DESIGN AND CONSTRUCTION OF A VIBRATING HYPODERMIC SYRINGE FOR RETROBULBAR BLOCK INJECTION

by

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Abstract

Many operations on the eyeball involve local rather than general anesthesia. The local anesthetic is administered via retrobulbar block injection into the muscle cone of the eye. Complications can arise, however, due to inadvertent damage to the delicate inner tissues. A vibrating hypodermic needle was developed to lessen tissue tearing as well as penetration force. Electromechanical actuation methods were attempted, but they were eventually discarded after three unsuccessful prototypes. A purely mechanical system was then developed, and the results were very successful. Penetration force was reduced from 60gf. to 7-5gf. with a steel needle, and from 160gf. to 70gf. with a plastic needle. Further testing with blunt needle geometries is recommended. A final design should revert to a precision electromechanical driver in order to maintain compact size and ease of sterilization.

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CHAPTER 1

Background

Many operations on the eyeball, such as thos involving corneal incision, cannot involve the application of a general anesthetic due to the nature of the patient's health. In these cases, a local anesthetic is administered via a technique termed **retrobulbar block injection**. Retrobulbar injection, if done properly, will provide akenesia of the extraocular muscles, the muscles forming a cone behind the eyeball, by blocking certain cranial nerves.

Procedure. The patient is instructed to look upward and nasally. A 1.25 inch 25 gauge needle with a blunted tip, to prevent the tearing of tissue, is inserted through the lower lid midway between the lateral and inferior rectus muscles (Fig. 1). After the needle penetrates the orbital septum, and passes through the equatorial region of the globe, it is directed upward through the apex of the orbit. The bevel of the needle faces the globe, allowing the best possibility of a glancing rather than penetrating injury if contact with the globe is made (Fig. 2). A small amount of anesthetic may be injected as the needle progresses, hopefully pushing vessels out of its path. The operator can feel the resistance offered by the orbital septum and the intramuscular septum. He can also usually judge when the tip of the needle is resting within the muscle cone and further penetration is unnecessary. Figure 3 is a cross-sectioned view of two needles penetrating the face. The lower needle has entered the muscle cone while the second needle has administered a secondary anesthetic.

Complications. Retrobulbar hemorrhage is an infrequent but unfortunate complication of retrobulbar injection. Blood may not become visible until the following day. Bleeding in a closed space raises the pressure and limits further

hemorrhage, but intraocular is elevated and surgery must usually be postponed from 2 or 3 days to 1 week.

Although retrobulbar injection with or without retrobulbar hemorrhage is not associated with sequalae, it has rarely been associated with total permanent loss of vision and optic atrophy. This is thought to be due to direct injury to the nerve by the needle, damage to its blood supply, or injection into the optic canal with compressive ischemia of the optic nerve [this entire background section is taken from Ophthalmic Surgery, edited by G. L. Spaeth, 1982].

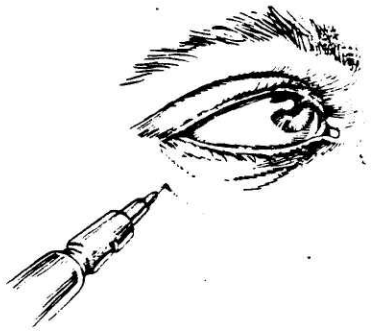


Figure 1 The needle during a retrobulbar injection should pass midway between the lateral and inferior recti with the eye elevated and adducted.

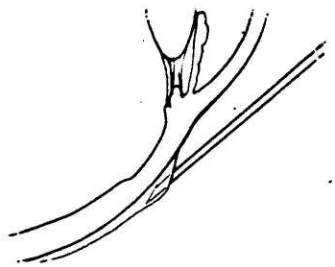


Figure 2 With the bevel of the needle facing the globe, there is more chance of a glancing rather than penetrating contact if the globe is encountered during a retrobulbar or sub-Tenon's injection.

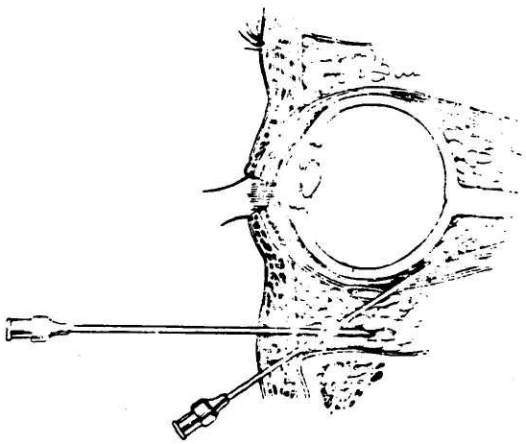


Figure 3 The anesthetic agent need not be injected deep in the orbit. Injection within the muscle cone is all that is necessary.

CHAPTER 2

Introduction

As seen in the background section, a successful retrobulbar injection is in large part determined by the tactile abilities rather than the visual acuity of the operator. A main consequence of this is accidental penetration of the eyeball, or globe, which is extremely injurious. Out of the operator's control is the prevention of damage to the small blood vessels and nerves behind the eyeball. This too leads to serious injury. Because the latter form of injury is not a result of a fault in the operator's skills, the cause of damage must be examined more closely.

The damage to the various delicate tissues behind the eyeball comes as a result of the tearing action of the penetrating needle as it makes its way into the muscle cone. This particular phenomenon has been given notice, as evidenced by the blunted needle used to push tissues aside. Blunting, however, cannot be too severe or the penetration forces will increase dramatically. Another negative aspect of the retrobulbar procedure in general is that it is often characterized by a high level of pain.

In order to simultaneously solve the problems of inadvertent tissue damage and high levels of pain, it was proposed to vibrate the hypodermic during penetration. The hypothesis was that the vibrating effect would lower the penetration force and subsequently reduce the associated pain. Used in conjunction with a blunted needle, now significantly less sharp those used without vibration, the vibrating hypodermic system would cause succeptible tissues to separate rather than tear. Thus the pain resulting from the tissues impaling on the tip of the needle would be alleviated.

