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Systematic Analysis of Mechanical Hazards from Toys

Bal M. Mahajan

Consumer Product Systems Section
Measurement Engineering Division

May 23, 1973

Final report 07/72 – 02/73

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U. S. DEPARTMENT OF COMMERCE, Frederick B. Dent, Secretary

NATIONAL BUREAU OF STANDARDS, Richard W. Roberts, Director

ABSTRACT

The information necessary to establish criteria for differentiating between hazardous and non-hazardous toy components consists primarily of (1) levels of severity beyond which mechanical injuries are unacceptable, (2) knowledge of various injurious objects that may be found as toy components and their injury potential and (3) the reasonable ranges of loading conditions for various child-toy interactions.

Mechanical injuries are described and classified into six levels of severity, and a procedure to decide on the level of severity beyond which injuries are unacceptable is suggested.

The various injurious objects that may be found as toy components and loading mechanisms probable from various child-toy interactions are identified. Some of the procedures for determining the injury potential of such objects are outlined.

Pertinent studies required to obtain other needed information are recommended.

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LIST OF SYMBOLS

A	contact area
B	bulk modulus = $E/3(1-2V)$ of skin tissue
C	compressibility = $1/B$ of skin tissue
D	base diameter or base dimension of interacting object
E	modulus of elasticity of skin tissue
F	force
g	geometric variables of interacting object
G	shear modulus of elasticity of skin tissue
h	height above the supporting surface of projection, point or edge
I.P.	imjury potential
K.E.	kinetic energy
l	length of wound
Lo	initial gage length
L	final gage length
M	mass
P	pressure = F/A
Pr_1	properties of injurious object
Pr_2	properties of human tissue
r	tip radius of sharp point tip
s	resistance to shearing or cutting
T	thickness of skin tissue
t	contact duration

V	velocity
W	modulus of resilience = $\sigma_o^2/2E = \sigma_o \varepsilon_o/2$
X_o	energy absorbing distance or resilience distance of skin tissue with the backing material intact
α	tip included angle or angle of impact
ε	$(L - L_o)/L_o$ unit strain or elongation or extensibility
ε_o	elastic limit strain
σ	stress F/A
σ_o	elastic limit stress
μ	viscosity
ν	Poisson's ratio
ϕ	roughness of edge

Subscript

1	interacting object
2	human body and its various tissues
n	normal component
h	horizontal

Systematic Analysis of Mechanical Hazards from Toys

INTRODUCTION

This study was undertaken by the Consumer Product Systems Section in support of the Toy Safety Program of the Bureau of Product Safety, Food and Drug Administration. The objective of this study was to recommend pertinent procedures and studies required to obtain information necessary for establishing criteria to differentiate between hazardous and non-hazardous toys or toy components so that mechanical hazards can be minimized.

For the purpose of this study a mechanical hazard* may be defined as any toy, toy component, or product that presents a risk of unacceptable mechanical injury during normal use or reasonably foreseeable abuse (or misuse) of the toy. Mechanical injury is the injury likely to be inflicted on the human body by any type of mechanical loading. Whether an injury is acceptable or unacceptable is determined primarily by its severity. The severity of injury is dependent upon many factors and is discussed in the section entitled Mechanical Injuries.

BACKGROUND

Many investigations have been conducted over the past three decades to study the biophysical response of the human body to various types of mechanical loadings. Human tolerance to the applied loads have been variously defined and different researchers have established different end points as criteria. Several methods to measure, calculate and estimate human tolerance have been devised. These methods

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*Hazards resulting from performance failure of toys are not included in this study.

utilize data from sources such as clinical reports of accidents, experiments with cadavers, living animals and human and animal tissue in vitro, and mathematical and mechanical models. Each contributes to our overall knowledge, although each, by itself, presents problems and imperfections.

A number of attempts have been made to bring human tolerance data together into summary form in order to permit predictions of ranges of injury for any specified mechanical loading condition. An excellent discussion of the subject and a comprehensive list of references may be found in papers by Snyder 1/ and 2/, VonGierke 3/, and Benjamin et al. 4/. Also, some injury scales have been developed to provide a universal means of assessing and evaluating human tissue damage 5/, 6/, 7/, and 8/. Nearly all of these developments fall short of their intended objectives, primarily because the weight given in each respective criterion varies significantly in individual judgements. Unfortunately, until all the parties (or individual researchers) concerned agree with each other, diversity of subjective elements cannot be eliminated.

The injury criteria and threshold or tolerance limits established by these studies may not be applicable to the Toy Safety Program because most of these studies were mainly concerned with impacts which occur in vehicular accidents and in some other loading conditions which do not relate to toys. However, data from some recent papers 9/ to 15/ and some recent studies 16/ and 17/ shed some light on the injury process and provide some information on the biomechanical properties of human tissue.

During the past few years mechanical hazards associated with toys were given a great deal of attention by the National Safety Council, Toy Manufacturers Association, Underwriters' Laboratories, etc. However, little research has been directed to the systematic assessment of mechanical hazards from toys and to assess the injury potential of various objects which may be found as toy components. Recently some studies dealing with these subjects have been conducted by the Consumer Product Systems Section, Product Evaluation Technology Division of the National Bureau of Standards 18/ to 21/.

For establishing safety regulations to minimize mechanical hazards from toys (or consumer products in general) one should have the information necessary to differentiate between hazardous and non-hazardous components of toys or products. The acquisition of such information requires knowledge of injurious components of toys,the injury potential of these components, and the level of severity beyond which injuries are unacceptable. The injury potential of any object is defined as the type and severity of injury such an object is capable of inflicting on the human body for any probable loading condition. The present study deals with these subjects. It describes and classifies mechanical injuries and suggests procedures to determine an unacceptable level of severity. It identifies most of the injurious objects which may be found in toys and probable loading mechanisms involving these objects. In addition, this report identifies the factors influencing the injury potential of injurious objects and recommends pertinent procedures and studies to assess their injury potential.

MECHANICAL INJURIES

Descriptive Classification

As stated in the Introduction, injuries inflicted on the human body by any type of mechanical loading are termed mechanical injuries. Because of the probable loading conditions (loading mechanism and load magnitudes) probable from various child-toy interactions, most injuries sustained by children are injuries involving skin and soft tissue damage and damage to the eyes. Impact loads under certain conditions may also cause damage to the bone, ligament, muscle, tendon, etc., and internal organs. However, impacts leading to these types of injuries probably are less likely to occur under most forseeable conditions.

This section of the report is an attempt to describe various mechanical injuries and the damage mechanism responsible for producing them. For this purpose, the mechanical injuries are placed in the following three groups: 1) injuries involving damage to the skin and adjacent soft tissue; 2) injuries involving damage to bones, ligaments, muscles, etc.; and 3) injuries involving damage to the internal organs. Injuries to the eyes will not be discussed in this report. Ocular injury potential by blunt toy projectiles is discussed by Fischler and Mahajan 18/

Skin and Adjacent Soft Tissue Injuries

Injuries involving damage to the skin and soft tissue are described below. (A typical cross-section of human skin is shown in Figure 1, while Figure 2 shows a simplified schematic cross-section of human skin required to define various levels of severity of skin injuries.)

Blisters. A blister represents collection of fluid in the epidermis causing elevation of the horny upper layer and its separation from the underlying parts. A blister may be caused by pinching and impact, but is often due to persistent friction.

Contusions or bruises. Contusions or bruises are superficial injuries resulting from impacts that damage the soft tissue without breaking the epidermis. A bruise may lead to blistering and swelling. They are caused by excessive compressive loads with failure ranging from crushed or torn tissue to vessel or nerve damage. Injuries of this type usually result from impacts involving the human body and relatively blunt objects. The severity of contusions varies depending upon their location and other factors; but in general, they are not considered serious.

