

Contents

Physical Basis for the Discussion..... 2

Condoms with non-cylindrical shape 5

Approaches to the problem..... 6

Studies involving different sizes of condom 7

Studies involving penis measurements 11

Flaccid penis size..... 11

Erect penis size..... 16

Non-quantitative reports 18

Market information..... 18

In-vivo data..... 21

Discussion 22

Conclusions..... 24

Introduction

The value of condoms in preventing STIs and unwanted pregnancies is widely recognised. But their effectiveness depends on a number of factors, of which the three most important are:

1. The condom should be used
2. The condom should not break
3. The condom should not slip off during use.

It is highly plausible that the risk of slippage and breakage depends on the relative size of the condom and the penis onto which it is put.

It is also clear that using condoms is a chore for many people, who would ideally prefer to have their sexual activities without condoms. It is therefore desirable to make them as easy and comfortable as possible to put on and to wear.

Natural rubber latex is the raw material for well over 99% of the condoms made today. Its elastic properties are ideally suited for the purpose, because it stretches so easily. For many years, manufacturers adopted a “one size fits all” policy, with all condoms in any one market being virtually the same size.

Experience gained by USAID in Thailand in the 1970s first illustrated to international donor agencies that the US-sized condoms were too big, and a smaller size was introduced. Subsequently, international standards were modified to allow a wider range of condom sizes.

Nonetheless, in most markets, there is little choice of size, and what choice there is, is not widely advertised. The issue can only become more important if the current generation of plastic condoms becomes more widely used, because these products have a higher elastic modulus (ie are more difficult to stretch) than natural rubber products.

Research on how well condoms fit is inherently difficult. It involves dealing with parts of the body and with activities that are regarded as private in most cultures, with measurements of inherently variable quantities, and with individual (and hence variable) behaviours and reactions to various stimuli.

Physical Basis for the Discussion

The basic design of condom is a cylindrical tube of rubber, closed at one end, and finished with a bead at the open end.

The condom functions by providing a barrier between the two partners. It needs to stay on the penis, even though the penis may be moving vigorously in the partner's body. It grips the penis partly due to friction from the bead (rim) and partly due to friction from the film along the shaft of the penis. Most condoms are lubricated. The

lubricant tends to be located towards the closed end, but is spread over the inside and the outside of the condom. The relative effects of the bead and the film can be calculated for unlubricated condoms, but can only be estimated for lubricated ones. It is necessary for the unstretched circumference of the condom (at least for part of its length) to be less than the circumference of the penis. This causes a radial force, which in turn gives the frictional resistance to movement. If there is no stretch in the condom, it will not stay in place if there is any force attempting to move it. It could be pulled or brushed off during sexual activity. This is especially the case as a result of the lubricant on the condoms.

On the other hand, if the condom is unduly stretched, then it may feel uncomfortable in use, or it may break due to the stresses introduced. The actual pressure and force on the penis depends on the relative circumferences of the penis and condom, the thickness of the rubber, and its elastic modulus.

These physical effects are summarised in Fig 1¹ for a simple cylindrical condom. It is clear that if a certain range of pressures is acceptable to users, the condom design can stay within that range by adjusting the condom circumference, the thickness or the elastic modulus.

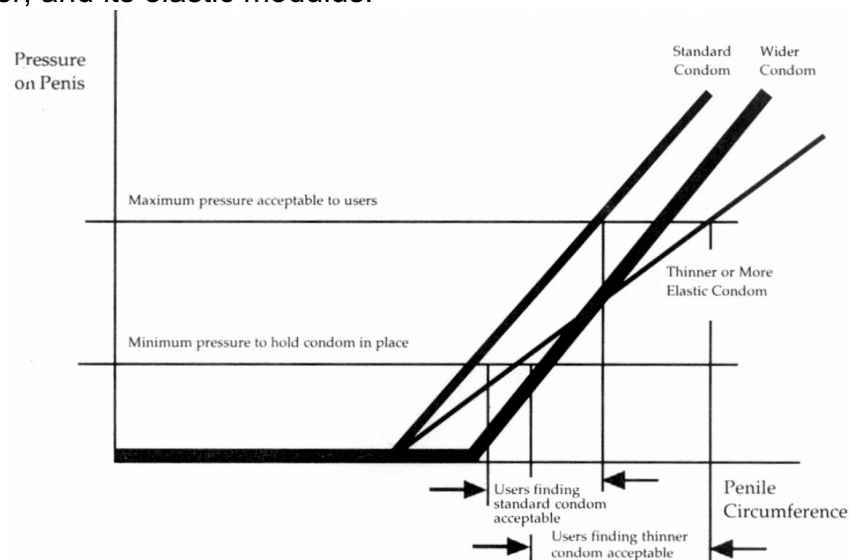


Figure 1 : Effect of design factors on comfort and wearability of a cylindrical condom.

Condom size is related to comfort in use in two ways - comfort during use and comfort during donning. The most important size-related quantity is the circumference. For sake of convenience, it is usually the laid-flat width that is measured. It is half the circumference.

When the condom has been applied, the user could feel pressure from the film and pressure from the bead. While the pressure from the film is over a large area, its actual value is much lower (roughly proportional to the ratio of thicknesses). For a normal condom, therefore, the pressure due to the bead is about 15 times that from the film. (On the other hand, the total retaining force from the film is greater than from the bead, because of the former's large area.)

During application of the condom, virtually the entire condom is rolled up to form a thick rubber band (typically 4 mm in diameter) which applies pressure to the glans. The pressure may be uncomfortable, and the tightness of initial fit may make unrolling difficult.

In all cases, the pressure on the user's penis is approximately proportional to the difference between the circumference of the penis and the circumference of the condom. Condom size is normally measured as the laid-flat width, which is half the circumference.

Perceived reaction to stimuli depends on the individual concerned. The most easily analysed situation in which the body, including the penis, is exposed to such pressures is immersion in water. If a man stands up to his neck water, his penis will be about 0.8 metre below the surface, and will be subjected to a pressure of about 8 kPa. Complaints that the resulting sensation is uncomfortable are unknown to the author. Assessments of what men may find uncomfortable will be related to this benchmark.

Two dimensions are significant with regard to condom fit - length and circumference. The issue of length is a relatively simple one. The aim of using the device is to prevent pregnancy and transmission of disease. As far as pregnancy is concerned, the device should do its job as long as it stays on the penis. For disease prevention, it is important for certain categories of disease (the ulcerative diseases) for the condom to cover as much of the penis as possible, but if the penis is very long, it is unlikely that it will all fit into the partner without causing pain.

If the condom is a little long, the user does not need to unroll it fully. If it is too long by a large amount, then the portion left rolled up could become uncomfortable, simply because there is a lot of stretched rubber concentrated at one place. It acts like a thick rubber band, similar to what happens when the condom is first put on the glans.

If the condom is too short, then it will not cover all the penis. Apart from potentially increasing the risk of disease prevention, there is the possibility of the condom being moved as the bead passes in and out of the partner's labia minora or anus. This possibility depends on the anatomy of both partners, and what they are doing.

The pressure due to the unrolled film can be calculated, and turns out to be considerably less than the 8 kPa benchmark, even for large penises. The bead, typically with a diameter of 1.5 mm, exerts more pressure. Approximate calculations suggest that typical bead pressures can be in the range 30 to 40 kPa for men with (large) penile circumference 145 to 165 mm using 52 mm condoms.

For comfort during unrolling, one must consider a band of diameter around 4 mm. As a result, the pressure due to the roll will be about 2.5 times the pressure due to the bead alone. On most men, the glans is a little smaller than the circumference at the base. A man with a 145 mm glans (very large) will experience a pressure of around 65 kPa when he first starts to unroll a 52 mm condom.

