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SURGICAL GOWN REQUIREMENTS CAPTURE:
A Design Analysis Case Study

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ABSTRACT

Design is a process best undertaken through an organized effort and a problem solving approach. Understanding the complex set of requirements that must be addressed by a successful new product, be they end user, legal, financial or other requirements, demands extensive research. Design analysis is a major thrust of the research. This paper presents a method for the existing product design analysis component of the functional design process utilizing a case study of surgical gowns.

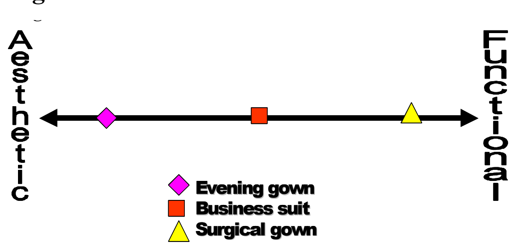
KEYWORDS: Surgical gown, functional design, design process, medical textile

INTRODUCTION

Successful creation of functional apparel products requires a disciplined, structured approach to design and development. An effective, integrated approach progresses through investigation of the design problem, delineation of design requirements and critical analysis of those requirements before arriving at a design solution. This is best accomplished through four major thrusts. The first two, materials analysis and design analysis, initiate the process in a manner consistent with that described by Watkins (1995). The latter two thrusts, design development and evaluation, move in the direction of the design solution. This paper will focus on the design analysis component of the functional design process using a surgical gown case study to illustrate.

It seems appropriate to preface discussion of design analysis with a clarification of the term "functional apparel". All apparel items must meet minimal functional requirements including being supported by the body and allowing some degree of body movement. Likewise, all apparel products meet at least a minimal range of aesthetic requirements such as color and texture. Therefore, it is helpful to envision apparel products as existing at some point along an aesthetic to functional continuum (Figure 1) where the location along the continuum reflects the balance of requirements. Examples of three

Figure 1: Aesthetic - Functional Continuum



common products clarify the continuum. Note that those items considered to be functional apparel, such as a surgical gown, have requirements dominated by performance needs and are located near the functional end of the continuum.

FUNCTIONAL APPAREL

Creating a functional apparel product that addresses all relevant requirements is a complicated undertaking that necessitates objectifying the design process (Orlando, 1979). Orlando's process was also utilized successfully by Tan, Crown and Capjack (1998) in developing functional apparel. A similar process was described by Rosenblad-Wallin (1985). Watkins (1995) described the stages in a functional design process a little differently. Unlike the other methods, Watkins' approach emphasized analysis as the initial stage of the design process. Initiating the design process via analysis allows for effective requirements capture and comprehensive understanding of the design problem, in turn providing a strong foundation for functional apparel design.

THE CASE OF SURGICAL GOWNS

MEDICAL TEXTILES

In August 2001, it was estimated that sales of medical textiles equaled approximately seven billion dollars (Lickfield, 2001). The market has gotten its biggest boost from advancements in nonwovens. Kimberly-Clark has leveraged their nonwoven technologies, such as Spunbond Meltblown Spunbond technology, capture 30% of the market in 2001. Du Pont holds the second position with its Sontara non-bond spunlace nonwoven composed of short staple fibers (Lickfield, 2001). Even so, sales of medical textiles are not meeting market potential (Table 1). This represents an opportunity for new medical textile products.

Table 1: Medical Textile Market

	Potential Market	**Actual Market**
North America	$3.4 Billion	$1.3 Billion
Europe	$3.9 Billion	$1.3 Billion
3rd World	$3.9 Billion	$ 260 Million

SURGICAL GOWN BACKGROUND

In the early 1900s the first surgical gowns were introduced as 2 sterilized pieces of lightweight fabric (Belkin, 1998). These garments reached the floor and had elbow length sleeves. They were worn with neither gloves nor masks. In the 1920s, gowns began to be constructed of muslin, which was viewed as a barrier material. In 1939, concerns were raised about the evident fluid penetration with muslin. So, rubber was applied to increase the barrier and sleeves were extended to ¾ length. Although protective, such gowns were considered uncomfortable (Belkin, 1993).

