	gm/mm	Slope of force vs. skin deflection
SL_{fp}	gm/mm	Slope of force vs. tip penetration
SL_{pf}	mm/gm	Slope of tip penetration vs. force = $1/SL_{fp}$

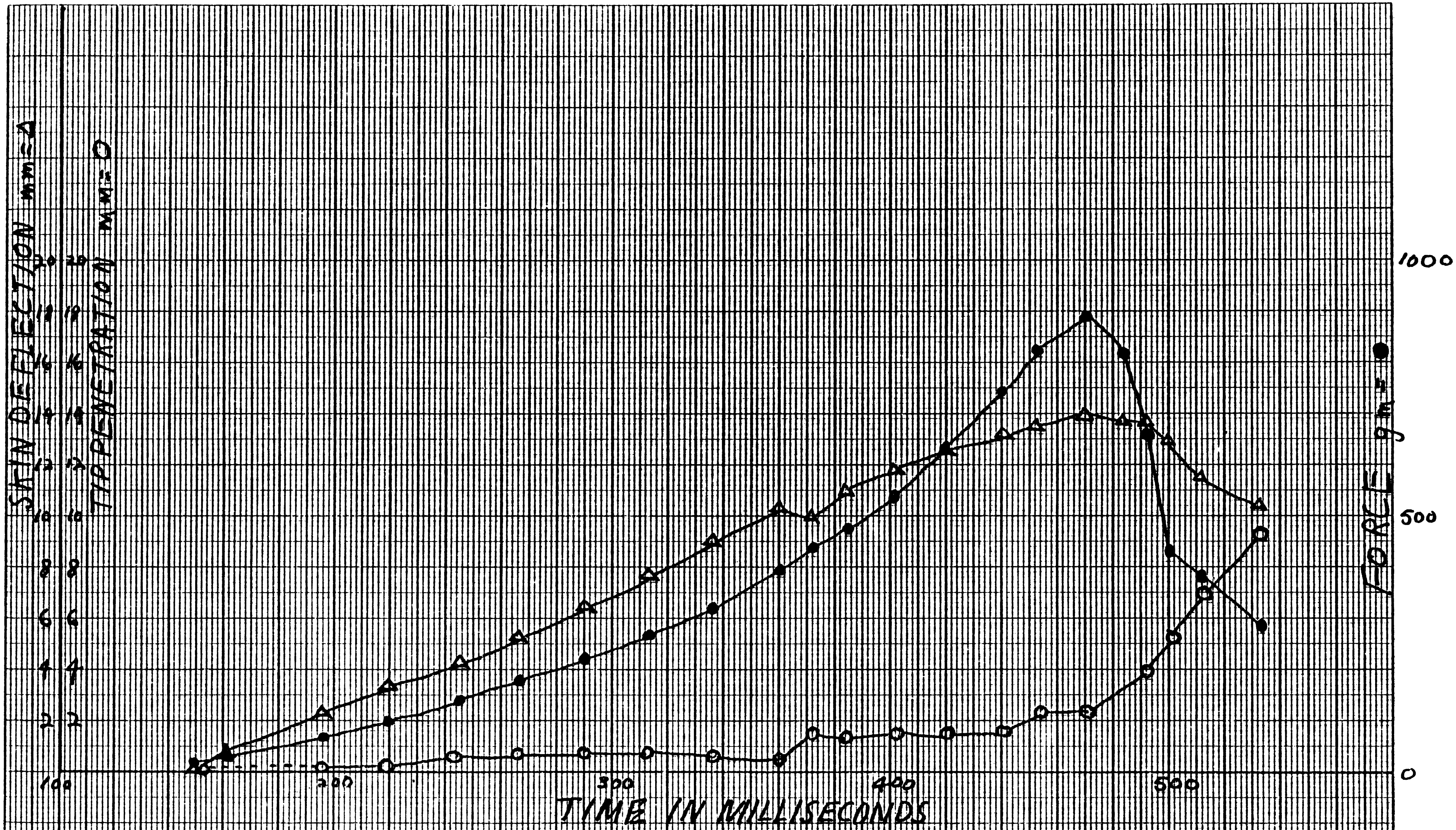

FIGURE 1 - Test 2-Con. Sol. 20g dry

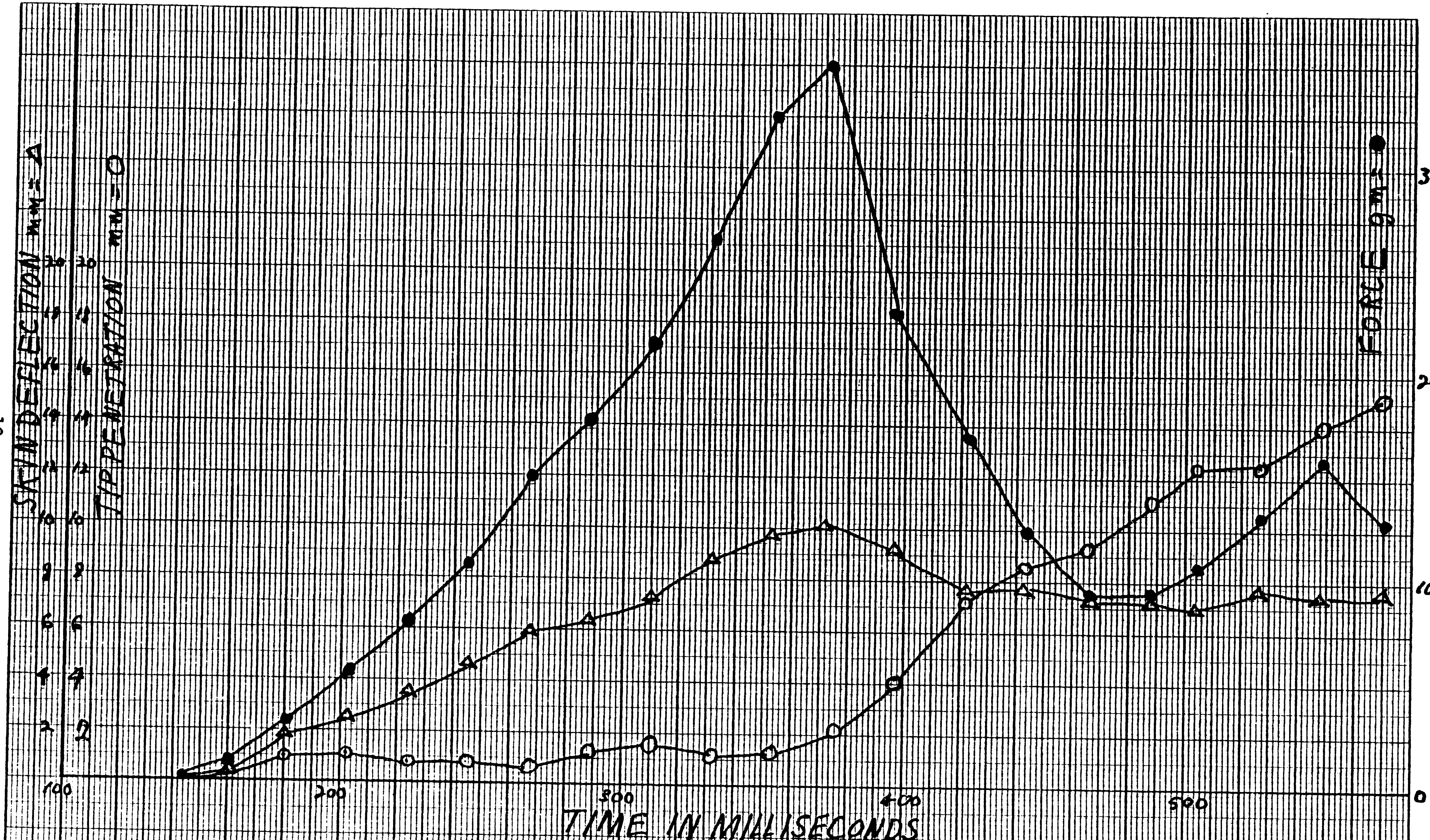

FIGURE 2- TEST 3- TET. SOL. 20g DRY

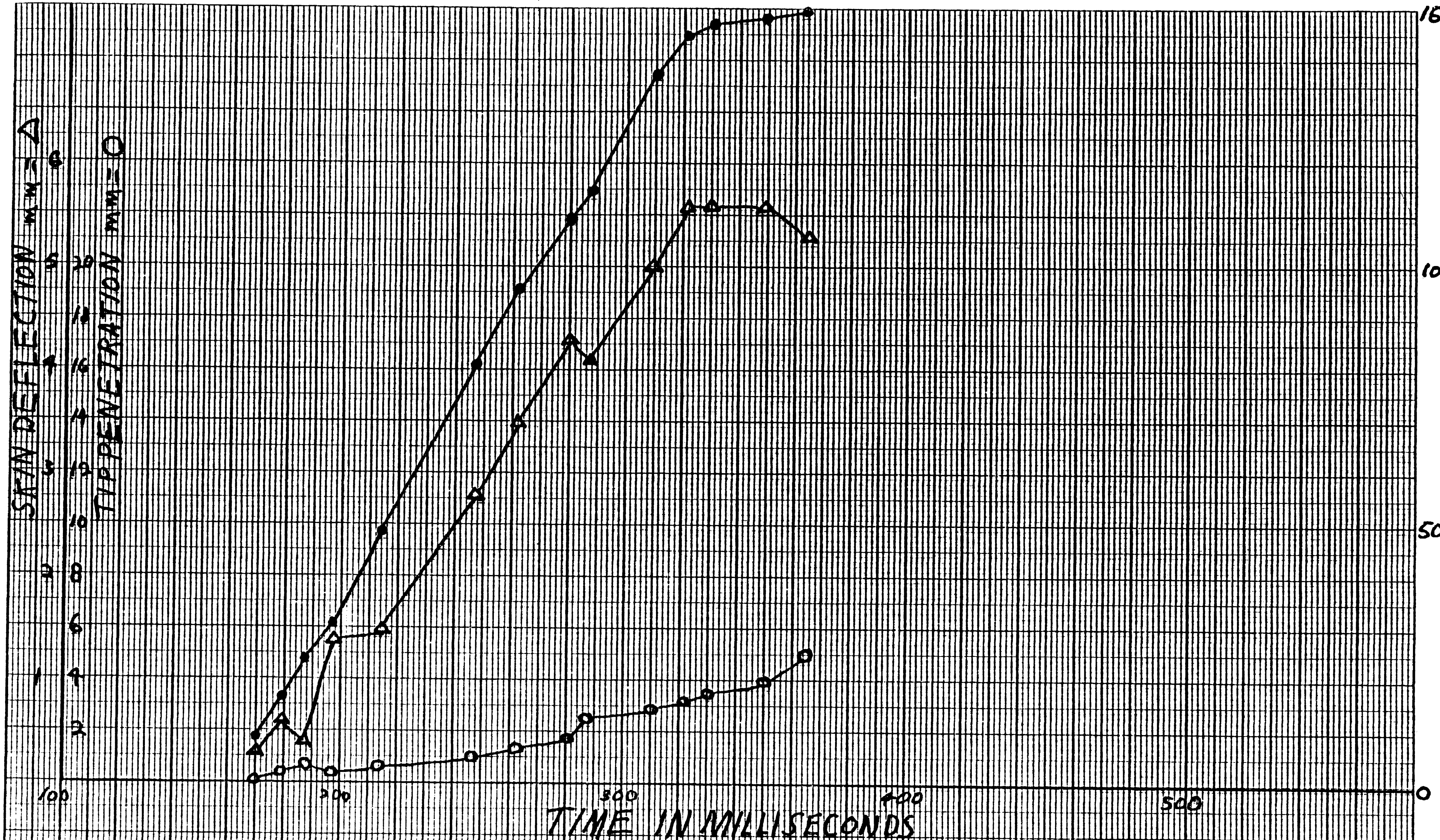

Figure 3-Test 4-42 solid 20g dry

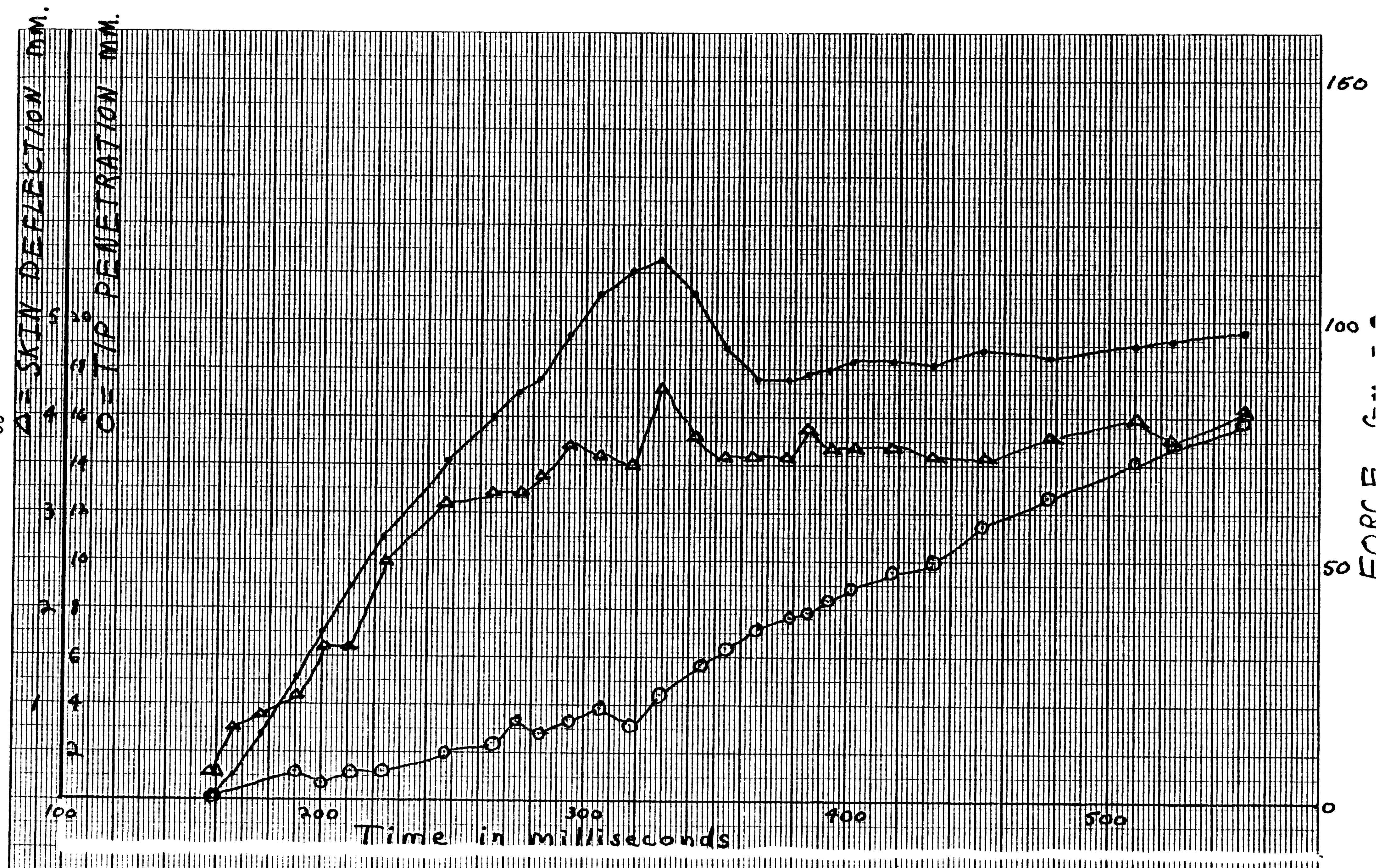

Figure 4 - Test 5 - Stock 209 1249

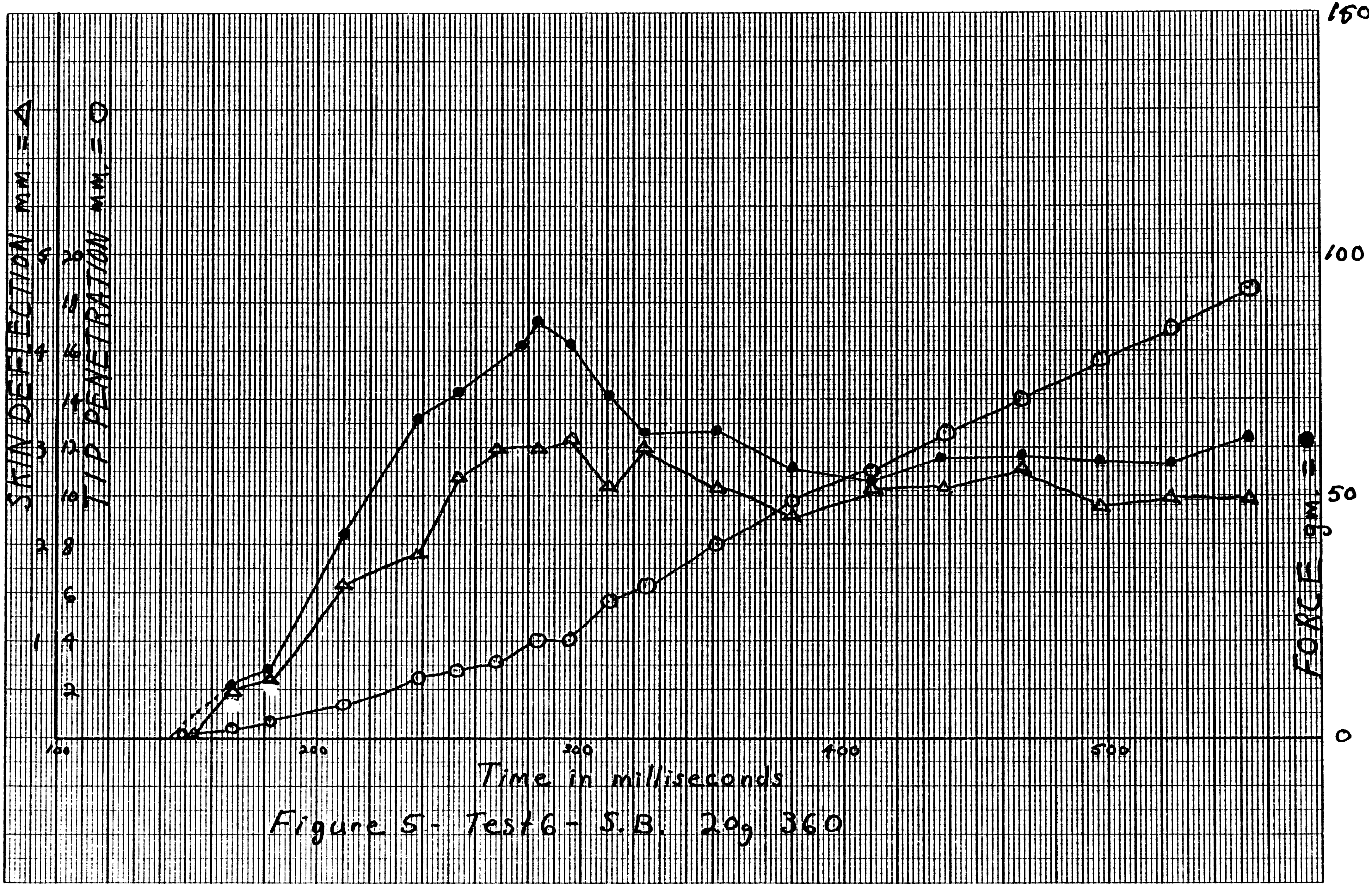

Figure 5- Test 6- S.B. 20g 360

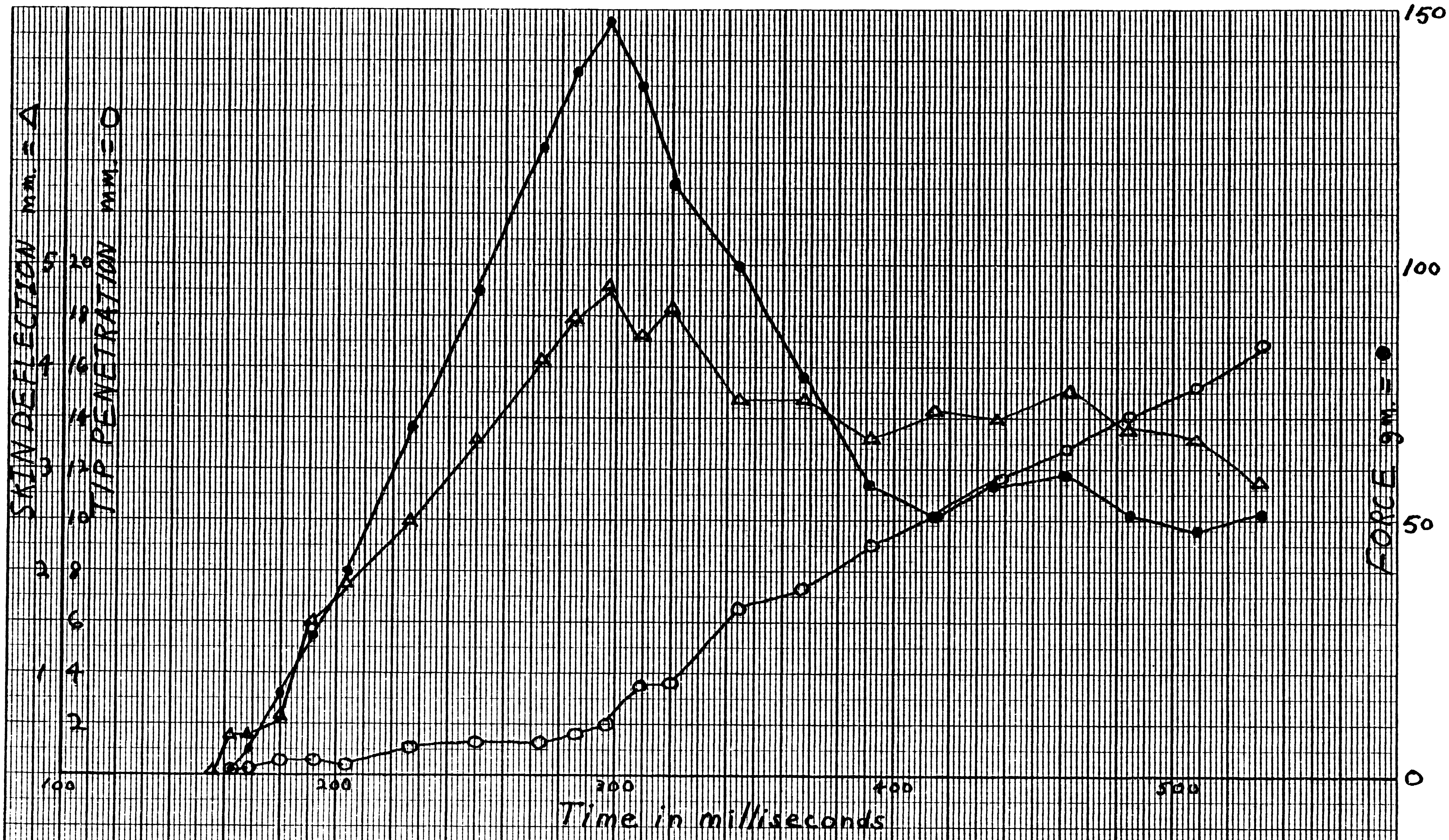

Figure 6 - Test 7 - B.B. 22g 360

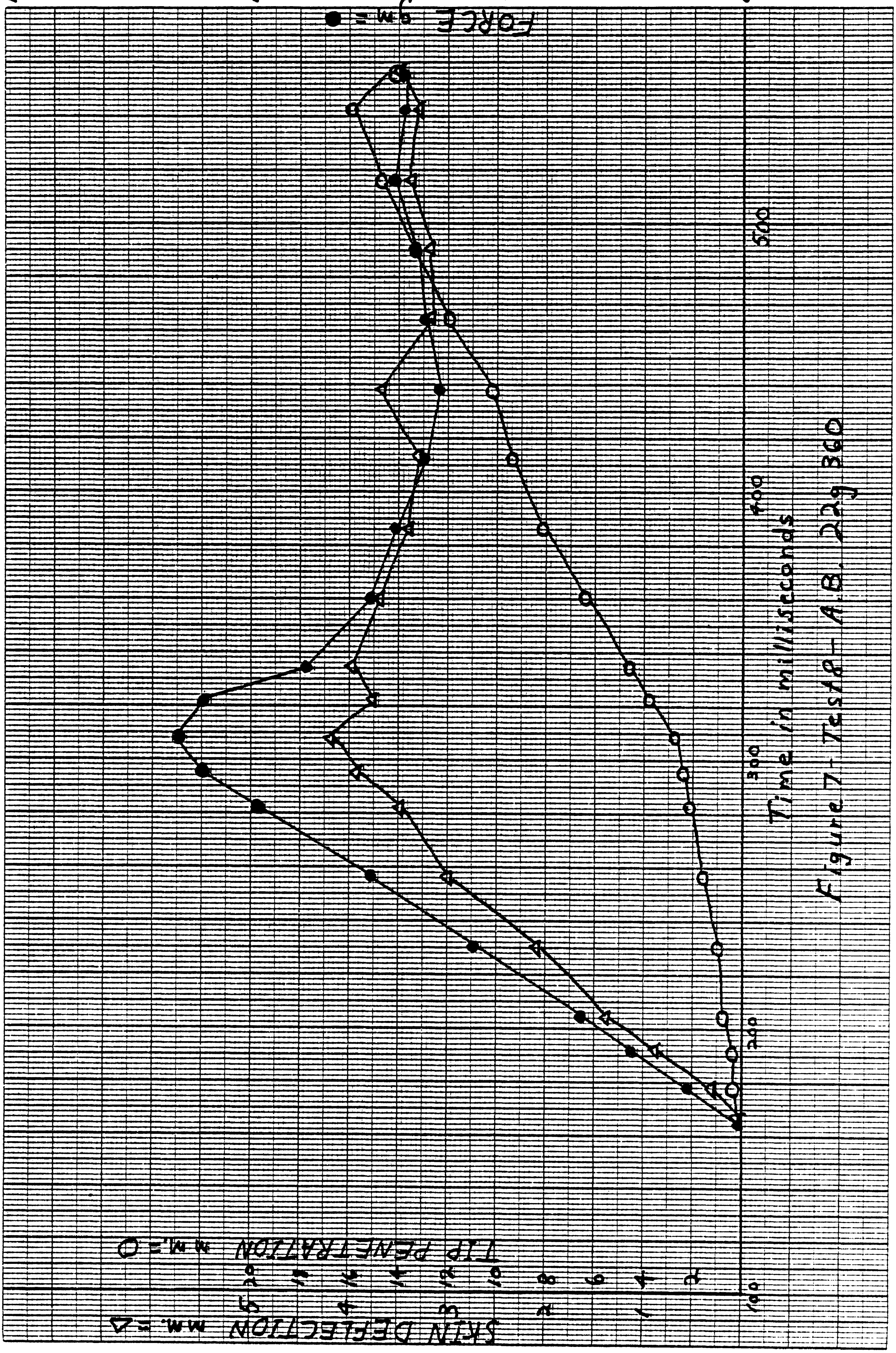

Figure 7- Test 18- A.B. 229 360

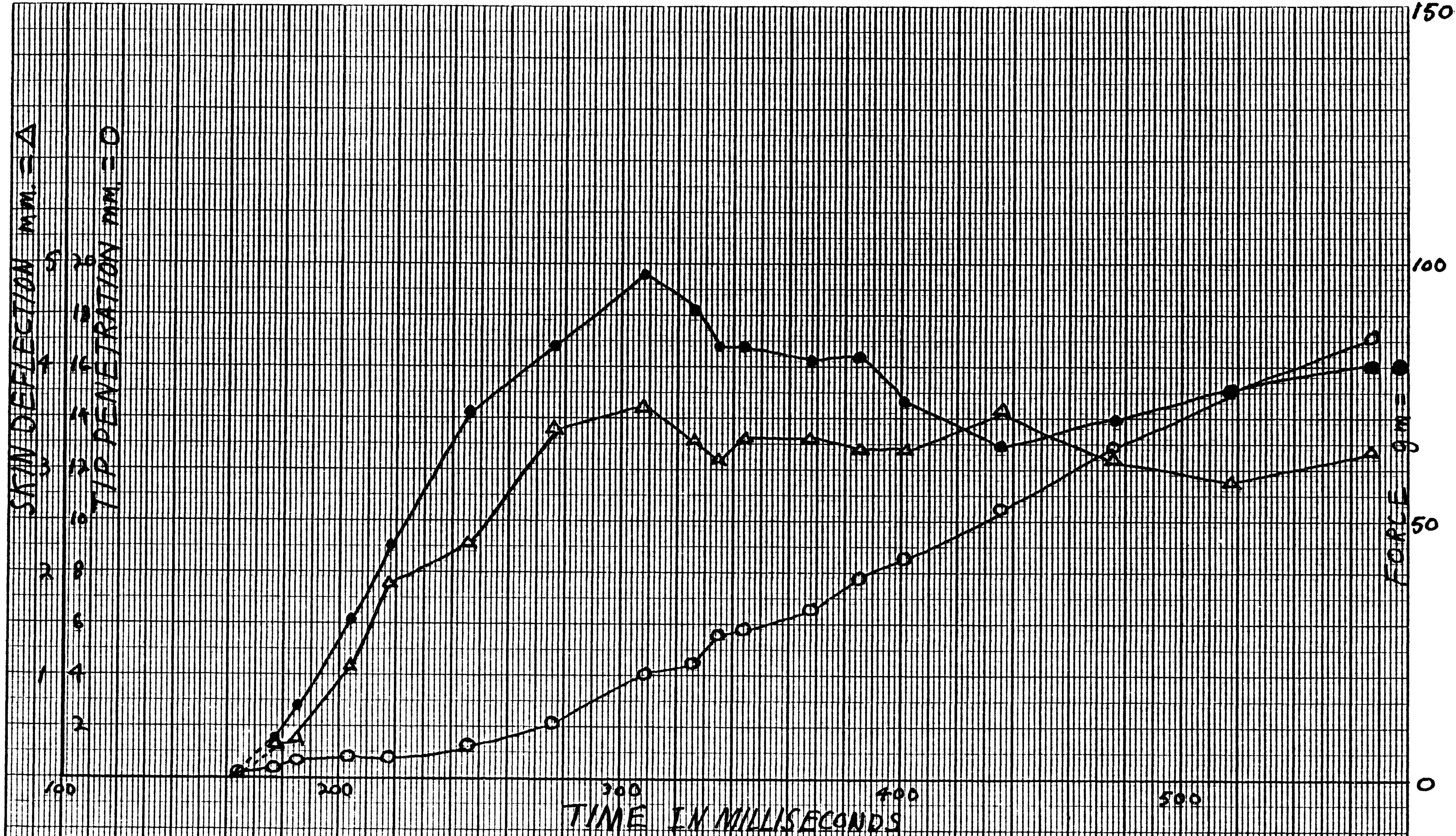

Figure 8- Test 9-42 22g dry

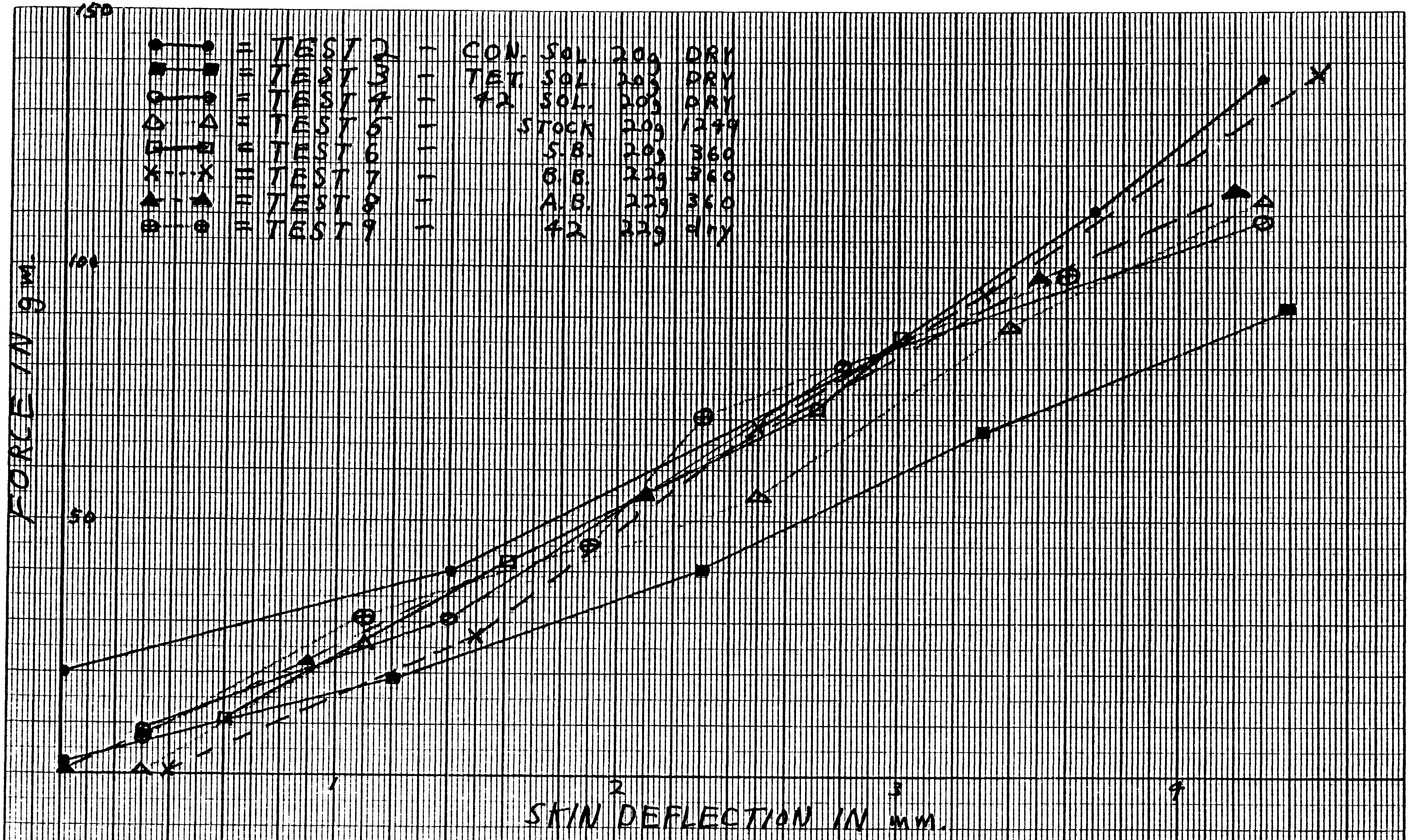

FIGURE 9 - FORCE vs. SKIN DEFLECTION

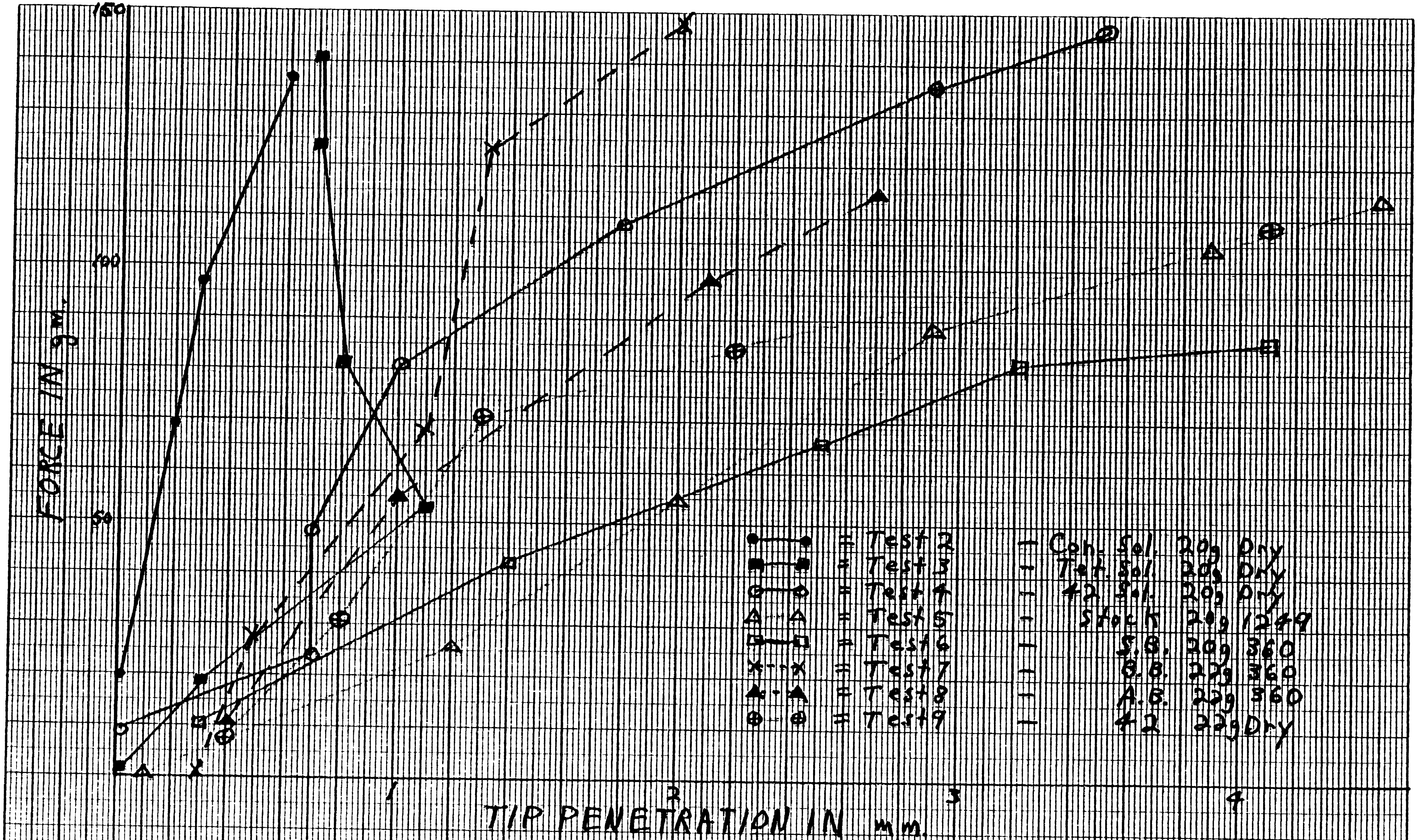

FIGURE 10 - FORCE vs. TIP PENETRATION

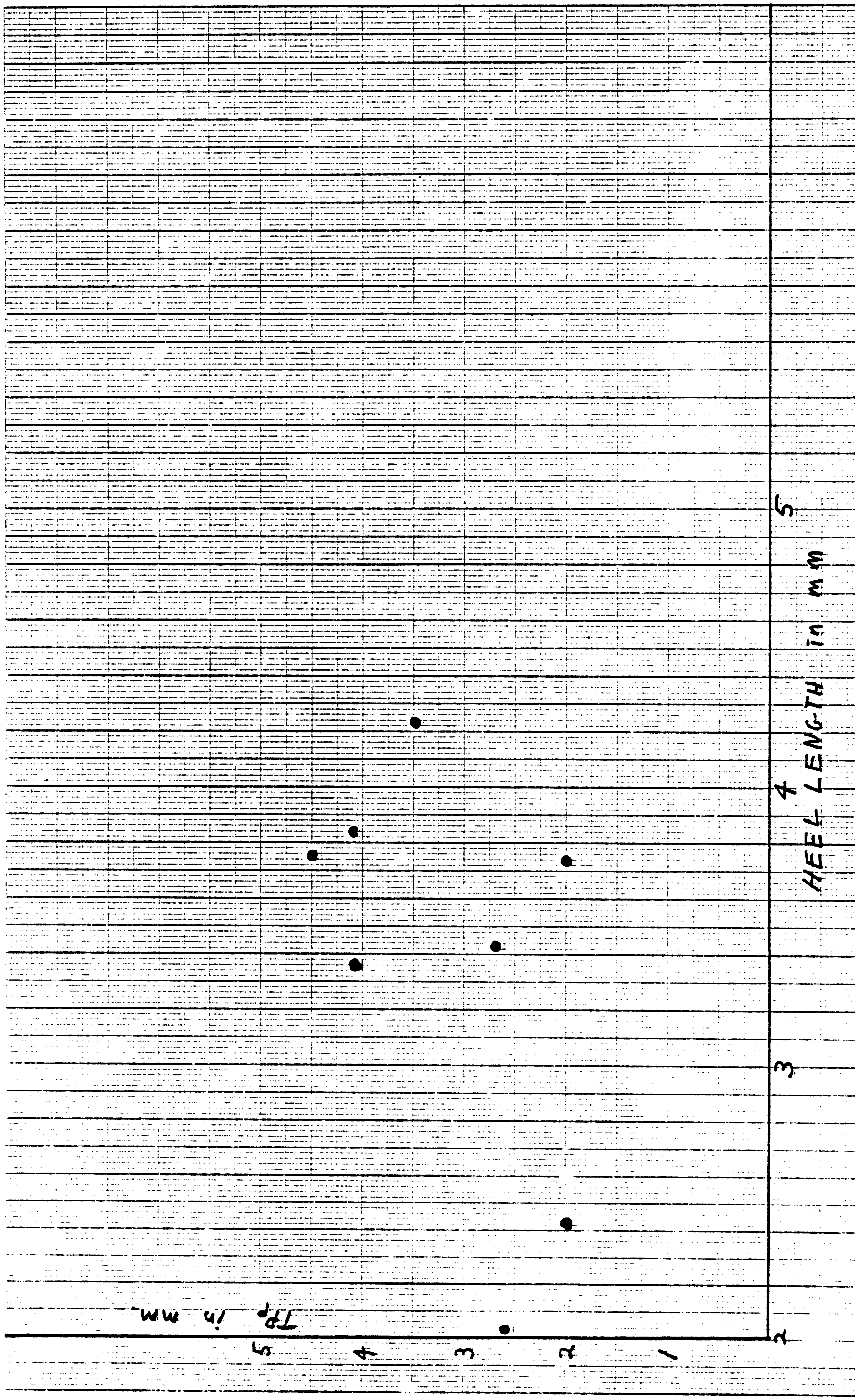

Figure 11 TPo vs. HEEL LENGTH

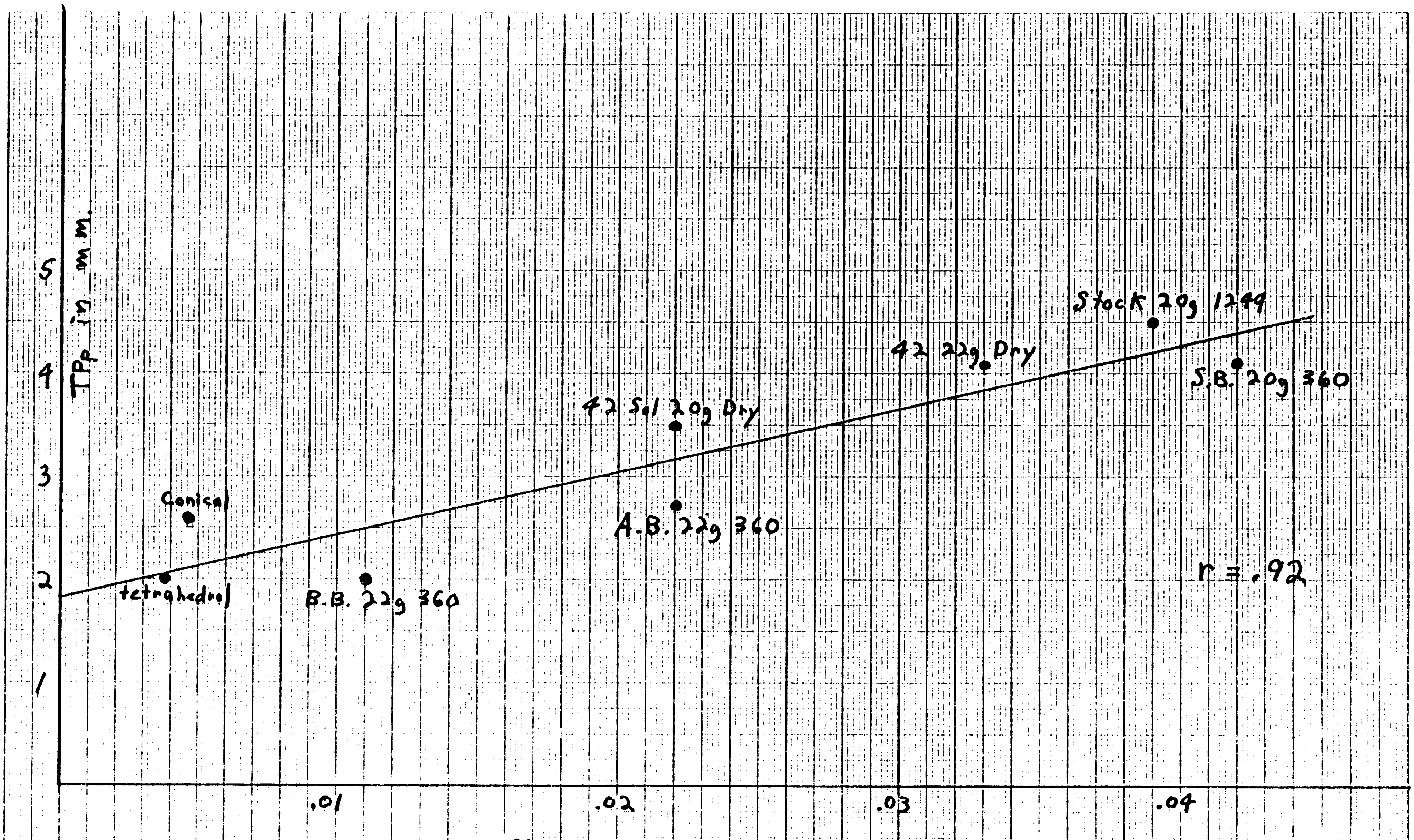

Figure 12 TP_p versus SL_{PF}

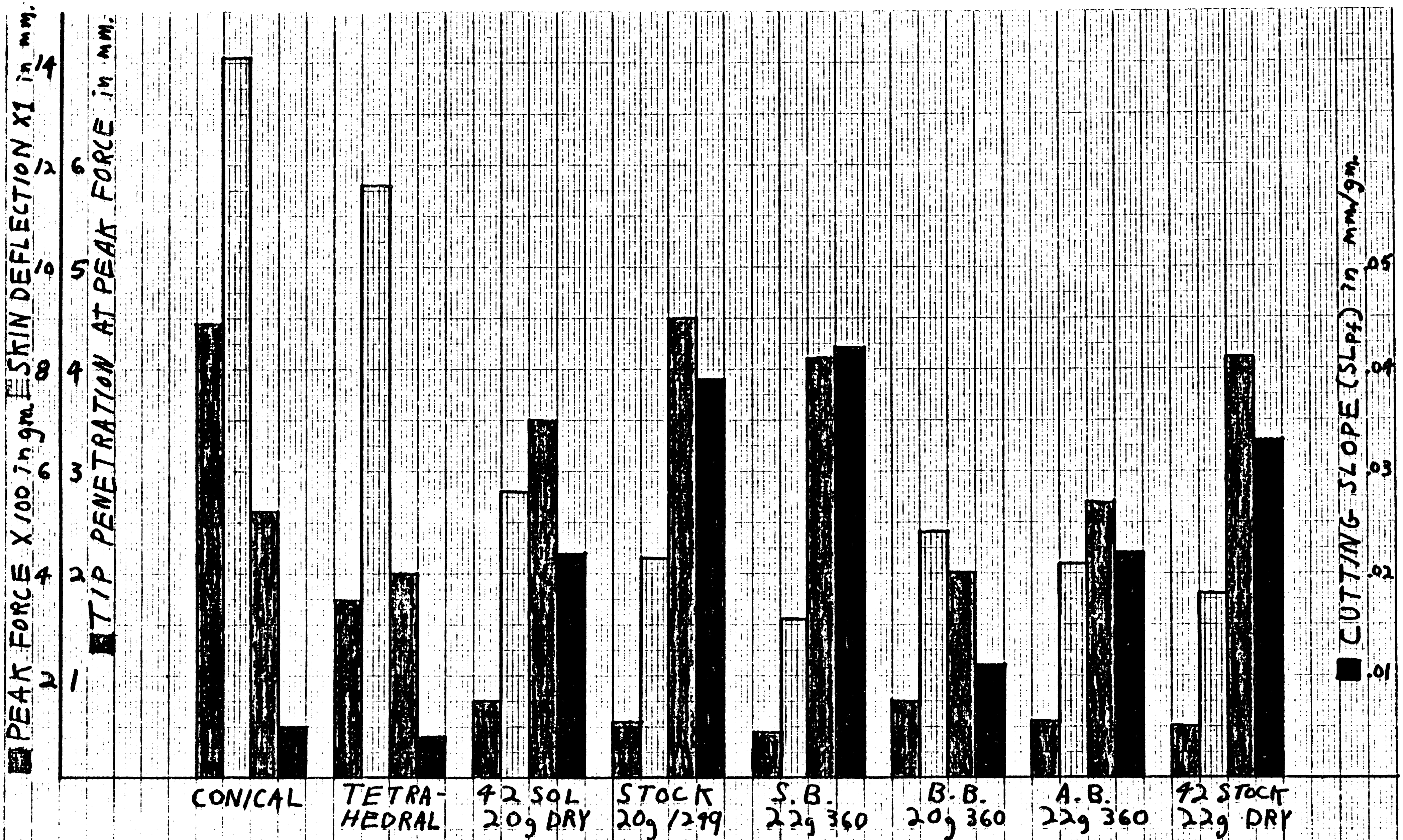

FIGURE 13 BAR GRAPH OF NEEDLE PARAMETERS

DISCUSSION

1. General

The results shown in Figure 1 through 8 illustrate two general and important points which seem to be consistent for all needles tested. The first point is that peak force, peak skin deflection and the change in slope in tip penetration all occur at the same point in time. Thus, peak force represents the point at which the skin suddenly yields to the force of the needle tip and is punctured. While this has always been suspected it could not be confirmed until simultaneous measurements of skin deflection and force could be made.