A humorous comparison could be made to the woodpecker, whose lifelong process of drilling trees would not be possible without the pecking action involved. If one were to take his small head and force it into the tree, the results would be somewhat less than pleasant.

As will be seen, the development of a compact reliable instrument was a long, occasionally frustrating process. Many seemingly ingenious ideas were scrapped only to be followed by others that were similarly unsuccessful. This is, however, something to be expected of the design process; open-mindedness and a willingness to forget past blunders are two characteristics that the designer must possess in order to ultimately accomplish his or her goals.

CHAPTER 3

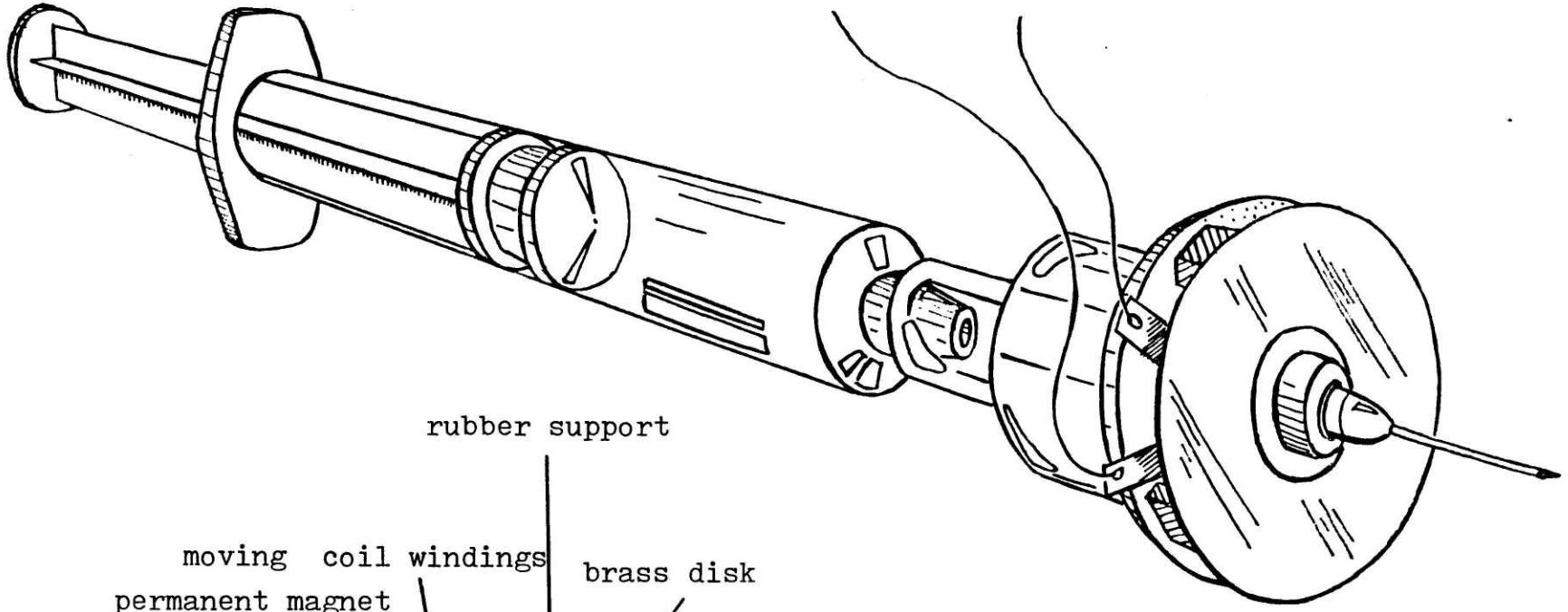
Design and Testing of Apparatus

The design for a vibrating hypodermic syringe passed through four prototypes, the fourth being successful due to a radical change in the design plan. This section will illustrate the evolution of the instruments and the subsequent experimentation, if any, performed.

3.1 Prototype 1. The original idea for vibrational actuation was to accomplish oscillation through electromagnetic means. Instead of designing and building a device from scratch, it was decided to utilize the moving coil system from a small speaker, 1.5 inches in diameter.

A quick refresher on the principle behind the workings of a speaker explains that the oscillations produced are caused by the magnetic interaction of the wire-wrapped moving coil, attached to the speaker cone, with the stationary permanent magnet, which the coil circumscribes but does not touch. A current sent through the wire forming the coil is magnetically deflected, moving the coil. If the current is quickly and continuously reversed in direction, due to a sine wave input for example, the speaker cone will oscillate accordingly and thus produce a tone equal in frequency to the sine wave input.

The 1.5 inch speaker was modified so as to fulfill two main considerations. First, the device had to be able to accept a standard disposable hypodermic needle, equipped with a twist-lock attachment flange, and the body of the syringe, which holds the fluid to be injected. The second consideration was that the fluid had to be able to pass through the interior of the moving coil system, from syringe body to needle tip, without contacting any critical areas. Figure 4 is an illustration of the entire device fully equipped to give an injection, and a



