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FOR
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ENTER INFORMATION ONLY IF NOT INCLUDED ON COVER OR TITLE PAGE OF DOCUMENT

1. Project/Subproject Number
9363041

2. Contract/Grant Number
DPE-CA-4047-00

3. Publication Date
1990

4. Document Title/Translated Title
Condoms: Overview of Technology, Materials, and Development

5. Author(s)
1. AC Tanquary
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6. Contributing Organization(s)
Family Health International

7. Pagination
16 pages

8. Report Number
90-06

9. Sponsoring A.I.D. Office
POPULATION

10. Abstract (optional - 250 word limit)

11. Subject Keywords (optional)
1. condoms
2. design
3. materials
4. new development
5.
6.

12. Supplementary Notes

13. Submitting Official
Debbie Wade

14. Telephone Number
919/544-7040, ext 247

15. Today's Date
July 30, 1990

DO NOT write below this line

16. DOCID

17. Document Disposition
DOCRD [] INV [] DUPLICATE []

AID 590-7 (10/88)

PN-ABG-096

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Condoms: Overview of Technology, Materials, and Development

A. Charles Tanquary and Julie Hull Witte

Better condoms have been needed since the first products appeared several thousand years ago. A major technological advance occurred in the mid-1800s, when crepe rubber condoms were developed soon after vulcanization was discovered. In further advances 60 years ago, latex was substituted for crepe, and mechanized dipping was introduced [1,2]. Although the industry has considerably improved quality and reliability in recent decades, improvements are still needed, especially since condoms are the first line of defense against acquired immune deficiency syndrome (AIDS).

Condoms should be free of defects, stable during storage and use, easy to use, comfortable, safe, and effective. Condoms also should resist deterioration on exposure to sunlight, ultraviolet light, atmospheric pollutants, and lubricating oils. To the extent possible, condoms should enhance sexual pleasure, or at least detract little from sensation.

Where needs are not fully met by commercial products, or where use is low and potential consumption is high, opportunities exist for introducing new and better products that are manufactured at lower costs or are sold at higher prices. Since present condom manufacturing processes are capital-, energy-, and labor-intensive, the best route to new products is through the application of technologies now foreign to this industry.

Historically, mature industries such as the condom industry are wedded to raw materials and processes and do little to create their own obsolescence. Condom manufacturers are expected to resist

Heterosexual Transmission of AIDS, pages 339–354
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change for many reasons. One is the perception that the present products are unique and can never be matched by alternative means. Another is that the market has scarcely been tapped, and shortages are projected. A third is the increasing concern about product liability actions. In a litigious society, continuing with an old line of products whose deficiencies are well known to the public is safer than embarking on something new that may create unrealistic expectations of safety and efficacy. Major changes in concepts and practices are likely to originate outside the condom industry or at its fringes. Indeed, a number of new condom products, most of which originated elsewhere, are at various stages of development.

HISTORICAL BACKGROUND

Innovators will find the past instructive for assessing the present state of the art and predicting trends. Figure 1 depicts some milestones in the history of condoms. Condoms may have been used in

