The barrier performance of latex rubber

by C.M. Roland, Naval Research Laboratory

One would not expect a device intended for private use to generate such a public brouhaha. The humble condom has been the object of much press coverage, legislative action, lawsuits, vituperative school board meetings, novelty items and artwork, and there even exists a National Condom Week. It has become the countermeasure of choice in the war on sexually transmitted diseases (STD), in particular AIDS (ref. 1). Since 1986 condom sales have increased 60%, with a similar rise in the prophylactic use of latex gloves. Ironic amid the recurrent media attention is the fact that the $400 million condom market spends only $1.8 million a year on paid advertising (ref. 2). Many condoms are distributed freely, for example, 2.4 million in New York City alone last year (ref. 2).

Certainly the campaign for "safe sex" has been successful in promoting condom usage; however, sometimes science trails the pomp in highly politicized realms. This article is intended as a review of the facts concerning the barrier function of rubber, specifically in preventing the transmission of HIV, the causative agent for AIDS. Since animal membrane prophylactics ("skin condoms") are considered ineffective for this purpose (ref. 3), the focus herein is limited to latex rubber. Social science studies of the correlation of high risk sexual behavior and AIDS infection rates with condom availability (ref. 4), while germane to the problem of STD prevention, are outside the scope of this article.

It may be an apocryphal tale, but the original condom (Latin *condus*: receptacle) is reputed to have been invented by a Colonel Cundum (var. Dr. Condon) to protect his king from venereal disease (ref. 5). Today condoms are classified by the FDA as a Class II medical device "for contraceptive and for prophylactic purposes" (ref. 6). Concerning their effectiveness for the latter, the FDA has stated that "the latex condom may prevent the transmission of many sexually transmitted diseases such as ... AIDS. It cannot eliminate the risk" (ref. 7). Presently they are promoted predominately for disease prevention, rather than as a contraceptive device. The label of the leading brand avers that "no contraceptive provides 100% protection... condoms, when properly used, aid in the prevention of pregnancy." A condition of less than 100% pregnant being implausible, this statement apparently refers to the frequency with which condoms fail to prevent conception. This failure rate, defined as the probability of pregnancy over the course of one year in a woman relying solely on condoms for contraception, lies in the range of 5-30% (refs. 8-10). This high contraceptive failure rate, though a woman is fertile only 10-25% of the time, does not bode well for the effectiveness of condoms in preventing STDs.

Human immunodeficiency virus (HIV)

The cause of AIDS is infection with HIV, which refers to any of a large number of viral stains (ref. 11). HIV is a retrovirus, a small class of viruses having RNA as their genetic material. The RNA serves as a template for the production of DNA, which invades a host cell's chromosomes, reproducing and killing the cell. With AIDS infection, the victimized cell is a white blood cell, hence the eventual suppression of the immune system. Direct contact with semen is the primary means for sexual transmission of HIV (refs. 12 and 13). The free virus exists in the seminal fluid (refs. 14 and 15), at concentrations as high as 10^8 viral particles per ml (ref. 16). HIV is also found in sperm-free, pre-ejaculatory fluid obtained from HIV-positive men (refs. 17 and 18).

The defining feature of viruses is their diminutive size; electron microscopy reveals the AIDS virus to be only 100 to 120 nm (0.1 micron) in size (ref. 19). This is consistent with their passage through polycarbonate filters with holes in the 0.1 to 0.2 μm range (ref. 20). The size of HIV is 60 times smaller than the bacteria causing syphilis and 450 times smaller than human sperm (ref. 21). Indeed, the fact that it survived the filtering used to remove fungi and bacteria from blood plasma helped early investigators identify the causative agent for AIDS as being a virus (ref. 11). Clearly, the use of a condom or rubber glove for barrier protection from a virus represents a different problem from that of preventing bacterial infection or conception.