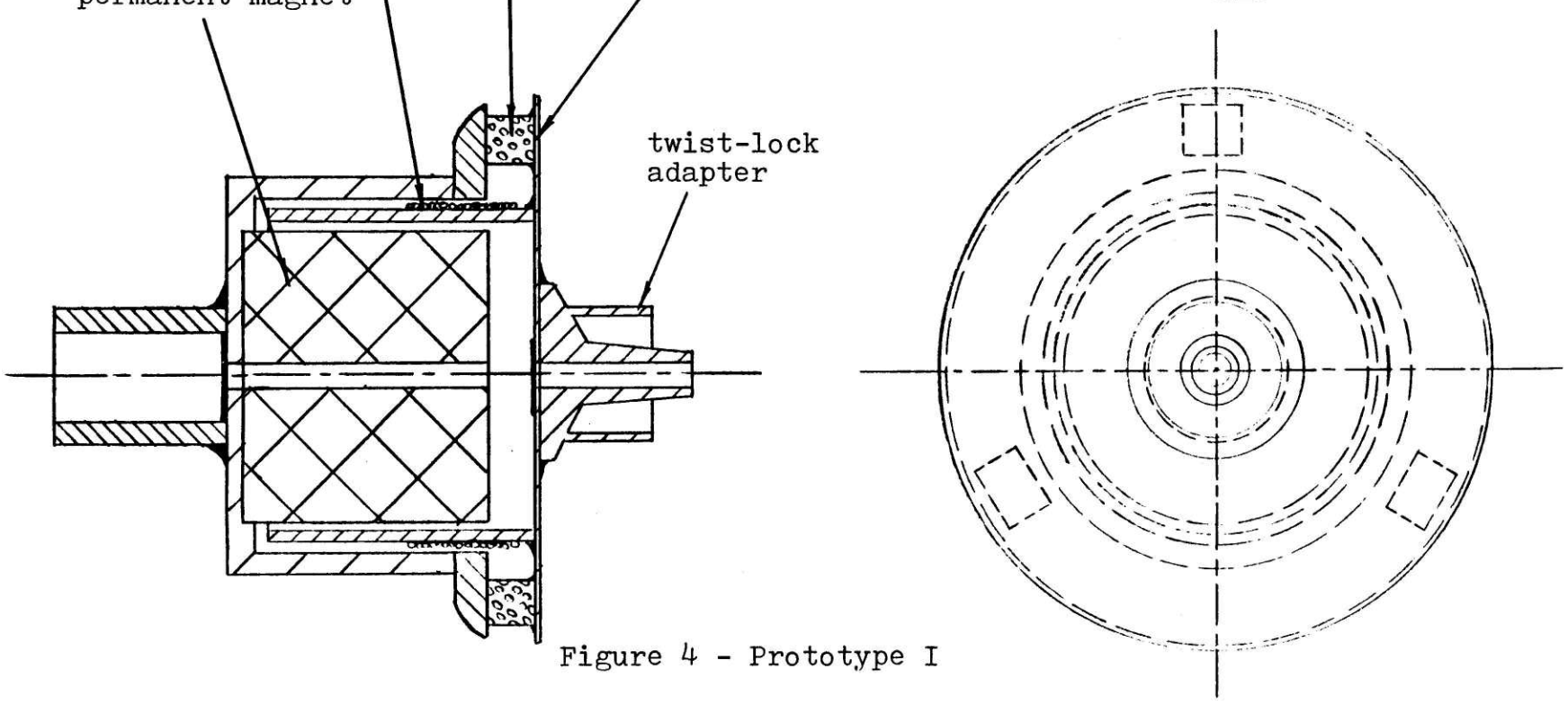


Figure 4 - Prototype I

cross-sectional view of its inner workings drawn three times actual size. The cardboard speaker cone and the flexible fabric disk which supports the floating moveable coil are both removed and replaced by a thin brass disk to which the coil is attached. The disk is supported by three rubber pieces equally spaced around the perimeter of the disk. The twist-lock portion of a standard syringe is attached to the top center of the disk in order to accept a needle. A plastic cylinder is attached to the base of the magnet housing in order to accept the body of a syringe via press-fitting. Not shown for the sake of clarity is a section of needle tubing running axially through the device in order to carry fluid from the syringe body to the needle. The tubing pierces two rubber seals, included to prevent internal leakage. They are flexible to allow for vibration.

This fairly simple design was first tested in order to determine the system's natural frequency. Output amplitude is maximized and power consumption is reduced in a system that is driven at a frequency close to its natural frequency. A strip of piezo-electric material was utilized because of its property to produce a voltage across its two faces when deflected. The strip was attached to the twist-lock portion of a needle and two wires were soldered to either side (Fig. 5a). The free end of the strip was clamped to prevent motion, and the end with the twist-lock was mated with its counterpart on top of the vibrating brass disk. The vibrating coil system was attached to a stationary base (Fig. 5b). Output from the strip was compared with the input to the vibrating coil system on an oscilloscope. The input was provided by a function generator (not shown) in the form of a sine wave. Examining the sine wave input and output, one could see that for certain frequencies, either the natural frequency or its multiples, the output would substantially increase in amplitude. The natural frequency of the vibrating coil system was determined to be approximately 520 Hz. This, of course, included the additional spring constant effects of the piezo-electric strip. The strip itself was determined to have a natural frequency of