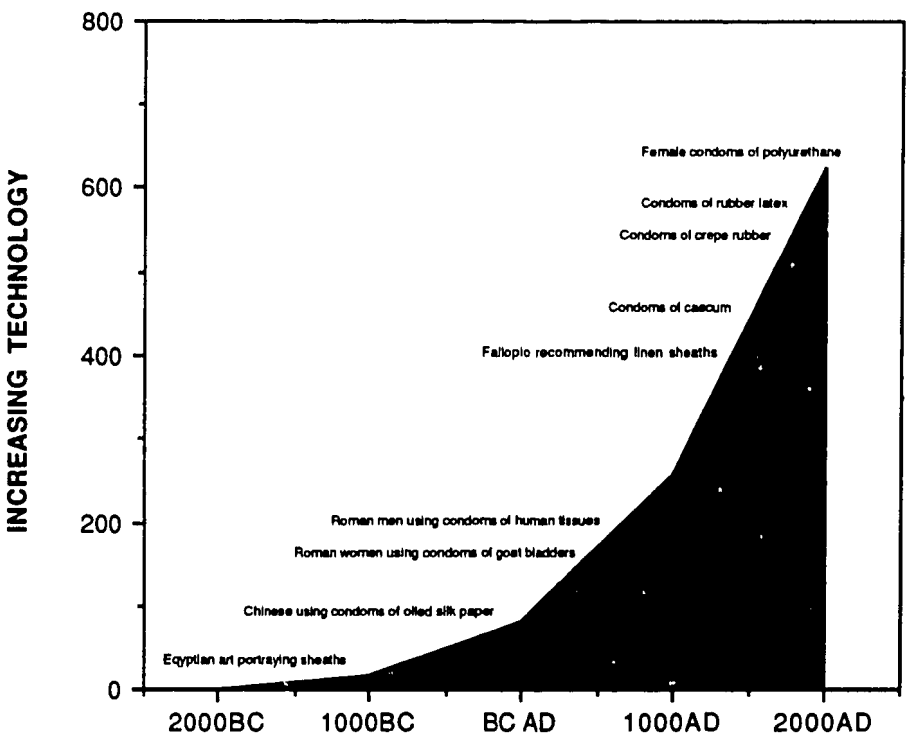

Fig. 1. History of the technology of condoms.

Egypt as early as 3000 years ago. Egyptian art of the time portrayed men wearing sheaths [3,4], but the purpose served by the sheaths is not clear. That the sheaths were dyed various colors to denote social status suggests adornment rather than function [5].

Three thousand years ago, the Chinese made condoms using oiled silk paper according to their ancient medical treatises [4]. Both Greek and Roman mythologies include tales of gods and mortals using condoms of goat bladders to protect women. These condoms probably were worn by women, since the Romans prescribed the use of goat bladder for forming a pouch that was placed in the vagina to receive the penis and trap semen [4,5]. In recent times, a primitive New Guinea tribe was found to be using a large, flexible plant pod as a female condom. This pod was cut off at one end to form a long pouch [5].

In the 1500s, Fallopius described a linen sheath that was intended to prevent syphilis. By the 1700s, the only material commonly used for condoms was derived from animal intestines [3]. Although ox caecum was used at first, lamb caecum soon predominated because of its greater softness. The advent of natural rubber condoms a century later did not totally displace these "natural skin" products.

Shortages of natural rubber during the early 1940s led to the use of nylon as a replacement, but the products were unacceptable. Other efforts in the 1960s to develop condoms from alternative materials, including films of ethylene copolymers, were unsuccessful. A polyurethane condom made by dipping was promising, except for its high cost [6].

PRESENT COMMERCIAL PRODUCTS

It is not surprising that condoms have been made of animal membranes for thousands of years, since these materials had long been used as containers for various purposes. What is surprising is that the natural condom made of caecum remains a viable commercial product, retaining up to 5% of the market, even at premium prices. Most users choose them because of their combination of comfort and increased sensation. These qualities are believed to derive from the higher heat transmission and the exchange of fluids during intercourse. One patent, a decade ago, suggested perforating rubber condoms with arrays of 2 μm holes, sufficient to permit fluid exchange while retaining sperm. This product obviously was not intended for prophylaxis. Other patents have described the use of collagen and other hydrogels for improved heat transmission. The use of hydro-

TABLE 1. Comparison of Commercial Products

	Natural rubber	Natural skin
Source	Latex of tree	Caecum of sheep
Chemical composition	Polyisoprene	Proteinaceous membrane
Polymer class	Hydrocarbon elastomer	Hydrogel
Mechanical properties	High strength	Low strength
	High elongation	Low elongation
	Low modulus	High modulus
	High toughness	Low toughness
	High tear resistance	Moderate tear resistance
	High puncture resistance	Good puncture resistance
Mechanical behavior	Elastic	Limp
Size	49–52 mm	62–80 mm
Fit	Tight fitting	Loose fitting
Permeability	Impermeable to sperm	Impermeable to sperm
	Impermeable to viruses	Permeable to HIV

gels has been proposed as a route to superior condoms that possess some of the qualities of natural skin [6].

The existence of dissimilar products that serve the same market demands attention. Analyses of their relative merits may suggest ways to combine their best qualities in new products. A comparison of natural rubber and natural skin condoms follows, and the large differences between them are shown in Table 1.

Natural rubber is hydrophobic, a hydrocarbon, whereas natural skin is hydrophilic, a hydrogel. Their mechanical properties appear to be totally different, except for resistance to puncture and tear. Table 2 lists typical values of tensile and tear properties and contrasts the rubbery behavior of natural rubber with the leathery behavior of natural skin. These values are normalized to unit thickness and cross-sectional area. The wall thickness of the skin condom is 150 μm, three times the thickness of the rubber condom. Figure 2, which is a graph of tensile force vs. strain, shows that the breaking forces are approximately the same due to the differences in thickness (Russell DD, personal communication), but the force required to stretch the natural skin condom is 20 times that for rubber. This means that a natural skin condom stretches hardly at all. Therefore, different widths must be available to allow for the lack of stretching.