Shallow lacerations. Lacerations represent tearing or cutting of the skin. A laceration usually occurs when a sharp point or sharp edge, pressing down on the skin, is pulled across the skin. The sharp point or edge, by pressing down on the skin cross-section, pierces the skin (probably by tension or shear) and starts the tearing process. This type of loading conditions occur in such phenomenon as abrading scraping, scratching, etc. Figure 3 schematically shows some loading conditions that may result in laceration.

Penetration wounds. Penetration wounds are tissue damage caused by either puncture or localized crushing of the skin and soft tissue. Puncture is a piercing of the skin by a sharp object (such as a needle, nail, etc.) when the applied load is essentially directed along the longitudinal axis of a sharp point (see Figure 4). The epidermis and upper part of the dermis provide very little resistance to puncture. Most of the resistance to puncture is provided by the fibrous part of the dermis known as the reticular layer 17/ and 22/ (see Figure 2). Puncture injuries are discussed in a greater detail by McGuire and Moore 19/.

Penetration wounds caused by localized crushing of the skin and soft tissue may be considered as contusion combined with lacerations or punctures or both. This is so because in this type of injury the insulting object breaks and penetrates the skin tissue while in contusion epidermis is not broken. Injuries of this type are probably caused by a combination of excessive compressive stress and tensile and shear stresses. These injuries usually result from impacts with moderately blunt objects involving those parts of the body where soft tissue is backed by bone. For example, a projectile impacting the buttocks or stomach with energy just enough to cause a bruise may penetrate the skin tissue by crushing when impacting the forehead, elbow or knee with the same energy. This difference in the resulting injury may be attributed to the following reasons: 1) the impact force developed during impact with the forehead, etc., is greater than that developed during impact with the buttocks or stomach, since the latter locations provide a longer stopping distance; 2) the properties of the skin vary with body location, with locations such as the forehead, elbow and knee offering less resistance to puncture and laceration than the buttocks and stomach. The information (data) concerning the variations in the biomechanical properties of the human skin may be found in references 17/, 19/ and 22/.

Injuries to Bone, Ligament, Muscle, etc.

Injuries involving damage to the bone, ligament, muscle, tendon, etc. are of numerous variety. Although these injuries are mechanical injuries, their description is beyond the scope of this investigation. This is so because a large variety of such injuries do not involve mechanical hazards from toys. For example, injuries such as sprains, dislocations, pulled ligaments, muscles or tendons are usually caused by unusual muscular efforts or movements.

However, some injuries, representing damage to these anatomical body components, may be caused by impact loads involving certain toys and their injurious components. Some of these injuries are discussed below.

Deep penetration wounds. Puncture of bones, muscles, etc. can be caused by impact with a sharp point (or sharp projectile such as a dart, arrow, etc.), when the impact velocity is essentially directed along the longitudinal axis of the sharp point. Since the sharp point, puncturing the bone, must first puncture the skin and soft tissue covering the bone, the impact load (momentum) required to puncture the bone is considerably larger than that required to puncture only the skin. Such high momentum impacts probably are not likely to occur under reasonable conditions. Therefore, the likelihood of such injuries resulting from child-toy interactions is probably negligible.

Bone fracture. Fractures occur when the ultimate strength of bone is exceeded. The applied load required to exceed the ultimate strength of bones in vitro will vary with body location and thickness of the soft tissue and skin covering them. Depending upon the contact area during impact, bone fracture can occur by bending, compression or shearing. For example, Hodgson et al. 10/, studying the fracture behavior of the skull frontal bone against cylindrical surfaces, found that for impacts with 10 ft/sec velocity the curved surface of a 1-inch radius cylinder behaved as a blunt surface and produced linear fracture (by producing excessive tensile stress due to bending); while the curved surface of a 5/16 inch radius cylinder behaved more like a sharp area surface and produced local elliptical fracture (by producing excessive localized compressive or shear stress or both).

In most situations, bone fractures are accompanied by injuries to skin and soft tissue. However, under certain loading conditions bone fracture may occur without breaking the skin. For example, Hodgson and Thomas 9/ found, while dropping human cadaver heads against several surfaces, that in a few cases involving a 10-inch drop onto a flat plate, the skull was fractured with no apparent indication of skin rupture.

Skull and facial bones are the most susceptable to fracture because of their fragility and vulnerability, especially in automobile accidents involving the instrument panel and windshield 23/.

Injuries to internal organs. Injuries to internal organs can include contusions, laceration, and ruptures arising from the various types of stresses and strains produced by impacts to different parts of the human body. Internal head injuries (brain damage) probably occur more frequently than the injuries to other internal organs. The most frequent causes of such injuries are vehicular accidents, free falls, and impacts occuring in various sports.

Severity Classification

Mechanical injuries may be classified in a number of ways, but classification by severity is best suited for the assessment of hazard. Severity of injury inflicted on the human body is determined primarily by such considerations as the recoverability of damage, time of rycovery, need of hospitalization, body part injuried, seriousness of permanent disability if any, psychological factors, etc. However, it is difficult to develop a universally acceptable injury classification because of the presence of subjective elements and the intended use of the classification. For example, a wound that leaves a scar on the forehead, face, or other parts of the body that normally is not clothed may be considered by a cosmetologist to be of higher severity than a similar wound that leaves a similar scar on the upper arm, buttocks, or on those parts of the body which are normally clothed.

The classification of injuries based on severity considerations given below may be used for the assessment of mechanical hazards from toys and for the purpose of defining or establishing acceptable-unacceptable types of criteria for various injurious objects. It differs only slightly from the injury classification recently reported by Mahajan 21/, but differs considerably from other injury classifications or injury scales 5/, 6/, 7/ and 8/ present in the literature. Injuries involving damage to the skin and adjacent soft tissue make up the first four of the six levels of severity of the injury classification.

Level 1

Insignificant injury. Such injuries can cause considerable pain and some tissue damage, such as blisters or bruises involving only crushed or torn tissue. (Bruises involving vessel or nerve damage is placed in the second category.) Injuries of this type do not provide ease of entry to harmful bacteria and are fully recoverable.

Level 2

Slight injuries. Slight injuries include contusions involving damage to vessels or nerves and injuries when the injurious object completely damages the epidermis but barely damages the dermis by lacerating, puncturing or crushing the tissue. These injuries (with the exception of contusions) may cause slight external bleeding and provide ease of entry to harmful bacteria. However, these injuries heal easily and do not leave scars.

Level 3

Minor injuries. Minor injuries include those in which there is damage to epidermis and dermis by lacerating, puncturing or crushing of the tissue, but the damage does not extend beyond the reticular layer of the dermis. These injuries will cause some bleeding and do provide ease of entry to harmful bacteria which can cause tetanus, or other infections. These injuries, however, heal easily but may leave scars.

Level 4

Moderate injuries. Moderate injuries represent damage to all three layers of the skin (by lacerating, puncturing or crushing of the tissue). These injuries present all the problems described in the above category and in addition require a longer time to heal and usually leave scars.

Level 5

Serious injuries. Serious injuries represent damage to ligament, muscle, tendon, bone, etc. or contusion of various internal organs. These injuries may require hospitalization for treatment, take a long time to heal, and may leave some permanent disability.

Level 6

Critical injuries. Critical injuries include those in which there is rupture or laceration of internal organs puncture of the eye, contusion of vital areas such as the brain, amputation of a finger, a toe or a limb. Such injuries require hospitalization, take a long time to heal, and usually leave some sort of permanent disability. Injuries of this type may result in fatality.

Unacceptable Level of Severity

The determination of level of severity beyond which injuries are unacceptable is a highly controversial issue, primarily because subjective factors must be included in the decision. Concensus of opinion of physicians, parents, etc. obtained by using the severity classification given above and carefully planned questionnaires should prove very useful for a conclusive settlement of this issue.

Consideration of the ranges of children's activities during various play conditions involving toys; the relative seriousness of various levels of severity; and discussions with a few parents, one histologist, and a few colleagues, led the author to make the following suggestions concerning the levels of severity beyond which injuries are unacceptable: 1) during normal use of toys, injuries beyond level 1 (insignificant injuries) should not be acceptable; and 2) during reasonably foreseeable abuse of toys, injuries beyond level 3 (minor injuries) should not be acceptable. However, these suggestions are derived from a very limited and informal analysis and cannot substitute for the kind of careful and comprehensive investigations described in the previous paragraph.