Figure 2: Modern Surgical Apparel

During the 1950's, not only were surgical gown fabrications evaluated, new designs were explored. The notion that patients were a threat to surgeons, along with development of innovative fabrics, drove evolution in gown design. Nonwovens were introduced in different grades and weights leading to development of a range of gown types for different levels of protection (Lickfield, 2001). Today, different gowns are designed to handle different surgeries. The cost of gowns varies with the amount of protection afforded. To perform a surgery with several risks and a high blood count, a higher barrier, and frequently reusable, gown will be chosen. For less risky surgeries, a lower barrier disposable gown is used (Stanley, 1994). Disposable gowns offer benefits in that hospitals can dispose of the contaminated textiles quickly, they reduce laundry costs, and they can be donned and doffed quickly in locations such as Emergency Rooms (Lickfield, 2001). Nonwoven disposables are not as heavy as reusables, and are in turn cooler (Stanley, 1994).

In 1991, the Occupational Safety & Health Administration (OSHA) implemented the Final Rule requiring that all health care workers be protected from blood born pathogens at the expense of the medical facility (Lickfield, 2001). Though protection is of critical importance, surgeons are still unwilling to sacrifice comfort and fit (Belkin, 1993; Stanley, 1994). Gowns of proper fit more effectively repel dangerous infections and fluids providing improved protection for both medical personnel and the patient (Stanley, 1994).

PERFORMANCE REQUIREMENTS

Surgical gowns are worn by doctors and nurses in the operating theater to address a dual function of preventing transfer of microorganisms and body fluids from the operating staff to the patient, and also from patient to staff (Slater, 1998). Many of the performance requirements for surgical gowns are well documented.

Surgical gowns must repel diseases and infections yet provide adequate freedom to move. They must allow necessary mobility without rubbing and chafing, and must resist tearing and linting. They must fit closely but not restrict movement. Since there is generally excess fabric, the gowns must withstand constant pulls on the fabric during routine movements. These gowns must be designed to fit a diversity of body shapes and sizes with a limited range of sizes as hospitals will only stock limited quantities (du Pont, 2001). The gowns must control the bacteria released into the theater and aid in maintaining the sterile zone required for patient safety. They must provide for easy donning and doffing without contamination, yet not have openings where the barrier might be breached. Gowns must be durable enough to last the intended useful life of the garment, be that single or multi-use. They should repel fluids but ventilate the surgeons extreme body heat (Belkin, 1993). And all of this must be accomplished in a cost-effective manner (Love, 1987; Slater, 1998; Zerrath, 1987).

Since 2/3 of the production cost for surgical gowns is in the fabric, effective fabric utilization is essential. And, like other apparel segments, garment production costs must be carefully controlled.

DESIGN ANALYSIS

Design analysis involves study of the end use, and of existing products. Although the literature clarifies many of the performance requirements, the strengths and limitations of existing products must also be understood in order to create superior, or even revolutionary, new products. Design analysis provides an understanding of existing products. Four strategies are employed in analyzing existing garment designs: structural analysis, sizing analysis, fabric utilization assessment and fit evaluation.

Design analysis included thirteen disposable gowns and two reusable gowns (Figure 3). The reusable gowns were included to gain a more complete understanding of the products on the market. In general these gowns are constructed of heavier, more impermeable materials. The lack of permeability and ventilation tends to create a warmer microclimate within the gown than that associated with disposable gowns. Table 2 lists the gowns included in the analysis.

STRUCTURAL ANALYSIS

Structural analysis is undertaken to assess the design features of existing products and to characterize the market. For surgical gowns, comfort issues related to product design were of particular concern as comfort is a critical product requirement. Although comfort is somewhat dependent on the permeability and flexibility of the fabric, there is a design influence (T-PACC, 1997).

