An Approach to Product Design
Using a Product Performance versus Cost Model

by

Hong Mo Yang
S.B., Mechanical Engineering
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Signature of Author

Department of Mechanical Engineering
MIT Sloan School of Management
May 1991

Certified by

Professor Ernesto E. Blanco
Adjunct Professor of Mechanical Engineering
Thesis Advisor

Certified by

Professor Charles H. Fine
Associate Professor of Management Science
Thesis Advisor

Accepted by

Dr. Jeffrey A. Barks
Associate Dean, Sloan Master's and Bachelor's Programs

Accepted by

Professor Ain Sonin
Chairman, Committee on Graduate Students, Mechanical Engineering
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ABSTRACT
Product features should be designed with considerations to both performance and cost. Product design and manufacturing capability are at the core of a manufacturing organization's strategy. As product design and manufacturing capability are closely intertwined in a way that is difficult, if not impossible, to untangle, the two aspects need to be studied concurrently. As opportunities for new product features arise in an increasingly competitive market, the need for an approach to making rational decision on a new design based on both performance and cost becomes more acute.

This thesis proposes an approach to consider the cost and performance of a new product design to determine its desirability and its alignment with the strategic aims of the organization. This approach involves the following steps:
1) Define product requirements
2) Translate product features to engineering parameters
3) Establish and use test procedure to measure engineering parameters
4) Perform experiments to gain knowledge of the effect of design parameters on performance
5) Understand and simplify manufacturing processes
6) Establish relationships between product attributes and manufacturing processes
7) Use cost model tools to estimate product cost
8) Use quantitative information along with strategic issues to make product design decisions

A medical instrument device design was investigated using the above approach. Penetration performance of the device was studied using designed experiments. A prototype cost model was also developed to estimate costs. Using quantitative information from performance testing and cost estimation, a cost versus performance was constructed to assist in the design decision making.

Thesis Advisor: Ernesto E. Blanco
Title: Adjunct Professor of Mechanical Engineering

Thesis Advisor: Charles H. Fine
Title: Associate Professor of Management Science
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Chapter 1
Introduction

1. Overview

This thesis investigates product design and cost in an integrated way to come up with quantitative information to aid in the decision-making regarding product design.

Aims of the project at its inception were two-fold:

1. Investigate the factors in the design of a medical device which affect its penetration performance. As a result of investigation, quantify the effects of the various design factors on the penetration performance and establish a predictive model for penetration performance of a device. Use the knowledge gained from the study to improve the quality, reliability, marketability, and profitability of the medical device line.

2. Given the information about product performance, determine the effect of the product features on the cost and manufacturability.

A product performance model for medical device is constructed using designed experiments. The performance model takes into account important design factors and quantifies their effects on the product performance. This model enables comparisons of product designs for performance optimization (specifically, the penetration performance of a specific medical instrument), product line differentiation, and competitive differentiation.

A prototype of a product cost model is also proposed. The cost model is separated into direct and indirect cost models. The direct cost model tracks the usage of direct costs (e.g., direct labor, direct materials, etc.) for various designs and attempts to predict the direct cost consumption for proposed designs. Activity based costing is used to account for indirect costs. As manufacturing becomes less labor-intensive, the indirect cost portion of the total product costs becomes greater. As a result, the traditional approach to allocating overhead costs becomes inadequate in understanding why and how indirect costs are being spent. In some cases, the traditional method of allocation may provide misleading information about
the desirability of a proposed product. Activity based costing enables a better understanding of those characteristics/attributes of the products which cause (or drive) activities in the manufacturing support departments.

The goal was to improve a manufacturing firm by coming up with a more rational approach to design improvements. Through an integrated model that looks at both the performance (covered in Chapter 2) and the cost of a design (covered in Chapter 3), a manufacturing firm can make a better informed decision regarding some of the tradeoffs between performance and cost. Figure 1 shows an overview of the linkage between product performance and cost.

2. Project Approach

Much of the approach in investigating the product design borrows Quality Function Deployment techniques (QFD, also known as House of Quality). Concepts borrowed from QFD are applied here very simply. The steps taken are listed below.

1. Define product feature requirements from customer input.
2. Translate the customer features into engineering parameters.
3. Establish and use testing techniques to measure the engineering parameters.
4. Perform experiments (using statistical methods) and scientific investigations.
5. Understand and simplify the process steps used to manufacture the product.
6. Investigate empirical relationship between design features and process parameters (these are the bases for direct, indirect, and yield models shown in Figure 1).
7. Use cost estimation tool to determine cost.
8. Use quantitative information (along with qualitative strategic issues) of performance and cost to assist in design decisions.

Chapters 2 and 3 discuss product performance aspect of the project. Chapter 2 follows steps 1, 2, and 3 in defining customer requirements, coming up with engineering
Figure 1. Overview of Product Performance versus Cost and Manufacturability

parameters, and testing those parameters. Chapter 3 presents results from experiments performed using various devices. Work in chapter 3 corresponds to step 4 of the approach.

Chapters 4 and 5 discuss product cost issues. Chapter 4 describes efforts to follow steps 5 and 6, as well as describing the cost model. Chapter 5 presents preliminary analysis using the information gathered from the cost model. Work in chapter 5 corresponds to steps 7 and 8.
3. Scope

As was mentioned in the introduction, only the penetration performance of the medical device was investigated. The penetration tests were performed using both straight and curved devices in the range of diameters from 8 to 17. The test medium used for the penetration tests is a polyurethane material commonly used as artificial shoe leather, which is fast becoming a de-facto standard within the company. No attempt has been made in this thesis to correlate the penetration results using the polyurethane material to penetration results using actual tissues.

A prototype cost model for medical devices was developed. Because of the lack of applicable historical data, the system was tested using fictional data and interrelationships between product features and process parameters. The costs calculated by the cost model do not, and are not intended to, reflect actual costs.

4. Literature Review

Literature referenced for this project falls into one of two categories: technical (including statistical) references, and cost modeling. Towler [10] provides technical reference on penetration testing. Hauser and Clausing [5] describe the House of Quality for use in the product design process. Hogg and Ledolter [6], Phadke [8], Ryan [9], and others provide information regarding statistical methods.

In the area of cost modeling, Ulrich and Fine [13] provide the basis for the cost model system prototype. Allan and Dentsis [1] describe a model for obtaining manufacturing costs that are directly sensitive to changes in the process. Friedberg [4] utilizes a technical and economic model for analyzing part presentation equipment. Activity-Based Costing (ABC) described in several articles helped in incorporating ABC into the cost model for handling the indirect costs.
Chapter 2

Medical Device Performance Testing

This chapter discusses the first three steps of the approach outlined in the previous chapter. Namely, defining customer requirements, translating those requirements into engineering measurements, and testing for those requirements.

1. Define Product Feature Requirements from Customer Input

The primary customers for the medical device studied in this project are hospitals and/or surgeons (directly) and patients (indirectly). Surgeons want a device that provides: (1) ease of penetration, (2) uniformity of force along the length of the device for better control (as opposed to radical changes in force which may lead to jerking motions), (3) durable performance over multiple penetrations, (4) resistance to bending and breaking, and, (5) with the rising health care costs becoming a big concern, low cost. Patients (and/or insurers) want low cost devices that cause less trauma on the tissue, thus, enabling a quicker recovery. In both instances, the customer has clear requirements for both performance and cost of a device.

Performance of a device as defined by Product Development Group includes penetration, strength (resistance to bending or breaking), and stability (how securely a device can be held by a surgeon). Penetration performance is a measure of a device sharpness and its ability to pass through tissue with minimal trauma. Penetration performance was selected as the topic of study for many reasons: 1) ease of penetration for minimal trauma; 2) the durability of the performance over multiple passes; and 3) reduced penetration force to reduce the chance that a surgeon will apply excessive stresses on the device. Two aspects of device penetration performance were examined. The first is the ease of penetration as characterized by the maximum force for each penetration. Secondly,
the degradation of the penetration force over multiple penetrations was studied to determine the "durability" of the sharpness.

A lack of quantitative information gathered from surgeons as to which features are important made it difficult to determine the appropriate measurement for ease of penetration. Information such as an ideal force curve (signature analysis of force as a device is penetrated through a test medium), and a prioritized list of desired features have not been explicitly documented. For instance, how much weight should be placed on the maximum penetration force compared to the uniformity of force throughout the penetration of the device? If force characteristic curves for various devices were as shown in Figure 2, which device would a surgeon prefer? Unfortunately, this type of quantitative information was unavailable from either marketing or marketing research groups. Instead, the voice of the customer is informally known by a few people who have access to surgeons. This information needs to be written down in a document and distributed.