INJURIOUS OBJECTS

Due to a large variety of toys present on the market and a large number of new toys manufactured each season, the number of injurious toy components is enormous. The injurious objects include (1) components with sharp points, edges, corners, etc., and (2) such components as blunt and sharp projections, chains, belts, springs, etc., each having a variety of different configurations and material properties. This makes it extremely difficult and hopelessly impractical to provide for the specific testing and evaluation of the injury potential of each of these objects. Nevertheless, the consideration of only a few basic objects having generic characteristics may adequately cover most of the important ones.

Studies should be made of the following components.

1. Sharp points and projections. A few simple basic shapes of points to represent nails, pins, staples, wire-ends, splintery wood, corners, etc.
2. Edges. A few simple basic shapes of edges to represent thin or sheared metal, burrs, screws, fractured brittle material, etc.

3. Blunt projections. A few simple basic shapes such as cylinders on their ends and sides, and spherical surfaces to represent unprotected ends of axles, actuating levers, shafts, decorative features, etc.
4. Missiles. A few basic shapes of toy projectiles, and points, edges and projections to represent toy projectiles, darts, arrows, ejected broken parts of toys, ejected wind up springs, etc.
5. Pincers. A pincer with simple configuration to represent chains, belts, springs, pincers, closing boxlike toys, etc.

Figure 5 represents in summary form a number of these injurious objects along with the loading mechanisms of their involvement and probable resulting injuries.

LOADING MECHANISMS

A tremendous variety of child-toy interactions can result from the activities of children associated with the normal use or reasonably foreseeable abuse of the toys. Some of these activities are: 1) normal use - unpacking, handling, holding, operating and occasionally assembling the toys; and 2) reasonably foreseeable abuse - squeezing the toys, stepping or sitting on toys, rolling over the toys, falling onto the toys, sliding or rubbing toys on various parts of the body, grabbing or snatching a toy while it is held by another child or resting on the floor, kicking toys, throwing toys for playing catch or in anger at other children, inserting fingers, toes and other parts of the body in various openings or springs of certain toys, shooting toy projectiles at other children, being hit by broken ejected parts, dismembering the toys, etc.

In all of the probable child-toy interactions, mechanical loads are applied locally to the body surfaces by different loading mechanisms. Each situation involves physical contact with the toys or their various components. However, each situation is different, each having a unique set of loading conditions (i.e. loading mechanisms, ranges of load magnitude, interacting objects, body parts, etc.). The child-toy interactions, apart from being tremendous in variety, are also very complex and extremely difficult to simulate. Nevertheless, a large number of child-toy interactions may be adequately simulated by the following loading mechanisms.

Compression. This involves interaction with sharp points and edges, and occurs in situations where the applied force is essentially directed along the longitudinal axis of the sharp point (interacting object). This may result in injuries such as contusions or punctures. See Figure 4.

Abrading, cutting, scraping, scratching, etc. This loading mechanism involves interaction with points and edges and occurs in situations where the interacting object, pressing down on the skin, is pulled across the skin. In this loading mechanism the resultant load essentially has two components, one directed along the longitudinal axis of the interacting object passing through the point of contact and the other parallel to the skin cross-section. See Figure 3. This may lead to lacerations of variable severity.

Impact. Impact loading occurs in two different types of child-toy interactions. First, in situations where the child or any part of the child's body is hit by a missile. Second, in situations where a child (or any part of the child's body) hits the toy, such as when the child falls onto a toy or kicks a toy. Interactions involving impact loadings can lead to all six categories of injuries discussed in the section entitled Mechanical Injuries.

Pinching (compressing or shearing). This loading mechanism is typical of certain types of toys including closing-box and scissor-like toys, and toys possessing chains, belts, springs, gears, etc. The child-toy interaction involving pinching loads can result in injuries to skin, soft tissue and bones.

INJURY POTENTIAL

Having identified various injurious objects and loading mechanisms involved in child-toy interactions in the previous sections of this report, an attempt will now be made to identify the various factors which influence the injury potential of these objects and to outline the procedures needed for the determination of injury potentials. As stated in the introduction, the injury potential of any object is defined as the type and severity of injury such an object is capable of inflicting on the human body for any probable loading conditions.

The determination of injury potential of various objects involved in child-toy interaction is affected by many factors including characteristics (mechanical properties and geometry) of the injurious object, the part of the body involved and its biophysical properties, the loading mechanism, and the magnitude, direction, distribution, and duration of load. In addition, certain physiological factors such as age, sex, and physical and mental condition of the individual involved have been known to affect the outcome of accidents even though the manner of their influence is not completely understood.

The variability of biophysical properties of human tissue from person to person as well as from part to part within the same person make it difficult to determine the injury potential of injurious objects for universal use, even for stipulated loading mechanisms and sets of loading conditions. The presence of several possible modes of injury, involving different tissue failure mechanisms, further complicates the problem.

Until the influence of physiological factors on the resulting injuries is better understood and our knowledge of biophysical properties of the human tissue is greatly improved, the exact solutions to the problems described above are improbable. Nevertheless, data obtained by carefully planned experiments may still allow us to differentiate between hazardous and non-hazardous toy constituents. These experiments should be aimed at determining the various combinations of relevant geometric characteristics of injurious objects and ranges of loading conditions that produce unacceptable injuries. This will require experimenting with cadavers, living animals, and human and animal tissue in vitro and using various injurious objects and loading mechanisms. The validity of data thus obtained, however, may always be questioned because animal tissue and dead tissue do not have the same biophysical properties as those of living human tissue.

Experimental procedures to obtain the desired data, for each of the loading mechanisms, are outlined below:

Compression. This involves interaction with points, edges, and corners, and represents situations where the applied force is essentially directed along the longitudinal axis, passing through the point of contact of the interacting objects and is perpendicular to the skin cross section. Because the applied load is essentially pressing down on the skin, it is therefore termed compression loading. This can result in two types of injuries, contusions or punctures, depending primarily upon the applied force, contact area, and body location. Contusions are usually caused by high compressive stresses while punctures are generally caused by high tensile or shear stresses. However, punctures can also take place along with contusions, and once the skin is punctured it is difficult to determine whether a contusion has occurred or not.

According to Gadd et al. 11/, under this type of loading, skin tissue fails from a combination of: 1) tensile stress arising from the downward stretching of the skin by the advancing interacting object, and 2) a "pinching off" action as the indentation produced by the interacting object has reached a certain depth (in the case of Gadd's experiment, as the interacting object closely approaches the platen, i.e., the rigid background of the tissue), the effects of which combine to produce a sudden cleavage of the skin tissue in a plane essentially perpendicular to the applied force.

Deck 17/ observed essentially the same skin failure mechanism under this type of loading, while puncturing the skin with points having a contact area less than or approximately equal to that of Gadd's tips, even though Deck's points had different geometric characteristics than Gadd's points. However, points having larger contact areas (i.e. the cross-sectional area contacting the skin) did not puncture the skin in a similar manner; instead the skin failed by a combination of crushing and piercing of the tissue.

Deck 17/ and McGuire et. al. 19/ also observed that the tips with larger contact areas required a larger force to puncture the skin. However, probably due to difficulties associated with measuring the contact area, the applied pressure required to puncture the skin was not calculated. An examination of their data indicates that even with the same sharp point a different force was required to puncture the skin at different body locations, apparently because of variations in the biophysical properties of the tissue.

Estimates made from the data provided by Deck 17/ show that the pressure required to puncture the skin completely (i.e. to produce moderate or level 4 injuries) varies from 8000 to 60000 psi depending upon the body location and tip geometry. The pressure required to produce minor or level 3 injuries (i.e. to produce punctures not to penetrate beyond the reticular layer of dermis) varies from 1300 to 10000 psi depending on the body location and tip geometry. No data is available to determine the pressure or the force required to produce lower level injuries.