The second point concerns the beginning of tip cutting. It has been suggested by B-D personnel that there must exist some point between skin contact and peak force where a needle tip begins to cut (i.e., where skin deflection and needle position begin to differ). The value of force at which this occurs has been termed F1 and it has been hypothesized that "good" cutting needle tips will have low values of F1 while poor cutting needles will have high values of F1. The results of this study suggest that all needles begin cutting or penetrating immediately after skin contact and therefore that F1 is always zero. Since it is really not possible from our x-ray film to distinguish needle tip cutting from severe point deformation of the skin, we cannot, of course, be sure that the initial slope in tip penetration is due to actual tissue cutting. In every case, however, no other clear inflections in tip penetration were observed prior to peak force. Thus, if the initial slope in tip penetration is not due to cutting, it would seem that for all needles the point at which cutting began was either at peak force or was indistinguishable from the point deformation of the skin which was then measured as tip penetration from our films.

2. Differences in Needle Parameters

It can be seen in Table 2 that there are differences in parameters between the various types of needles. In general, the conical and tetrahedral needles are the two most different from the rest. Their values of peak force (F_2), peak skin deflection (SD_p), percent force drop after peak (F_d) and slope of force vs. penetration (SL_{fp}) are the largest for the group of needles which were tested. These needles also have low values of tip penetration at peak force (TP_p). Some of the differences between these parameters can be explained in terms of the tip geometries of these needles.