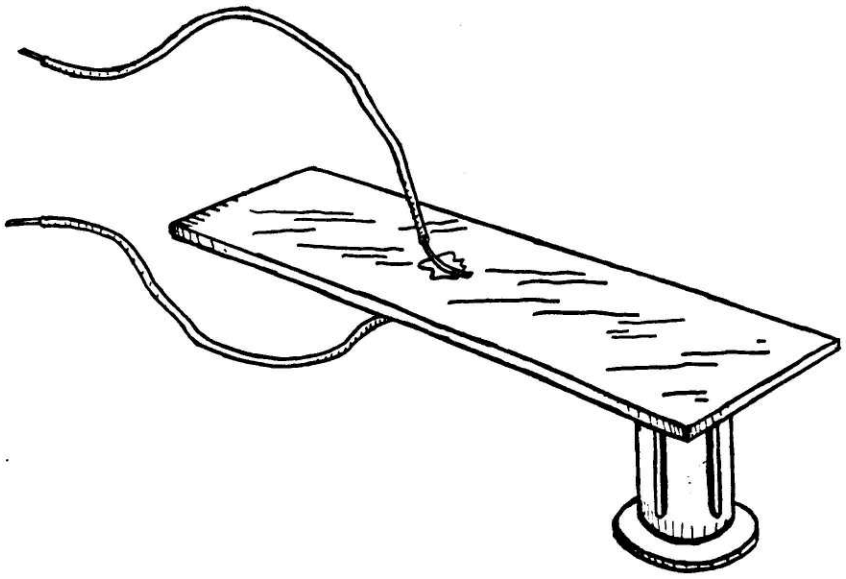


Figure 5a - Piezo-electric Strip

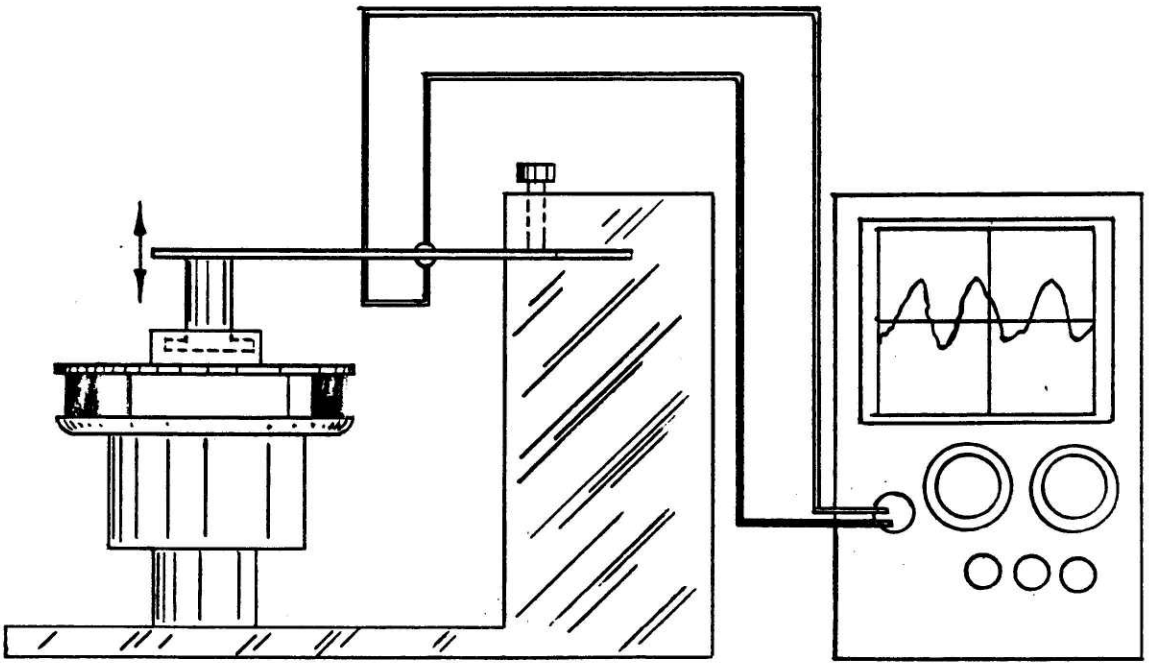


Figure 5b - Determination of Natural Frequency

approximately 20,000 Hz by manually flicking the free end and observing the resulting voltage trace.

A second test performed with the first prototype was the determination of penetration force versus input frequency. Measurement was accomplished with the device in Figure 6a. It is a weighted pendulum with a mount for a piece of fresh steak. The steak simulates some of the more compliant tissues behind the eyeball. There is a scale with a pointing indicator in order to observe the angle of tilt. The mount for the steak tilts to remain essentially vertical as the needle penetrates (Fig. 6b). Penetration force is given by

$$F = W \tan \theta$$

where F is the penetration force, W is the weight of the pendulum, and θ is the angle of tilt.

Unfortunately, the moving coil drive system for the needle did not provide enough of a driving force, and therefore the differences between vibrational and non-vibrational penetration were indiscernible. They each ranged from 50gf. to 70 gf..

3.2 Prototype II. This version (Fig. 7) is similar to its predesessor except that it has two thin brass disks. One disk, as before, is supported by three equally spaced rubber pieces; the other is mounted on the opposite side of the magnet housing and similarly supported by rubber. The largest change is in the geometry of the disks themselves. They consist of a solid rim with a three-spoked hub.

The basis of this design was to reduce the stiffness of the disks, to guide the needle more axially, and to produce a slight twisting motion of the needle as it vibrated in and out. It was thought that the twisting would reduce penetration force. Although the compliance of the disks themselves was improved