The condom length interacts with the circumference in generating pressures when the condom is not fully unrolled. If a man has a 145 mm circumference penis that is

short, and he leaves the last 50 mm of condom rolled up, then he will feel a pressure of 40 kPa at the bead, compared with 30 kPa from the bead alone.

It seems, then, that ideally, the length of a condom should be tailored to the user's penis. But the elasticity of rubber makes the product forgiving - the effect of increased thickness at the bead is relatively slight as the above example shows, so most users should be able to use a condom that is either the right length or a little too long.

While individuals vary in their reactions to these pressures, it does seem likely that pressures above about 60 kPa may cause discomfort, although there is no experimental data to quantify this in any detail.

Rubber's very high extensibility and low modulus makes it the ideal material for condoms, and one size of condom fits a wide range of men. But the range of penis sizes varies widely in both length and circumference.

The condom needs to grip the penis, otherwise it is likely to come off in use. On the other hand, one study (using only a single size of condom) has shown that a large penis is associated with more frequent condom breakage.

The radial force is provided both by the film and by the bead at the open end. The radial force is responsible for the frictional force which holds the condom in place. It is difficult to calculate the relative contributions of the two exactly, because of variations in penis shape and the distribution and effect of lubricant. For a cylindrical condom on a cylindrical penis, the ratio of these two, and hence of the contributions can be calculated assuming that the effect of the lubricant is small. It is necessary to know the bead diameter, the condom thickness and the length over which the film grips. The result for typical values of these parameters is that the grip of the film is several times greater than the grip of the bead.

Pilot studies conducted by the author confirm that for a stretch of 25% in the film, a lubricated condom will stay well anchored in position even if the bead has been removed.

On the other hand, the bead is virtually the only restraint on "natural" condoms made from lambs' caeca. Thus if the bead diameter is made much smaller than that of the rest of the condom, then the bead will hold it on. Such an arrangement is more likely than a cylindrical condom to cause discomfort once the condom is on, although it is possible that it will be easier to unroll onto a large penis.

Condoms with non-cylindrical shape

Several manufacturers have introduced "shaped" condoms. In general, these are condoms whose circumference varies along their width. Early designs were generally intended to mimic the shape of the penis, and had a constriction which was supposed to fit behind the glans. More recent products tend to be wider in the glans

area, and are often referred to as flared.

One recent study² described in more detail later involved preferences, as well as slippage and breakage rates, for “anatomically shaped” condoms, with a constriction behind the glans, flared condoms and parallel-sided condoms. For condoms of the same nominal width, the preferences for each type were similar. Interestingly, women had a slight preference for the flared products while men preferred the anatomically shaped condoms.

Most of them retain circular symmetry, but there are two more complex designs, the Pleasure Plus and the Inspiral, which do not. These products have been discussed very favourably in the popular press, but they are not widely distributed. It is difficult to find a rational explanation for any superiority over other condoms, especially other flared designs.

On the other hand, the simpler flared designs are widely sold. Given the softness and flexibility of the rubber film, it is unlikely that the user would perceive much difference once the condom was on, especially as the glans on most men has a smaller circumference than the shaft. Nonetheless, the fact that part of the condom has a larger circumference may reduce the pressure of the rolled film, and make it easier for men with larger penises to unroll. It seems that the enlarged part should be confined to approximately the 50 mm closest to the closed end, in order for the grip to remain effective. This matter could be investigated using relatively simple in-vitro tests if suitable products and controls were identified.

The amount of flaring or taper should be limited (to about 15%) to make it easy to remove the product from the dipping and testing lines, and to ensure it can easily be rolled for packing.

There is no evidence that flared (ie tapered or conical) condoms perform any better than cylindrical ones, in terms of slippage and breakage. The only study known to the author³ on this issue shows identical breakage rates for the two types and, surprisingly, a slightly higher slippage rate for the parallel-sided condom (result not statistically significant).

Approaches to the problem

The question of condom fit is a delicate one that is difficult to research. The essential issues are:

1. Is the condom easy and comfortable to put on?
2. Is the condom comfortable to wear?
3. Does the condom tend to slip off?
4. Is the risk of breakage increased by use of inappropriate sizes?

In order to turn results from such inquiries into data which leads to a rational choice of condom sizes, it is desirable to relate the individual responses to the dimensions of the penis involved.

Addressing these questions directly generally involves self-reporting, and the nature of the questions and data gathering usually results in large drop-out rates from any studies. Direct observation by the researchers is less acceptable, especially if function during intercourse is to be observed. Data is most meaningful if it can relate the penis size and condom size (and other properties) to the user's reaction to the condom, and the frequency of slippage and breakage.

A less intrusive approach, available within a relatively homogeneous population, would be issue volunteers with different sizes of condoms and to ask them to use the condoms and rank them in terms of comfort and performance. Without the accompanying penis size data, this approach gives less valuable information than a study which involves penis measurements, since the most likely causal factors are not measured..

A totally non-intrusive approach is to study the sales of different sized condoms in those markets where it is possible.

Conclusive data would best be obtained by correlating the experiences of condom users to different sizes of condom with their penis sizes. Unfortunately, such studies do not exist, and the closest data available involves only a single size of condom. The studies that offered users more than one size of condom did not include any penis measurements. The studies that involved penis measurements only used one size of condom (or no condom at all).

It is important to understand that there is a variation in penis size within ethnic groups, that there is a variation in the distributions from one ethnic group to another, and that there is a variation with age, at least during adolescence.

Studies involving different sizes of condom

The only studies known to the author were carried out by FHI in 1990 to 1994. One series of studies involved the "standard" 52 mm size and a 49 mm condom, in Nepal, Sri Lanka and the Philippines^{4 5 6}.

The second study was also done in three countries, Kenya, Mali and Ghana⁷. In this study, a 52 mm and a 55 mm condom were compared. The choice of sizes in the studies was apparently based on some a priori assumptions about what sizes would be suitable in each country. The results are summarised in Tables 1 and 2.

Overall, the findings were very similar - some men preferred one size, some preferred the other, while others had no preference or noted no difference (5% to 30% - depending on the question and the country). A majority of the men could

distinguish which was the larger condom, but a majority found both sizes offered acceptable (ie they did not dislike either condom).

On the other hand, there were some differences from country to country. In the African group, when offered free condoms after the trial, 61% of users in Mali chose the larger size, while only about 35% chose the larger size in Kenya and Ghana. During the trial, users were asked which condom they preferred, and which they regarded as more comfortable. In Mali, the answers to these questions were consistent, with about 60% of users opting for the larger condom. In Kenya, the two questions were consistently answered in favour of the standard condom, while in Ghana, 57% of users preferred the smaller condom, but the two ranked equally for comfort.

In Mali, the slippage rate for the larger size was much less than for the standard size, while in Ghana it was reversed. In Kenya, the slippage rates were about the same. The breakage rate for the larger condom was lower than for the standard condom in Ghana (7% vs 13%) and Mali (4% vs 1%) but in Kenya the situation was reversed, with 9% breakage for the larger condom and 4% for the standard one.

Table 1**Standard vs Larger Condoms**

	Ghana	Kenya	Mali
Slippage - 52 mm	1%	11%	8%
Slippage - 55 mm	15%	9%	2%
Breakage - 52 mm	13%	4%	4%
Breakage - 55 mm	7%	9%	1%
Prefer 52 mm	58%	63%	28%
Prefer 55 mm	30%	31%	60%
52 mm easier to don	25%	47%	27%
55 mm easier to don	43%	44%	57%
Recognise larger	67%	68%	56%
Believe 52 mm stays on better	13/53	9/47	3/30
Believe 55 mm stays on better	0	5/27	3/59
Believe 52 mm more comfortable	38%	52%	25%
Believe 55 mm more comfortable	38%	44%	64%
Chose 52 mm after trial	54%	63%	32%
Chose 55 mm after trial	34%	36%	60%
Total number of subjects (& condoms per type)	98	75	99

In the African studies, there were 75 to 100 men in each study, and each used one condom of each type. All participants were circumcised, except in Kenya, where 20% were not circumcised.