Figure 3, which is derived from data from the Kinsey study [4],

TABLE 2. Tensile and Tear Properties of Commercial Products (Russell DD, personal communication)

	Tensile strength psi (MPa)	Elongation at break (%)	Stress at 20% strain psi (MPa)	Tear strength pli (kN/m)
Natural rubber latex	3,300 (22.8)	710	35 (0.24)	287 (50.2)
Natural skin, wet	970 (6.7)	25	205 (1.41)	166 (29.1)
Natural skin, dry	1,450 (10.0)	26	1,080 (7.44)	233 (40.8)

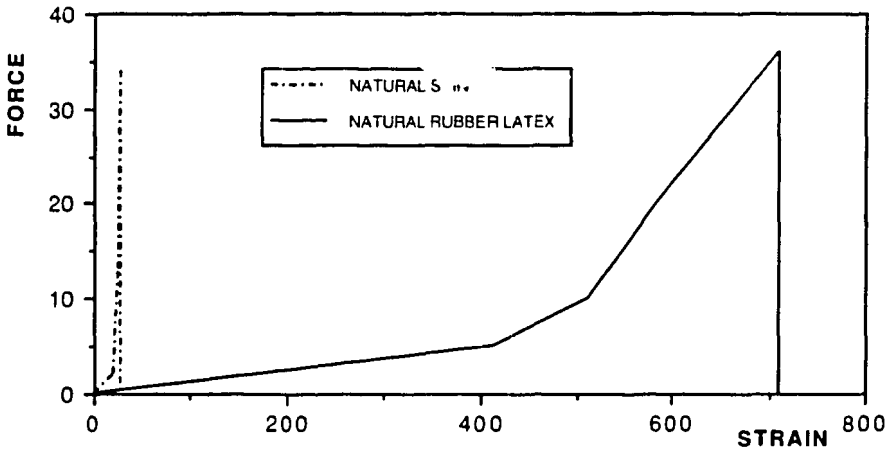

Fig. 2. Force vs. strain for commercial condom products.

shows the distribution of penis circumference for white U.S. males. Natural skin condoms range in size from 62 to 80 mm in layflat width (124–160 mm in circumference). Therefore, a 62 mm condom is large enough to fit 70% of this population, and an 80 mm condom fits 100%. A 52 mm rubber condom must stretch 20–50% to cover the same range. A rubber condom is held in place by the retractive forces of the condom itself, while a skin condom is held by an elastic band at the open end.

This comparison leads to the conclusion that the properties of a synthetic material need not match those of natural rubber for the synthetic material to merit consideration. The latitude permitted depends on other factors, including whether the condom is designed for a man or a woman. Therefore, a wide range of materials can be considered and choices made using the criteria of process cost, raw materials cost, and product quality and performance.