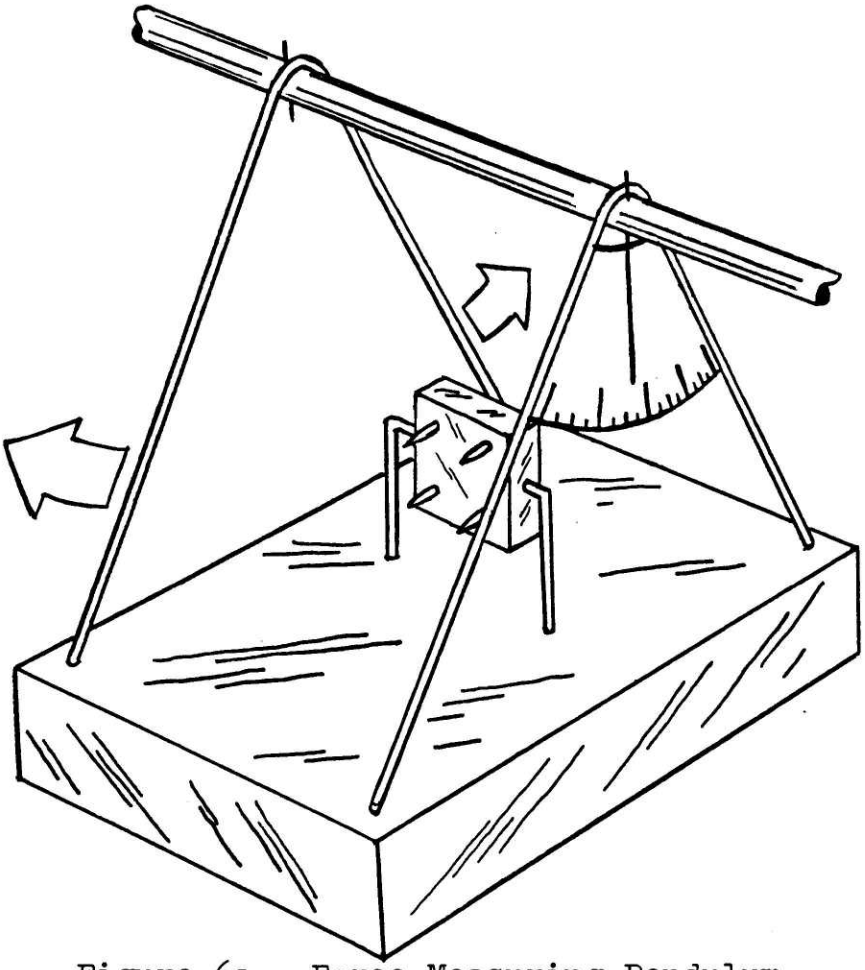


Figure 6a - Force Measuring Pendulum

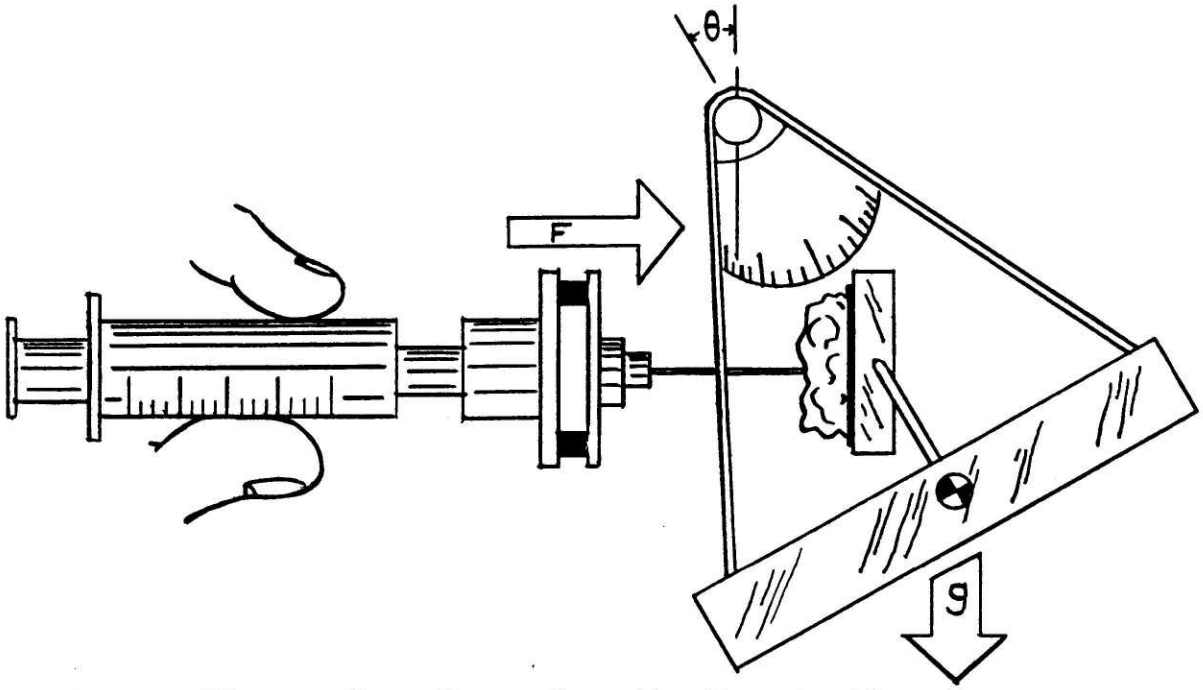


Figure 6b - Measuring the Penetration Force

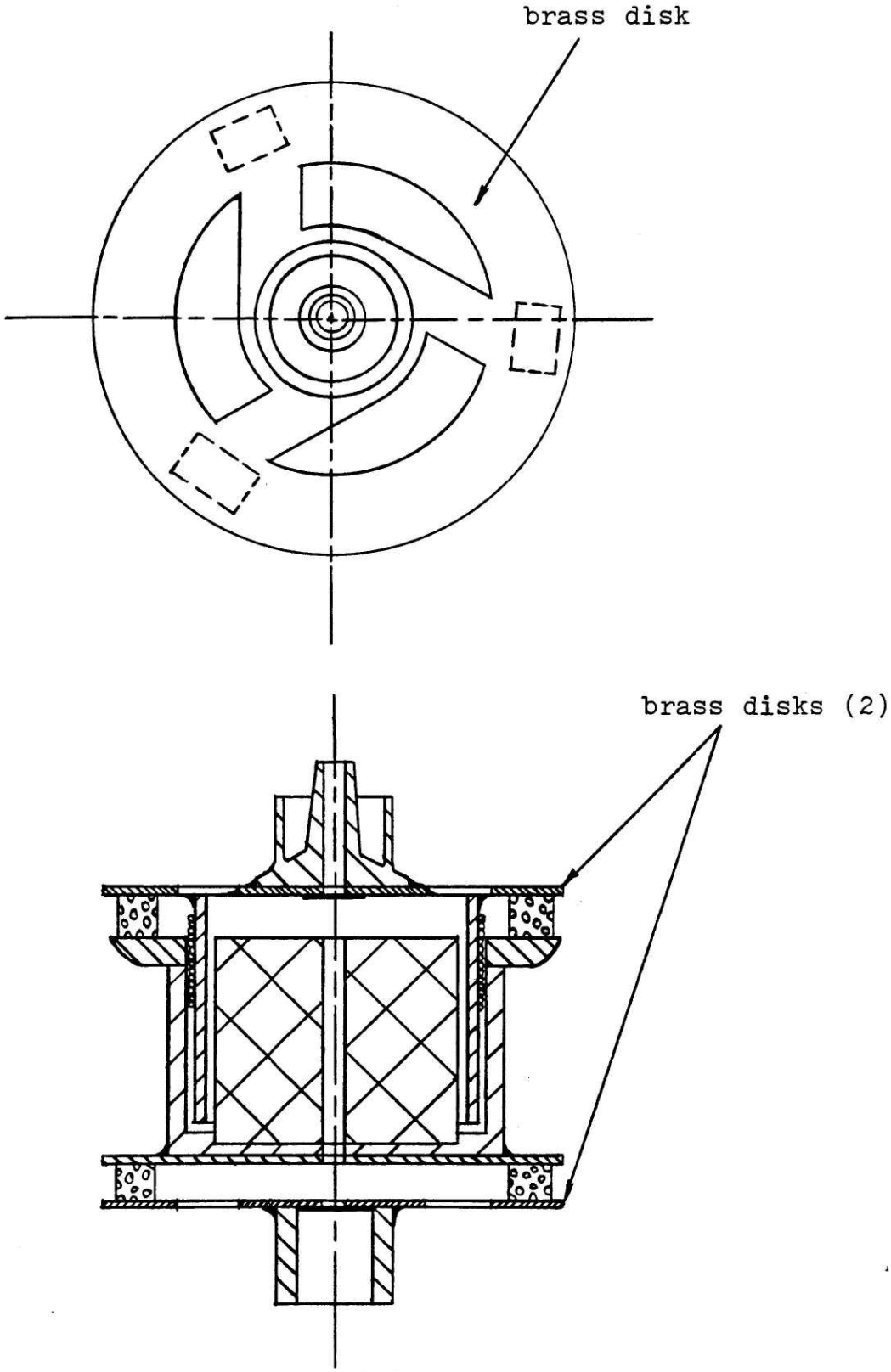


Figure 7 - Prototype II

upon, the overall system was flawed by an error in its fabrication and its vibrational abilities were therefore hampered. No tests were performed.

3.3 Prototype III. The concept of electromechanical vibration was retained, but it was ambitiously decided to build the new device from scratch. By incorporating a more powerful magnet and a longer coil with more windings, it was hoped that the device would vibrate more strongly and with a greater amplitude than earlier speaker-coil based designs.

Figure 8 is an illustration of the device minus an attachment area for the body of a syringe. Also missing is the thin tubing needed to carry fluid to the needle. The corresponding cross-section is also drawn at three times actual size. It is similar to the speaker coils in design except that it possess a much longer coil with more turns of wire. The wire is wrapped 300 times around a core made of Teflon to reduce sliding friction. A three-spoked