The Asian studies were larger, involving at least 597 condoms per type per country. In Nepal, the smaller condoms had lower slippage and breakage rates, and there was a slight preference for them, although the participants reported the 52 mm as being easier to put on. In the Philippines, there was a preference for the 52 mm condoms on all indicators, and more users thought the 52 mm condoms less likely to slip. The breakage rate for the 49 mm condoms was higher than for the 52 mm ones. In Sri Lanka, there was a perception that the smaller condoms stayed on better, but in fact their slippage rate was higher than for the 52 mm ones, and

overall, more users preferred the 52 mm condoms.

Table 2

Standard vs Smaller Condoms

	Nepal	Philippines	Sri Lanka
Slippage - 52 mm	26/750	0	7/597
Slippage - 49 mm	3/750	0	14/600
Breakage - 52 mm	30/750	1	16/597
Breakage - 49 mm	24/750	4	13/600
Prefer 52 mm	59%	41%	39%
Prefer 49 mm	34%	35%	33%
52 mm easier to don	58.7%	43%	16%
49 mm easier to don	34%	31%	20%
Recognise larger	64.7%	91%	na
Believe 52 mm stays on better	40.7%	44%	27%
Believe 49 mm stays on better	48%	40%	39%
Believe 52 mm more comfortable	42.7%	45%	36%
Believe 49 mm more comfortable	52%	40%	29%
Future preference 52 mm	9%	54%	54%
Future preference 49 mm	12%	42%	34%
Total condoms used	750 each	744 and 750	600 and 597

FHI interpreted the results from some of the countries as a case for having both sizes of condom available. In other cases, this recommendation was not made, even though the results were very similar.

It should be noted that many of the differences shown in the tables were not statistically significant. In particular, the differences in breakage rates between the two types of condom was not significant for any of the African countries. Nonetheless, the results in Mali, consistent across breakage rates and preferences, are very persuasive. In Nepal, the difference in slippage rates was statistically significant in favour of the smaller condom, as was the users' preference for the larger one.

The fact remains that in each country, a significant proportion of users expressed a preference for each of the two sizes offered. A maximum of 28% of participants preferred the two study condoms equally.

A more recent study in the UK, by the UK Family Planning Research Network² compared men's and women's preferences for four different condoms, of different shape. Of these, three were basically 52 mm condoms, contoured in various ways near the closed end, and one was a 49 mm condom, contoured like one of the other three. About 16% of men and 18% of women ranked the 49 mm condom best for comfort, 18% of men and 19% of women rated it best for sensitivity, and 17% of men and 21% of women rated it best for security. Thus although in general, roughly 80% of users found one or other of the 52 mm condoms preferable, there was a sizeable minority which preferred the smaller condom.

There were three different shapes of 52 mm condom in the study - a cylindrical one, a flared one and an "anatomically shaped" one. Preferences were close to equal for each, but when asked about safety, security and comfort, the flared condom was most preferred by women on all three counts, while the men preferred the "anatomically shaped" condom on these counts.

Studies involving penis measurements

Some studies have been done on flaccid penis size, not in connection with condoms. In some of these, there has been an attempt to measure erect penis size as well, and to develop some correlations.

Other studies have been conducted on erect size, and of these, many were directed at the issue of condom fit.

Flaccid penis size

Penis size is a classical indicator of maturation in endocrinology. The measurements are typically taken on the stretched flaccid penis. A correlation between this measure and the size when erect has been reported.

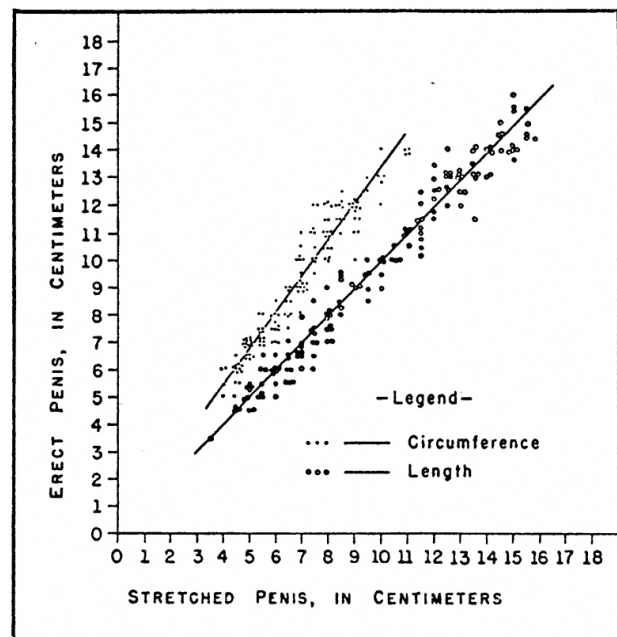


Figure 2 : Correlation between stretched flaccid penile dimensions and erect dimensions (from Schoenfeld and Beebe)

Penis size has also been studied by urologists and sex researchers, to guide in advising patients who ask for penile enhancements because of perceived small size.

The first reported measurements date from the 1930s, but the first detailed ones are those of Schönfeld and Beebe⁸ and Schönfeld⁹, from 1942. They made measurements of the length and circumference of the stretched flaccid penis, and reported self-measurements of the erect length and circumference, for 150 men and boys (see fig. 2). He presented correlation equations, relating the flaccid and erect measurements. The correlation coefficients were good, at 0.983 for length and 0.965 for circumference. For circumference, the constant in the equation was relatively small, making the relationship almost proportional in the range of interest. Nonetheless, there were significant individual variations. For example, different penises with an 8 cm flaccid circumference had erect circumferences of between 10 cm and 12.5 cm. The point at which the circumference was taken was not stated.

Wessells et al¹⁰ also conducted a comparison of flaccid and erect penile length. The erect measurements were taken by a researcher, and injections of Prostaglandin E1, phentolamine and papaverine were used to ensure full erection. The correlation coefficient between stretched flaccid length and erect length (0.793) was not as good as Schönfeld's. A stretched length of 12 cm could correspond to an erect length of 10 to 16 cm. Wessells' results are shown in Fig 3.

Contrary to the correlation found by Schönfeld and Beebe and Wessells, Masters and Johnson¹¹ reported that smaller penises increased more in size during erection than large ones. This was later supported by Jamison and Gebhard¹² in their re-analysis of Kinsey data. It appears, therefore, that prediction of erect penis size

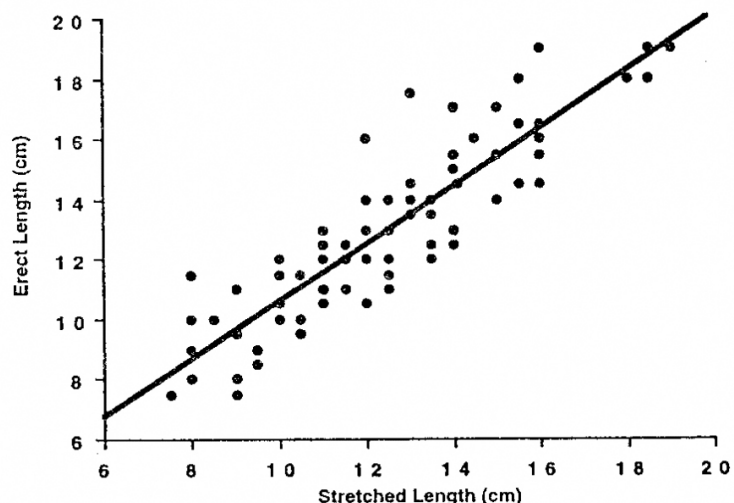


Figure 3: Correlation between stretched penis length and erect length (Wessells)

on the basis of flaccid measurements has not been demonstrated to be reliable.