Defects in condoms

In the use of surrogate viruses to evaluate barrier materials, it is considered that a virus will pass through any hole of diameter greater than the viral diameter as seen in electron micrographs (ref. 22). This fact has been explicitly demonstrated for HIV, which was found to pass through filters having holes 0.10 μm or larger (ref. 20). The barrier integrity of condoms is assessed using a leakage test (ASTM D 3492-89). This test is based on the original ASTM standard, which consisted of visual observation for leaks in a hanging condom containing 300 ml of water, and an FDA method, in which the filled condom was rolled on paper to facilitate leak detection. A sampling scheme is employed with an acceptable quality level of 0.4%. The sensitivity of the test to small defects is governed by the smallest observable volume of leaking water, about one microliter (ref. 23). Based on the highest HIV concentration level reported in the literature (ref. 18), this quantity of seminal fluid would contain 100,000 viral particles.

A criticism of the leakage test is its failure to reproduce the magnitude and dynamics of the hydrostatic pressure applied to condoms during coitus (ref. 24); nevertheless, the test appears to be a valid measure of the condom's ability to prevent passage of sperm. Its reliability in assessing the existence of small holes (e.g., diameter < 10 μm) is more dubious. It is sometimes erroneously stated that since a water molecule is smaller than the AIDS virus, holes passing the latter would surely pass the former. Actually the relevant considerations for passage through a capillary involve the surface tension of the fluid and the hydrostatic pressure (refs. 25 and 26). Since a leakage test is based on volume flow rates through an orifice, the sensitivity limit decreases as the fourth power of the hole size (refs. 26 and 27).

The smallest hole detectable by the leakage test under ideal conditions has been calculated to be 10-12 microns (refs. 23, 27 and 28). In one laboratory study (ref. 29), holes were introduced into 24 condoms using a 100 μm diameter wire with a pointed end about 10 μm wide. Seventy-five percent of these passed the ASTM leakage test, even though they contained holes two orders of magnitude larger than the HIV virus. Improved sensitivity to the presence of holes was reported when the contained liquid had added surfactant, which improves wetting of the rubber in the vicinity of the hole (ref. 29). In another evaluation of the leakage test (ref. 30), holes were introduced into condoms obtained from various manufacturers, with the size and location of the holes verified by optical microscopy. To facilitate wetting, in all cases surfactant was added to the water contained in the condoms. Those containing holes 1 micron in size (ten times the size of HIV) passed the leakage test 90% of the time.

These results indicate that the water leakage test is not adequate for the detection of the small holes relevant for viral transmission. This was directly demonstrated in a study of the ability of latex condoms to prevent passage of fluorescence labeled polystyrene microspheres, 110 nm in diameter (i.e., equivalent in size to the AIDS virus) (ref. 31). One-third of the condoms, none of which contained holes large enough to be rejected by the water leakage test, allowed passage of the microspheres, with fluid flow rates lying in the range of 0.4 to 1.6 nanoliters per second.

Although wetting and consequent fluid passage facilitate the detection of holes during inspection, enhanced wetting is obviously undesirable during end-usage. For example, the surfactant properties of the spermicide nonoxonal-9, recommended as a biocidal agent for HIV (ref. 8), may facilitate passage of semen through small holes, which might otherwise present an air gap (ref. 32). The introduction of charged surfactants to condoms has been suggested as a means to reduce the transmission of STD agents having like surface charges (ref. 33). Of course, transmission would be enhanced whenever the surface charges were of opposite sign.

In addition to the leakage method, every manufactured condom is subjected to an electrical test. Typically, the condom is placed over a steel mandrel. When an electrode is brought into proximity, the presence of a hole in the condom is signaled by dielectric breakdown. Alternatively, the mandrel containing the condom may be submersed in water and the capacitance or its discharge rate measured. This reveals the presence of a hole, at least to the extent the hole dominates the resistance. A limitation of the electrical tests is that polarization at the mandrel tip can mask the contribution of small holes to the resistance (ref. 23); consequently, the electrical method is considered to be insensitive to micron sized holes (ref. 30). A newly developed resonance technique (ref. 34) overcomes this problem and has potential for the detection of micron-sized holes in latex rubber. It is not yet commercially available.