Figure 3:Compel (left) and Gore-Tex (right) reusable gowns

General construction

Most of the gowns examined were constructed from 3 to 5 major pieces. Although many of the gowns had no seams at the side, they had front and back panels defined clearly by the sleeve placement. The fronts of the gowns were continuous with no seams or breaks in the fabric surface. This is extremely important as the front of the torso is a critical area for barrier performance (Lickfield, 2001).

Table 2. Gowns Used in Analysis

Manuf.	Composition	Uses
Johnson & Johnson	HDPE	Disposable
Kimberly-Clark	SMS	Disposable
Kimberly-Clark	SMS	Disposable
Kimberly-Clark	SMS	Disposable
Kimberly-Clark	SMS w/ film	Disposable
Kimberly-Clark	Film reinforced SMS	Disposable
Allegiance	woodpulp/ polyester spunlace	Disposable
Allegiance	woodpulp/ polyester spunlace	Disposable
Allegiance	woodpulp/ polyester spunlace	Disposable
Allegiance	woodpulp/ polyester spunlace	Disposable
Allegiance Converter	SMS polypropylene	Disposable
Kimberly-Clark	spunbonded polypropylene	Disposable
Compel	100% polyester multifilaments	Reusable
Gore-Tex	100% polyester with Gore	Reusable
Allegiance	Breathable Impervious	Disposable

The back was composed of two overlapping panels providing access for donning and doffing. Ties, used in various locations to secure the gowns, were typically nonwoven strips similar to the material used to construct the gown.

Though most gowns featured straight hems, the back panels of one Kimberly-Clark gown angled upward from each side. This feature was designed to provide improved heat release and ventilation for the surgeons and nurses.

Figure 4: MicroCool Specialty Gown

Most of the gowns were partially assembled using traditional stitches and seams, commonly a 401 double thread chain stitch with a simple superimposed seam. Exceptions to this generalization included an Allegiance gown and the Compel reusable gown that were assembled using a lapped seam structure and two parallel rows of 401 stitching. A large stitch length was used to minimize puncturing of the fabric and limit interference with the barrier performance. Sleeve seams, critical zones for barrier performance, were typically fused. For improved barrier performance at the seams, one Kimberly-Clark gown was entirely fused at the seams.

Closures

To close the body of the gowns, mechanisms were attached to the right and left back panels. The right back panel had an internal tie attached approximately 20” down from the shoulder. It also had an external tie attached about 20” from center back. The corresponding tie was on the front panel, located about 20” from the shoulder. Several of the gowns had a fused reinforcing tape placed over the location where the exterior tie was stitched onto the front panel for added strength and to restore the compromised barrier. The left back panel had a tie located on the outside usually about 20” below the back neck in the center back.

The necklines of the gowns were closed in a variety of ways, all providing some adjustability for fit. Snaps provided one means of closing the gown neckline. The right back panel contained two male snap components. The female components were found near the neckline of the left back panel. Snap components were arranged 1 – 1.5 inches apart to provide four adjustment choices and flexibility in the fit. Closer spacing of the snaps enables more accurate fitting of the neckline region. Snap neckline closures were found on several Kimberly-Clark gowns and also on the Compel reusable gown.

Figure 5: Snap closure

Hook and loop tape closures were also used to secure some of the sample gowns. The loop component of the tape was placed at the neckline of the left back panel. The corresponding hook component was found on the right back panel. The hook component is about 1.5” long, and the loop component 7” long providing great flexibility and accuracy in the neckline fit. This closure was found on the Allegiance samples. An alternative to the hook and loop tape, is an adhesive tape similar to that found on disposable diapers. On the right back panel, a tab of tape was attached. After the backing is removed, the tape can be affixed to any location on the left back neckline. Tape closures were used on a Johnson & Johnson gown, and a Kimberly-Clark gown. Hook and loop closures and tape closures provide great ease, accuracy and flexibility in fit, but often elicit complaints from surgical personal due to easy entanglement of hair in the closure.