Schönfeld also published graphs of "normal" penis stretched length and penile circumference as a function of age. These are reproduced in Fig 4 to 7. The median "normal" length starts to increase significantly at the age of about 13, and finished about 16. The median "normal" circumference increases over a longer time, starting around 10 years and finishing about 18. It is likely that this process takes place earlier nowadays.

The median length approximately doubles, while the circumference increases a little less.

There is no data for the increase in size of erect penises during puberty, except Schönfeld's regression equation. It is highly likely that correlation is at least approximately applicable, that the increases are of similar proportions to those for flaccid penises, and that they take place over the same timespan, and at a similar rate.

It is unlikely that boys will start having intercourse at the beginning of puberty, but it is reasonable to assume that some will start around the middle of that period - 14 years in Schönfeld's data, and 2 years before their penises are fully grown. It is plausible that the "normal" erection size of a 14 year-old boy will be around 70% of the fully grown size. Of course some will be smaller and some larger.

Thus, it is highly likely that boys who become sexually active around the middle of puberty will start with penises considerably smaller than adult penises, and that their penises will be smaller than adult penises for around two years.

The only specific data on the relationship amongst age, penis size and condom size was published in 2001¹³. This study compared flaccid and erect penis sizes for two groups of men, one 18 to 19 years old, and the other 40 to 68 years old. As other studies suggest that the penis is usually fully grown by the age of 18, and as the researchers hypothesised that the younger men may have trouble with condoms because of smaller penises, this study did not confirm its hypothesis. The data presented is also difficult to relate to others in this report, because penile width is used instead of circumference. Indeed, it may be more meaningful to study whether older men (say, over 60) have smaller erections than younger men.

Although the data on flaccid penis size is useful, it should be remembered that there are some inherent problems that limit reproducibility and repeatability:

1. The method for length is not clearly defined. The photos published by Schönfeld show the penis being stretched by pulling on the frenulum, not on the glans. Wessells does not describe his method.
2. The method for circumference uses rings which are pushed over the penis, but does not indicate how far down the penis the measuring rings should be pushed. Also, penises are not round, but the rings were.
3. Stretched length is not invariable in each individual. Experiments by the author indicate a variation from measurement to measurement with a range of up to 3 cm.
4. The correlation equations developed, while being reasonable predictors in general, do not account for the variations found in individuals.

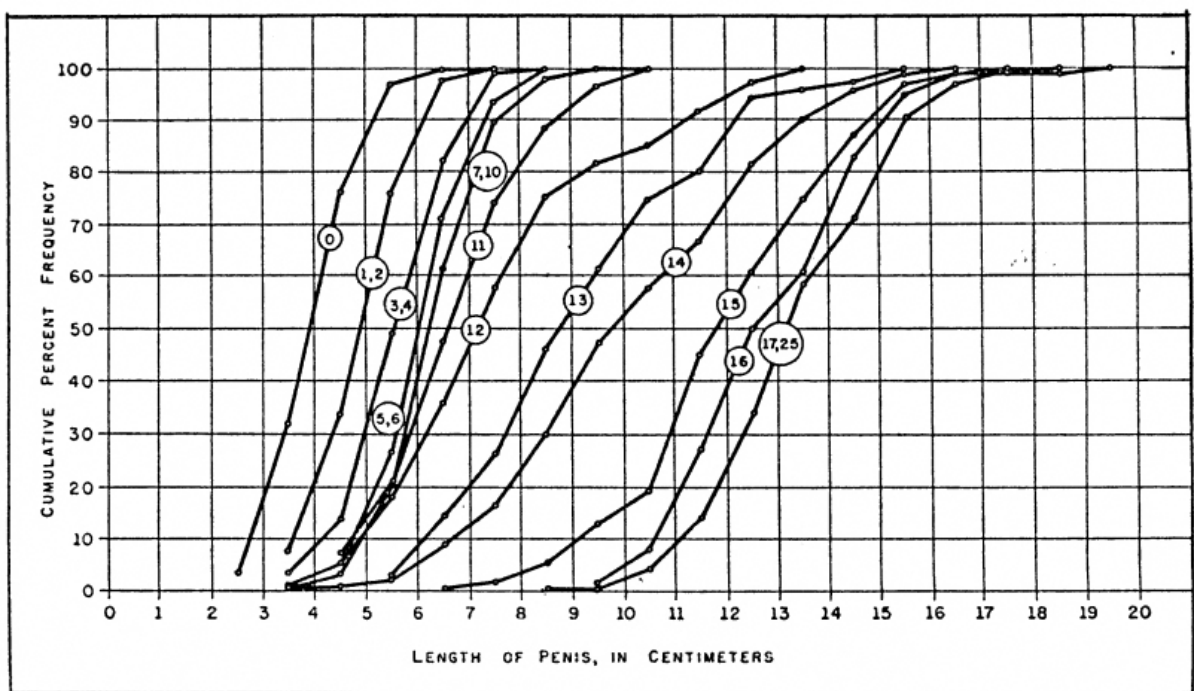


Figure 4 : Cumulative distribution of stretched flaccid penis length by age

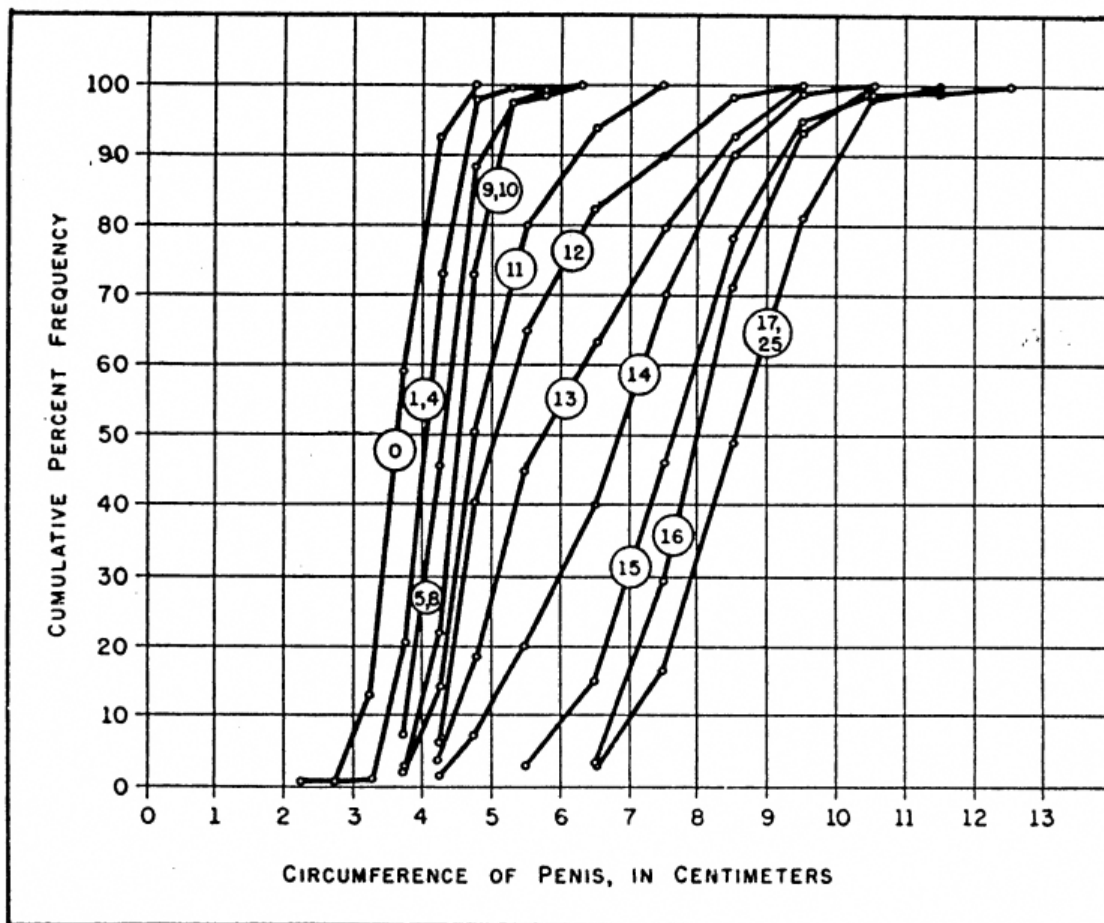


Figure 5 : Cumulative distribution of stretched flaccid penile circumference by age (from Schoenfeld and Beebe).

