United States Patent

Spence

[15] **3,663,973**

[45] **May 23, 1972**

[54] CUSHION STRUCTURE

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[73] Assignee: **Stryker Corporation,** Kalamazoo, Mich.

[22] Filed: **Dec. 16, 1970**

[21] Appl. No.: **98,816**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 621,056, Mar. 6, 1967, Pat. No. 3,548,420, which is a continuation-in-part of Ser. No. 515,525, Dec. 22, 1965, Pat. No. 3,308,491.

[52] **U.S. Cl.** **5/348,** 5/355, 5/361, 3/20, 128/83, 260/46.5

[51] **Int. Cl.** **A47c 27/08,** A61f 5/04

[58] **Field of Search** .....260/29.6 B, 91.3 A; 3/20; 5/338, 355, 361; 297/452, 556; 128/581, 594, 24, 83

[56] **References Cited**

UNITED STATES PATENTS

3,273,179	9/1966	Ridenour	5/361 R
3,140,086	7/1964	Lawson	267/111
3,308,491	3/1967	Spence	5/348
3,309,714	3/1967	Porten	3/20
3,548,420	12/1970	Spence	3/20

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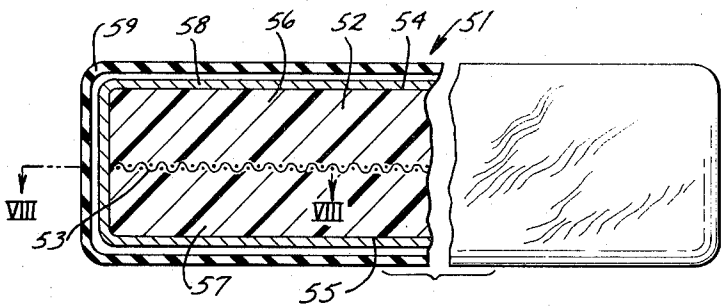
[57] **ABSTRACT**

A cushion structure constructed of a gel-like substance, such as an organosiloxane gel comprising the reaction product of an organosiloxane and a hydrogenosiloxane which is preferably a copolymer of a particular combination of siloxanes combined with an additive such as dimethylpolysiloxane. The gel is preferably covered, at least on one side, by sheet material which may be cloth, rubber, leather, foamed plastic or paper, depending upon the particular use. A flexible mesh-like member, such as dacron net, is preferably embedded within the cushion. The cushion structure is used to at least minimize pressure necrosis.

10 Claims, 9 Drawing Figures



Patented May 23, 1972 3,663,973

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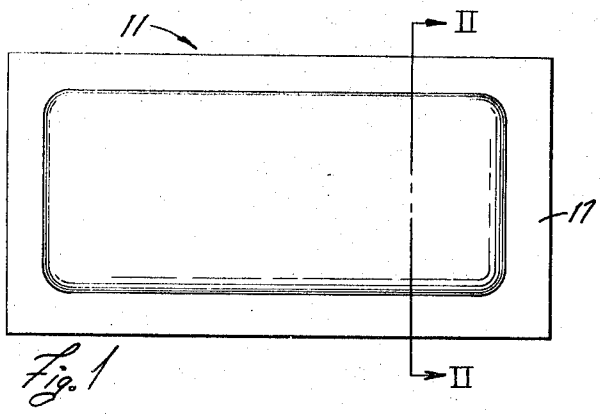