Figure 6: Hook and loop closure

Figure 7: Tie closure

Closures featuring a pair of ties may be used to secure neckline, as in the Gore-Tex reusable gown. The right back panel includes a tie at the neckline edge and another inside the neckline near the shoulder. The corresponding ties are located outside of the left back panel near the shoulder and at the edge, respectively.

Sleeves/cuffs

A majority of the sleeves on the gowns were a raglan style. Although this style is often perceived to provide superior ease of movement, it can provide so much bulk and excess fabric that comfortable movement is inhibited. Two Kimberly Clark gowns had set in sleeves, limiting excess fabric in the shoulder and upper chest area. Excess fabric in this area, as well as excess sleeve length and width, inhibits mobility in reaching, especially reaching over an obstacle, such as a patient in surgery.

The sleeve edges were contained with a cuff stitched on at the wrist. In use, surgical gloves are worn pulled up over the cuffs, so it is important for the cuffs to fit snugly. All of the gowns except one from Kimberly Clark used a rib knit cuff. The Kimberly Clark gown used a band of rubber attached to the outside of the sleeve at the wrist. The sleeve is pleated before fusing on the band creating folds rather than the more bulky gathers.

SIZING ANALYSIS

The designs of disposable gowns allow them to accommodate several body types and sizes, but they are generally too big. Additionally, medical institutions tend to order L-2XL sizes for the whole staff (du Pont, 2002). Reusable gowns have a fit that is more true to size with easier to adjust necklines and closer fit in the torso.

Measurements were taken on the surgical gowns to form a sizing analysis. Not all gowns utilize the same sizing system, so the size most commonly stocked by hospitals was used. Prior to completing measurements, the gowns were tied closed, and were then laid flat on a table. Measurements were taken at:

- Front Panel,
- Back Panels,
- Sleeves,
- Cuffs,
- Tying Closures,
- Circumferences

A database was created to facilitate later analysis of the gown measurements. Table 3 summarizes the largest, the smallest, and average measurements among the gowns.

MATERIAL UTILIZATION ANALYSIS

As mentioned previously, material cost can be 2/3 of the total cost of manufacturing a gown (du Pont, 2002). A material utilization analysis was performed to determine the amount of fabric needed to cut the components of each gown. Unlike woven or knitted fabrics, the nonwoven materials used in disposable gowns can be ordered from the vendor in any desired width. Gown manufacturers often order two different fabric widths, one for the sleeves and one for the body of the gown, in order to minimize fabric waste. Hence, utilization is commonly expressed in square yards for comparison.

To conduct the analysis, all of the disposable gowns were taken apart at the seams and the pieces laid out, gown by gown, on a table. The fabric requirement for each gown was determined and stored in a database. The fabric requirements ranged from 2.53 to 5.66 square yards and averaged 3.12 square yards. Most of the gowns also required an average of 30 inches of a 2.5to 3.5 inch wide tubular rib knit for the cuffs.

Table 3: Selected gown dimensions

	Location	**Smallest Measurements Inches**	**Largest Measurements Inches**	**Average Measurements Inches**
Sleeve Width	Biceps	9.5	10	9.75
Cuff	Length	3	3.25	3.13
	Width	2	3	2.50
Sleeve Length	Neckline to Cuff	30	36.5	32.80
	Underarm to Cuff	20.25	25	22.63
Front Panel	Length	41.5	54.5	48.00
	Side Seam to Side Seam	22.25	48	35.13
	Side Seam Length	36	43.25	39.63
Circumference	Total Bottom	60.75	69	64.88
	Back Right Panel Bottom	15.5	25	20.25
	Back Left Panel Bottom	13.75	18	15.88
Center Back	Length	20.5	53	36.75
Right Back	Underarm Width	15.5	22.5	19.00
	Inside Tie Length From Shoulder	17	20	18.50
	Inside Tie Diagonal From Underarm	18	9	13.50
	Outside Tie Length from Neck	17.25	21	19.13
Left Back	Underarm Width	13.5	16.5	15.00