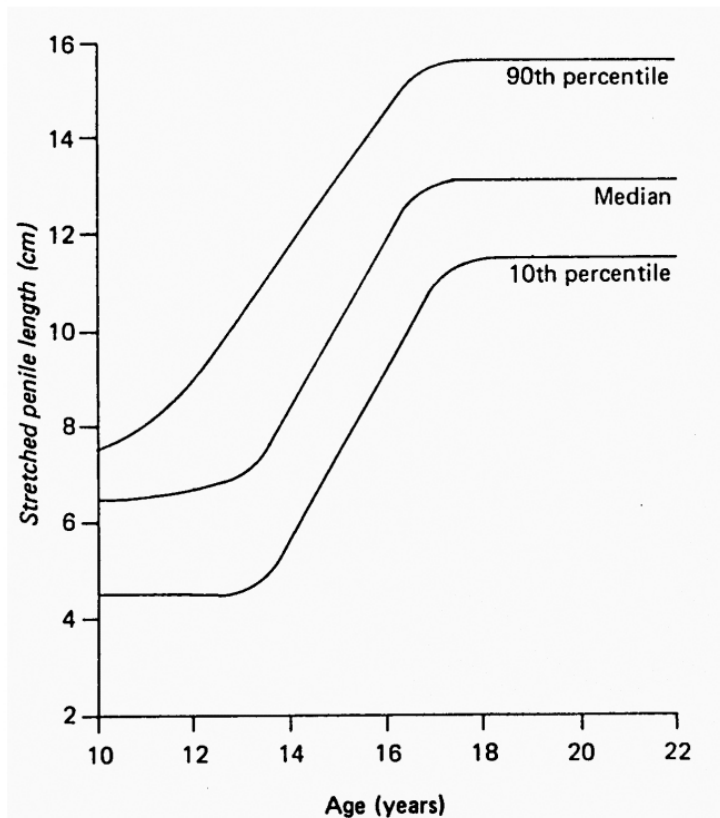


Figure 6 : Stretched penile length as a function of age (from Schoenfeld).

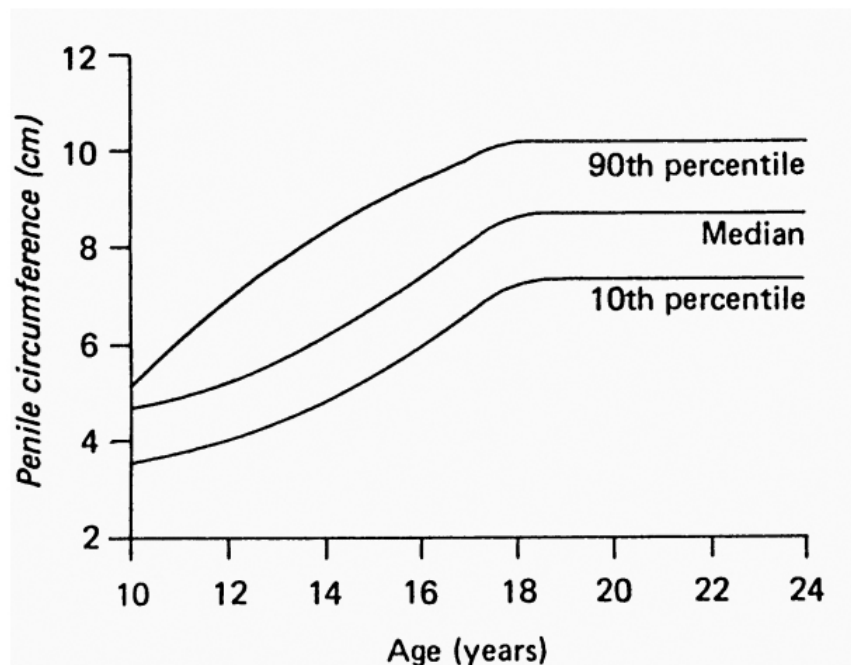


Figure 7 : Flaccid penile circumference by age (from Schoenfeld).

Erect penis size

There have been a number of studies which specifically measured erect penis size. The earliest known to the author was part of the Kinsey study, but published later by Gebhard and Johnson¹⁴. Data were collected on the penile length and circumference of Caucasian and African Americans. On average, the African Americans had longer penises, but the circumferences were very similar.

In 1978, there was an unpublished study conducted by Muangman¹⁵ in Thailand. The measurements were taken by sex workers using paper tapes.

A more comprehensive set of measurements was conducted in Australia in 1989 by Richters et al¹⁶. In this study, five measurements were taken to characterise the shape of the penis, and user reactions were related to penis size. The technique involved self-measurement, with very precise instructions given to the participants. Histograms showing four of the five dimensions are shown in Fig. 8.

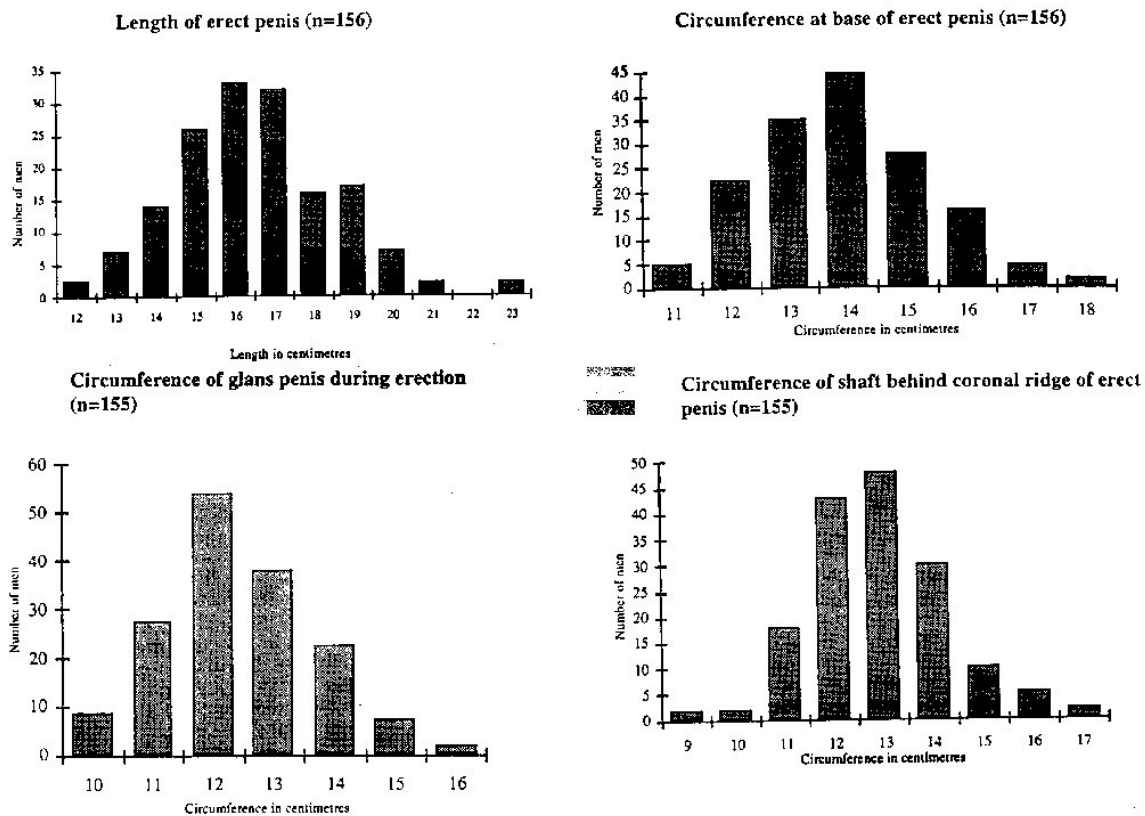


Figure 8 : Erect penile measurements from Richters et al.