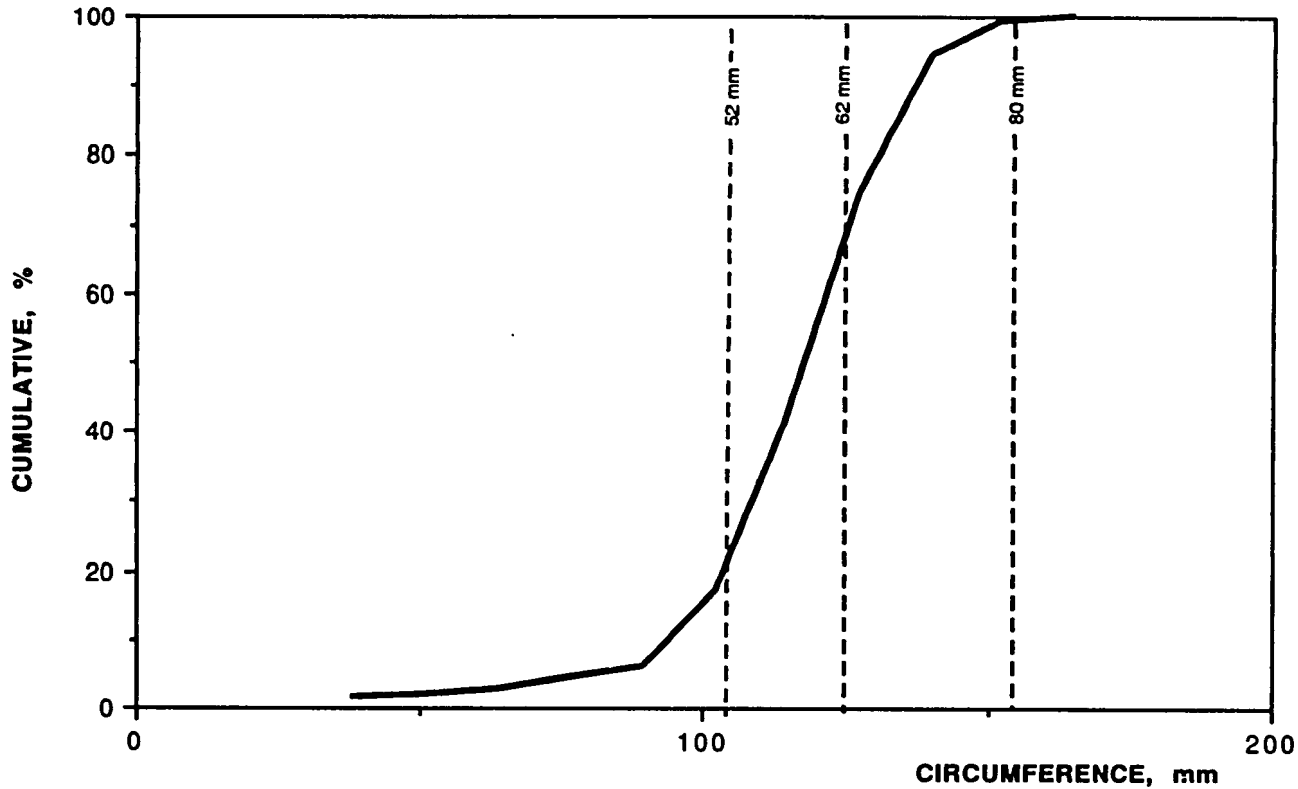

Fig. 3. Erect penis circumferences of U.S. white males [4], with vertical lines showing the sizes of commercial condom products: Rubber latex, 52 mm (104 mm circumference); and natural skin 62 and 80 mm (124 and 160 mm).

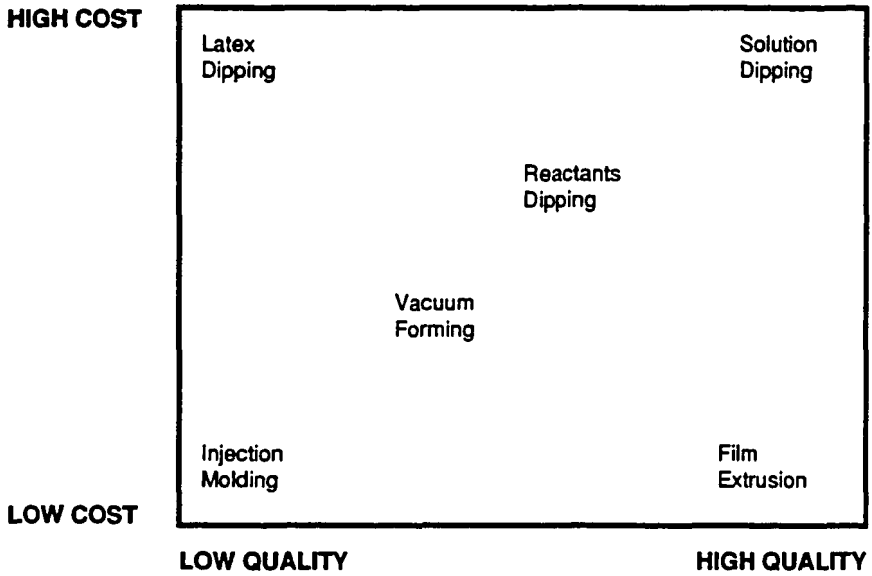

Fig. 4. Process cost vs. product quality.

SELECTION OF PROCESSES

Figure 4 shows some processes that have been used for condom manufacture. Injection blow molding, the process commonly used for making bottles, was proposed many years ago, and equipment was promoted for this purpose, but the products were crude. Thin, uniform walls were difficult to achieve. Vacuum forming requires the extrusion of a thick film, or billet, and then the deep drawing of the material into a cavity. This process is being explored in Europe as a way to make a female condom. The use of reactive prepolymers to form polyurethanes is the basis of a number of patents, and one product appears to be on the verge of being introduced. The problem here is the necessity to remove extractables to avoid toxicity.

Solution dipping (tried in the 1960s) resulted in high costs, because most effective solvents for polyurethane are toxic and carcinogenic and must be removed by heating and washing processes. Adding further to the cost is the necessity of removing these pollutants from air and water effluents. This process, nevertheless, is feasible and should prove attractive for premium products that are likely to appear soon, according to industry sources.