Defects in latex rubber

Since existing tests are often oblivious to holes less than 10 microns, the nature of any defects inherent to elastomeric materials becomes a critical issue. Latex condoms and gloves are produced by dipping a form, coated with a coagulant for the latter product, into a concentrated natural rubber latex. The thickness is governed by the solids content of the latex and the immersion time. The coated form is then heated to dry and vulcanize the rubber. The material is exposed to a leach bath to extract water soluble residues. The rigid quality control standards associated with condom and medical glove manufacture avoid the routine problems of latex rubber operations, such as surface defects in the form, incorporation of air into the latex, blistering of the film, etc. Traditionally, prophylactics are obtained by double dipping, which minimizes the probability of through-going defects caused, for example, by a defect in the form (ref. 35).

The structural integrity of latex material depends on the formation of a coherent film by the coacervation and co-

Figure 1 - scanning electron micrographs: A - film prepared by coagulant latex dipping onto a glass form; B - a wet-gel leached latex film dried at 70°C (ref. 37) (scale bar 5 microns)

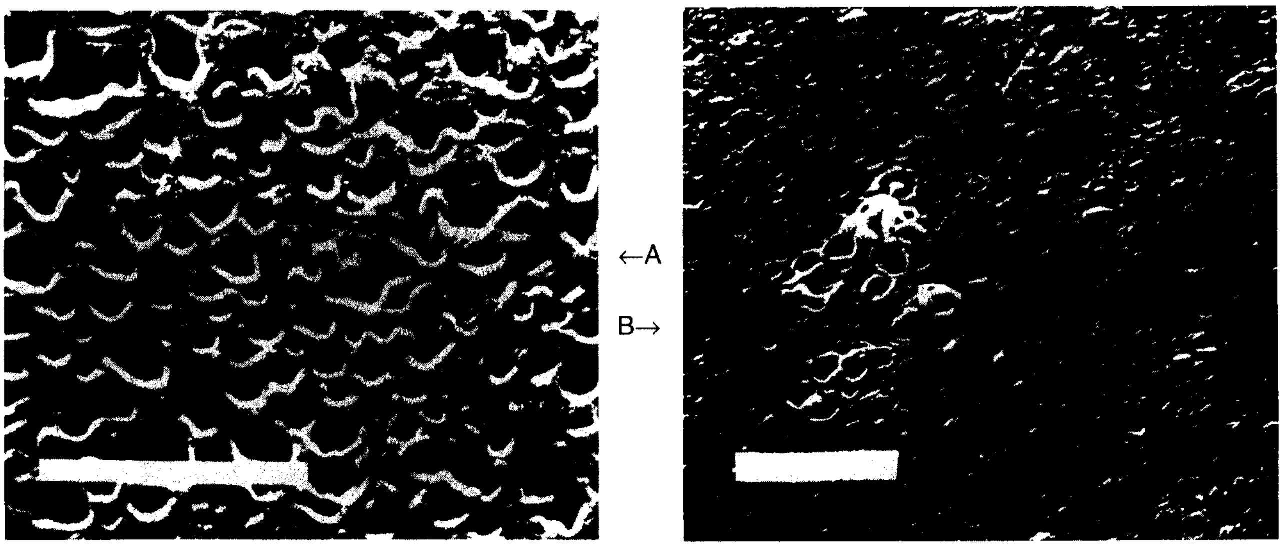

Figure 2 - scanning electron micrograph of the cross-section of a freeze-fractured section taken from a latex glove (ref. 38)

alescence of the rubber particles. In natural rubber latices, these particles range in size from 0.1 to 5 microns. It has been demonstrated that, at least with respect to conventional physical properties, the latex particle size is not important (ref. 36). Nevertheless, the vanishingly small size of viruses places unusual demands on any prospective barrier material. For example, the leaching process relies on the presence of through-going interstitial pathways for the osmotic extraction of residues. Although this capillary structure is presumed to ultimately collapse in the dried film, optical microscopy suggests the existence of a persistent structure reflective of the original rubber particles (ref. 37).