The second measurement, the durability of the device sharpness, is an indication of how well it performs in a surgery requiring multiple passes. A device which is very sharp in the first penetration, but which degrades rapidly in performance is not desirable. An ideal device is one that is very sharp (i.e., requiring a small penetration force) initially and throughout the multiple passes.

This study assumes that the features desired by customers are:

- ease of penetration,
- durability of the device sharpness over multiple passes,

and that these features were equal in terms of desirability.

2. Translate Product Features to Engineering Parameters

For each penetration of a device through a test medium, a force versus time curve can be obtained. Measures other than the maximum force were considered for characterizing
Figure 2. Schematic force curves showing different aspects of device performance. (a) shows a steep curvature at the beginning of the taper region. (b) shows a more gradual curvature but a higher peak force. (c) shows a more uniform force throughout but a higher peak force.

the ease of penetration (refer back to Figure 2 for mock examples of penetration force curves). These measures include: (1) the area under the force curve, (2) the rate at which the penetration force increased up to the maximum, and (3) the drop-off in force after the maximum point (for controllability). However, these measures were not adopted for three reasons: 1) the data collection for these measures were much more difficult; 2) the measurements in most cases required subjective judgments -- e.g., the area under the curve for penetrations was not always comparable because the point at which the maximum force occurs may shift from one penetration to the next and one device to another; and 3) the benefit derived from having these measurements over the maximum penetration force for the ease of penetration was questionable, and was perceived as not worth the increase in efforts. Furthermore, as the penetration force for the devices is reduced, the maximum penetration force becomes more indicative of the sharpness and the ease of penetration of a device.

Initially, the engineering parameters assigned to measure each of the desired product
features were as listed below.

- Ease of penetration
  
  ==> Maximum penetration force (*)
  
  ==> Uniformity of force along the length of the device

- Steadiness of medical instrument penetration
  
  ==> Uniformity of force along length of the device
  
  ==> Rate of change in force along the length
  
  ==> Maximum penetration force (*)

- Durability of device sharpness over multiple passes
  
  ==> Rate of increase in the maximum penetration force over multiple passes using one device. (*)

Because of the tradeoffs that exist between the value or usefulness and the ease of collection, some of the measurements were dropped. These measurements included uniformity of force, rate of change in force, and area under the force curve, which all required some sort of subjective judgments. The chosen engineering measurements for each feature are shown with an (*) in the above list.

3. Establish and Use Testing Techniques to Measure Engineering Parameters

3.1 Test Apparatus

Penetration performance was measured using two different testing equipment - a curved tester and a straight tester. Both testers measure the vertical force while penetrating a device perpendicularly through a constant and uniform sample of material. RS-232 connections were constructed from the gauges to a data acquisition board on an IBM PC in order to automate the collection of data. A data acquisition software was used to collect and analyze data.
**Curved Tester**

A curved tester (shown in Figure 3) is used to test the finished products. A curved device is aligned so that a device being penetrated the test medium stays perpendicular to the test medium. Maintaining the device perpendicular to the

![Diagram of Curved Tester](image)

**Figure 3. Curved tester -- A side view**

surface of the test medium is critical because the tester measures only the vertical force. If a device is not held perpendicular, forces in other directions develop and decrease the
magnitude of force in the vertical direction.

Two factors affect whether a device is held perpendicular to the test medium: grip along its length, and height of the device above the test medium. If the device holder does not grip a device along the curvature but in the straight tail end of the device, it is likely to develop a force in the horizontal direction away from the center of curvature. This phenomenon is described as device "pushing" against the test medium. One way of ensuring that a device is not misaligned is to grip it anywhere in the curved section. However, because of the limited range (45 degrees in one direction, 90 degrees total) of rotation of the curved tester, gripping a device too close to the point may end testing before critical sections, such as the end of the taper region, have passed through the test medium.

Another factor that affects the penetration force is the height of a device relative to the test medium. A device's height should equal its radius to maintain the perpendicular relationship as the device is rotated. If the height is greater than the radius of a device, the device will tend to "push" against the test medium (i.e., develop a horizontal force in the direction away from the center of curvature.) If the height is less than the radius of a device, the device will tend to "pull" (i.e., develop a horizontal force in the direction toward the center of curvature of the device). Both "pushing" and "pulling" effects will decrease the vertical force.

These effects are illustrated in Figure 4. The correct alignment is at height = .291 and pinch = 0. A height less than .291 indicates that the device is held too close to the surface. A pinch of +.05 indicates that a device is being held too far away from the tip; a pinch of -.05 indicates that a device is being held too close to the tip. The maximum force occurred at height = .291 and pinch = 0. All other alignments exhibited a smaller force primarily due to the presence of horizontal force component.

**Straight Tester**

A straight tester, shown in Figure 5, was put together precisely to eliminate the
alignment problem in the curved tester. Once a device is mounted on a grip in a straight tester, the motion is straight downward, perpendicular to the surface of the test medium. The straight device tester also measures the vertical force required for a device to penetrate the test media, but unlike the curved tester, it has less variability in the set up.

![Graph showing force index vs penetration number with different markers for different conditions.](image)

**Figure 4.** Effect of grip and height alignment on penetration performance

Whenever possible, and especially for development purposes, a straight device tester is recommended. However, for comparison of curved devices for sale, and for process control purposes, a curved tester is necessary.

3.2 Sensitivities and Limitations of the Test Procedure

Understanding what is being measured means also understanding the effects of the testing procedures on the resulting performance of the product. In the case of testing surgical devices, the sensitivities exist in testing parameters such as speed of device penetration and thickness of the test medium.
An experiment was performed with a sample size of five replicates per setting to determine the effect of rate of testing on device penetration force. For knife-like devices, the rate of penetration had no significant effect on penetration force for the ranges of speed tested.

![Diagram of straight tester](image)

**Figure 5. Straight tester -- A side view**

(see Figure 5). However, for the same range of speed, taper point devices exhibited a slight change in penetration force only when tested using thick test medium as exhibited in Figure 6. Penetration force for a taper point device increased as the rate of penetration...
increased. The faster rate of penetration allows less time for the test medium to react (and relax) to the device, thus resulting in a higher penetration force.

Figure 6. Knife-like devices tested using various speeds and thicknesses

Figure 7. Taper point devices tested using various speeds and test medium thicknesses

The rate of penetration during testing was set close to the maximum for both straight tester and the curved tester in order to closely simulate the conditions in surgery. The rate
of testing differed between the straight tester and the curved tester, however, due to the limitations of the test apparatus. Both testers were set at their maximum possible rates.

The thickness and uniformity of the test medium had a significant effect on device penetration performance. The same experiment used to determine the effect of speed of penetration was designed to determine the effect of thickness of test medium on device penetration. Two thicknesses of test medium were used. The result from using cutting edge devices showed that penetration forces using thick test medium was more than doubled those using thin test medium. Furthermore, any slight variation in the thickness could have a tremendous impact on the penetration force. For example, a slight variation in a thin medium will cause the force to vary significantly for knife-like devices (it is likely to be even greater difference when using taper point devices). This is a significant effect especially considering that receiving inspection tolerance for polyurethane test medium is ±.05 mm. Using the data gathered from testing two thicknesses of test medium, the device penetration performance was predicted for varying thicknesses of test medium. The results are listed in Table 1 and graphed in Figure 8.

No attempt was made to establish a correlation between the results gathered from using polyurethane test medium to those using human tissue. Polyurethane was chosen as the test medium because it was fast becoming the de-facto standard within the company. Polyurethane also had advantages in that it is fairly consistent and uniform. It is easier to understand device penetration performance, and the difference between devices when a consistent and uniform test medium is used. However, applicability of polyurethane as a model for human tissue is questionable since no formal correlation study has been performed. Therefore, no general conclusions should be drawn from testing on polyurethane as to the applicability to human tissues until the correlation has been established. This point is especially important when considered in the context of device
Table 1. Predicted penetration performance (force indexed) on varying thicknesses of test medium

<table>
<thead>
<tr>
<th>Penetration Number</th>
<th>Thin</th>
<th>Thick</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>-0.05</td>
<td>+0.05</td>
</tr>
<tr>
<td>1</td>
<td>0.46</td>
<td>0.64</td>
</tr>
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<td>0.87</td>
</tr>
<tr>
<td>10</td>
<td>0.60</td>
<td>0.90</td>
</tr>
</tbody>
</table>

Figure 8. Effect of test medium thickness on penetration performance

optimization. One cannot make the statement that a device optimized on polyurethane is also optimized for use with human tissue. There is a chance, however slight, that a device
that is optimized on polyurethane may, in fact, adversely affect the performance on human tissue. When looked at in this context, perhaps, the scope of the device testing on polyurethane should be as a process control mechanism, but not as a design optimization tool until that correlation is established.