Film extrusion appears to offer the best properties at the lowest cost. The failures to achieve satisfactory products in the 1960s were due mostly to the lack of appropriate raw materials. Today, the ther-

mopiastic elastomers (TPEs) that are available can be extruded into film and fabricated into shapes by heat sealing, welding, and other processes common in the plastics industry.

SELECTION OF MATERIALS

The major classes of TPEs are ranked by performance and cost in Figure 5 and compared in Table 3 [7]. The cost refers to raw materials only and does not include potential savings in process costs. The best performance is obtained from the polyamides, polyesters, and polyurethanes.

The cheaper materials are notably deficient in strength, tear resistance, and resistance to oils [8]. Resistance to oils is an important criterion in view of the catastrophic deterioration of natural rubber on exposure to many common household lubricants [9]. Although offering advantages in many industrial applications, the polyamides and polyesters appear to be poorly suited to condoms, since they are hard materials, intermediate between rubber and plastics. The thermoplastic polyurethanes (TPUs) offer the best combination of properties, and both the polyester- and the polyether-based materials have been used extensively for biomedical purposes [8,10]. Of the

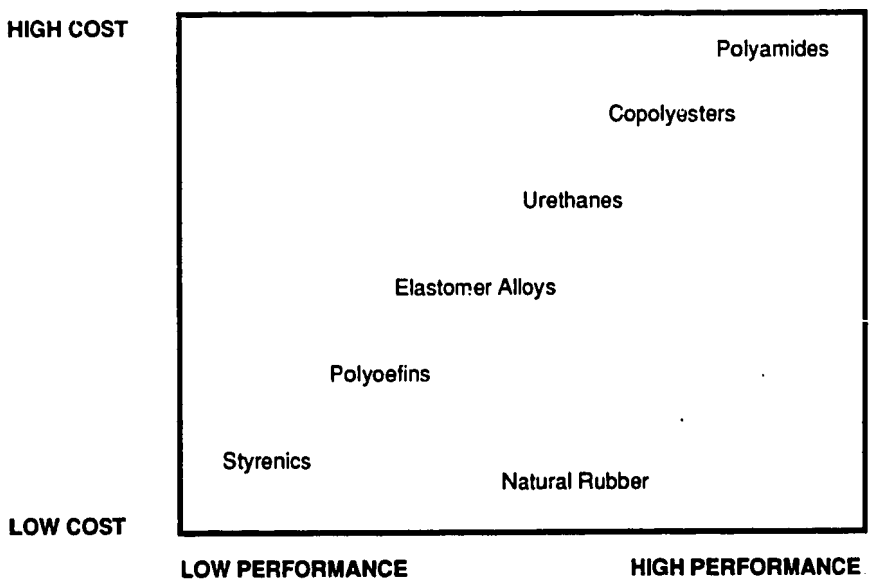

Fig. 5. Materials cost vs. performance of thermoplastic elastomers.

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TABLE 3. Characteristics of Thermoplastic Elastomers

	Retention of properties on exposure to								
TPE class	Oils	Water	Oxygen	Ozone	Light	Softness	Tear strength	Tensile strength	Implant studies
Styrenics	P[a]	E	P	P	P	E	P	F	Few
Polyolefins	P	E	P	P	P	G	F	P	Few
Elastomer alloys	P	E	P	P	P	E	P	P	Few
Polyester urethanes	E	P	E	E	E	G	E	E	Numerous
Polyether urethanes	G	G	G	G	F	G	E	E	Numerous
Copolyesters	E	P	G	G	P	P	F	G	Few
Polyamides	E	E	G	G	E	P	G	G	Few
Natural rubber[b]	P	G	P	P	P	E	F	G	Numerous

[a]Scale: E, excellent; G, good; F, fair; P, poor.
[b]Control.

two, the polyether-based material is superior because of its hydrolytic stability.

Two biomedical TPUs are compared with natural rubber in Table 4. Since each is twice as strong as rubber, film half as thick could be used to provide the same breaking force. Figure 6 shows the stress-strain behavior at low extensions, in the range of interest for most condom products. The top two curves are for the same material, first as produced by the extrusion process, and then as changed by stress-softening. Stress-softening, also called the Mullins effect, is a well known phenomenon that occurs when thermoplastic elastomers are stretched [10,11] (Wheeler RG, personal communication). The hard segments are disrupted to create a fine-grained structure, which is more elastic. The result is a substantial drop in tensile modulus to values less than half that of the untreated material.