This original particulate structure is ultimately manifested in materials produced by coagulant dipping as an extensive array of pores (ref. 37). These pores have diameters as large as 1.5 microns, as evident in electron micrographs (see figure 1A). Wet-gel leaching appears to restrict the porosity to the surface (figure 1B), suggesting the pore structure may be a consequence of water soluble residues impeding coalescence of the rubber particles. The high water absorption rate exhibited by latex films has been ascribed to the residual capillary structure (ref. 37).

Microscopic investigation of latex rubber for assessment of HIV barrier effectiveness is difficult due to the size of the defects of interest. Latex gloves produced by four different manufacturers were examined with an electron microscope (ref. 38). Pits as large as 15 microns wide and 30 microns deep were present. More relevant to HIV transmission, 5 µm wide channels, penetrating the entire thickness, were found in freeze-fractured sections from all gloves (figure 2). Whether these through-going holes were pre-existing flaws or artifacts of the freeze-fracturing is uncertain. Based on these findings, the investigators recommended double-gloving for those handling virus-infected material (ref. 38). A similar recommendation has been made with respect to condoms (ref. 39). There also exist anecdotal accounts of bodily secretions passing through latex gloves worn by examining physicians and nurses (refs. 40 and 41). These results refer to new latex rubber. The performance of latex condoms is known to deteriorate with age. For example, one study found breakage rates during use increasing from 3.6% for new condoms to as high as 18.6% for condoms which were several years old (ref. 42).

The failure properties of elastomers are dependent on the size of the largest defects present in the material, and thus represent an indirect method to characterize the size of "inherent" defects. The strength (refs. 43-47), fatigue lifetime (refs. 48 and 49), and time to failure under strain (ref. 50) all directly indicate the presence of imperfections in rubber. The strength will vary inversely with defect size (refs. 44 and 45), while the fatigue of natural rubber is inversely proportional to the length of the defect (refs. 48 and 49). Experimentally deduced sizes (actually effective sizes, corresponding to a given degree of stress concentration [ref. 50]) for the inherent defects in natural rubber range between 5 and 70 microns. This distribution is consistent with the scatter intrinsic to failure properties (ref. 43). It is noteworthy that the different experimental techniques yield results in good mutual agreement. Indeed, although the strength and crack growth rates of rubber vary strongly with compounding variables (particularly crosslink density), measured intrinsic defect sizes are sensibly independent of compound variables (ref. 49) and temperature (ref. 44). This gives credence to the authenticity of the inferred intrinsic flaws.

The relevant question in the present context is the exact nature of the flaws revealed by mechanical tests. They are not considered to be surface imperfections resulting from the molding process (ref. 43). When molded against optically smooth glass, natural rubber stocks still exhibit inherent flaws as large as 20 microns (ref. 44). Conceivably, the flaws represent the upper range of a broad distribution of flaw sizes, whose concentration and size distribution are unknown. Unfortunately, strength measurements are unable to distinguish between surface defects and through-going flaws, and only the latter are directly relevant to the barrier function of rubber.

Conclusion

Latex rubber devices originate as a suspension of particles coated with surfactants intended to prevent the particles from coalescing. The use of such a material for barrier protection for a 100 nanometer virus seems counter-intuitive. Certainly the presence of defects in latex rubber is well established; however, the origin, detailed nature and hence relevance of these flaws to the prophylactic performance of latex rubber is open to question. Channels penetrating the entire thickness of latex gloves have been directly observed, but more evidence of this type is needed. Unfortunately, condom inspection methods currently in use are inadequate for the detection of micron-sized flaws.