The absence of any cutting edge on the conical needle and the large cutting angle of the tetrahedral tip probably result in little actual cutting as the tip passes through the dermis. Rather, penetration may occur as a result of stretching and tearing of the tissue. The data show that a much higher force is required to tear through the dermis than to cut through it. Consistent with this hypothesis is the finding that peak skin deflection (SD_p) is large for the conical and tetrahedral needles. Skin deflection will increase to large values if force increases and if little penetration has occured. This is perhaps better illustrated by examining the slope of the force versus tip penetration curve (SL_{fp}). SL_{fp} reflects the amount of force in grams necessary to penetrate 1mm into the dermis and is the slope of a regression line drawn through the force vs. tip penetration data points. For the conical and tetrahedral needles the cutting slopes were 220 and 260 grams/millimeter, respectively. These values are in order of magnitude higher than those observed for some of the other needles. SL_{fp} is an important parameter because it is a good measure of a needle tip's ability to cut through the dermis.

Table 2 also shows that the percent drop in force after peak (F_d) is high for the conical and tetrahedral needles (66 percent). This value reflects the relative difference in force between that required for penetration of the dermis and that required for penetration of the subcutaneous tissue. It is of interest because it may correlate with the subjective feeling of "hang-up" and sudden "give way" during the hand held injection of a needle. It is suggested that high values of F_d are undesirable from a user's point of view. A high F_d means that a much higher force is required to break through the skin than that required to go through subcutaneous tissue. This could mean loss of control during an injection,* when the sudden drop in force occurred following dermal puncture.

The parameters discussed so far for the conical and tetrahedral needles have clearly indicated that these tips have undesirable injection characteristics. Differences can also be observed among the needles with cutting tips. For the side bevel 20g 360 needle in test #6, for example, peak force (F_2) and peak skin deflection (SD_p)

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*Probably not so important for IM punctures but very important for I.V. and other needle types.

are the lowest of the needles tested. The slope of force vs. tip penetration (SL_{fp}) was also the lowest. This indicates that the tip of this needle has a good ability to cut the dermis (only 24 grams are required for 1mm of penetration as compared to 260 grams for the tetrahedral needle). The low value of F_d (30 percent) means that there is less of a tendency for a sudden "give way" and loss of control as compared to the conical and tetrahedral needles with F_d's of 66 percent.

The parameters chosen to describe the data collected in this study are very consistent with respect to one another. Consider tests 6, 7 and 8 with the side bevel, back bevel and A bevel needles. These needles all utilize 360 lubricant. Their primary differences are in the type of secondary bevel grind. The side bevel needle has the most desirable characteristics. It has the lowest F_2, SD_p, F_d