Similar decreases in modulus can occur when polyurethanes are plasticized, and two effective plasticizers are water and nonoxynol-9 (Russell DD, personal communication; Wheeler RG, personal communication). It should thus be possible to make TPU condoms that approach the modulus of rubber while retaining good strength and tear resistance. However, plasticizers are known to decrease resilience, which for the polyurethanes is already low. If the resilience becomes too low, the condom may fit snugly at first but become loose during intercourse due to the slow recovery from cycling

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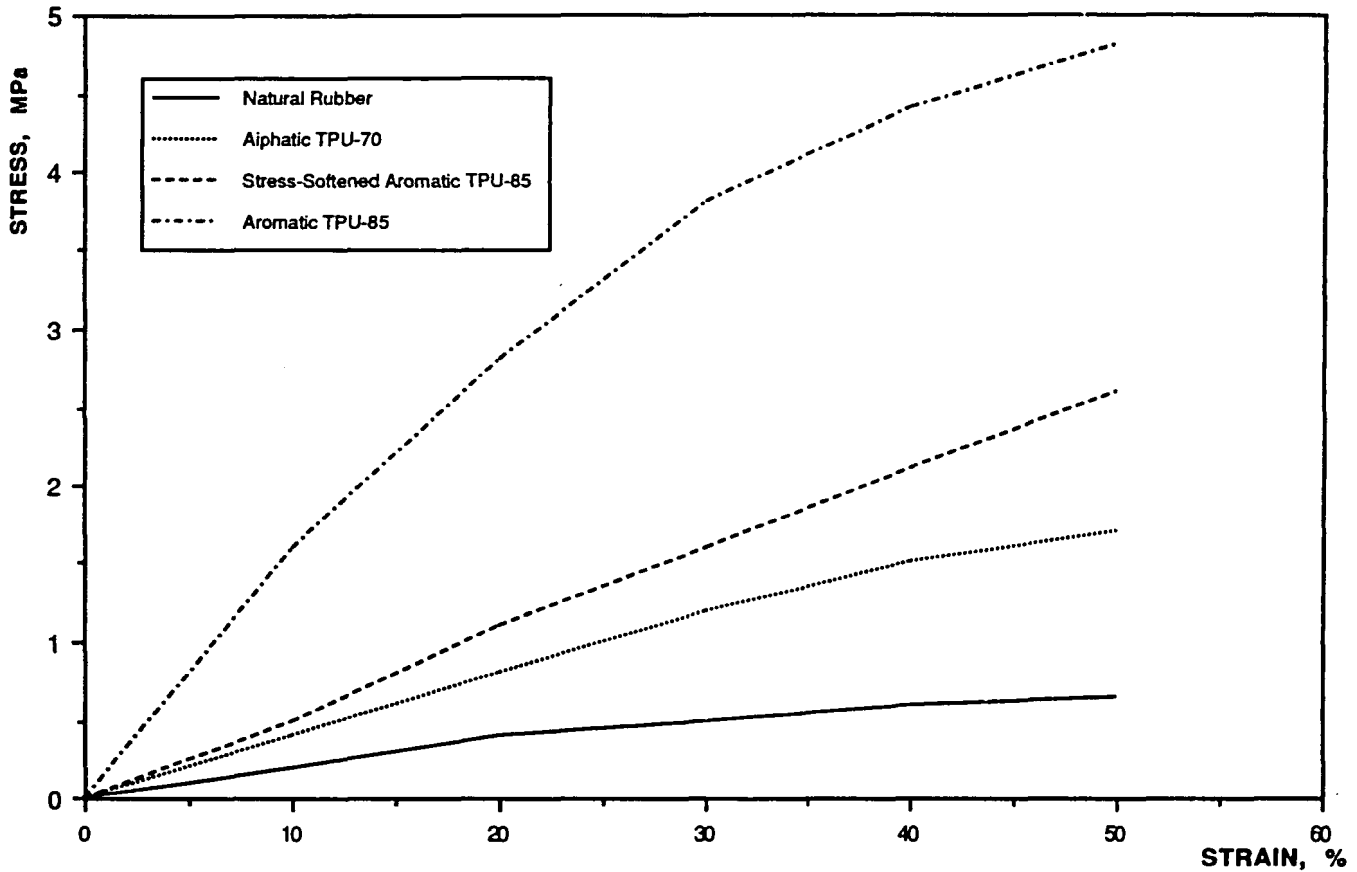
STRESS, MPa
STRAIN, %
Natural Rubber
Aiphatic TPU-70
Stress-Softened Aromatic TPU-85
Aromatic TPU-85
0
1
2
3
4
5
0
10
20
30
40
50
60