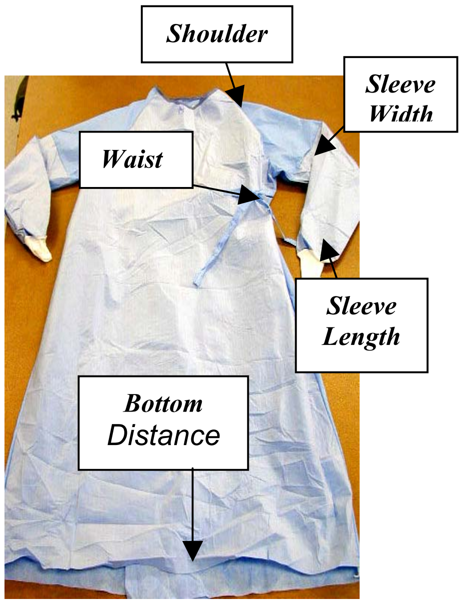
FIT ANALYSIS TESTING

To evaluate the fit of the gowns, an analysis strategy was devised. For the evaluation, participants tried on each of the 15 gowns and both objective and subjective measures of fit were obtained. Selected physical measurements provided an objective measure of fit. Evaluations completed by participants provided subjective measures of fit. For each gown, participants evaluated the fit first while standing in a relaxed posture, and then following performance of a minimal range of motions that mimicked those of operating room personnel.

Physical measurements

Participants were assisted in donning and closing each gown properly prior to evaluation. Then, to provide an objective appraisal of fit, excess fabric was measured and recorded using a measuring tape.

Figure 8: Measurement location



Measurements included (Figure 8):

- Excess sleeve length and width
- Distance between the gown and the floor with arms at side and with arms raised
- Excess fabric in the shoulder area
- Excess fabric at the waist

Subjective evaluation

Evaluation instruments were developed based on past research (T-PACC, 1999) and literature review. Videotapes of medical procedures were also used to determine an appropriate range of motions to include in the evaluation. Movements by medical personnel are not permitted to extend beyond a limited sterile zone during surgery. So, selected activities included a limited range of motions expected during surgery or in moving from a dressing area into the operating theater. The activities were performed while attired in each gown. A pilot test was used to fine-tune each activity and to determine the time required to complete the procedure. Activities included walking, a series of arm movements and reaches, and two bending/stretching motions.

Two evaluation instruments were used to record participants' evaluations. Each gown required completion of a separate set of instruments. Instrument I consisted of general questions. The questions related to the comfort, fit, and restriction level of the gowns. This instrument was filled out three times for each gown, first for rating period one (standing), then for rating period two (activities), and finally subjects provided an overall rating. Figure 9 is the item from Instrument I that was used for rating gown restrictiveness. Similar items were provided for rating fit and comfort.

Comments:

Instrument II was designed to obtain detailed information on gown fit (Figure 10). For each gown, the subjects filled out the instrument for rating period one (standing) and again for rating period two (activities). Five choices of terms were available to describe how the garment felt for each time period. For comparison, averages were determined for each rating on each item.

CONCLUSION

The data accumulated in the design analysis of existing products provides a firm foundation for undertaking product redesign. The next step in the design process is to examine the data for relationships between structure, measurements, and fit evaluations. Each learning from the analysis helps to define product requirements and informs the design and development process.

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Figure 9: Gown Restrictiveness Rating Item from Rating Instrument I

RATING PERIOD	1	2	Overall
RATING			

1. Very Restrictive
2. Restrictive
3. Slightly restrictive
4. Neither restrictive/giving
5. Slightly giving
6. Giving
7. Very giving

Figure 10: Gown Rating Instrument II

	Totally	Mostly	Mildly	Partially	Not at all
1. Stiff gown (no drape)					
2. Loose neckline					
3. Tight neck (cuts throat)					
4. Tight at top shoulder					
5. Tight armhole					
6. Sleeve is too long					
7. Sleeve is too short					
8. Tight sleeve cuff					
9. Bulky bunched material					
10. No stretch					
11. Long: pulls in the front					
12. Nonconforming					

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