brass disk is used again. Difficulties arose in obtaining a suitable permanent magnet to fit inside the Teflon core, so an attempt was made to wind around a piece of iron; the wire is wrapped 1200 times. The electromagnet has a resistance of approximately 30 Ohms, and it was therefore calculated by Ohm's law that 6 volts could be applied without melting the wire. A function generator was again used to excite the moving coil.

Unfortunately, the device did not work at all. This was probably the combination of several factors. First of all, machining the critically fitting moving parts was extremely difficult; second, the mass of the moving coil was too large due to the aluminum piece cradling the twist-lock adapter; and finally, the strength of the electromagnet was not formidable. It was very difficult to realize that many hours of hard work culminated in a functionally useless device.

3.4 Prototype IV. The breakthrough came with this design. All ideas of electromechanical vibration were discarded, and a purely mechanical solution

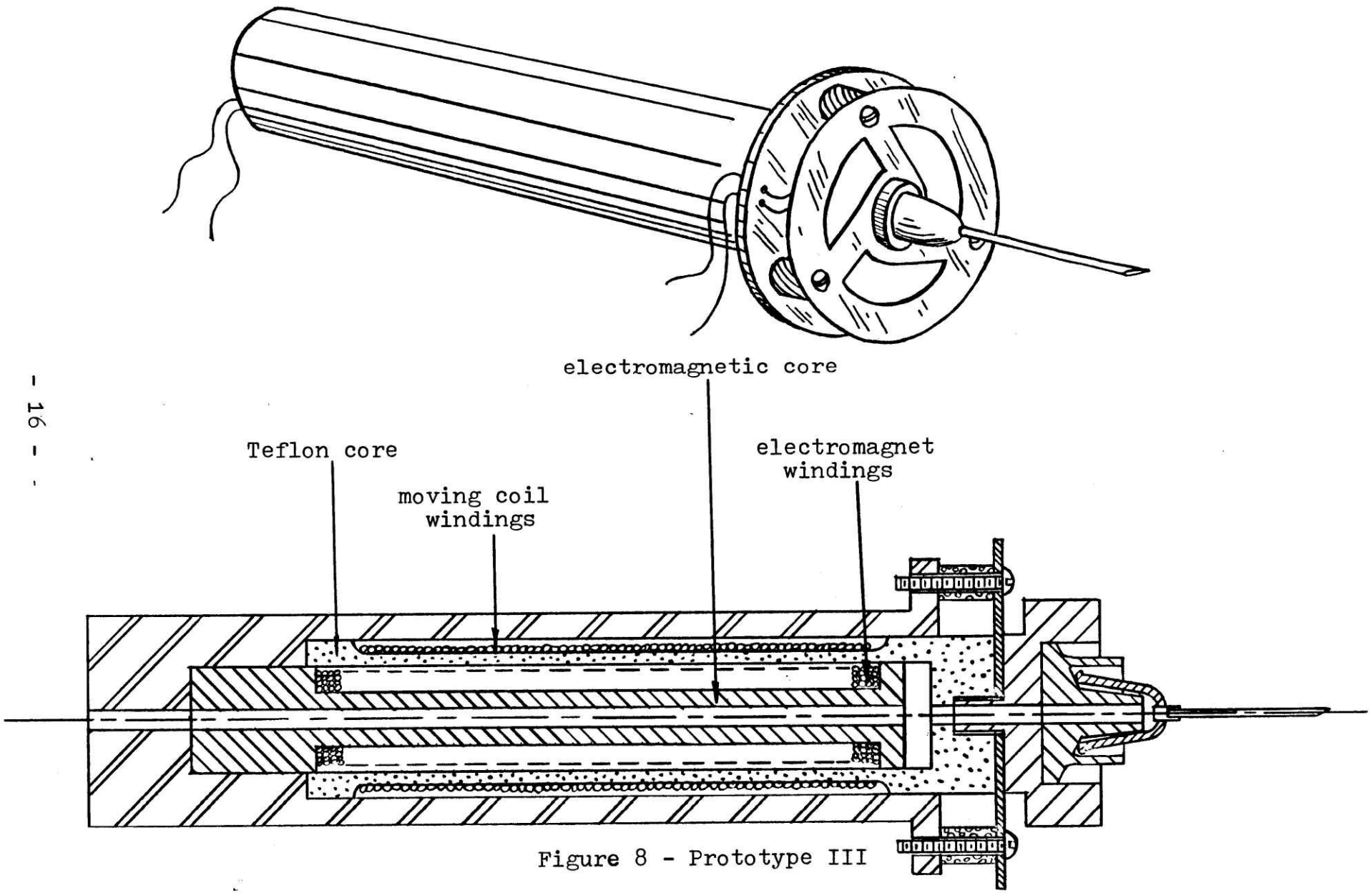


Figure 8 - Prototype III

was pondered utilizing the rotary action of a small d.c. motor.