In 1994, da Ros et al¹⁷ conducted some measurements in Brazil using intracavernous injections of a vasoactive mixture. Only means and ranges were reported. The length ranged from 9 cm to 19 cm, with a mean of 14.5 cm. The circumference near the base ranged from 9 to 15 cm, with a mean of 11.92 cm.

A later study in Australia¹⁸ used the same measurement technique as in the Richters study, except that participants were also trained beforehand using a penis model.

This study also involved an extensive slippage and breakage study, which will be discussed below.

The measurements obtained in the Australian studies were very similar to those in the Kinsey study.

The repeatability of the method was examined by Richters et al, and found to be good. The reproducibility between the two Australian studies was also found to be very good.

In 1999, penis measurements were conducted by Lee et al¹⁹ in Korea. The mean results were similar to the Thai and results. While the method was similar in principle to that of the Australian studies, the length measurement was made against a stiff cardboard strip, rather than against paper.

In 2000, a small informal pilot study was conducted in Nigeria²⁰, using the Australian techniques. The mean length was higher than the Australian results, and similar to the results for African Americans. However, the sample size was very small and the participants were not pre-trained to the same extent as in the Australian studies.

The mean results for the studies mentioned above are shown in Table 3. It should be noted that the location and methodology for the measurements is not described in each case.

Table 3 - Mean length and circumference - erect penis

Study	Country	Number	Length	Circumference
Kinsey	US Caucasian	2770	15.8	12.3
Kinsey	US African	55	16.6	12.5
De Ros et al	Brazil	156	14.5	11.9
Richters et al	Australia	150	16.0	13.5
Smith et al	Australia	184	15.7	13.2
Muangman	Thailand	527	13.5	11.2
Han et al	Korea	279	12.7	11.3
Gerofi	Nigeria	18	17.0	13.4

There are many internet sites which have information on penis size, and some which offer participation in size surveys. The quality of measurement and of the resulting data in such studies is variable and the results are not subject to peer review. They have not been considered in this report.

A recent report describes plans for a penis size study in India, in which digital cameras will be used to measure the penises in what is intended to be a less invasive method than those used in earlier studies. It is doubtful that the level of technological complexity involved is justified by the potential to get more accurate results, and one must wonder whether having one's erect penis photographed is less intrusive than the tape measurements used earlier.

Self-measurement studies are vulnerable to unintentional mis-measurement, and also to mischievous mis-reporting. One must suspect some of the very high individual results in such studies. On the other hand, if a researcher does the measurements, the situation is hardly normal, and many men may be less aroused than when having intercourse. If the erection is caused by an injection of a vasoactive drug, there is no evidence that the effect is the same as a naturally occurring one.

Most penises are tapered to some extent, so there is no unique definition of penile circumference. There are differences among the studies in the point at which the measurements are made, and it is not always defined in the study reports. For analysing condom fit, the Australian studies use the circumference about 1 cm from the body. Smith et al showed that this dimension showed the greatest correlation with condom breakage, and Richters et al demonstrated that the same measurement was a predictor of whether the user found a standard condom comfortable or not. See fig 9.

The results of selected studies, all of which were conducted on adults, are compared in fig 10.

Non-quantitative reports

Sex workers have been asked about their impressions of the causes for condom breakage in several studies. Penis size is frequently mentioned^{21 22}.

In addition, sex workers in Australia often mention the need for a smaller condom, primarily for clients from South East Asia.

Market information

In the 1970s, it was noticed that condoms of the standard 52 mm size being supplied under international aid programmes in South East Asia had very low acceptance, and it was eventually discovered that they were too big. As a result, 49 mm condoms have been supplied to some countries as a matter of course for some decades. There is no published data to support the choice of size.

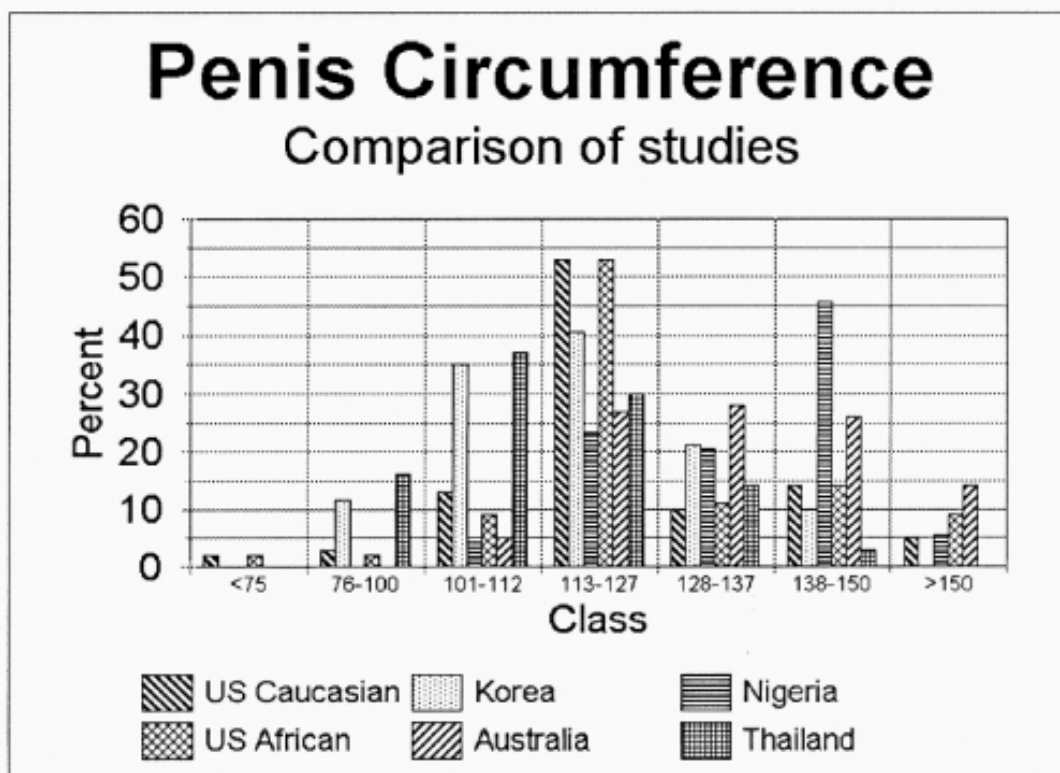
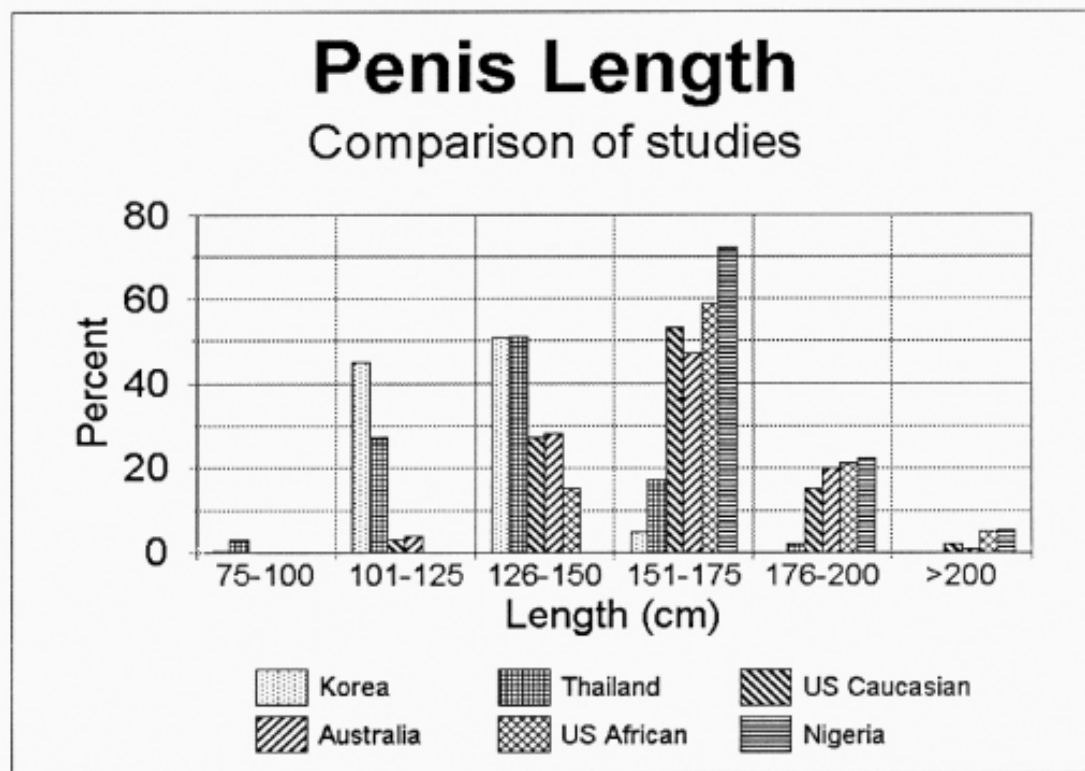