These studies show that the injury potential of points, corners, or edges is dependent upon applied force, body location, and the interacting objects geometry, and that the geometry (especially at the contacting area) of the interacting object also affects the damage mechanism.

Hence, for this type of loading, the injury potential

$$\text{I.P.} = f(F, A, Pr_1, Pr_2) \quad \text{(See list of symbols)} \qquad (1)$$

and if the interacting object is harder and tougher than the skin, as it usually is for the objects of interest to us for this study, the properties of the interacting object (Pr_1) can be omitted from equation 1.

The biophysical properties of human tissue (Pr_2) of interest include: C, E, G, s, T, W, X_o, ε_o, σ_o, μ.

The contact area (A) depends primarily upon the geometry of the interacting object although the skin tissue properties, such as resilience, also exert some influence. See Figure 6 for geometric variables.

Therefore, Equation 1 may be rewritten as follows:

$$I.P. = f(F, A(g), Pr_2) \qquad (2)$$

Skin puncture potential of points and corners under essentially static conditions has been adequately studied by McGuire et al. 19/. The skin puncture potential of edges under this type of loading can be determined by procedures similar to those used by McGuire et al. 19/ to study injury potential of points.

Abrading, cutting, scraping, scratching, etc. This loading mechanism represents children's interactions with edges and points that may result in skin tissue lacerations. As stated previously, this type of loading occurs in situations where the applied load essentially has two components. One component is directed along the longitudinal axis of the interacting object passing through the point of contact. This component is usually perpendicular to the skin cross-section and for the purpose of this study may be considered as a concentrated force (F_n) or pressure (P_n). The second component of the applied load is directed in a direction perpendicular to the first one. It is usually parallel to the skin cross-section. In some cases this may be a pulling force that causes the interacting object to move across the skin, and in other instances it may be a body motion that causes the tissue to be dragged across the interacting object. In any event, the second component of the applied load may be represented by a horizontal force (F_n) between the skin and the interacting object.

In some cases a sharp edge or point, due to load component F_n, punctures the skin and starts the tear process. The tear is then lengthened (i.e. the cut is made larger) by the second component of load F_n in the direction of pull. In other situations the interacting object, due to the normal component of load F_n, just indents the skin but cannot puncture it. The indented skin may then be torn by the interacting object, due to the horizontal component of load F_n.

Situations which occur in real life are not as simple as described above. The injury mechanism is very complex and not completely understood. The various loads acting simultaneously on the tissue, induce certain combinations of stresses and strains that excite the damage mechanism and cause injury. The injury potential of various injurious objects obtained by simple experiments in accordance with the loading mechanism described above will, however, be adequate for our purpose.

The injury potential of a point or an edge, for this type of loading, primarily depends upon the applied loads (F_n, F_h), the mass and velocity of the moving object, the geometric characteristics of the interacting object, the biophysical properties of the skin tissue involved, contact duration (t), and angle of attach θ i.e. the angle made by the longitudinal axis of the injurious object with the skin cross-section. (See Figure 3 for θ and Figure 6 for geometric characteristics.)

Mathematically,

$$I.P. = f(F_n, F_h, M, V, g(\alpha, D, r, h, \phi), Pr_2, t, \theta) \qquad (3)$$

If the contact areas $A_n \perp F_n$ and $A_h \perp F_h$ were measurable, the number of variables present in Equation 3 could be greatly reduced and Equation 3 could be rewritten as follows:

$$I.P. = f(F_n, F_h, M, V, A_n, A_h, Pr_2, t) \qquad (4)$$

Furthermore, if the damage mechanisms were known, the application of dimensional analysis techniques could further simplify Equation 4. For example:

a) when both the load components and the velocity of moving object (tissue or injurious object) are known, injury potential may be expressed as;

$$I.P. = f(F_n/A_n \sigma_o, \quad F_h V_h t/A_h(ls) \text{ or } F_n t/A_h \mu, \text{ etc.}) \qquad (5)$$

and b) when F_n is known and F_h is not known, but V_h and M of the moving object are known, the injury potential of the injurious object may be expressed as;

$$I.P. = f(F_n/A_n \sigma_o, \ MV_h/\mu A_h \text{ or } MV^2/A_h(ls), \text{ etc.}) \qquad (6)$$

Unfortunately, the determination of contact areas is very involved and extremely difficult. One may roughly estimate the contact area A_n, because it is dependent primarily upon geometric variables of the object and angle of attack θ. However, even rough estimates of the contact area A_h are highly improbable, because A_h, apart from being dependent upon geometric characteristics of the object and angle of attack θ, is also affected greatly by F_n and properties of the tissue involved.

Moreover, neither the damage mechanisms nor the biophysical properties of human tissue are completely known. Therefore, at the present state-of-the-art such simplifications as described above are not justifiable.

Nevertheless, a knowledge of various combinations of F_n and V_h with which a given injurious object can lacerate the skin tissue would adequately serve our purpose. The basic data necessary for the acquisition of the aforementioned knowledge may be obtained by the experimental procedures outlined below.

A given injurious object, with a constant force F_n and a constant velocity V_h, should be brought into contact with a stationary skin tissue specimen to observe whether it lacerates the skin or not. In tests where skin is lacerated, the size of the wound should be recorded. A test series should be conducted with a constant value of force F_n and varying values of velocity V_h, starting with $V_h = 0$ and increasing it in small increments until the velocity necessary to produce observable laceration is reached. The experiment should then be repeated with a different values of F_n. After one injurious object is tested for the desired ranges of F_n and V_h, the experiment should be repeated with other objects. The data for each object may be plotted on a rectilinear graph paper with F_n as ordinate and V_h as absicissa as shown in Figure 7.

The experiments can also be conducted by bringing the injurious object, with Force F_n, into contact with the skin tissue moving with a constant velocity V_h. Various combinations of F_n and V_h, at which the object can lacerate the skin can be found.

A small number of points and edges having simple basic shapes (geometric characteristics) should be selected to represent injurious objects. Some such experiments are already underway at the Consumer Product Systems Section, NBS 24/.

Impact. As stated previously, a child-toy interaction involving impact can lead to all six levels of injuries. The injury potential of a projection when impacted by a falling person is given by the following equations 20/.

Sharp projections - $I.P. = f(h/X_o , MV/\mu A)$ (7)

Blunt projections - $I.P. = F(h/X_o , KE/ATW)$ (8)

The injury potential of projectiles impacting the human body is given by equations similar to Equations 7 and 8.

The procedures to determine the injury potential of various injurious objects outlined in references 18/ and 20/ are probably adequate for the Toy Safety Program. Data obtained by Sorrells 24/, from his recent experiments, are in reasonable agreement with the injury threshold curves postulated by Mahajan 20/.

Pinching (compression and shear). The injury potential of objects involved in this mechanism depends primarily upon applied load, the object's geometric characteristics, geometric characteristics of the body part involved, and the biophysical properties of the tissue. For example:

$I.P. = f(F, g_1, g_2, Pr_2)$ (9)

The geometric characteristic of both the injurious object (g_1) and the body part (g_2) in Equation 7 can be easily replaced by contact area A. This is so because g_1 and g_2's main influence on the injury potential is the determination of contact area.

Hence,

$I.P. = f(F, A, Pr_2)$ (10)

The basic injury data collected for the other three loading mechanisms can be easily used, by interpolations, to determine the injury potential of injurious objects for this loading mechanism.

HAZARD CRITERIA

Any constituent of a toy that presents the risk of unacceptable injury due to any child-toy interaction during normal use or reasonably foreseeable abuse of the toy is considered hazardous.

To establish criteria that can effectively differentiate between hazardous and non-hazardous toy components (or toys), one should have a clearly defined level of severity beyond which injuries are unacceptable. Furthermore, since the severity of injury is dependent upon loading conditions, a set of loading conditions should be stipulated. To define the level of severity beyond which injuries are unacceptable, and to make a reasonable assessment of the ranges of loads that are developed in various child-toy interactions, the studies indicated below are necessary. Some such studies of limited scale have already been made.