While latex rubber prophylactics reduce the probability of viral transmission, the critical issue is the degree of risk reduction. Reliable data are scarce and the contribution of user error to measured failure rates is uncertain. In one study, condoms failed to prevent HIV transmission 17% of the time (ref. 51). A review of several studies found that HIV infection rates for couples using condoms ranged from 13-27% (ref. 52). Another investigator concluded that conscientious utilization of condoms in conjunction with anti-HIV spermicide would "probably reduce but not eliminate HIV transmission" (ref. 53). From a broad assessment of data on HIV transmission rates during heterosexual contact, the use of a condom was estimated to provide only a tenfold reduction rate risk of contagion (ref. 54). This compares, for example, to the 5,000-fold increase in protection level afforded by avoiding coitus with partners from high risk groups (ref. 54). HIV infection rates as high as 70% have been estimated for unprotected heterosexual coitus (refs. 10, 52, 55 and 56). Thus, the use of a condom reduces the probability of HIV infection by roughly a factor of three (ref. 57). Presently, it is unknown to what extent the limited success of condoms in preventing HIV transmission reflects inherent limitations of latex rubber. Better insight into the prophylactic capabilities of latex rubber probably will come from the rubber science community. It is one area of rubber research that could have a substantial societal impact.

Disclaimer

Any opinions expressed are the author's own not those of the Department of the Navy or the Naval Research Laboratory.

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Latex films are barriers to viruses

by M.D. Morris and T.D. Pendle, Malaysian Rubber Producers Research Association

The article by Roland (pages 15-18) on the barrier performance of latex rubber raises some valid points. The central thesis of the article, however, that thin latex films are inherently pervious to particles the size of the AIDS virus, is not supported by the evidence available.

Condom usage

At the outset it must be accepted that the use of condoms is not 100% effective in preventing transmission of AIDS, just as it is not 100% effective in preventing conception. We contend that the main reason for this inefficiency is the relatively high incidence of misuse, and not any inherent defect in the product. Misuse, in this context, covers a range of eventualities including damage caused by fingernails, jewelry or unacceptable lubricants, failure to use the condom before first genital contact, and slippage during withdrawal of the penis. These are known to be important factors affecting condom efficiency, and explain why the pregnancy rate among condom using couples far exceeds the incidence of holes in condoms. Data of an epidemiological nature showing the apparent spread of AIDS among condom users should be considered with this in mind. There is certainly a need for better education in the correct use of condoms. Roland points to the relatively small amount spent by the condom industry on advertising. This is surely not because of a lack of desire to promote the product but rather the reluctance of advertising regulatory authorities to permit such advertising.

Do pores exist in latex films?

During the manufacture of condoms and other dipped latex products, the possibility of holes occurring in the latex film clearly exists. Condom manufacturers try to minimize the occurrence of holes by employing good manufacturing practices and by electrically testing every condom. Leaving aside this quality control question, it is important to know whether latex films of condom thickness which are made properly, contain pores of a size which could allow passage of the AIDS virus.

Evidence in favor of the pore hypothesis

Roland refers to microscopy work carried out in these laboratories which shows the presence of a capillary structure in latex films. Such a structure may well exist in air dried latex films, but it is equally well known that the porous structure effectively disappears after leaching in water - part of the normal condom production process. The interstitial pathways referred to, which allow some absorption of water by latex films, are considered to have dimensions measured in nanometers rather than microns. The one claim of direct observation of a sufficiently large channel in a latex product has not been repeated and has been attributed to an artifact by scientists familiar with microscopic examination of latex rubber films (ref. 1).

The other evidence presented in support of the pore hypothesis falls into two categories. The first can be described as anecdotal or epidemiological which, as discussed above, should be treated with caution. The other evidence is based on physical properties. The work referred to by Roland on physical properties alludes to the presence of flaws in molded rubber specimens. It is important to note that these flaws are unrelated to the interstitial pathways or particulate structure mentioned above. Indeed, all of the studies on this subject have been carried out on dry rubber in which a particulate structure does not exist.