Determining how well polyurethane models human tissue is difficult because human tissue characteristics vary depending on its location in the body. For instance, cardiovascular tissues are vastly different from ophthalmic or epidermal tissues. One approach is to take a look at the spectrum of characteristics represented by human tissues, and choosing maybe three points (two extreme points plus a center point) with which to establish correlations with polyurethane. Another approach may be to look at different segments of the product's market and establishing a correlation between polyurethane and a representative sample from each of the segments. Given the time constraints, and a lack of uniformity and availability of various human tissues for testing, this approach was not aggressively pursued.

Perhaps the most significant factor in penetration testing condition is the wetness of test medium. Most surgeries are performed with the aid of some kind of natural or external lubrication (blood or other fluids such as saline solution). In order to closely simulate the actual usage conditions, wet test medium should be used. Test results show that wetness of the medium has a profound impact on penetration performance of devices. These results are discussed in the following chapter.

4. Chapter Summary

This chapter discussed the first three steps of the project approach outlined in Chapter One:

1) Define customer requirements in a product.
2) Translate product features into engineering parameters which can be measured.
3) Establish testing techniques to measure the engineering parameters.

While defining customer requirements in a product is an obvious step, my observation is that many companies do not perform this step thoroughly or explicitly. Much of the knowledge is qualitative and is held in the minds of only a few people in the organization. The challenge is to systematically translate this knowledge into quantitative information upon which some appropriate action may be taken. Some useful techniques exist to aid in defining customer requirements. These include Quality Function Deployment (QFD, also known as House of Quality), or even simpler approach of identifying which features are "musts" and "wants", and implementing the "musts" and prioritizing the "wants."

Implications of experimental results from speed versus thickness of test medium can be summarized by two observations. First, since the rate of testing had a minor impact on the device penetration performance, testing speed should be set at the highest setting available on the curved tester and straight tester. There are two advantages to the high speed setting: 1) it closely simulates the actual usage conditions and 2) it reduces testing time (this is a significant factor because so many devices have to be tested ten times each). Second, while polyurethane seems to be constant and uniform, the significant impact of the thickness of the test medium means that extra caution must be taken in checking the thickness and uniformity of test media. Slight variations in the thickness of the test medium may yield misleading information.

Further adding to the complexity is the variation from device to device. Most of the variation arises from how well lubricant adheres to the surface of the device. Standard deviations for samples vary drastically (standard deviation for a 350 gram penetration may be as high as 75). An experiment performed by the Product Development Group indicates that lubricant adheres better to the devices when they are cured longer after being lubricated. This helped in lowering the standard deviations in the penetration force.

The new manufacturing process currently being implemented will provide consistency
and repeatability in diameter and taper ratio of the devices. Further work to stabilize the lubrication process can lead to a reduction in the number of samples being tested while still obtaining the same amount of information.

Polyurethane as a test medium has advantages in that it is a consistent, uniform material. Further study is needed before determining the suitability of polyurethane as a model for human tissue, and to determine whether a device that is sharp on one medium is sharp in all other media. One recommendation to address the suitability issue of test medium is to select three or four test media that spans the entire range of human tissue characteristics. In order to closely simulate surgery conditions, devices should be tested using wet media. Over ninety percent of human body is composed of water, and in no surgery will there be a lack of lubrication. If this mode of testing is not practical, then an experiment should be performed to establish a correlation between dry medium test results and wet medium test results.
Chapter 3

Penetration Performance

For simplicity, all surgical devices have been classified as taper point or cutting edge (see Figure 9). A tapered device has a conical shaped point and does not tear the tissue as it penetrates. The tip of the tapered device creates a minuscule hole in the tissue, which gets enlarged as the rest of the tapered section penetrates the tissue. The primary application of the tapered devices is in cardiovascular surgery, where a leak in stitching can lead to serious complications. Knife-edged devices have multiple number of edges which cut the tissue as they penetrate. Knife-edged devices are used in applications such as general wound closures and plastic surgery. The two different categories of devices were studied sequentially, with tapered devices investigated first.

1. Tapered Devices

Penetration force required to pass a taper point device through the test medium is a function of two factors: the final hole size and the surface drag between the device and the test medium. Important design features affecting the above factors include: (1) taper ratio, (2) surface finish, (3) lubrication, and (4) diameter.

Taper ratio of devices produced will be labeled high and low for confidentiality reasons. One ratio is 50% higher than the other. Surface finish of a device is either "matte" or "shiny". Although varying degrees of matte and shiny were possible by changing the process settings, for the sake of simplicity, surface finish was considered a binary attribute. The lubrication under study was limited to lubricant solution currently being used in production. Diameter of devices ranged from 4 mil to over 40 mil. The diameters tested in this study ranged from 8 to 17 mil (one mil = one one-thousandth of an inch).
Figure 9. Tapered versus knife-edge devices

a). Tapered devices

Taper Point

Blunt Point

b). Knife-edge devices

Conventional

Reverse

Tapercut

Spatula
1.A. Qualitative Description

The effect of each of the design features can be explained in terms of the final hole size and surface drag. Taper ratio has an impact on the penetration force via surface drag. The higher the taper ratio, the lower the vertical component of the normal force. Since force due to drag is defined as coefficient of friction multiplied by the vertical component of the normal force, a higher taper ratio requires a smaller penetration force (see Figure 10).

![Diagram showing difference in vertical force due to taper ratio of a device](image)

**Figure 10. Difference in vertical force due to taper ratio of a device**

Surface finish also affects drag force. As will be discussed later in this chapter, penetration performance for the same geometry of devices differ depending on surface finish of matte or shiny. Since there is no geometrical difference between a matte and a shiny device, the difference in force can be attributed to the difference in the coefficient of friction between the matte or shiny device surface and polyurethane. Initially, two hypotheses were considered for the cause of the difference in coefficient of friction between matte and shiny devices: 1) different processes used in achieving the surface finish left residues which have different coefficient of friction; and 2) difference in the surface roughness changes the contact area between a device and polyurethane. In order to
isolate the cause of this difference, matte and shiny devices were analyzed using XPS (X-ray Photoelectron Spectroscopy also known as Electron Spectroscopy for Chemical Analysis or ESCA). Results indicated no difference in the chemical composition on the surface between matte and shiny devices. Whatever residues that may have been left on the surface by different processes are washed away in the subsequent washing process.

Therefore, the difference in penetration force seems to be a result of the difference in surface roughness. Shiny devices have a very smooth surface even when magnified 1000X under scanning electron microscope (SEM). Matte devices, however, have a rough surface with consistent ridges or striations running longitudinally along the long axis of the device. The reduced surface contact area between matte device surface and polyurethane, and possibly the lubrication effect of "valleys" due to air and lubricants, aid in making matte devices perform better than shiny ones.

Lubrication changes the coefficient of friction between device surface and test medium. Coefficient of friction changes after each pass because lubricant wears off. How well the lubricant is attached to the device surface determines how fast the coefficient of friction degrades. An experiment performed by the device development group indicates that one of the manufacturing processes can make a significant difference in how well the lubricant stays on the device surface.

Diameter of a device has an impact on the penetration force through the size of the hole required to pass a device through the test medium. The larger the diameter of the device, the bigger the hole the device needs to open, resulting in a higher penetration force.

The force characteristic curve for a taper point device penetration is marked by four distinct regions as shown in Figure 11. The first region is the initial ramp-up region which characterizes the slack of test medium being taken off by the device before the point tip penetrates it. The second region characterizes the point tip going through the test medium, with the peak of the penetration curve coming very close to the end of the taper region of a
tapered device. The third region is the body of the device going through the test medium, and shows the penetration forces decreasing rapidly from the peak. The fourth region shows where the device is being pulled out of the test medium.

![Diagram of force curve](image)

**Figure 11.** A force curve acquired from one device penetration

As mentioned before, the reason for the higher penetration force on the tenth pass as compared to the first pass of the same is the increase in the drag force. Tenth penetration of a device leaves a much deeper depression around the hole it created on polyurethane than the first. This is caused by an increased surface drag between the device surface and polyurethane. The point tip may have been dulled, but the major driving factor is the wear of lubrication. This is especially noticeable with shiny, lubricated tapered devices because the lubricant wears off on the polyurethane test medium very quickly. As more of the test medium surface comes in contact with the device, more drag force needs to be overcome in
order for the device to penetrate.

When devices are unlubricated, the tenth penetration force may or may not be much higher than the first penetration. In fact, in some cases, the tenth force was lower than the first. This variation seems to be a result of the interaction of the device surface finish and the test medium. When a device has a very rough surface, penetration forces may decrease over multiple passes because rough surface is gradually smoothed. When a device has a shiny surface, however, penetration forces increase over multiple passes.

1.B. Quantitative Description

An experiment was designed as shown in Table 2 in order to quantify the effects of the various factors on penetration performance. Ready availability of devices put some constraints in the four factor factorial design. Various sizes of straight devices were

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obtained, processed and lubricated under conditions identical to the production flow. They were then tested using the straight tester.