Figure 9 is an illustration and corresponding cross-section of the device, drawn twice the actual size. The heart of the system consists of an adjustable rotating wobble plate and a grooved follower which translate the motor's rotary motion into periodic linear vibration. The wobble plate pivots in order to produce the desired amplitude of vibration; it can be locked in place with the two opposing set screws. The follower is made of Nylon to minimize rubbing wear from the wobble plate. Running axially through the device is a stainless steel tube which transmits vibrations originating at the wobble plate while carrying the fluid from the syringe body to the needle. The tube is suspended by two rubber disks which dampen any radial vibration and prevent back leakage.

The frequency of vibration is equal to the motor's rotational velocity due to the mechanical linkage. At 6 volts, the motor runs at approximately 6000 rpm, giving a vibrational frequency of about 100 Hz. By varying the input voltage, the motor's rotational velocity, and therefore the vibrational frequency, can be adjusted.

The device was connected to a variable voltage power supply, and the piezo-electric strip was attached in order to determine the relationship between input voltage and output frequency. This relationship was linear due to the inherent linear correlation between voltage and rotational velocity in d.c. motors. Then, pieces of fresh steak were pierced again in order to determine the penetration force as a function of vibrational frequency. An electronic scale, instead of the weighted pendulum, was used to measure the penetration. These tests were first performed with a standard 30 gauge needle, and then with a .062 inch plastic needle made by cutting a piece of tubing at a 20 angle.

Figure 10 is a graph of the results, which are striking. By applying vibration to the needle, penetration force is reduced from 60gf. to 5-7gf. with a steel