and SL_{fp}. The back bevel is the least desirable of the three. It has the largest F_2, SD_p, F_d and SL_{fp}. The A bevel needle has parameter values intermediate to the other two needles. The parameters are consistent in that they all say the same thing about the desirability of the three needles and suggest that the stock 20g with 1249 lubricant and the 42 point 22g dry are the most desirable (bearing in mind a sample size of one). The 42 point solid 20g dry would be judged as relatively undesirable by the parameters.

3. Determination of Needle Tip, Side Bevel and Heel Structures in Relation to Skin Surface

An accurate determination of tip penetration is necessary to locate the relative position of needle and skin structures and thereby correlate needle tip geometry with force characteristics. Due to the finite grain size of the film and other limits on resolution, the measurement of skin deflection and needle position (and therefore tip pentration) are subject to some random error as indicated by the noise seen in some of the test results. In addition, and as was previously mentioned, it was not really possible to distinguish true penetration through the dermis from an extreme deformation or stretching of the dermis around the needle tip.

Regardless of these uncertainties in tip penetration, there is clearly a line of increasing penetration which may be drawn through the individual points of tip penetration. Because about 10 points were taken before peak force there is little doubt that the general trend is upward at a fairly constant rate. The average error between the actual tip penetration at breakthrough and the value predicted by a constant slope regression line is small for most needles.