1. Consensus of opinion. Consensus of opinion of physicians (such as pediatricians and surgeons) parents, etc, should be obtained by means of carefully planned questionnaires to define level of severity beyond which injuries are unacceptable and to determine the parts of a child's body that are most vulnerable to injury from various child-toy interactions.

2. Case studies. A complete and thorough study should be made of child-toy interactions resulting in injury. These studies should investigate the injurious objects (or toys) involved, type and severity of injuries inflicted, the interaction conditions, the part of the child's body injured, etc. For such studies the cooperation of pediatricians, parents, and children is essential.
3. Physical measurement of children. These measurements should include the following: the effective mass of various parts of children's bodies and their geometric characteristics; the ranges of forces or energies children are capable of exerting during their various activities; the ranges of velocities for various motions of different body parts during typical activities of children; ranges of velocities with which different parts of a child's body can hit a toy or an injurious constituent of a toy under reasonable fall conditions, etc.
4. Experiment determination of injury potential. Experiments with animals in vivo, human cadavers, and human and animal tissue in vitro should be conducted to obtain data on the injury potential of various objects in terms of the relevant geometric characteristics of the object and appropriate load magnitude for various loading mechanisms.
5. Injury mechanisms. Experiments should be conducted to study and understand the mechanisms of tissue failure during injury processes, and to obtain data on the basic biophysical properties of the human tissue. This study requires a team effort of histologists, rheologists, and engineers.

6. Correlation between the biophysical properties of living human tissue and dead tissue. For a better assessment of the injury potential of various injurious objects, correlations between the biophysical properties of living human tissue and dead human tissue is essential. Such correlation could probably be obtained by finding the correlations between the biophysical properties of the living animal tissue and dead animal tissue and applying the findings to human tissue by interpolation and scaling.

When the level of severity beyond which injuries are unacceptable is defined, and a reasonable range of loading conditions (especially the load magnitudes in the ranges in which children are capable) are known and the injury potential of various injurious objects is determined, it becomes possible to determine whether any given toy constituent (or toy) is hazardous or not.

CONCLUDING REMARKS

At the present state-of-the-art it is extremely difficult to establish universally acceptable injury criteria that will differentiate between hazardous and nonhazardous objects. The major reasons are that humans are complex and variable, and available techniques for testing living bodies are limited. Furthermore, injury mechanisms are not exactly understood, and the biophysical properties of the human tissue are not completely known.

Nevertheless, from the data obtained by carefully planned experiments for a given family of injurious objects a specified loading mechanism, criteria to differentiate between hazardous and nonhazardous objects can be developed. The criteria thus obtained have to suffice until our knowledge about the injury mechanism and properties of human tissue is greatly improved.

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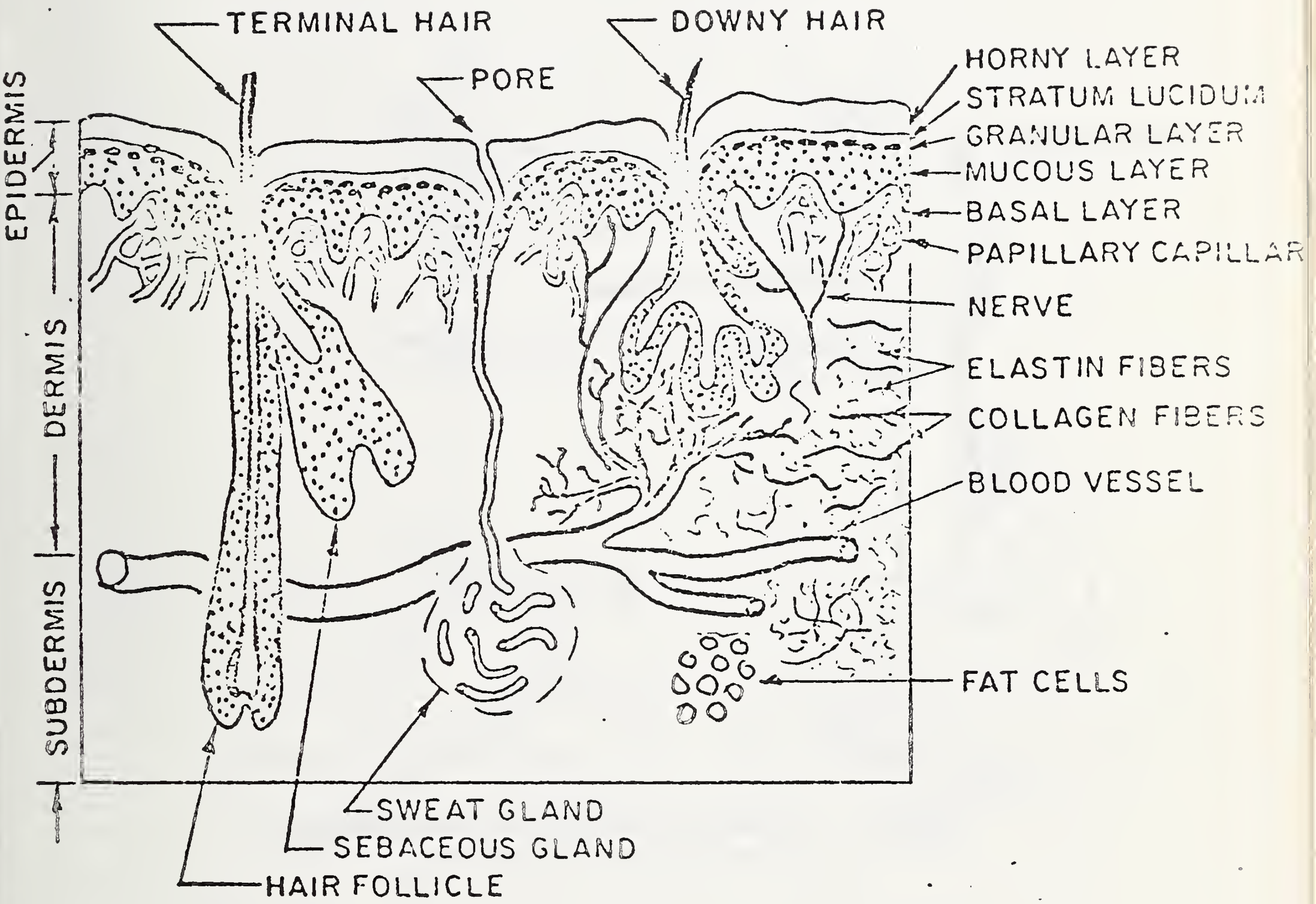

Figure 1. Typical Cross-Section of Human Skin

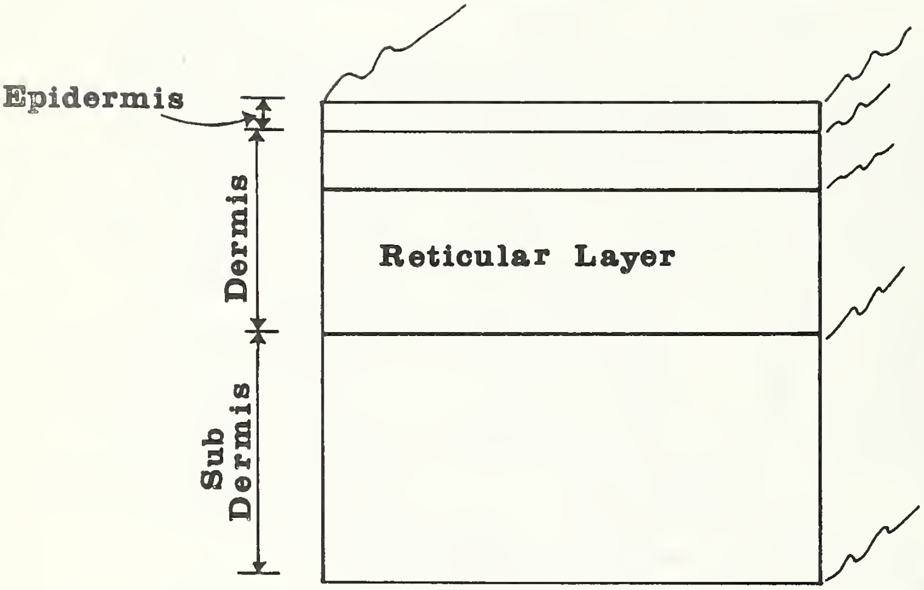

Figure 2. Schematic cross-section of human skin to indicate reticular layer.