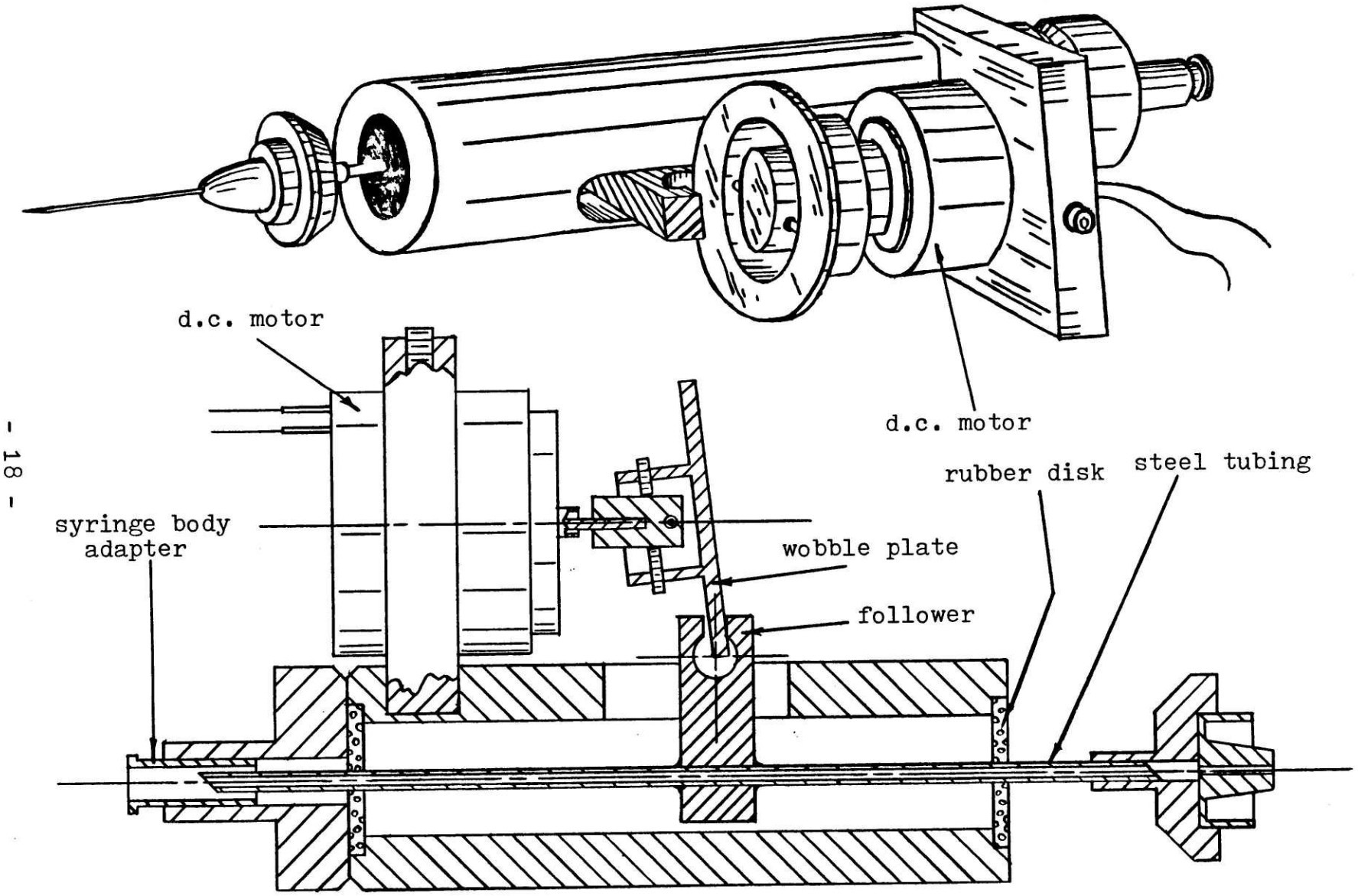


Figure 9 - Prototype IV

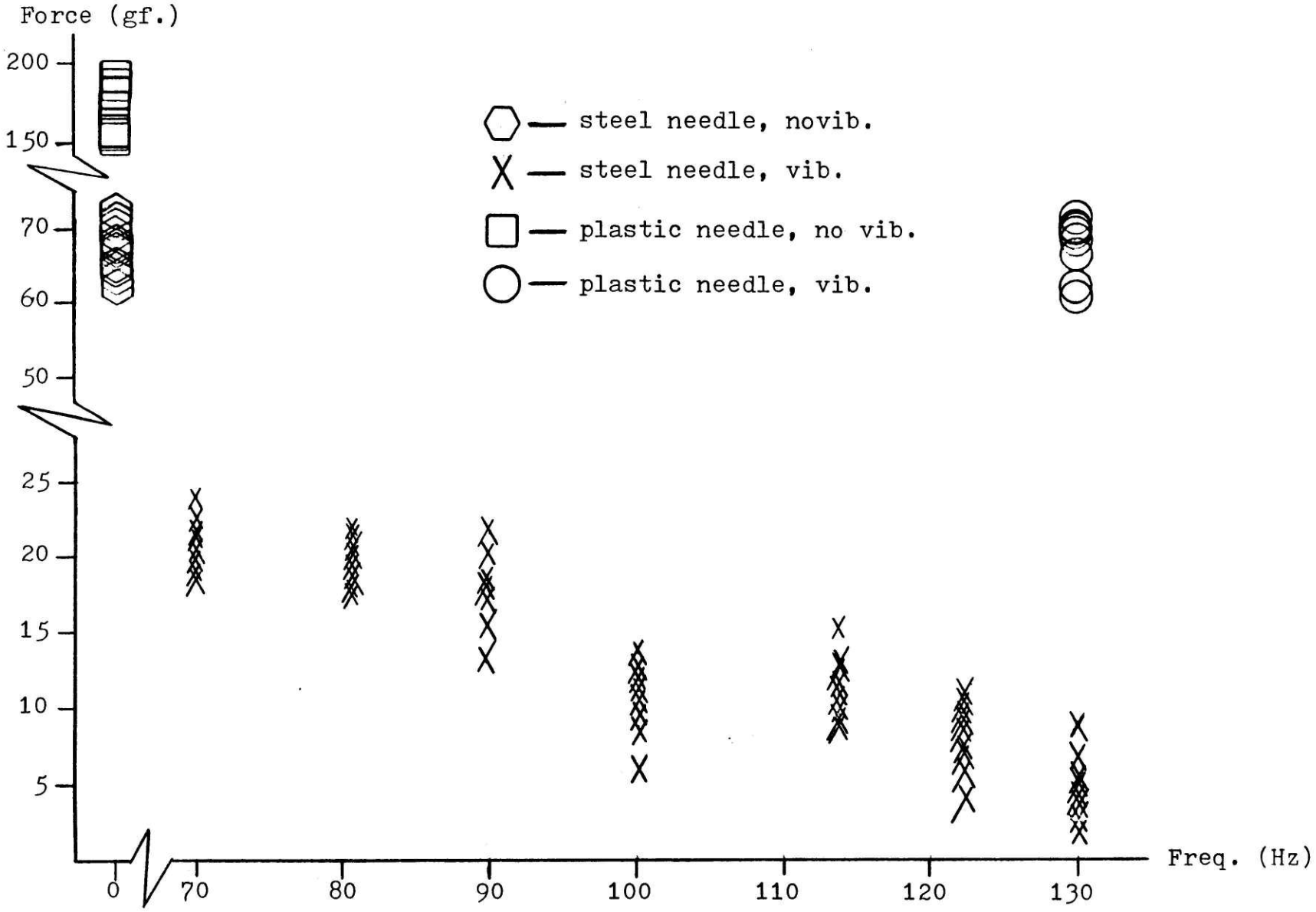


Figure 10 - Penetration Force vs. Input Frequency

needle. With a plastic needle, penetration force is reduced from 160gf. to 70gf.. In other words, the plastic needle can be made to behave as if it were steel under non-vibrational conditions. The fairly narrow range of operating frequencies was due to the limiting effects of motor stall on the lower end, and motor coil meltdown on the higher end.

After four prototypes and almost two years work, the idea finally materialized and performed remarkably well. If the purely mechanical solution to the problem was decided upon earlier, much work would have been saved. It must be realized, however, that in design it is easy to call upon hindsight.

CHAPTER 4

Conclusions and Recommendations

It is concluded that vibrational excitation of a hypodermic needle will greatly reduce the penetration force. From the data taken,, it appears that increased frequency results in reduced penetration force. A lower limit must exist, however, because a certain amount of energy must be expended in order to insert the needle into live tissue. The fourth prototype demonstrates a penetration force approaching this limit.

There is still much work to do in developing the vibrating hypodermic needle system. It is recommended that many tests be performed in order to determine the effect of needle tip geometry on penetration force. One very interesting geometry suggests a needle with a smoothly rounded tip, much like a sewing needle, and a ring of holes a small distance back from the tip to let the injected fluid escape. This shape would spread delicate tissues off to the sides of the penetrating tip, greatly reducing damage due to tearing.

Injection with a plastic needle is also something to be considered. It is possible that the needle would penetrate the more compliant tissues while harmlessly glancing off the tougher tissues of the eyeball, such as the sclera. This is how the plastic needle behaved as it pierced pieces of meat containing sections of tougher connective tissues.

Pain reduction is a difficult issue to tackle because it is very subjective. On a human being, actual injection deep into the flesh must be performed only with sterile instruments. A few shallow (.040 inch) insertions were performed on the author, but it is difficult to quantify the results. If the device were to evolve into a fifth prototype, and sufficient funds were available, the author

recommends the development of a precision electromechanical device similar to the third prototype. The d.c. motor device is fine for experimentation, but the electromechanical method is far more elegant and more easily sterilized.

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