TABLE 4. Tensile and Tear Properties of Biomedical Polyether Thermoplastic Polyurethanes (TPUs) (Russell DD, personal communication)

TPU	Tensile strength psi (MPa)	Elongation at break (%)	Stress at 50% strain psi (MPa)	Tear strength pli (kN/m)
Aromatic (80A)	6,500 (45)	580	600 (4.1)	400 (70)
Aliphatic (70A)	7,200 (50)	460	245 (1.7)	410 (72)
Natural rubber[a]	3,300 (23)	710	100 (0.7)	290 (51)

[a]Control.

stresses. This engineering design problem can be solved in several ways, the simplest of which is to offer a range of sizes.

NEW PRODUCTS

Industry innovators are focusing on polyurethanes, especially the polyether-based polyurethanes, for condoms. Most condoms under development are being made of these materials. Wisconsin Pharmacal is introducing a female condom of a polyether-based TPU [12] (Fig. 7). The film is made of a biomedical material, Estane (from BF Goodrich), and the inner ring is fabricated from a harder TPU. Early versions of the condom had seams, which showed that the device had been made from film by heat sealing, but recent versions are seamless, perhaps through the use of vacuum forming. The narrowest portion of the condom, below the outer ring, is 80 mm in layflat width, which is the same as the largest natural skin condoms (Fig. 7). Thus it should be equally accommodating. This female condom has been tested extensively in Europe, where it is called the "Femshield," and it is being tested in the United States and elsewhere in preparation for approval for marketing. However, the National Women's Health Network (NWHN) is challenging the approval process, contending that any device bearing the name "condom" should be proved effective against STDs through trials of appropriate duration [13]. In its petition, the NWHN is questioning the approval of a female condom of natural rubber latex. The outcome may affect the introduction of other condoms that differ significantly in design from conventional rubber condoms.

Fig. 6. Stress-strain behavior of elastomers at low extensions.

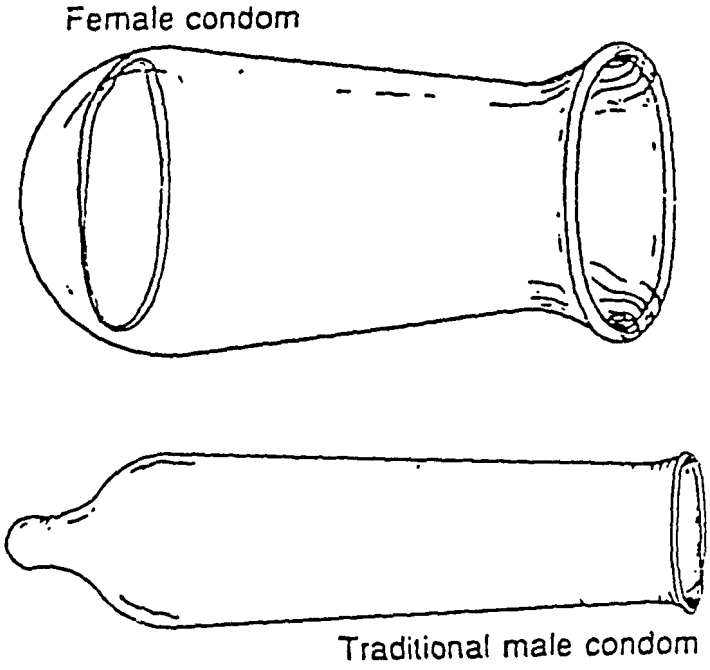

Fig. 7. Comparison of Wisconsin Pharmacal's female condom with typical male condom. (Courtesy of Margaret Pyke Centre, London.)

ACKNOWLEDGMENTS

This project was funded by Family Health International (FHI) under a Cooperative Agreement with the U.S. Agency for International Development. FHI is an international not-for-profit organization that conducts research and provides technical assistance in health, family planning, STDs, and AIDS. It is based in Research Triangle Park, North Carolina. The views expressed are solely those of the authors.

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DISCUSSION

DR. PHANUPHAK: Besides the physical specifications or physical testing of the condoms, do we know anything about acceptability by clients or by those who tested the condoms? For example, would the color or texture of the condom make a difference in terms of more people using it? We find that the acceptance of condoms depends a lot on the psychology of the one who uses it. Also, ethnic groups may have different reasons for not using condoms. For example, people in the Middle East were reluctant to use condoms.