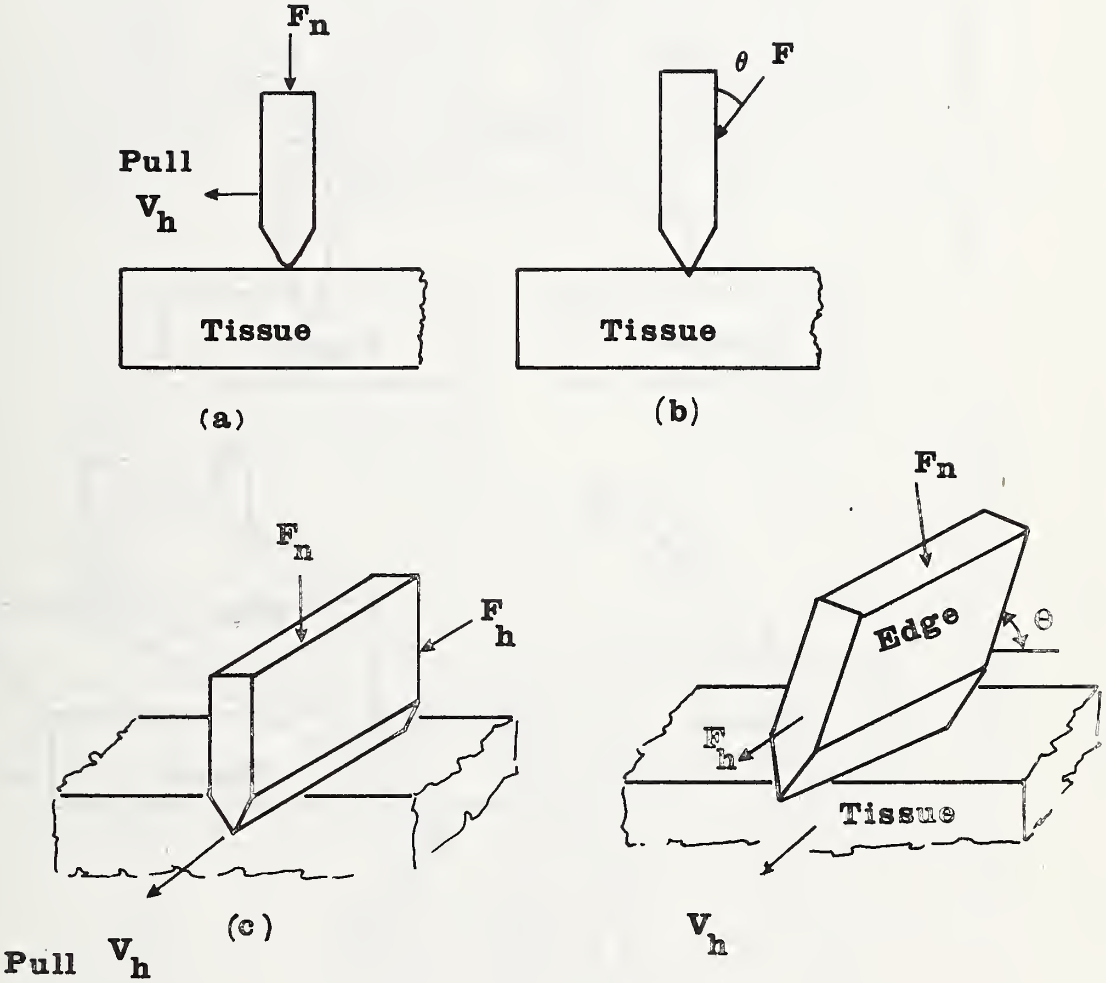

Figure 3. Schematic representation of loading conditions which may lead to lacerations.

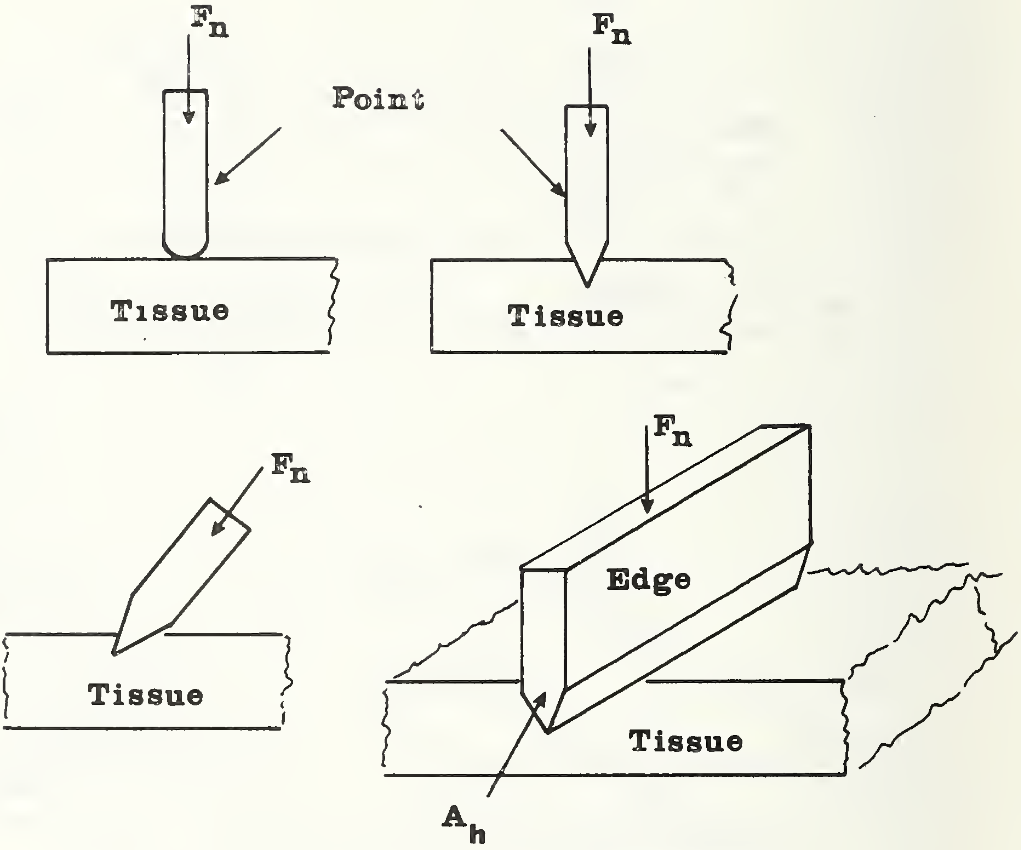

Figure 4. Schematic loading which may result in penetration wounds.