Sample size of five devices per setting was used for a total of 100 devices for the whole experiment. Each device was penetration tested ten times and the average was calculated for the five devices within each setting. Sample size of five replicates enabled a significance testing at a resolution of 20 grams at 97.5% confidence level.

Matte and shiny devices exhibited very different penetration force curves. Therefore, they were analyzed separately. As Figure 12 indicates the matte surface finish devices exhibited a "linear" degradation characteristics. That is, the increase in the amount of force from one penetration to another was relatively constant for the ten penetrations. On the other hand, the shiny devices exhibit a non-linear characteristics, where the degradation of the penetration force is great in the first four penetrations before becoming level after the sixth penetration.

![Graph showing force index vs penetration number for different surface finishes and lubrication conditions.]

**Figure 12.** 17 mil, high tapered devices with various surface finish and lubricant
Matte devices exhibited a significant improvement in penetration performance over the shiny devices. What is even more surprising is that even the unprocessed devices (i.e., devices that have not been through processing) exhibited a better performance than the shiny devices. An explanation for this phenomenon is that the matte and unprocessed devices have striations, ridges, or grind marks (see figures 13 and 14 for different surfaces under higher magnifications) which are parallel to the longitudinal axis of the device. These grind marks help penetration by reducing the surface contact area between the device and the test media. The shiny devices have a very smooth surface even under 1000 times magnification (SEM) which means a greater area of contact with polyurethane.

Results are even more overwhelmingly in favor of matte devices when lubricant is applied to the devices. The matte surface helps the lubricant to stick to the device even after many penetrations. The lubricant on the shiny surface is worn off after only a few penetrations, because the shiny surface is very smooth and the lubricant coating comes off easily as a result.

Point tip sharpness of a device was important in the first three or four penetrations, but after that, surface finish becomes a bigger factor in the penetration force. This result was observed by watching where the maximum force occurs for the ten sequential penetration tests using the same device. Initially, penetration force has the highest force when point tip penetrates through the test medium. By the fourth or fifth penetration, however, maximum occurs near the end of the taper region. This behavior implies that for devices that will be used for multiple passes (i.e., more than 6 or 7), the surface condition is just as important, if not more so, than the point tip sharpness.

**Matte Taper Point devices - A Predictive Model**

Matte devices consistently exhibited significantly lower penetration forces (therefore, better performance) and much better (linear) degradation characteristics. Overall, the matte devices were clearly preferable over the shiny devices. The fact that the matte devices
Figure 13. Shiny, lubricated surface (before testing) under high magnifications: a) 500X and b) 1000X.
Figure 14. Matte, lubricated surface (before testing) under high magnifications: a) 500X and b) 1000X.
exhibited linear wear characteristics made the task of coming up with a statistical model (based on diameter, taper ratio, lubrication, and surface finish) easier.

The average of each of the ten penetrations were fitted to a best-fit line using the linear regression method. Two outputs were intercept and slope of the best fit line. The intercept corresponds to the initial penetration force of the device; the slope corresponds to the amount by which the force went up from one penetration to a subsequent penetration. The average of the slopes for the different matte devices were calculated to be about 2.46 force index per penetration (with a standard deviation of 0.7) for the lubricated devices; and 2.0 force index per penetration (with a standard deviation of 0.62) for the unlubricated devices. At 95% confidence levels, the confidence interval for the slope of lubricated devices ranges from 1.3 to 3.62; similarly, for the confidence interval for the slope of the unlubricated devices is 1.02 to 2.98.

For the intercept, a plot of the log(intercept) and the log(standard deviation of intercept from 5 data points) showed a sloping line (see Figure 15), thereby violating the assumptions of a simple regression model. Therefore, intercept data was transformed (using the inverse transform) to linearize the model. Using the data transformation, the model (adjusted $R^2 = .9856$) was determined to be:

\[
\text{Inverse of Penetration } 1 = 0.0089 - 0.0023\text{(diameter level)} + 0.0032\text{(lubricant level)} + 0.00041\text{(taper ratio level)} - 0.00069\text{(diameter level)\*(lubricant level)}
\]
Figure 15. Log(intercept) versus log(std dev of intercept) for matte devices

Once the first penetration force was determined, subsequent penetration forces were calculated by adding the index constant of 2.46 per penetration for lubricated devices, and 2.00 per penetration for unlubricated devices. That is, because the matte devices exhibited a linear slope in increasing from one penetration to the next, the model used a constant slope to estimate the increase in force. Thus, the maximum force in the i-th penetration, \( P(i) \) can be calculated as

\[
P(i) = P(i-1) + x^*\tag{1}
\]

where \( x^* = 2.46 \) for lubricated devices

\( = 2.00 \) for unlubricated devices

Using the model, the predicted penetration values were calculated and included in Table 3.

Confirmation Experiment

In order to confirm the results, more devices were obtained. Since the model was based on the test results using straight devices on the straight tester, and most of the devices are curved, the curved devices were treated to the same conditions and tested on the
curved tester. The goal was to determine (1) whether the model is verifiable, and (2) whether there was correlation between the straight tester and the curved tester. Theoretically, the curved tester and the straight tester should result in the same penetration values since they both measure only the vertical force.

17 mil and 20 mil curved devices were obtained and treated to matte finish, with and without lubricant. The results, listed in Table 4, seem to be a lot more flat (i.e., the increase in penetration force over multiple passes is smaller than for the straight tester). This difference may be due to either variations in the devices, or difference in the testing procedure. Nevertheless, the results seem pretty well correlated with the model. One should be careful in applying the model too far outside the range of factors tested (e.g., diameter of 20 mil is outside the tested range of 8 mil to 17 mil) as accuracy of the model decreases dramatically.

Shiny devices

Shiny, tapered devices were more difficult to model, because they exhibited more variability from device to device. In every instance, shiny devices exhibited higher penetration forces and faster degradation characteristics than matte devices (refer to Figure 12).

The type of process used to achieve the shiny surface also made a difference in the penetration force. Devices treated using one process exhibited a slower degradation than those using another process.

A small experiment was performed using the matte devices, shiny devices processed using process A, and shiny devices processed using process B. These devices (which were not lubricated), were penetrated ten times, rinsed in water, and then penetrated ten times again. The goal was to remove residue from the surface of the device by the first set of ten penetrations and then by rinsing. By the second set of ten penetrations, most residue should have been removed (or at least minimized).
Table 3. Matte, tapered device predicted performance through dry polyurethane

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<td>6.4</td>
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<td>3.3</td>
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<td>4.6</td>
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<td>6.0</td>
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<td>10.1</td>
<td>10.5</td>
<td>10.9</td>
<td>11.1</td>
<td>11.2</td>
<td>11.3</td>
<td>11.2</td>
<td>11.4</td>
<td>11.1</td>
<td>11.3</td>
</tr>
<tr>
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<td>2.8</td>
<td>3.6</td>
<td>3.6</td>
<td>5.4</td>
<td>5.8</td>
<td>5.6</td>
<td>6.7</td>
<td>7.1</td>
<td>7.4</td>
<td>7.5</td>
</tr>
</tbody>
</table>

The results of the experiment were somewhat as expected. Before the rinse, the test results were consistent with previous experiments. The matte devices exhibited a low and flat curve throughout the ten penetrations. The shiny devices prepared using process A
required lower penetration force than those devices treated using process B, but not by as much as was seen in the previous experiments. The degradation in force over ten penetrations was somewhat similar for both of the shiny devices. Results suggest that residue is not the cause of the difference, but that the surface condition left by the two process may be the difference.

The major area of improvement regarding shiny devices is in reducing variability. Much of the variability in the penetration force of shiny devices comes from variability in the lubricant adhering to the device surface. Because shiny devices have a smooth surface, lubricant rubs off on the polyurethane material each time the device is penetrated through the test media. Therefore, processing which applies lubricant on the surface becomes very critical in ensuring a bond between lubricant and the device surface.

3. Wet Test Medium Experiment

All results described up until now were performed on dry penetration medium. Most surgeries are performed in the presence of natural or external lubricant. In order to simulate usage conditions, test media were immersed overnight in water and in lubricant. Shiny, tapered devices, both lubricated and un lubricated, were tested on dry, water-soaked, and lubricant-soaked test media to determine the effect of lubrication of the test medium on penetration performance. The results are presented in Figures 16 and 17.

For tapered devices, there was little, if any, difference between test medium soaked in lubricant or water. However, there was a significant difference between results between wet and dry test media. Lubricated, shiny, tapered devices, which exhibited a fast degradation in performance when tested using a dry medium, shows little degradation when penetrated through a wet test medium. A wet test medium more closely simulates the conditions in surgery, and thus, results from tests using wet medium provides more relevant information regarding the penetration performance of a device. Hence, the results
from wet test medium testing should override any information gathered from tests using dry test medium. This means that shiny devices, which performed not so well when tested on dry test medium, are in fact, good when used in wet medium (such as human tissue). Interestingly, when test medium is lubricated, lubricated devices had a significantly better performance than unlubricated devices.