We think about the males who will refuse to use them, but at the same time women are also sometimes reluctant to use them. For example, consider that when a man uses a condom, he will reach climax much slower than when not using a condom. So, the prostitute may favor not using condoms because she can then serve more clients. Also, some women complain that it hurts when men use condoms. Do we, then, know anything about the psychological and physical acceptance of condoms?

DR. TANQUARY: You have asked an excellent question. Not nearly enough is known. When I entered this field a brief time ago, I was expecting to find answers easily to many of these kinds of questions, but I find that very little work has been done in trying to assess what I would call consumer preference for various products.

We know that natural skin condoms, for example, appeal much more to men than to women. Women dislike the product because it is messy and smells bad, but men consider it comfortable. Also, some women prefer the rubber condom because they enjoy the sensation. So there are very definite differences and preferences. I do not think we are doing enough to enhance the sexual pleasure associated with condoms. If we could, we would make condoms addictive.

MR. SPIELER: In the table comparing cost and quality, you showed latex having the highest cost and the poorest quality. I can understand highest cost if you are looking at technologies that are less expensive than latex, but do you also think latex is the lowest quality, particularly in light of what Dr. Shelton said about how remarkable it is that latex condoms work so well, given all the adversities of clinical trials, etc.?

DR. TANQUARY: Yes, I think it is remarkable that they work so well. We have a project at Family Health International (FHI) assessing the quality of condoms in developing countries. We have looked extensively at natural rubber condoms, and I think they are excellent products overall. The problems come, as you know, in the peculiar circumstances of condom storage in the developing countries, where they are sometimes stored in hot conditions for several years. So, what we are really looking for in new materials is stability. When I talk about quality, I am really talking about a lot of things, but one important criterion, as far as I am concerned, is stability. The condom has to be stable under long-term storage.

MR. SPIELER: So the baseline for your table comparing cost and quality of different materials starts with the assumption that you want to develop a product of higher quality and lower cost than latex?

DR. TANQUARY: Yes. However, there is a reverse side to that coin, which we all should recognize. If we develop synthetic materials that last for years and years, that are very stable in storage, that are not attacked by ozone, sunlight, and so on, how are we going to get rid of them? We are very worried about that. Dr. Potts tells me that we have a more important problem to worry about, forget about the environmental contamination. I agree, but I still worry about billions of condoms that might be piled to the ceiling.

These new condoms also are heavier than water and do not readily float. So, we also have a problem of contaminating lakes and streams.

DR. RIETMEIJER: Some in vitro studies claimed to have evaluated synthetic membrane or synthetic skin condoms. Do you have any idea what these products might be?

DR. TANQUARY: In terms of a synthetic skin, it is very possible that they are referring to a hydrogel. I am not sure. I know that one material that has received very extensive examination is the Biomer material of Johnson & Johnson that has been made into condoms. Whether it is that to which they are referring I do not know.

DR. WILLIAMSON: I just wanted to respond to the question on acceptability. I agree that we need to know more about acceptability, and there is some research going on in that area. We at FHI have been doing research on the acceptability of spermicidally lubricated condoms. We did a study last year in five countries and found that condom users liked the spermicidally lubricated condoms. This was quite encouraging. Now we are doing a test of stronger latex condoms to see whether some people are willing to trade off a slightly thicker condom for greater strength, and that study is going to be done in three countries.

The point about acceptability is that a number of delivery systems and social marketing projects have shown that you can increase acceptability of condoms by offering a great variety in color and size, and so forth, with a good delivery system and good advertising.

Japan has had excellent success in packaging condoms and delivering good products with very widespread household distribution. So I think even the condoms we have could be delivered much, much better.

DR. ROSENFIELD: You mentioned the linen condoms of the Middle Ages. I have visions of a condom tailor. I wonder whether they got involved with measuring and such things? This leads me to a question.

At one point, in Thailand, Meachi's sister was a columnist, and she wrote a series of rather scathing articles against the U.S. Agency for International Development about the condoms being distributed, which the Thais were having to tie on with a string because they were too large. Do we decide the right sizes of condoms for distribution? Is one condom the right size for all people in mass distribution programs, or should there be further research in this area?

DR. TANQUARY: Well, there definitely are differences in sizes. The size that is used most frequently in Asia is 49 millimeters rather than 52, and there have been some complaints in North America,

Europe, and Africa about 52 millimeters being too small. There is one approach to finding the appropriate size, and that is a social marketer's task. Give several sizes to the salesmen and see which products they can sell. This is a very direct approach. However, it does not answer your question. I do not know what the sizing should be, but I think we should have a greater variety of sizes than we have now.