The physical nature of the flaws in dry rubber is not known, but they have not been envisaged as holes or voids. Although the flaws have not been observed directly, they affect physical properties as if they were discontinuities or razor cuts on the order of 10 microns long. A channel large enough for the AIDS virus to pass through a condom would need to be at least about 60 microns long with a measurable width. Thus, even if the flaws postulated from physical properties do exist as pores, they are much smaller than would realistically be required.

Evidence contradicting the pore hypothesis

If pores were present in condoms, they would be expected to have a detrimental effect on tensile strength. It is worth remembering that condoms, like many other latex products, commonly have elongations at break in excess of 800%. The thickness of a condom is reduced to 6-10 microns under such an extension and any pore size is multiplied accordingly. The fact is that condoms, even under such high elongations, generally exhibit tensile strengths close to 30 MPa which is at least as good as, and usually better than, thicker products made from the same polymer. It is difficult to see how such strength could be obtained if pores of 0.5 micron diameter were present in the unstretched films.

The ideal way to settle a dispute about the possible existence of pores in condoms is by direct experimentation with the HIV virus. A search of the scientific literature reveals that such experiments have been carried out a number of times. In one study by Van der Perre et al (ref. 2), six commercial brands of condoms were tested in vitro with HIV at a concentration of 10^6 particles per millilitre. The virus-containing medium was placed inside the condoms and subjected to vigorous mechanical movements and changes in hydrostatic pressure. In no case could the virus be detected in the external culture medium. In a similar study by Conant et al (ref. 3), it was found that two other retroviruses completely failed to pass through three types of latex condoms. Minuk et al (ref. 4) tested five brands of latex condoms and one sheep intestinal membrane condom for permeability to radiolabelled Hepatitis B antigen (50% of the size of the Hepatitis B virus). A mechanical vibrator was used to simulate service. All five latex condoms proved to be totally impervious to the antigen, but it did pass through the intestinal condom. The three independent reports described above provide convincing proof that intact condoms provide a good barrier to HIV and to other micro-organisms. Further studies of a similar nature, with similar results, have also been reported (refs. 5 and 6).

Testing of condoms for holes

While accepting that existing methods are adequate for detecting holes large enough for the human sperm to pass through, Roland justifiably points out deficiencies of both the water leak test and the electrical conductivity test in detecting holes of the order of 10 microns and less. The 300 ml water test has in fact been replaced by a one litre test which is slightly more severe. Nevertheless, the sensitivity of the test could be improved by the simple measure of introducing a small amount of an appropriate surfactant to the testing water and standards authorities should consider introducing this modification.

Notwithstanding the deficiencies of the test methods, it is difficult to envisage how a hole of ten microns or less in diameter could occur in a condom. Condoms are made essentially of two rubber layers, each of which is 30-40 microns thick. Since wee are convinced that holes are only caused by foreign particles or air bubbles and are not an intrinsic feature of latex films, a particle of about 10 microns in size could at worst make a hole in one layer of the condom. The possibility of a hole being made through both rubber layers, or of a hole in each layer being perfectly aligned seems extremely remote.

Summary and conclusions

Natural latex condoms, if made properly, provide an effective barrier to HIV. This is not only an expectation based on our knowledge of latex films, but has been demonstrated experimentally by a number of in vitro studies. Failure of condoms due to extraneous circumstances or incorrect use is the main reason for their less than complete efficiency in preventing transmission of HIV. Other latex products, e.g. gloves, have essentially the same composition and structure as condoms but are thicker and are therefore even less likely to permit the passage of viruses.

While it is accepted that current test methods are incapable of detecting micron and sub-micron sized holes, the possibility of such holes occurring in a double-dipped film of condom thickness seems very remote.