The fact that unlubricated device penetrating wet test medium decreased in force as the number of passes increased suggests that the device surface was being lubricated during each pass. It seems probable that if the devices were penetrated enough times, penetration force will approach that of the lubricated device being passed through lubricated test medium.

![Graph showing force index vs penetration number for different mediums and conditions.](image)

Figure 16. Unlubricated tapered device on dry versus wet (water and lubricant) test medium
2. Knife-edged Device

Knife-edged devices have multiple edges which cut as they penetrate. Knife-edged devices used in this study were limited to the three-edged, triangular bodied devices. An important feature of the cutting edge devices seem to be the sharpness of the edge, which may be influenced by several factors: 1) edge angle, 2) processing, and 3) the length of the edge. Lubrication also has a considerable influence on the penetration performance of knife-edged devices. Unlike the tapered devices where hole shapes are random, knife-edge devices leave a distinct mark of "T" on test medium representing where the three edges have cut.

4.A. Qualitative Description

Three (3) seems to be the optimal number of edges on cutting edge devices for two reasons. First, in order to get the body of the device through the test medium, polyurethane needs to be cut in at least two dimensions (height and width). If only two cutting edges were used in a straight line, there needs to be a force that will open up the
hole as the body of the device passes through the test medium. This drag force will likely require a higher force than the force required for the third edge to make a cut. Secondly, although four edges will also result in a cut in at least two dimensions, the force required for the fourth cut is likely to be greater than the drag force after three edges have cut the tissue. (There is likely a principle of diminishing returns with the number of edges because lubricant plays an important role in penetration.) Since no testing was conducted to verify this observation, this observation remains a hypothesis to be proven by further work.

Edge angle of the device refers to the angle seen after cross-sectioning a knife-edge device. In a device with an equilateral triangle cross-section, edge angles are 60 degrees. However, edge angles can be reduced to under 60 degrees by changing geometry as shown in Figure 16. The reduced edge angle reduces the force required to penetrate the medium by reducing the vertical component of the normal force and by reducing the surface drag force.

Processing significantly affects the quality of the edges. When edges are under-processed, flashes or thin slivers are left on the edges. A flash is undesirable because it is fragile and may break off while the device is being used. Edges become rounded and dull when over-processed.

The taper ratio affects the knife-edged device penetration in the same way taper ratio affected tapered device penetration. The higher the taper ratio, the more gradual a cut may be made. It leads to a smaller vertical component of normal force on the device.

4.B. Quantitative Description

A survey experiment was performed to see the performance of many difference classes of devices that embody one or more of the features described in the previous section. Figure 18 shows the results.
Figure 18. Survey of knife-edged devices. All devices have a matte finish except for D, which has a somewhat shiny finish. F and B devices have a triangular cross-section; A, C, and E have pinched triangular cross-section; C and E have a higher taper ratio.

Unfortunately, testing knife-edged devices is difficult because of the variability in the quality of the edge due to processing and handling (handling may cause edge damage or dull edges). An experiment was performed to understand the effects of dull edges, excess wings, edge damage, and damaged point. Figure 19 shows the results. The results shown in Figure 21 should be viewed with an understanding that even the same devices exhibit a large variability in performance. For example, a device may be intentionally dulled (as is the case for devices shown in Figure 21), but the device may not be representative of all dull edges because there is a degree of dullness. The major area of improvement in reducing the variability of cutting edge devices is the processing and device handling in downstream operations.
Figure 19. Effect of edge condition on cutting edge device penetration performance

4.C. Wet Medium Experiment

As with tapered devices, knife-edge devices were tested using lubricated test medium. Few polyurethane test media were soaked in water, and few others were soaked in a lubricant overnight. Both lubricated and unlubricated knife-edge devices were tested using lubricated and dry test medium. The results are plotted in Figure 20.

Lubricated knife-edged devices showed very similar penetration performance regardless of whether test medium was lubricated. Unlubricated device penetration performance, on the other hand, was affected by whether test medium was wet or dry. The forces in penetrating a dry medium were significantly higher than those for a wet medium. Penetration forces for unlubricated devices on lubricated test medium show a constant penetration force across the ten passes. Thus, by the tenth pass, both lubricated and unlubricated devices require about the same force in order to penetrate through a lubricated medium. This suggests that the lubricant on the knife-edge devices are being wiped by the test medium.

45
Figure 20. Lubricated and unlubricated device testing on wet and dry test media

5. Chapter Summary and Recommendations

Coming up with a predictive model for device penetration performance is useful in that it gives a quantitative information about a proposed design. For instance, if marketing wanted a taper ratio of which is even higher than the "high" level chosen in the experiment, the model can be used to predict the improvement due to the higher taper ratio. (Further prototyping should verify whether the predictive model is accurate for the estimates for a higher taper ratio, since estimates are extrapolated.) Marketing, manufacturing, and product development then have to decide whether the improvement is significant enough to warrant changes in the manufacturing processes.

If lubricated device tested on wet test medium requires a constant penetration force over the ten passes (as seen in Figures 22), then each device no longer needs to be penetration tested ten times. Instead, the initial penetration force should suffice in providing all the information about the sharpness of a device. In such cases, more devices can be penetration tested once, as opposed to less devices ten times each.
When input from surgeons provide a clear requirements for the design of the device, one can also think about an objective function for a device's penetration performance. The idea of an objective function makes sense in that a device that is used for only a couple of passes should be evaluated based on what the device will do in the first couple of penetration. On the other hand, a device that will be used for ten passes should be evaluated based on full ten penetrations of the device. One of the difficulties in applying this concept of objective function to devices is that the same device may be used for different number of passes. One solution to this dilemma is to come up with the weight factor (i.e., coefficient for each penetration force) based on the likely usage of the medical device.

Why bother with an objective function? An objective function can be used to distinguish between two devices that have the same mean penetration performance, but different wear characteristics. For instance, suppose device A requires penetration forces of 10, 20, 30, and 40 grams to pass through a test medium; and device B requires 18, 20, 22 and 24 grams through the same test medium. If a device is to be used for an application where three passes are made, and a surgeon was interested in the mean force for the three penetrations, that surgeon should be indifferent to either device A and B. However, if a device was to be used for more than three passes, then depending on the individual weights placed on each penetrations, device B becomes preferable.

The point is that if an average of ten penetration is used as the measure of performance, it implicitly means that the first and tenth penetration force (and every one in between) are equally weighted. It also makes no distinction between a device that starts at 10 and goes up to 100, and one that starts at 51 and goes up to 60 because both devices average 55 grams over the ten penetrations. However, an objective function based on the device usage provides distinction in such cases.
Chapter 4
Cost and Manufacturability Model

1. Overview

Given a proposed design with some idea of its performance, a manufacturing organization must consider its cost implications. Only after specific design features have been proposed can relatively accurate estimates of product costs be obtained. By understanding the implications of the manufacturability and estimated costs before the design is finalized, a manufacturing firm can encourage and reward designs that promote not only performance but also manufacturability. A tool that provides such information can aid in new product decisions, and in integrating different functions (e.g., engineering, manufacturing, marketing) within an organization.

A prototype of such a tool is proposed in this section. The goal was to develop a product-attribute and process driven costing system that promotes designing for manufacturing. It can help in deciding whether a product with a complex design can justify its development and production costs in terms of that organization's strategic goals (whether they be to become a low cost producer/market share leader, to provide superior products and services, or to focus on a specific target segment).

The product features drive the cost model from one end, while manufacturing process flow and resource consumption at each of the process stations drive the cost model from the other end. First, product design features are defined and process flows (a sequence of processes required for producing a product) are established. Alternative stations or equipments may exist for each of the processes, and these equipment may have very different technological bases. The costing tool allows for more than one possible process flow for comparison of the desirability of one process flow over others, or one plant over another. Once process flows and product designs are established, relationships which
model the interaction between the product features and process parameters are programmed. Then, a user can specify which process flow to use in manufacturing a proposed design. As a result of the product-process interrelationship, process parameters and cost of the product are calculated. For instance, throughput rate and yield may decrease as the size of the product becomes smaller, which, in turn, will drive up the product cost. These relationships (obtained empirically from the engineers and designers who are familiar with the products and processes) between product attributes and process characteristics enable the user of the tool to obtain quantitative estimates of the product cost of a proposed design.