Table 1 presented the tip to heel and tip to side bevel lengths for the needles used in this study. Table 2 contains the values of tip penetration at peak force (TP_p). By combining these two sets of information it is possible to estimate the location of the tip, bevels and heel when skin breakthrough occurs. If tip penetration at breakthrough (TP_p) is less than heel length, the heel is above the top surface of the dermis at the time of breakthrough. If TP_p minus dermal thickness is greater than the heel length then the heel would be completely through the dermis at the time of peak force. Even if dermal thickness was as small as 1mm*(see Table 1), the needle heel would not be through the dermis for any of the needles tested. For the

*While dermal thickness was not measured, past data indicates that a thickness of 1 to 2mm is reasonable.

conical, 42 point stock 20g with 1249, side bevel with 360, and 42 point stock dry, the heel was in the dermis at the time of peak force (breakthrough). For the tetrahedral, 42 solid 20g dry, the back bevel 22g with 360, and the A bevel 22g with 360, the heel was above the surface of the dermis at the time of peak force.

If TP_p minus dermal thickness is greater than the tip to side bevel distance then the side bevels would be through the dermis at the time of breakthrough. Assuming a dermal thickness of 2mm, the side bevels of the 42 point solid 20g dry, 42 point stock 20g with 1249, side bevel 20g with 360 and the 42 point 22g dry, would be through the dermis at the time of breakthrough (See Table 1). If a dermal thickness of 1mm is assumed, the side bevels of all needles would be through the dermis at the time of breakthrough. For the tetrahedral and the back bevel needles the tip would be at the level of the lower surface of a 2mm dermis while the tips of the other needles would be through the dermis. For a 1mm thick dermis the tips of all needles would be through the dermis at the time of peak force. These findings indicate that at the time of breakthrough, the tips, side bevels and heels of different needles are in different positions in relation to the skin. This does not support the hypothesis that peak force represents the heel of the needle breaking through the dermis. Further evidence against this hypothesis is given in Figure 11 which shows that there is a very poor correlation between TP_p and heel length. There is, however, very good correlation (r=.92) between tip penetration at breakthrough (TP_p) and the slope of the tip penetration vs. force curve $SL_{pf}(1/SL_{pf})$. As illustrated in

Figure 12, needles with better cutting ability (large SL_{pf}'s) show greater amounts of tip penetration at breakthrough. This suggests that tip penetration at breakthrough is more dependent on cutting ability of the needle tip than on tip to heel length.

The following hypothesis may explain this finding. During penetration, the effective thickness of the dermis changes due to local compression and stretching under the needle tip. Poorly cutting tips require higher forces that compress the dermis more and cause a greater degree of local stretching. Thus, the needle tip does not have to penetrate very far in order to breakthrough. Conversely, dermis that is less deformed may require a greater penetration to "give way."

4. The Relationship Between Force and Skin Deflection

The constancy of the force vs. skin deflection slope (SL_{fd}) shown in Figure 9 suggests that the coupling between the needle tip and the skin does not affect the force-deflection characteristics. For tight coupling, skin deflection and needle movement would be nearly equal (i.e., little penetration). Loose coupling implies a different amount of skin deflection than needle movement (i.e., large amount of penetration). It can be seen from Figure 9 that the poorly penetrating needles in tests 2, and 3 have practically the same force-skin deflection slope as the much better penetrating needles in tests 5, 6 and 9. The average slope for all the tests is 28.4 gm/mm with a standard deviation of $\pm$ 2.5 gm/mm. Table 2 can be consulted for the numerical values of slopes for the individual needles.

The fact that the slope of force versus skin deflection is constant and independent of needle/skin coupling may have important consequences for the determination of needle penetration characteristics. Basically this says that if we know force, we also know skin deflection. The NOVA injection system records force and needle tip position. A blunt (non-penetrating) needle could be initially used to determine the force-deflection characteristics of the region being tested, the resulting slope could be used to compute skin deflection versus time (up to peak force) for future tests from the force versus time curves (i.e., at any point in time, skin deflection = Force/SL_{fd}). Since we also know needle tip position relative to skin contact (from LVDT output) we can compute tip penetration versus time from our computed skin deflection versus time curve. Thus, by using the fact that the relation between force and skin deflection is repeatable and constant* and independent of needle penetration up to peak force, we may be able to develop a procedure for routinely and accurately determining tip penetration in future tests.

*Note: Even if the slope were not constant (non-linear) in the region of interest we could use the tabulated relation to compute skin deflection at any force.

SUMMARY AND CONCLUSION

In this study we have successfully utilized x-ray cinematography as a means to simultaneously measure force, skin deflection, and tip penetration during the injection process. The ability to make these additional measures has resulted in several new parameters which are important for evaluating needle performance and developing optimal tip design features. The results have also yielded new information and ideas about the needle injection process and have made it possible to examine the mechanisms of peak force generation in terms of needle tip structures. In this regard, the results suggest that the time of occurrence of peak force is more dependent on the cutting ability of the needle tip than on the position of needle structures (i.e., heel, side bevels, tip) relative to the dermal surfaces as has been previously hypothesized.

It has also been possible in this study to compare the performances of the different needles tested using these new measured and computed parameters. Since only one needle of each type was tested, however, these comparisons should not be considered as the final word on relative needle performance. As with other needle parameters, such as peak force, it may be expected that substantial variations in these parameters will occur for needles of the same type. This requires that a significant sample size of tests be performed for each needle so that statistical comparisons can be made. The x-ray cinematography technique obviously has limitations in this regard since the collection and analysis of data is relatively expensive in both equipment and time. It therefore continues to be important to develop alternative procedures for routinely measuring skin deflection and/or tip penetration during testing on both cadavers and living subjects. Other instrumentation techniques have been proposed and should be investigated in future work. In addition, the constancy of the force versus skin deflection relation in conjunction with on-line digitizing capability may provide an alternative answer to this need.