Figure 9 : Comparison of erect penis size studies from different countries (class intervals are uneven to enable comparison of all studies).

As a result of the publication of histograms of penile circumference, and recommendations in a number of scientific publications, larger size condoms have appeared on the retail market in some countries. The sizes have been determined by inference from the penis size data.

The larger condoms are between 55 and 60 mm, depending on the brand.

In Australia, the Four Seasons brand offers and advertises three sizes (49, 54 and 58 mm). The sales are approximately 10% for the 49 mm, 75% for the 54 mm and 15% for the 58 mm size.

Also in Australia, the market leader, Ansell, changed its standard size from 52 mm to 54 mm in the 1990s, and its market share has grown since.

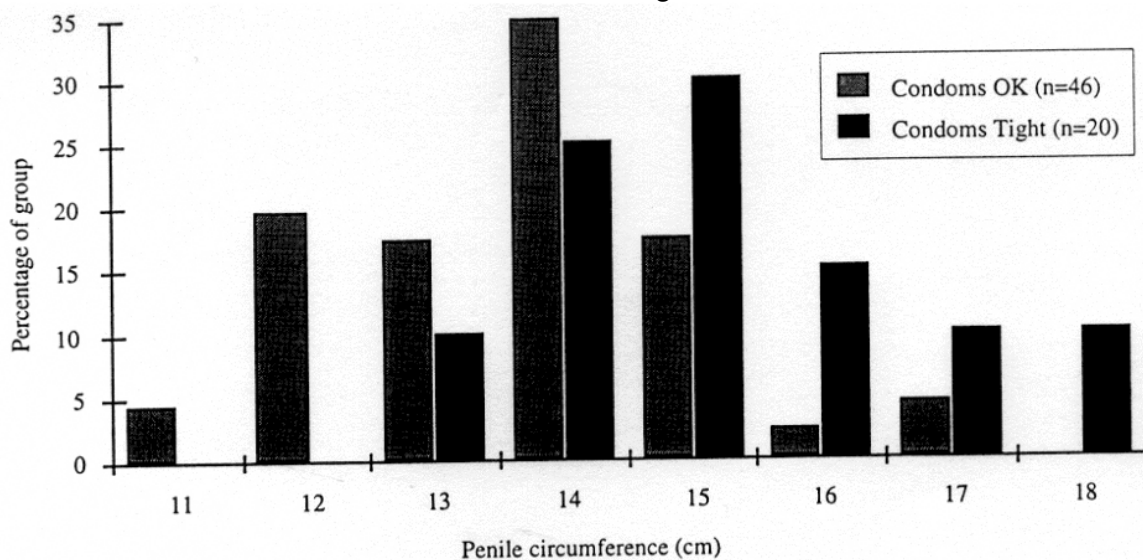


Figure 10 : Distributions of erect penile size for men who find condoms acceptable (left bar) and those who find them tight (right bar) from Richters et al.

In the USA, the market leader, Trojan, uses a 53 mm condom as its standard size. They have two larger sizes. Magnum has a conical shape. The bead is 53 mm, and the condom tapers to a width of 64 mm near the closed end. The largest size, Magnum XL, has a bead size of 57 mm and the shaft tapers out to 67 mm near the closed end. These products are believed to make up approximately 7% of the company's condom sales. There is no small size available in the Trojan range.

It is clear, then, that where purchasers are given a choice, a proportion of them will choose condoms which are wider and narrower than the traditional size. As discussion of the fine detail of condom design is not common in the public domain, it is likely that information about the availability and applicability of such condoms is not as fully disseminated among condom users. Many retail outlets do not stock a full range of varieties, especially those that have a small market share. Probably, if all condom users knew about the range of sizes available, and could purchase them easily and without inhibition, then the proportion choosing larger and smaller sizes would increase somewhat.

There are also proposals to market condoms graduated by length. One company (Oceans Seven International) intends to have 55 different condom sizes. It is believed that there will be five widths, and 10 mm graduations of length in each width, from 95 mm to 195 mm. The practicality of such an approach (other than by mail-order) is doubtful, because of distribution problems.

In-vivo data

Sixty six of the participants in the study by Richters also took part in an overlapping study on user-related reasons for condom failure, and reported on their perceptions of fit and comfort. They were asked whether they found the condoms they were using too tight or acceptable. The mean circumferences for both groups were calculated. The mean difference between the group saying that the condoms were too tight and those saying they were acceptable was 1.47 cm (95% CI 0.7 to 2.22 cm). The results are shown graphically fig 9. In this study, all complaints about tightness, whether at the bead or all over, were treated as equivalent, and the circumference at base was used as the sole size parameter.

It is significant to note that none of the 66 respondents complained that the condoms were too long.

Smith et al²³ conducted a slippage and breakage study comparing two types of condom, and recorded the penile dimensions of the participants. This study was based on data collected in ref 15. The data has been analysed in various ways. Using logistic regression, they found that penile circumference was a predictor of breakage.

For this analysis, 3658 condom uses had all the required information supplied, and of these 49 (1.34%) broke and 73 (2.05%) slipped off. Of the 184 men involved, 30 (16.8%) had at least one breakage and 35 (19%) had at least one slippage. Retrospective reports from the same men indicated that over the previous 12 months, 60 (32.6%) had experienced at least one breakage and 53 (28.8%) had experienced at least one complete slippage. Strong associations were observed between having reported breakage in the last 12 months and breakage in the study, and similarly between reported slippage in the last 12 months and slippage in the study.

Each of the circumference measures used in the study was positively associated with an increase in risk of breakage. The odds ratio per centimetre of circumference varied from 1.50 to 2.08. The highest ratio was for circumference behind the glans, at 2.08, followed by circumference near the base, at 1.83. This suggests that for a condom of a given size, a man with a penile girth of 140 mm is about twice as likely to experience breakage as one with a girth of 130 mm.

No significant effect of penile dimensions on slippage was observed in the study. This could be due to the fact that most penile circumferences in the study were

sufficiently large to make the problem of little importance.