This cost model can be used to estimate the product cost in one of two ways. First method is the "planning value" approach. That is, the costs are calculated based on what a string of processes can theoretically achieve given the capability of the equipment, and labor and materials requirements. The second method uses the "actual cost" information. Actual product volume along with actual spending by each of the departments in the areas of labor, materials, supplies, tooling, and utility provide information necessary to calculate the actual cost. Indirect costs, in both cases, are assigned to products based on activity based cost (ABC) method.

As a rule, whatever costs that can be directly attributed to a process station (in terms of direct labor, materials, supplies, tooling, and utilities) is directly assigned, not lumped as overhead costs and indirectly allocated. The cost system allows the user to enter the directly attributable process costs into one of two categories: (1) product-independent, process-related costs (such as monthly maintenance costs) and (2) product-attribute dependent process costs. The first category, the product-independent process costs, is entered by the user. The second category of process costs is calculated using empirically defined product-process interrelationships.
2. System Description

The tool is implemented on ORACLE relational database management system (DBMS) with user interfaces consisting of a series of menus and forms. What follows are brief descriptions and screen designs of the main features of the system. There are many other screens than are shown in this section, but most are maintenance and ancillary screens.

2.A. Design Feature Entry

One of the goals of the system was flexibility. The system was designed to be useful regardless of the type of product being studied. One example of flexibility of the system is in the design feature definition. Important features of a product are specified by the user of the system. Most likely, the important features of a design should include those characteristics that affect the product cost and manufacturability.

<table>
<thead>
<tr>
<th>Design Feature Entry</th>
<th>DESIGN</th>
</tr>
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<tbody>
<tr>
<td><strong>Design Name</strong></td>
<td>Product A</td>
</tr>
<tr>
<td><strong>Transfer Volume</strong></td>
<td>1500000</td>
</tr>
<tr>
<td><strong>Sales Type</strong></td>
<td>Device A</td>
</tr>
<tr>
<td><strong>Wire Size</strong></td>
<td>120</td>
</tr>
<tr>
<td><strong>Family</strong></td>
<td>YANG</td>
</tr>
<tr>
<td><strong>Description</strong></td>
<td>Medical device with diameter 120</td>
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</table>

<table>
<thead>
<tr>
<th>Design Feature</th>
<th>Value</th>
<th>Unit</th>
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</thead>
<tbody>
<tr>
<td>1. Product Type</td>
<td>Device A</td>
<td></td>
</tr>
<tr>
<td>2. Product Diameter</td>
<td>20</td>
<td>Euros</td>
</tr>
<tr>
<td>3. Surface Finish</td>
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</tr>
<tr>
<td>4. Lubricant</td>
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<td></td>
</tr>
<tr>
<td>5. Taper Ratio</td>
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<td></td>
</tr>
<tr>
<td>6. Material</td>
<td>AAA</td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
2.B. Process Flow Selection

A process flow is a sequence of manufacturing operations (process steps) and the specific machinery or stations that are used to perform the operations. Within each of the process steps, more than one station or equipment (which may or may not have the same technology foundation) may be capable of performing the operation. These stations may have different throughput rate, yield, and costs based on their product-process interrelationships.

Establishing more than one process flow allows the user to investigate the option of manufacturing a proposed product in alternative process flows. This enables what-if analysis as well as a comparison of product cost among alternative plants or process flows.

<table>
<thead>
<tr>
<th>Seq</th>
<th>Process Name</th>
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<th>No. of Shifts</th>
</tr>
</thead>
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<tr>
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<td>A</td>
<td>Primary Operation</td>
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<tr>
<td></td>
<td>B</td>
<td>Secondary Operations</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>Tertiary Operations</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>D</td>
<td>Not very descriptive name for an operation</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>E</td>
<td>Another dull name for an operation</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>F</td>
<td>Can't tell you the specific operation</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>G</td>
<td>Inspect equipment</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>H</td>
<td>Package</td>
<td>2</td>
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<table>
<thead>
<tr>
<th>Station Information</th>
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</thead>
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<td>Station</td>
</tr>
<tr>
<td>Primary #1</td>
</tr>
<tr>
<td>Primary #2</td>
</tr>
<tr>
<td>Primary #3</td>
</tr>
</tbody>
</table>
2.C. Product-process Interrelationship

Once design features and process flows have been chosen, the user can view the estimated results of manufacturing a product on a specific process flow. Information such as yield, throughput rate, cycle time, downtime, planning value, and station utilization rate are calculated as a result of user inputs and product-process interrelationship. For instance, in the medical device manufacturing, experience indicates that throughput rate and yield will vary as a function of diameter. The smaller the diameter, the smaller the throughput and yield rates.

<table>
<thead>
<tr>
<th>Seq</th>
<th>Process</th>
<th>Station</th>
<th>Man Req</th>
<th>Parts Per Minute</th>
<th>Cycle Time (min)</th>
<th>Sched Down Time</th>
<th>Unsched Down Time</th>
<th>Planning Value</th>
<th>Percent Util</th>
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<td>2</td>
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<td>128</td>
<td>23423</td>
<td>42</td>
</tr>
<tr>
<td>2</td>
<td>B</td>
<td>1</td>
<td>3</td>
<td>164</td>
<td>153</td>
<td>128</td>
<td>128</td>
<td>23423</td>
<td>42</td>
</tr>
<tr>
<td>3</td>
<td>C</td>
<td>1</td>
<td>4</td>
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<td>150</td>
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<td>128</td>
<td>23423</td>
<td>42</td>
</tr>
<tr>
<td>4</td>
<td>D</td>
<td>1</td>
<td>5</td>
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<td>128</td>
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</tr>
<tr>
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<td>E</td>
<td>1</td>
<td>6</td>
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<td>120</td>
<td>128</td>
<td>128</td>
<td>23423</td>
<td>42</td>
</tr>
</tbody>
</table>

2.D. Product Cost Estimate

The cost system can be used to calculate costs in one of two ways: (1) planning value and (2) actual cost. The costing method is specified by the user by setting the value of the
costing method field to 'PV' for planning value and 'AC' for actual cost. Planning value approach estimates cost based on theoretical manpower usage, wage rate, throughput capacity, and materials cost at each of the process stations. The result of the calculation may be interpreted as a theoretical goal of the product cost in a chosen process flow. The second method of costing is the actual cost approach. The actual cost approach takes actual salaries/wages of existing employees, throughput rate, yield, and materials cost, and calculates the product cost. The resulting calculation compared to the cost calculated using the planning value approach may be an indication of operations performance.

2.D.1. Planning Value Costing Method

Direct costs include direct labor, direct materials, supplies, utilities, and tooling/spare parts. Planning value approach calculates the direct labor costs using the planning value
(number of parts that can be relied upon to be produced day-in and day-out), manning ratio for the station, and the wage rate. Planning value (per shift) is calculated using the formula:

\[ \text{Planning value} = \text{parts per minute} \times (\text{minutes in a shift} - \text{downtime}). \]

Direct labor cost is then calculated using the planning value as:

\[ \text{Direct labor cost} = (\text{manning} \times \text{wage rate} \times \text{shift hours}) / \text{planning value per shift} \]

This direct labor cost is divided by the station yield before being added to the station’s total costs.

Direct materials cost is calculated by using the theoretical raw materials needed to produce the desired part. The calculated materials cost is then bumped up by the total throughput yield rate for the chosen process flow to give a yield adjusted materials cost. The simplifying assumption in calculating the direct materials cost is that all direct materials costs are incurred in the first manufacturing process step.

Other direct costs such as supplies, utilities and tooling/spare parts were assumed, for simplicity of the model, to be product-independent. The costs incurred for these categories can be entered at the process level. Other costs that can be identified as being needed to sustain specific process stations can also be entered at the process level. An example of this type of cost is monthly maintenance cost. One of the recommendations for improving this system would be to define these direct costs as a function of a relevant process parameter as related to a product. One candidate parameter, for example, is machine runtime. Supplies, utilities and tooling costs may be a function of how long the machine was run in order to manufacture a specific product. Product-process interrelationship needs to be defined in order to calculate the direct costs.

2.D.2. Actual Cost Method

Actual costs method uses information from departmental costs. Each department's total
spending is separated into labor costs, and materials costs. In order to support environments where a department may be involved in both development as well as production, only those portions of labor and materials costs dedicated to production is used in the calculation of the product cost. Other portions of the total labor and materials costs are tracked as development costs.

The next step in calculating the actual cost is to identify the percent of time that a department spends in supporting various process stations. Some departments may support only one process station, while others may support more than one process stations. The cost system calculates the department's contributions to production efforts at various stations, and assigns the department's costs to various stations accordingly. The station costs are then distributed among the different products based on the product volume on the machinery.