REFERENCES

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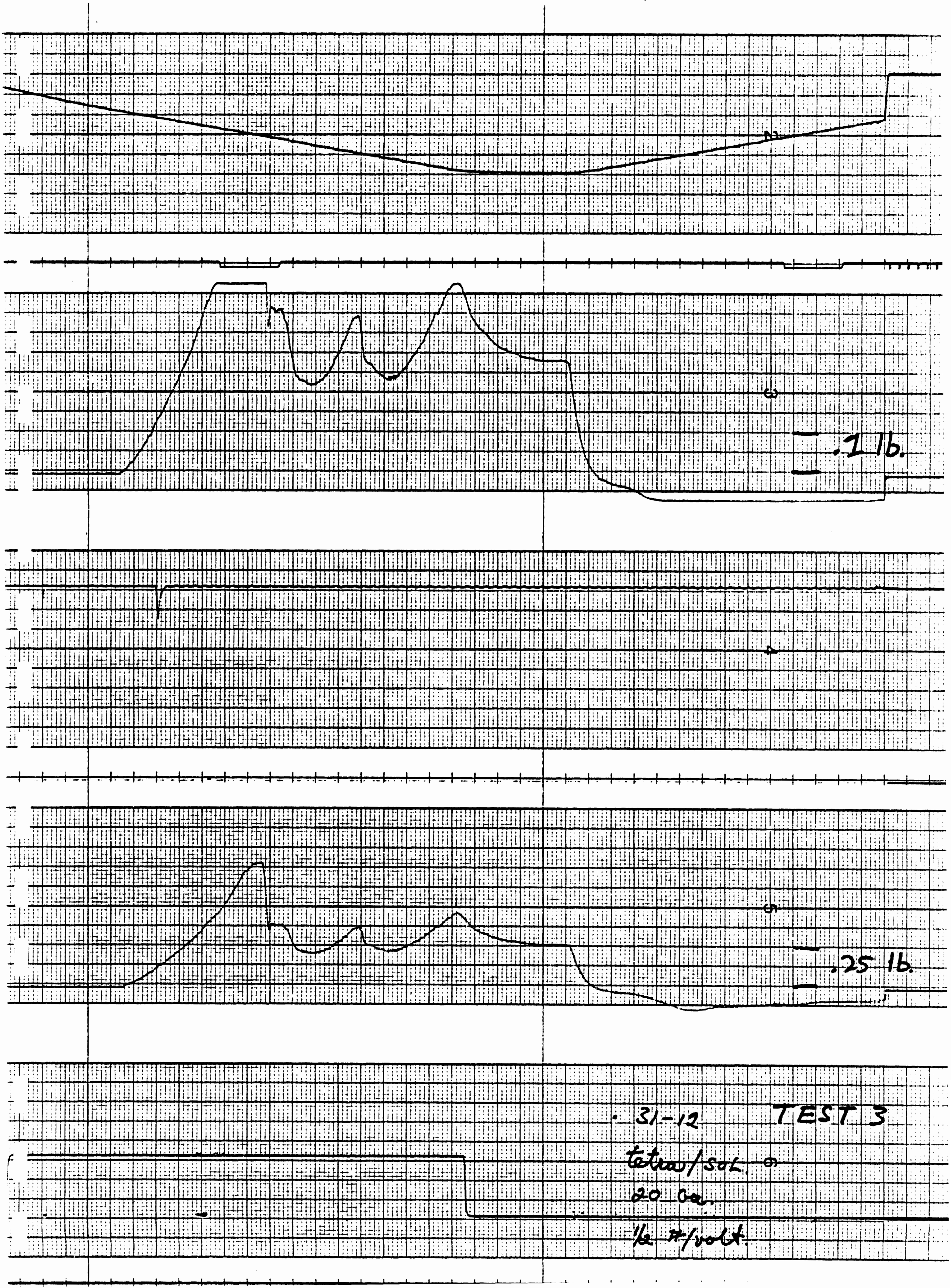
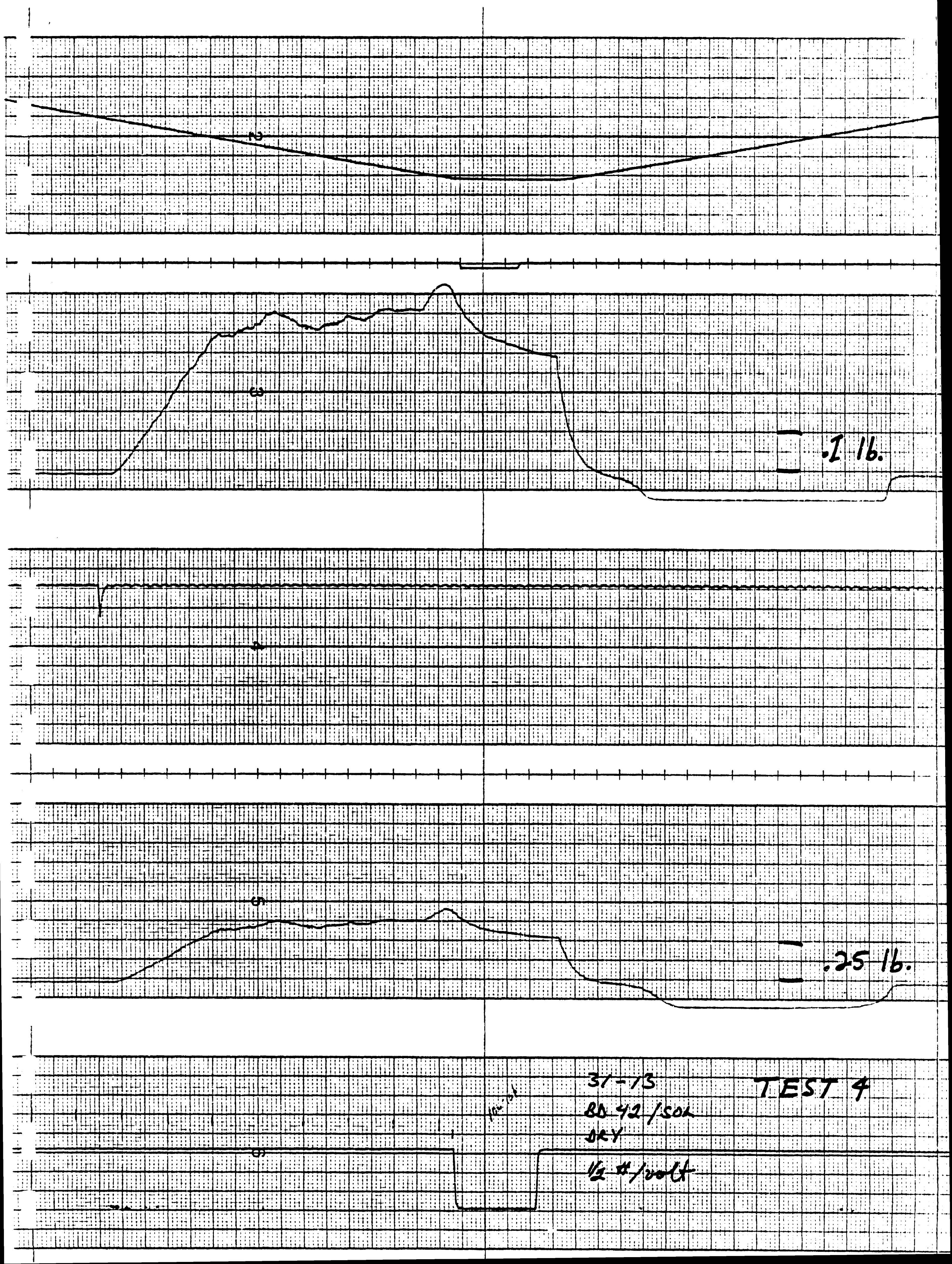
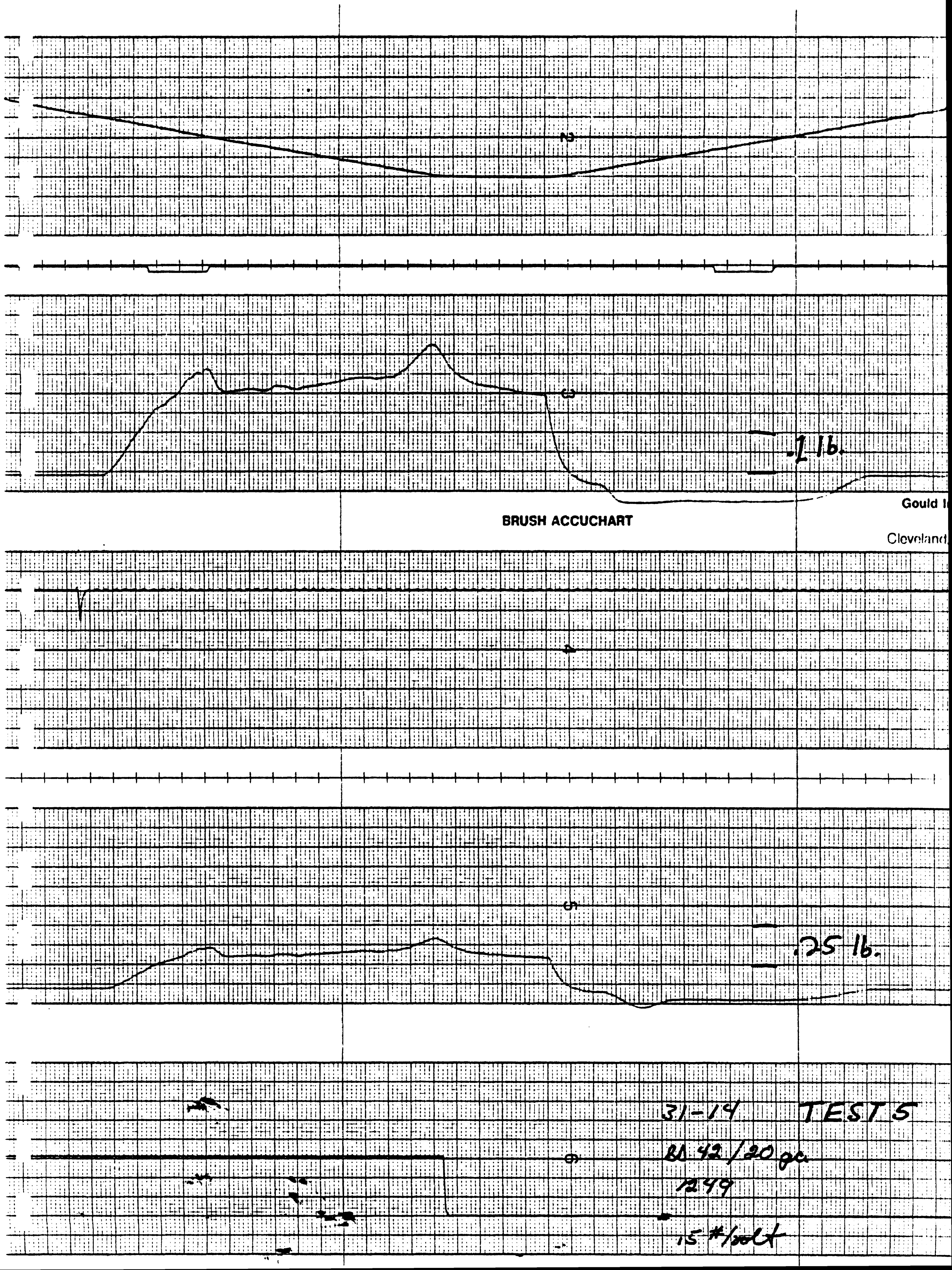
3. Bender, M., Rogers, W.L., and Melvin, J.W. "HSRI High-Speed X-ray Cinematography System For Biomechanics Research" In vol. 57 of Effective Utilization of Photographic and Optical Technology to the Problems of Automotive Safety, Emmissions and Fuel Economy. 1975.

APPENDIX

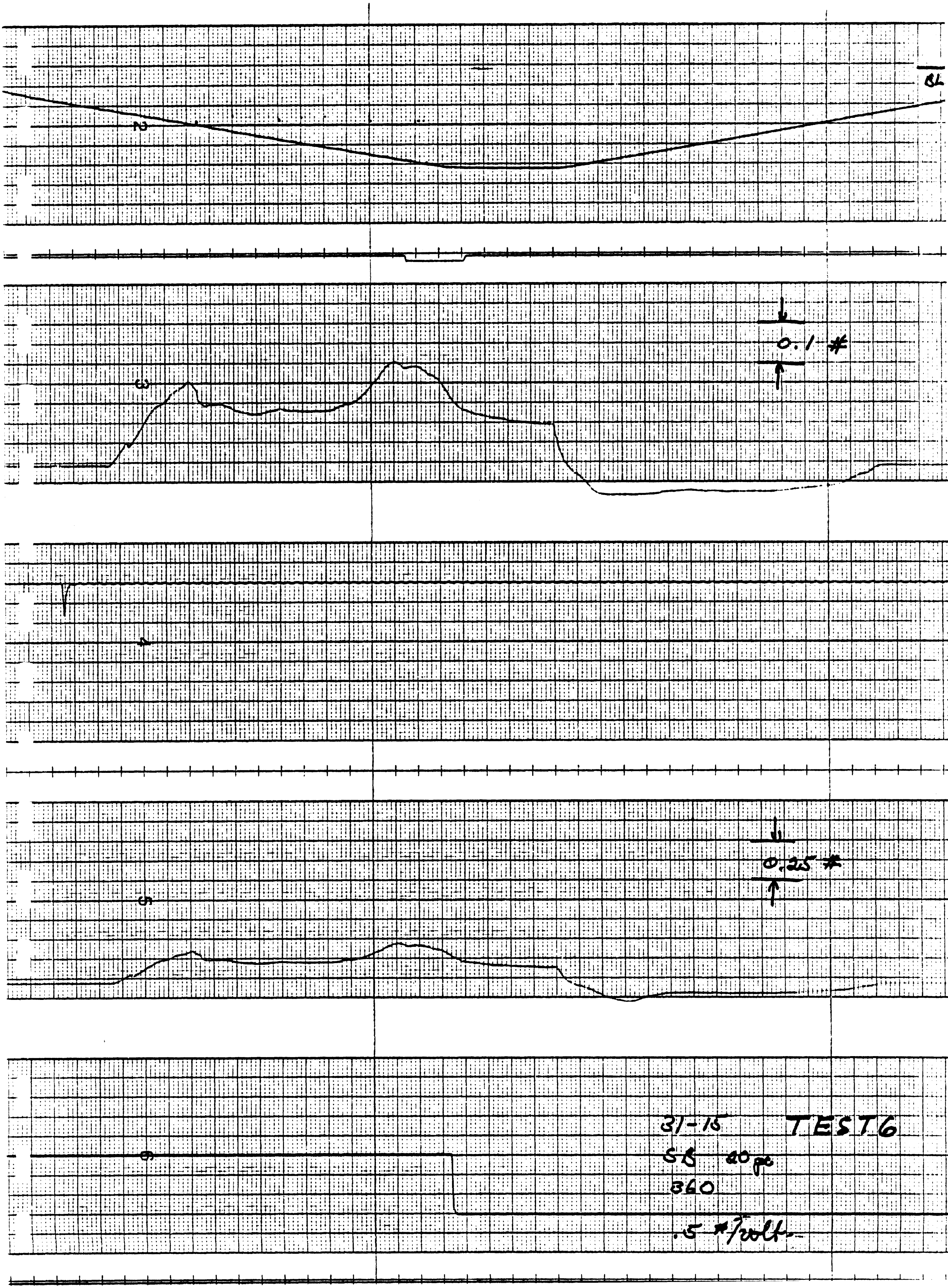
Original Chart Recordings of Force and Needle Displacement