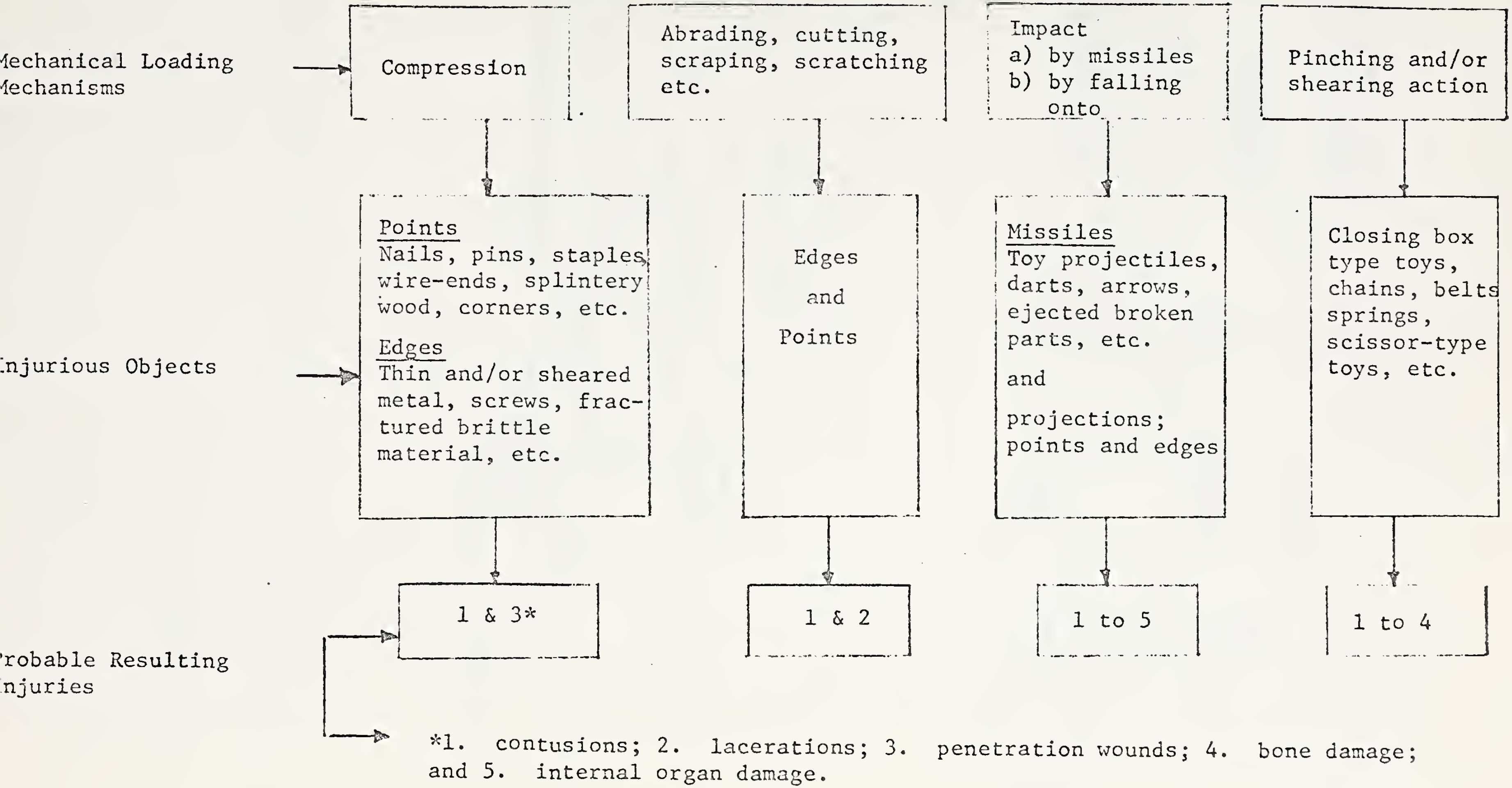

Figure 5. Various mechanical loading mechanisms, injurious objects and probable resulting injuries

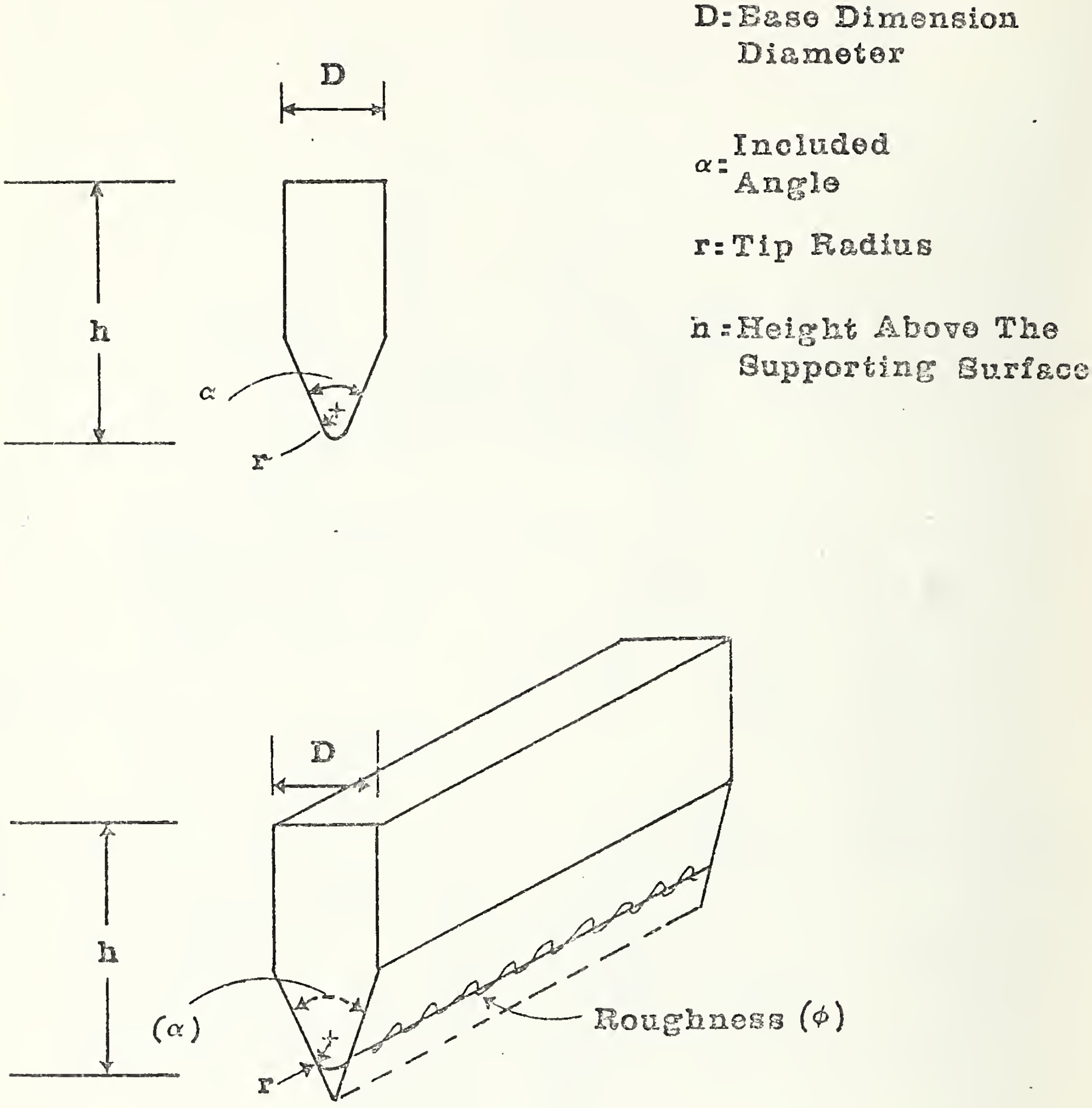

Figure 6. Geometric characteristics.