2.D.3. Indirect Cost - Activity Based Cost Method

Regardless of which method is used to estimate the direct costs, indirect costs are accounted for using activity-based costing approach. The first task in establishing an activity-based costing system is to identify the activities being performed in an organization in support of manufacturing. Then the cost drivers -- those things which cause or drive activities-- for each of the activities are determined. The number of cost drivers for each activity was limited to one for two reasons: 1) the activity based costing system itself should not become a cost driver to maintain, and 2) where there are more than one cost drivers, another driver can be defined that is a weighted combination of the multiple drivers. More cost drivers probably would have added a little more accuracy, but would also add more complexity and maintenance.
Activities and the cost drivers for a plant is identified as shown in Table 3. The justification for using the cycle time as the cost driver for the administrative costs (including plant administration, finance, and plant engineering) is that the longer a part stays in the plant, the more that part requires attention/administrative management. Similarly, the justification for using unscheduled downtime for the support engineering functions (process engineering, systems engineering, electrical engineering, etc.) is that the machines that are down more often require more support from engineering.

Cost drivers are used to assign manufacturing support costs to equipment. Costs assigned to equipment are then assigned to products based on equipment usage. If product A uses 50% of equipment Z's total runtime, then 50% of equipment Z's costs are assigned to product A's costs.
Table 5. Activities and associated cost drivers

<table>
<thead>
<tr>
<th>Function</th>
<th>Cost Driver</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plant Administration</td>
<td>cycle time</td>
</tr>
<tr>
<td>Finance</td>
<td>cycle time</td>
</tr>
<tr>
<td>Plant Engineering</td>
<td>cycle time</td>
</tr>
<tr>
<td>QA</td>
<td># of inspections/</td>
</tr>
<tr>
<td></td>
<td># of qualifications</td>
</tr>
<tr>
<td>Design</td>
<td># of engineering drawings</td>
</tr>
<tr>
<td>Process Engineering</td>
<td>downtime</td>
</tr>
<tr>
<td>Systems Engineering</td>
<td>downtime</td>
</tr>
<tr>
<td>Electrical Engineering</td>
<td>downtime</td>
</tr>
<tr>
<td>Equipment Costs</td>
<td>machine hours</td>
</tr>
</tbody>
</table>

3. System Flow Description

Figure 21 shows the conceptual flow of the system. The upper half of the diagram shows the direct cost portion of the product cost. As previously mentioned, the first steps are to specify product attributes and establish process flows. Using the product-process interrelationship, costs and process parameters are calculated. Also, product-independent process costs can be entered. These two costs add up to the total direct costs.

The bottom portion of the diagram shows how indirect costs are handled. Activities performed at the plant are identified along with their cost drivers. At the same time, costs for those activities are identified. The costs for the activities are then assigned to processes based on cost drivers. The process costs are further broken down and assigned to products based on volume and runtime.
Figure 21. Conceptual flow of the cost model
Chapter 5
Cost Analysis Using Cost Model

The cost tool was used to analyze the cost sensitivity and breakdown of devices produced at one of the plants. The cost tool enabled what-if analysis of cost in various scenarios. By allowing the change in process parameters, one can determine the sensitivity of cost to the process parameters. The first task in determining the manufacturing sensitivities is to determine which process steps are sensitive to changes in design parameters. For instance, some processes are insensitive to changes in diameter and taper ratio. Other processes are affected by changes in the design parameters. These processes contribute to the sensitivities in manufacturing costs. In the process flow for medical devices, process A (the first process step) contributes most to the sensitivities. Others in the flow only adjust the curve upwards, since they only add to the cost, not to the cost sensitivity. Process A's costs are shown as illustrations of the cost sensitivities.

1. Manufacturing Cost Sensitivities to Process Parameters

Figure 22 shows the effect of downtime on product cost. As downtime increases, labor costs increase as shown. However, since labor costs represents only a small fraction of the costs, even while labor cost triples, the total product cost remains flat because overhead portion of the cost at this station represents over 75% of the station cost, and labor costs and material costs account for only a small portion of the total station cost. Similarly, Figure 23 shows the sensitivity of process A's costs to yield. The shape of the curve for total cost for the manufacturing flow is very much determined by the shape of process A's curve, suggesting that most other processes are not very sensitive to yield changes as process A is.

Figure 27 shows a graph of the sensitivity of cost to various product features using the following product-process interrelationships for yield and throughput rate:

\[ \text{yield} = 100 - (\text{taper ratio}/2) - (5/\text{diameter}) \]

\[ \text{throughput rate} = 200 - (\text{taper ratio}/2) - (5/\text{diameter}) \]
As mentioned in the previous chapter, these product-process interrelationships are best determined from historical data or by engineers and other workers who are most familiar with the process in question.

![Graph showing the relationship between cost per 1000 and wire size with different taper ratios.]

Figure 24. Manufacturing cost versus wire size and taper ratio

Given a quantitative cost information, and some idea of the performance of a product, an organization must decide on which product to introduce. One way of aiding in the decision making process of product introduction is through plotting the performance of a product versus its costs. Since penetration performance of a device is measured over ten different penetrations, it is difficult to say which one of the penetrations should be used. However, an objective function, discussed in Chapter 3 comes in handy here because an objective function is one number that characterizes the desirability of the device.

The following example illustrates how an objective function can be used to plot the desirability of a device in the cost versus performance matrix. As mentioned in chapter 3, a useful objective function is one that reflects the usage of the device. For instance, if 50% of a device volume is to be used for 3 passes, 25% for 5 passes, and 25% for 8 passes,
then an objective function (let's call it $P$) for this device is:

$$P = 1*p1 + 1*p2 + 1*p3 + 5*p4 + 5*p5 + 0.25*p6 + 0.25*p7 + 0.25*p8$$

where $p1$ through $p8$ represent the forces for first through eighth penetrations. Because the objective function is a linear combination of the various penetration forces, the smaller the objective function, the better performing the device.

Given an objective function for device penetration performance, the cost versus performance matrix can easily be constructed. Assume that the objective function for size 10 devices were as shown above. Then the cost versus performance matrix is as shown in Figure 25. In deciding product introduction, marketing, design and manufacturing together have to determine whether the incremental improvement in the performance is worth the capital investment, increase in cost or other manufacturing concerns.

![Figure 25. Cost versus performance matrix for 10 mil devices](image)

3. General Observations

- Improvements in yield, parts per minute, uptime, etc. make a small dent.

Indirect costs represent a significant portion of the total product cost. Even not
including the new process technology, indirect costs represent a more than 50% of the product cost. Overhead is the first thing that should be investigated when looking for ways to streamline an organization. In order to find out more about the overhead costs, one should refer to the activity based costing screen shown in section 2.D.3 of Chapter 4 and answer the following questions:

1) Is the allocated costs accurate?

2) Is the cost drivers that assign those allocated costs appropriate for those activities?

3) What can be done about those components that are driving up the costs?

The cost tool provides valuable insights into an operation. Because indirect costs represent a large, and still growing, portion of total manufacturing costs, the traditional way of allocating overhead based on labor hours or headcount may distort what is really happening.

- The focus for the device business is more on process technology, rather than on product improvements. Medical device studied in this project is a mature product, and while there is still room for incremental improvements, more significant improvements have come as a result of improvements in process technology. As a result, process technology becomes a much bigger concern as companies become more conscious of costs, quality, and life cycle of the devices. Because process technology is highly capital intensive, there is more incentive to get product designs "right the first time."

- New process technology provides capabilities in consistency and repeatability that far exceed the capabilities possible with the existing processes, especially in terms of taper ratio and geometry. These new improvements contribute significantly to the quality of the product, and marketing would do well to understand and capitalize on them.
4. Organizational Impact of the Cost System

The cost model as developed has many "customers." In order for the cost model to be useful, it requires input from multiple functions including engineering, manufacturing, marketing, and finance. Engineering and manufacturing contribute information such as design of the product and the relationship between product attributes and the process parameters that constitute the bases for direct, indirect and yield models. Marketing provides customer input and new design ideas, as well as strategic issues such as new markets and segments. Finance contributes cost data and estimates for manufacturing processes as well as determining the desirability of new products/projects. The cost model can function well only when it has all the information from all the parties involved. It is well-suited for, and encourages, team oriented mode of working with all the functions represented.

One possible approach to getting better information to operations is for finance to "report" to operations in providing the type of information that are required to run operations. This model is good in that finance (at least that part of finance that works with operations) has a good understanding of who the customer is. This model exists in many companies in the form of financial analysts working for an operations manager. A major disadvantage of this model is that linkage between this "system" and the financial system that exists at corporate and division level is often weak, or non-existent. As integration of systems becomes more feasible, this link will become a less of a systems barrier, but an organizational barrier. A better model is one where finance, operations, marketing, and other functions in the company work as peers in a closely-knit team. This model is much talked about, but very seldom seen in practice.