We believe that it is misleading and possibly dangerous to those involved in AIDS to suggest that condoms are intrinsically pervious to HIV.

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Author's response to comments by Morris and Pendle

In the preceding note, Morris and Pendle ("M&P") take issue with some observations made in my article "The barrier performance of latex rubber" (hereafter referred to as I). Actually, we are in reasonable agreement concerning the facts; our differences concern only our emphasis of the implications of these facts. Specific points of Morris and Pendle are enumerated below, along with my response.

"a capillary structure ... may well exist in air-dried latex films, but ... the porous structure effectively disappears after leaching in water. The interstitial pathways referred to, which allow some absorption of water by latex films, are considered to have dimensions measured in nanometers."

The "disappearance" of the porous structure is obviously incomplete, since this same structure subsequently is responsible for water absorption. M&P consider, but cite no supporting data, that the interstitial pathways have dimensions "in nanometers." Certainly conventional physical properties are unaffected by such small defects; however, given the 100 nanometer size of HIV particles, the details of the size and size distribution of the interstitial pathways deserve more careful consideration than has heretofore been given.

"The one claim of direct observation of a sufficiently large channel in a latex product has not been repeated and has been attributed to an artifact by scientists familiar with microscopic examination of latex rubber films."

Actually, the direct observation of large (5 micron) channels was made in gloves from four different manufacturers. It should be pointed out that when Dr. Pendle and his colleague make reference to such results having been "attributed to an artifact by scientists," the scientists referred to are Dr. Pendle and a colleague. One's point of view is hardly corroborated by citing one's own earlier statements on the matter!

"flaws in molded rubber ... are unrelated to the interstitial pathways or particulate structure ... a particulate structure does not exist (in dry rubber)."

Having already stated that the interstitial pathways in dry rubber have nanometer dimensions and promote water absorption, M&P can not now claim their non-existence!

"The physical nature of the flaws in dry rubber is not known, but they have not been envisaged as holes or voids... they affect physical properties as if they were discontinuities or razor cuts of the order of 10 microns long."

Since the physical nature of the flaws in dry rubber is not known, any statement concerning their nature is speculation. Experimentally deduced flaw sizes in natural rubber range from 5 to 70 microns (see references 43-49 in I). As discussed in ref. 50 of I, these numbers only represent effective sizes, corresponding to a given degree of stress concentration.

"Condoms ... exhibit tensile strengths close to 30 MPa ... it is difficult to see how such strength could be obtained if pores of 0.5 micron diameter were present."

The very existence of the flaws under consideration comes from measurements of strength and other failure properties. There is certainly no inconsistency between 30 MPa tensile strength and an inherent flaw size of more than 10 microns; consequently, there should be no difficulty in envisaging a 0.5 micron flaw size.

"The ideal way to settle a dispute about the possible existence of pores in condoms is by direct experimentation with the HIV virus ... Natural latex condoms, if made properly, provide an effective barrier to HIV. This ... has been demonstrated experimentally by a number of in vitro studies."

It is true than some studies have failed to detect transmission of HIV through condoms. At the same time, other studies have indeed detected transmission (see references 10, 40 and 41 in I). One can imagine why certain experiments might fail to detect transmitted HIV particles, given their small size and low concentration. Rather than selectively embracing scattered negative results, the burden is on M&P to explain why in vitro experiments demonstrating HIV transmission should be ignored. Moreover, the over-riding conclusion drawn by various investigators from in vitro studies [references 51 through 54, and 57 in I] is that condoms do not reliably prevent transmission of HIV during heterosexual coitus.

"We believe that it is misleading and possibly dangerous to those involved in AIDS to suggest that condoms are intrinsically pervious to HIV."

AIDS is a fatal and incurable disease. Given the documented failures of condoms, it is misleading and certainly dangerous to promote the idea that they allow one to safely engage in sexual relations with HIV carriers. *C.M. Roland*