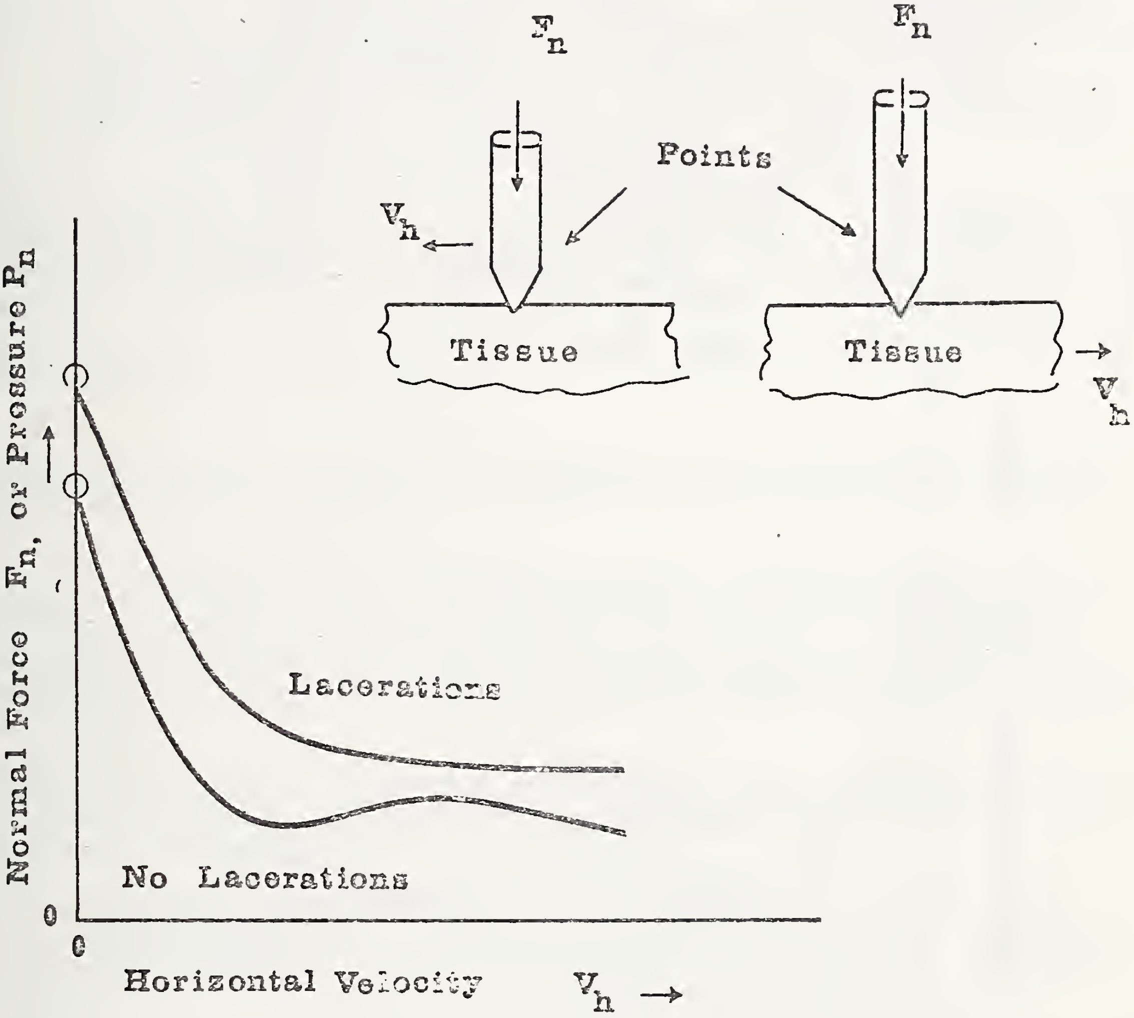

Figure 7. Postulated experimental injury threshold curve for lacerations by sharp points.

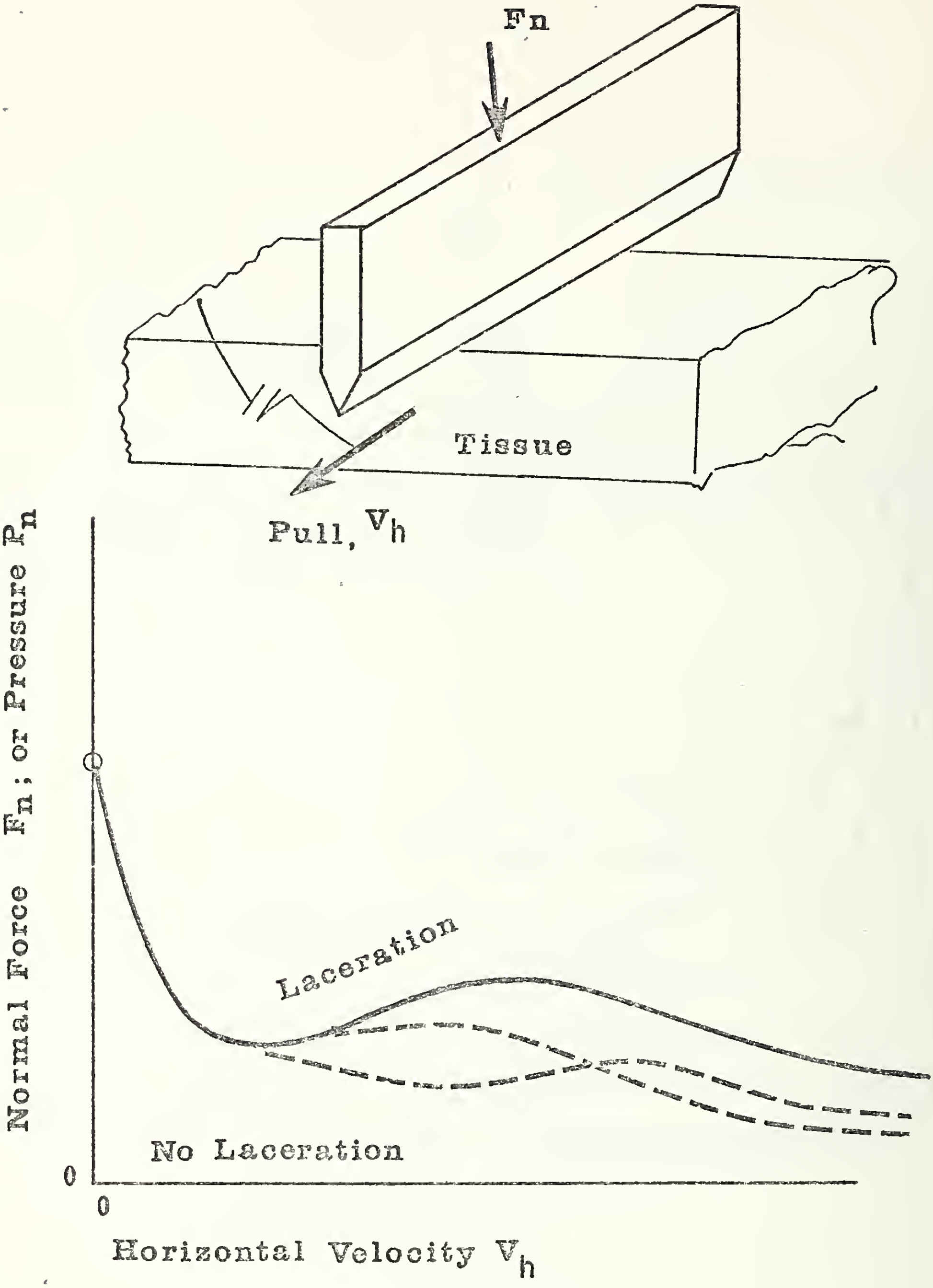

Figure 8. Postulated injury threshold for laceration by edges.

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16. ABSTRACT (A 200-word or less factual summary of most significant information. If document includes a significant bibliography or literature survey, mention it here.)

The information necessary to establish criteria for differentiating between hazardous and non-hazardous toy components consists primarily of (1) levels of severity beyond which mechanical injuries are unacceptable, (2) knowledge of various injurious objects that may be found as toy components and their injury potential and (3) the reasonable ranges of loading conditions for various child-toy interactions.

Mechanical injuries are described and classified into six levels of severity, and a procedure to decide on the level of severity beyond which injuries are unacceptable is suggested.

The various injurious objects that may be found as toy components and loading mechanisms probable from various child-toy interactions are identified. Some of the procedures for determining the injury potential of such objects are outlined.

Pertinent studies required to obtain other needed information are recommended.

17. KEY WORDS (Alphabetical order, separated by semicolons)
Analysis; child-toy; classification; description; determination; hazard; injury; interaction; mechanical; object, potential; procedure; safety; toys

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