This transformation of an organization can only occur when different functions change the way they work. Operations and finance must work closer to define what is relevant to both manufacturing and finance. In too many cases, finance prepares a stack of reports
which is not being used by the operations manager. In the plant where I worked, this was a source of frustration for not only operations but finance as well. Attempting to achieve world class manufacturing status requires change in not only operations but also in finance, human resources, and all other major disciplines within an organization.

There are several reasons why I think the cost model will not be used extensively, if at all, throughout the company:

1) Lack of end user training: The cost model was built on ORACLE relational database management system. ORACLE was chosen as the database standard, but being relatively new, only the people who were developing applications knew how to operate applications developed on ORACLE. In order for any of the applications to be effective, there is a critical need for significant training all potential users on Oracle. Also, because the database depends heavily on function keys, it takes time to learn to operate in an application.

2) Lack of involvement: Not all the functions (especially those in corporate headquarters) whose input was needed for a successful application were involved in the design and development of the cost model. One way of getting all functions involved (including people not in the plant) is to communicate to them about what is going on. Communication enabling tools such as electronic mail (e-mail) between the plant and corporate are available, but are seldom used at the plant. The company and plant culture that exists needs to change before e-mail would be utilized fully.

3) Lack of commitment: Even those who were involved were not fully committed to the cost model. The mentality was that the cost model was an "academic exercise," and was not looked upon as a system that can be used with production data. There was also a concern that the model needed to be compatible with the corporate financial system. The corporate finance was considering an upgrade to its financial systems, and therefore, the finance manager at the plant was not willing to commit too much time in defining a system.
which eventually may not be compatible with the new system. There was also a lack of resources at the plant already without having more responsibilities put upon it. Unfortunately, no one in Corporate was involved in the development of the system.

This incentive to not convert over to more relevant measures eventually hurts an organization because the information they are currently getting from the existing systems, and from which the managers base their decisions, have little relevance to what is happening on the manufacturing floor. In large corporations, the biggest obstacle in converting over to more relevant cost accounting measures seems to be the huge investment over a long period of time (some ten to twenty years) in a corporate-wide or division-wide financial system. Once they realize that costs for some of the outdated portions of the financial systems are sunk costs, they can begin to serve the organization with better, more timely information.

Conversion means a major overhaul of the financial system which has grown over the years. However, the state of the software technology is such that rapid prototyping is possible. One route to a successful conversion is to start at a departmental level to develop a prototype that provides the "right" kinds of information to the departmental manager. The next task is to make a link between this prototype to the financial system in such a way that satisfies financial requirements. Assumption in this scenario is that the upper management will review the departmental manager not according to the traditional measures, but more relevant, new measures. Once the link to the financial system has been established, the system may then be spread to other departments. After new measures and systems are in place at the departmental level, the financial system at division level may then be modified to take the information it has been fed from the departmental level and present that information in a meaningful way at a division level. In this way, the traditional financial system may gradually be updated to catch up with the current practices.

4) Lack of historical data: This is a short-term problem in that as production level at the
plant increases, and processes are brought under control, data will be available to determine the design attribute-process interrelationships.

and lastly, 5) I underestimated the magnitude of effort required to develop and transfer the ownership of the cost to the endusers. Spending only a part of my time on the cost model was insufficient, and obtaining only a part of the time from finance and operations groups was inadequate.

In terms of the challenges facing the company, one of the most important is the communications between plants. The cost model was developed in a plant whose mission was the development of and production using new processes. The plant comprised mostly of engineers working on new processes. All marketing, design engineering, and most of finance functions were performed at the corporate headquarters, which was about an hour away. The physical distance between the plant and the corporate headquarters was an additional barrier to already small amount of communications that existed between the plant and marketing, design, and finance. The culture and tradition of decentralized operations also make it easy for people in the plants to focus on their own plants. This is especially sensitive since the plants are “focused” in the tasks they perform, yet the final product is requires processing from multiple plants.
Chapter 6
Conclusions and Recommendations

Stated aims of the project at its inception were the following:

- Investigate the factors in the design of a medical device which affect its penetration performance. As a result of investigation, quantify the effects of the various design factors on the device penetration performance and establish a predictive model for penetration performance. Use the knowledge gained from the study to ensure the quality, reliability, marketability, and profitability of the product line.

- Given the information about product performance, determine the effect of the product features on the cost and manufacturability.

This paper described how the stated aims were approached. A quick outline of the approach listed below.

1. Define customer requirements in a product

   In the case of the medical devices, this step would involve input from surgeons in determining which features are important. As described in Chapter 3, one of the things that marketing function needs to determine how much weight to put on characteristics such as uniformity, rate of increase in force, and maximum force. Unfortunately, this information was not available or was available only qualitatively. One way to obtain this type of information is to have a set of devices that emphasized each of the characteristics and have the surgeons express what they liked and disliked about each of the devices. More information may be gathered by having the surgeons rank the needles in terms of usability or desirability.

2. Translate product features into engineering parameters which can be measured
Next comes the task of translating the customer desires into engineering parameters and measurements that can be worked on in design or manufacturing phase. This step involves relating or linking the customer "wants" to specific product feature in terms of engineering. For instance, ease of penetration may be achieved by many product features such as lubrication, taper ratio, and surface finish.

In addition, where more than one features are important, an objective function can be established which can help determine the desirability of one product versus another. This objective function must be based on the customer requirements in that the weights to place on one factor versus another is determined by how much the customer values one feature over another.

3. Establish meaningful testing techniques to measure the engineering parameters

   This step addresses the questions of "what to measure" and "how to measure" the various engineering parameters identified in step 2. Establishing incorrect testing technique can be disastrous if the information gathered from experiments leads to incorrect conclusions about product features. As a general guideline, the closer a testing procedure simulates actual usage conditions, the better the testing technique.

   Implications of this to device penetration testing is pretty significant. Experiments using dry versus wet test medium yield a significantly different information about device performance. If information based on dry medium testing were solely used in making the product feature decisions, the resulting device may be significantly different.

4. Perform experiments and studies to gain knowledge of how parameters affect performance

   Statistical methods can be used to gain understanding of how different product features affect performance. A predictive model can be constructed using designed experiments that quantifies the effect of various factors and the interactions of multiple
factors. This predictive model can then be used to determine optimal settings.

In addition to statistical (and empirical) models, other analyses may provide valuable insights into the effect of parameters on performance. In the study of devices, for instance, materials testing - Scanning Electron Microscope (SEM) and ESCA - contributed more information as to why parameters affect performance in the way they do. These analyses possibly explain experimental results that were obtained, and also point out new directions of study in the improvement of the product.

Another analysis that may have been useful (but were not investigated in this study) is the Finite Element Method (FEM). Although FEM analysis could not have been used to analyze the effect of surface conditions on penetration performance, it would have been very useful in several areas:

- Difference in penetration performance between a perfect cone versus real life profile (oblong profile not perfectly conical)
- Practical limits to optimal taper ratio due to column strength failure of the tip
- Difference in penetration performance between a conventional curvature versus a reverse curvature
- Cross-sectional geometry for optimal penetration performance (this includes number of edges, edge angle, edge length)
- Simulation of penetration testing in various characteristics of test media

5. Understand and simplify manufacturing processes

First step is to identify process parameters (control knobs on machine, materials, supplies, etc.) that influence the outcome of the manufactured product. Next, experiment with process parameters to gain understanding of the sensitivities and limitations of the process on producing the desired product.

An illustration of this step is the current practice of using two different acids to achieve matte and shiny devices. Experiments confirm that both matte and shiny surface on the
devices can be achieved using the same acid by varying process settings at the polishing process. The benefit of using only one acid is that the plant can stop carrying the other acid, thereby reducing supply inventory, total number of supplies, and associated overhead in terms of hazardous materials handling and documentation. Which acid to eliminate can be determined using factors such as cost, cycle time, and environmental and safety concerns.

6. Establish relationship between product attributes and manufacturing processes

This step answers the question, "how are the manufacturing processes affected by changes in product attributes?" Coming up with relationships between product attributes and processes require empirical (process history) data and process knowledge. These empirical relationships should reflect learning over time as well.

7. Use tools to estimate costs

Tools, such as one developed here, provide some quantitative indications of costs. Even if the costs are not exact, the rough estimates can provide insight on product and manufacturing process decisions. Major features of the prototype developed here include:

- Costs determined at each of the process step, before being summed up to get total cost
- Enable what-if analysis on process improvements and changes in operating conditions (e.g., wage increase)
- Enable comparison of alternative process flows
- Incorporate activity based costing method for manufacturing support costs

8. Use quantitative information along with strategic issues to assist in product design decisions

The product and manufacturing process technology and strategy should be aligned with the competitive strategy. After obtaining some quantitative information regarding performance and cost of a product, an organization must determine whether the
improvements in design and/or process technology support the strategy. A new product/process technology may be thought of in terms of whether it supports product differentiation, low cost, or segmentation of the market.
References