Hocking²⁴ re-analysed Smith et al's data, using generalised linear models that overcame some limitations of the earlier analysis. Typically, such data are analysed on the basis of each condom used, or of each user. In the first case, the fact that condoms used by one user are probably subjected to similar challenges is not accounted for. In the second case, information about the circumstances of use of the individual condoms is not included in the analysis.

Hocking's approach utilised each condom outcome, while recognising that not all the observations are independent. Nonetheless, she found penile circumference was a predictor of breakage with an adjusted odds ratio of 1.54 (95% CI 1.18-2.00). Thus, according to this more sophisticated analysis, a man with a penile girth of 140 mm is about 1.5 times as likely to experience breakage as one with a girth of 130 mm.

Discussion

From the various erect penis measurement studies, it is clear that:

1. There is a range of lengths and circumferences within all of the populations studied (typically of the order of 2:1)
2. The mean lengths and circumferences vary from population to population
3. The range within a population is greater than the range of means across populations.

From Schönfeld and Beebe's results, it can be seen that boys' penises grow over a period of years. The circumference increases over a longer period than the length - roughly six years. Assuming that Schönfeld's correlation of erect circumference with flaccid circumference is applicable, then the size of their erections also increases steadily over the same period. If boys become sexually active around the middle of their adolescence, then it is reasonable to assume there will be a period of about 3 years in each boy's life where a smaller condom than he would ultimately use could be appropriate.

From the FHI studies, we can learn that:

1. Most men can distinguish by how the condom fits, between two condoms whose widths differ by 3 mm
2. In five of the six countries where the study was carried out, a significant proportion preferred each of the two sizes offered, and fewer than one third had no preference between the two.

In the FHI studies involving larger condoms, the total number of condoms used was relatively small, so it is difficult to draw conclusions from slippage and breakage rates, which all involve very small numbers. Nonetheless, in Mali, where users expressed a strong preference for large condoms, the breakage and slippage rates

of the larger size were much lower than those for the standard condom. Similarly, in Nepal, the slippage rate of the standard condom was much higher than that for the smaller condom. The results from Sri Lanka showed the opposite trend.

The UK Family Planning study also shows that a significant minority of the study population prefers smaller condoms.

From the work of Richters et al, it can be seen that men who complained that condoms were too tight tended to have larger penile circumference than those who found the condoms were acceptable.

The analyses published by Smith et al and by Hocking suggest that the relative size of the penis and condom has a major impact on breakage - trying to use a condom that is too small results in increases probability of breakage.

The market response in those countries where different sizes of condom are available shows that within any one population there will be men who need or prefer a size different from the standard size. Within these populations, the proportion of users choosing sizes smaller or larger than the standard size is relatively small. This is to be expected if the standard size has been well chosen, but on the other hand, frank and clear information on the applicability of the different sizes is difficult to give, and not readily absorbed by condom purchasers.

On the basis of the data available, it is not possible to state definitively which sizes should be available, but it seems likely that the steps in width should be more than 3 mm but less than 7 mm. 4 mm or 5 mm steps seem likely to be appropriate. A reasonable proposal on the basis of the present state of knowledge would be 49 mm, 53 mm and 58 mm, although further research could result in these values varying by about 1 mm. Use of four sizes could also be considered (eg 48, 52, 56 and 60 mm). The benefits of a finer gradation of sizes are dubious, because of four factors:

1. The difficulties of labelling the condoms and getting men to work out which ones they need
2. The logistical problems of supplying a range of sizes in developing countries
3. The cost of having several sizes in retail outlets in developed countries
4. The large proportion of men in the FHI study who did not dislike either size of condom offered..

There are some men who would be best suited by condoms outside the range above. However, they represent a very small minority of the population, and the cost of making and distributing very large and very small condoms in small quantities is likely to be prohibitive. This applies particularly if several lengths must also be provided.

Some departure from the cylindrical shape may provide an opportunity to make the condom easier to put on a large penis. There is no published evidence either way on this issue. It seems likely that for optimum effect the taper should be confined to the part that would cover the glans and the area just behind it, otherwise the grip of the film will be reduced. A small laboratory test could determine the plausibility of this possible advantage, provided sufficiently similar tapered and non-tapered condoms could be found to test. It is likely that non-cylindrical condoms have more effect at the psychological level than the physical.

There is a logical argument for also varying the length of the condoms. This is less compelling than the circumference, as the user need not unroll the condom fully. Further, if the need for 3 or 4 circumferences (widths) is accepted, then even having two lengths for each diameter brings to six or eight the number of different sizes to be stocked for each design. It is likely that very long penises do not need to be covered right to the base, since it is unlikely that the entire length will be inserted into the partner. If there is a need for more than one length, then two would probably be enough, and the difference between lengths could be around 40 mm. Further study is needed to examine this possible need.

Conclusions

Few studies have been done on condom fit. Only two actually relate condom size and penis size with slippage, breakage or user reaction. There is no data available on the effect of a tapered or flared shape, beyond establishing that some users express a preference for it.

Richters et al presented data on user reactions to condom tightness and related that to penis circumference. The men complaining of tight condoms had a mean penile circumference 1.47 cm greater than those who found the condoms acceptable. Crudely, this suggests that 7 mm change in condom width is sufficient to cause a lot of complaints. Smith et al found a correlation between penis circumference and condom breakage rate, on logistic regression analysis.

The FHI studies record user preferences and breakage and slippage rates, but they cannot relate this to the penises involved, because that data was not collected. Nonetheless, the majority of men noticed that one condom was larger than the other and identified it correctly. Most had a preference for one or the other, even though the difference in width was only 3 mm. On the other hand, most men did not dislike the condom they did not prefer.

Schönfeld's data suggests that during adolescence, boys could need a smaller size of condom than they would ultimately use as adults.

Smith's results are the only ones that clearly suggest that if the condom is too small, the breakage rate will increase. It is only one study, and the results should be

replicated.

Whether or not Smith's conclusions are corroborated, the FHI results clearly point towards varying preferences amongst men in any one country, and a variation amongst ethnic groups. This variation in preferences is backed up by the distributions of penis measurements within one country and from country to country.

Non-use of condoms is one of the most pressing problems in HIV prevention. Anything, including offering a range of sizes, that makes condoms more acceptable to the potential users is worthwhile. This applies whether or not the breakage rate effect found by Smith et al is corroborated by other studies.

On the basis of the data available, it is not possible to state definitively which sizes should be available, but it seems likely that the steps in width should be more than 3 mm but less than 7 mm. 4 mm or 5 mm steps seem likely to be appropriate. A reasonable proposal on the basis of the present state of knowledge would be either 49, 53 and 58 mm or 48, 52, 56 and 60 mm, although further research could suggest these should be modified. The need for different lengths within one width is less clear. It is likely that condoms to fit extremely small and extremely large penises will be impractical to make and distribute in most situations.

Further research work on the acceptability, breakage and slippage rates of different sizes of condoms is needed.

Amongst adults, studies similar to the FHI study, but including erect penis measurement, and involving at least 100 men and 400 condom uses, should be conducted in several countries. Separate studies are needed to assess whether a flared shape provides any real benefit.

In addition, in at least one country, a similar study should be conducted on adolescents. The study should cover a cross section of ages, over puberty, with at least 50 participants of each age. Those who are not sexually active could be asked to measure their penises, to don one condom of each size being tested, and to report on comfort and fit.

A relatively small laboratory study could evaluate the possible advantages of flared condoms.

Ultimately, design variations which provide only marketing advantages should not be disregarded, if they lead to increased condom acceptability and use. In developed countries, a wide range of different products is possible. These can allow for the psychologically motivated preferences of users, as well as for scientifically based issues such as slippage, breakage and ease of use. But the variety comes at a cost in distribution logistics. In a developing country, the need to minimise costs tends to be far more important, and careful choice of condom designs and sizes is desirable to get the maximum public health effect using the minimum practical number of products.

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