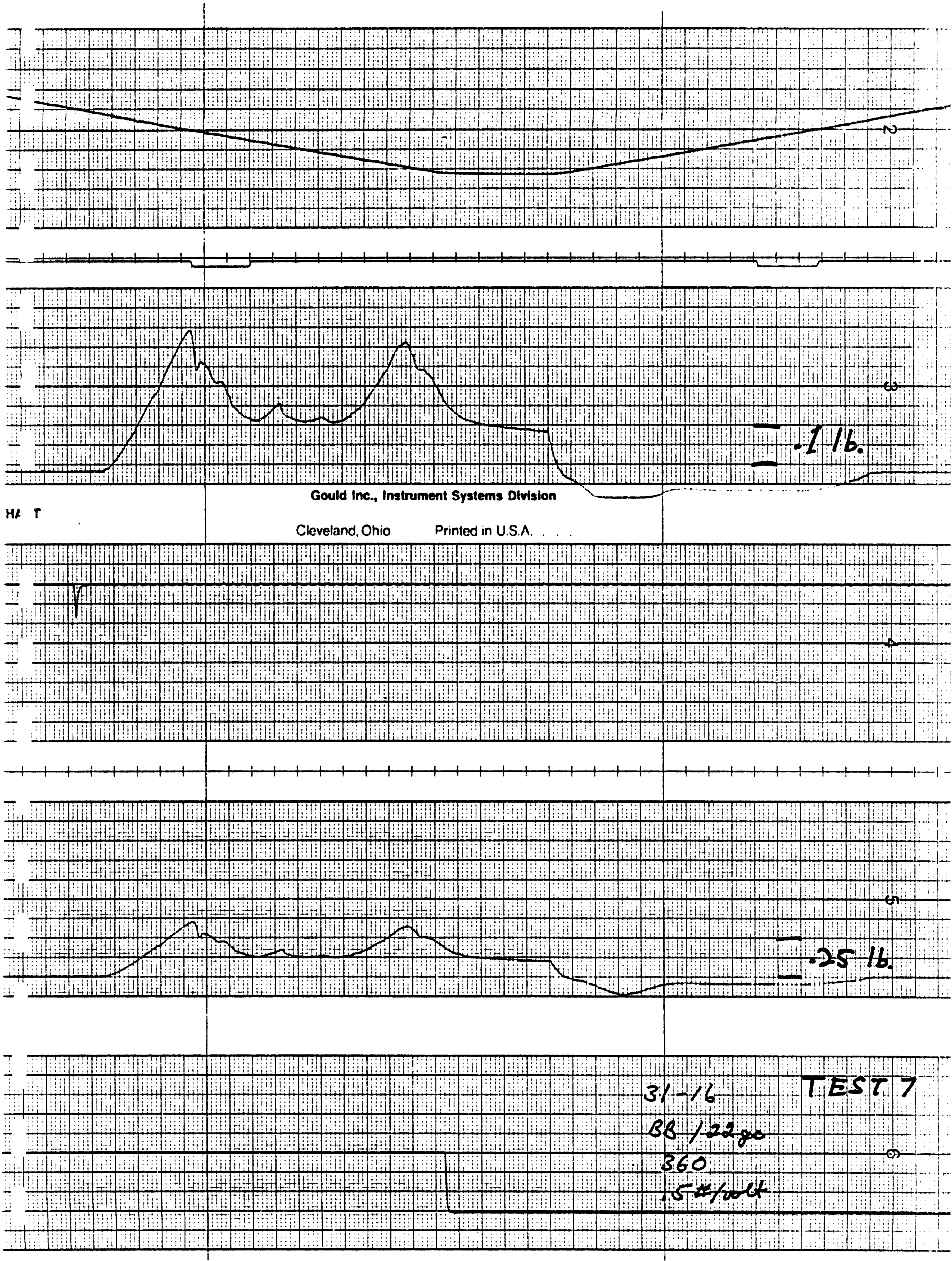

.1 lb.
.25 lb.
31-12
TEST 3
tetra/sol.
20 oz.
1/2 #/volt


.1 lb.
.25 lb.
31-13
BD 42 / SOL
DRY
1/2 #/volt
TEST 4

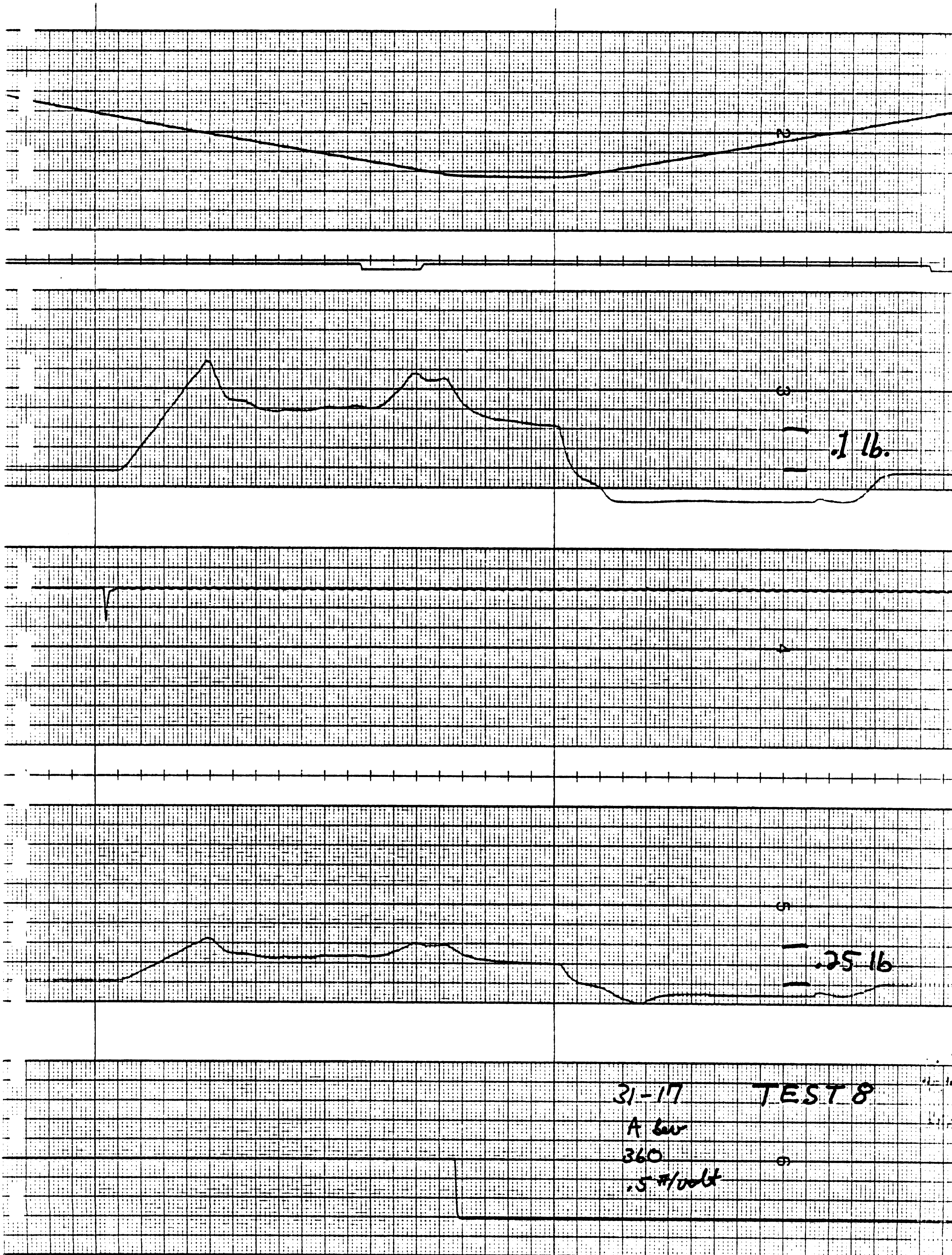


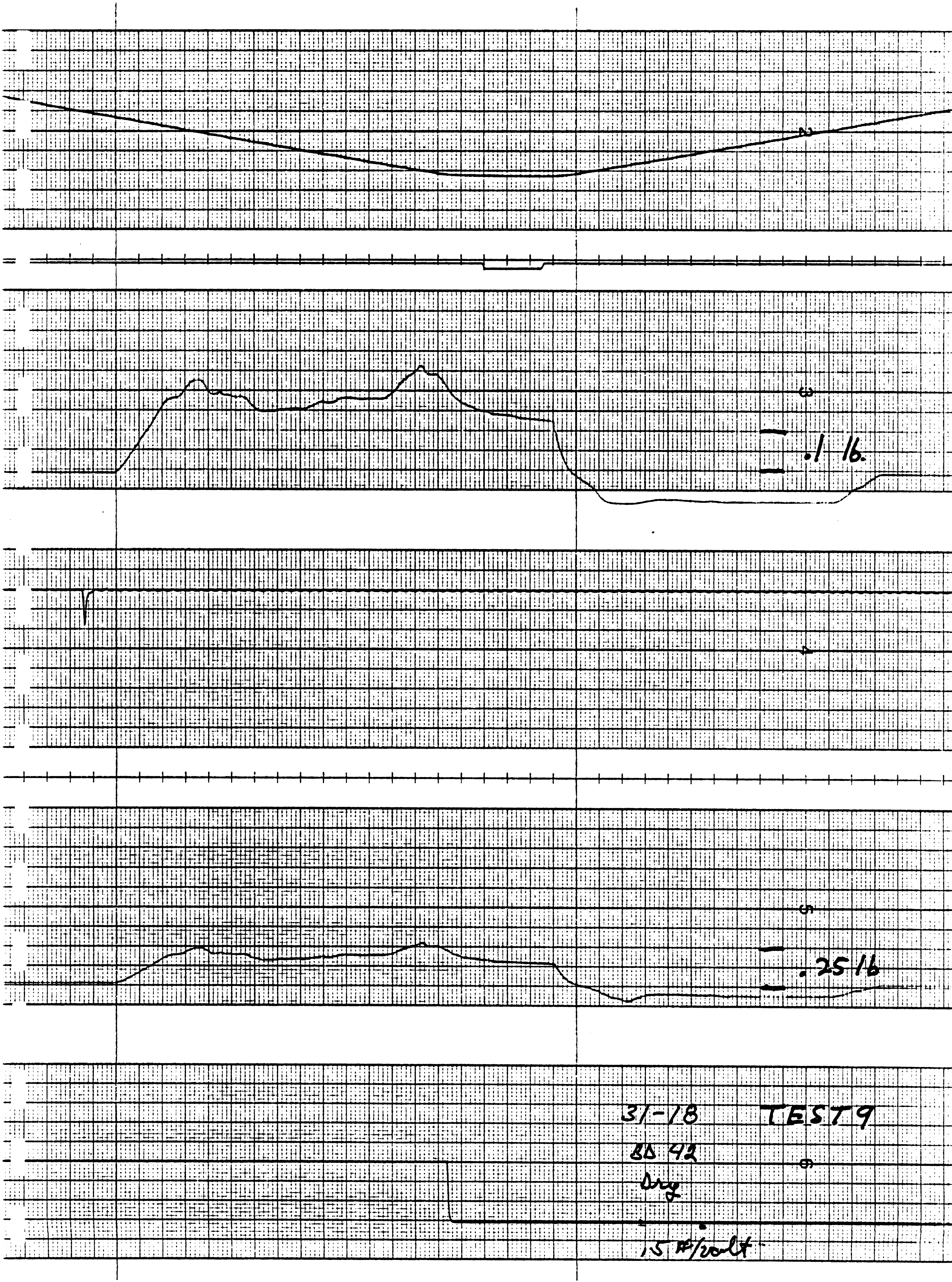
.1 lb.
Gould I
BRUSH ACCUCHART
Cleveland
.25 lb.
31-14 TEST 5
BL 42/20 ga.
1249
15 #/volt


BL
2
0.1 #
3
4
0.25 #
5
6
31-15
TEST 6
360
.5 #/volt



.1 lb.
Gould Inc., Instrument Systems Division
Cleveland, Ohio
Printed in U.S.A.
.25 lb.
TEST 7
31-16
BB /22ga
360
.5#/volt


.1 lb.
.25 lb
31-17
TEST 8
360
.5 #/volt


.1 lb.
.25 lb
31-18
TEST 9
BD 42
Dry
15 #/volt