Fig. 1

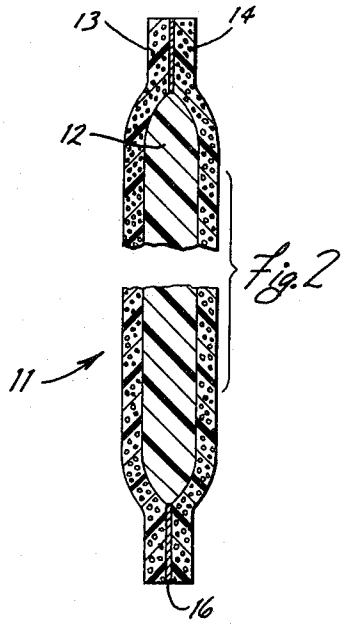

Fig. 2

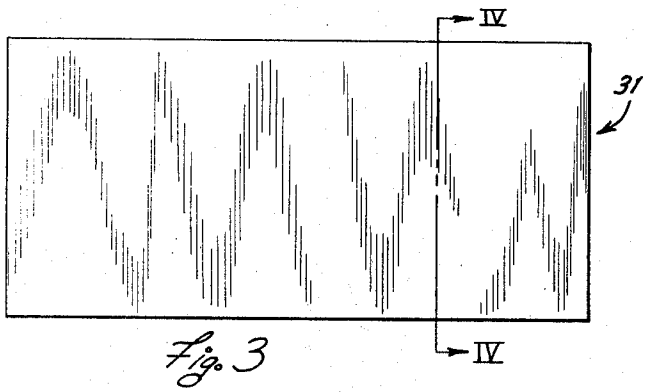

Fig. 3

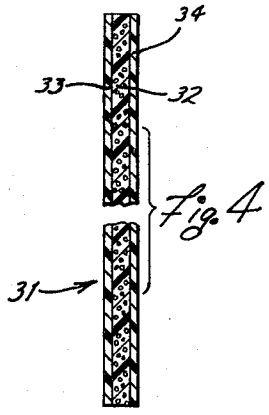

Fig. 4

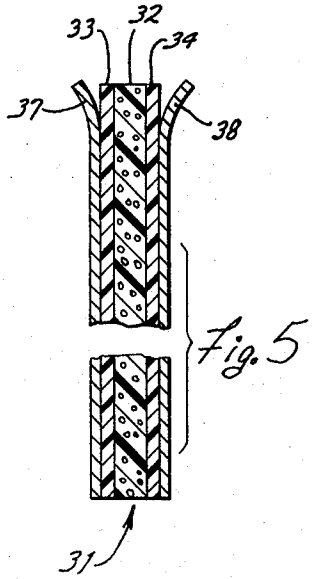

Fig. 5

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Patented May 23, 1972 3,663,973

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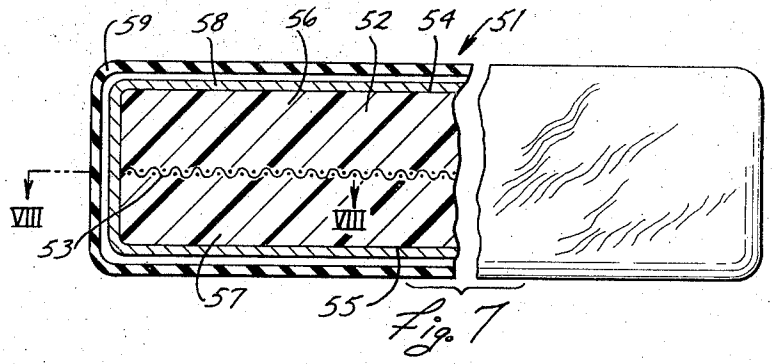

Fig. 7

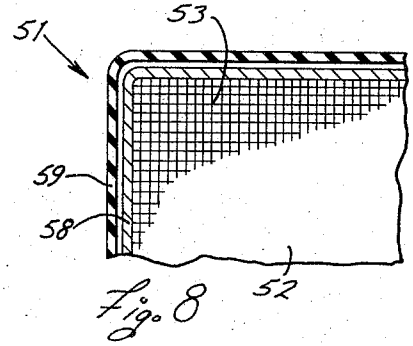

Fig. 8

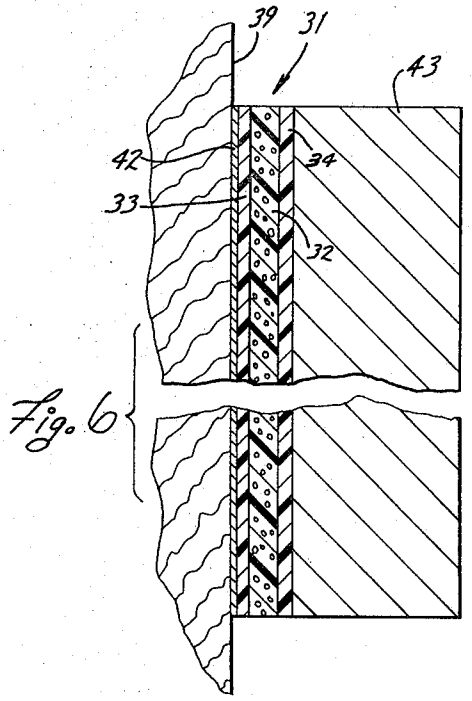

Fig. 6

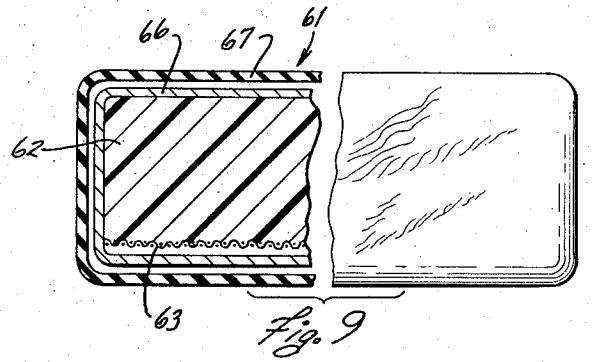

Fig. 9

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CUSHION STRUCTURE

CROSS-REFERENCE TO RELATED APPLICATION

This application is a continuation-in-part of my copending application Ser. No. 621,056, filed Mar. 6, 1967 and entitled "Cushion Structure," assigned U.S. Pat. No. 3,548,420, which in turn was a continuation-in-part of application Ser. No. 515,525, filed Dec. 22, 1965 and entitled "Cushion Structure," now U.S. Pat. No. 3,308,491.

FIELD OF THE INVENTION

This invention relates to a cushion structure and, in particular, to an improved cushion structure usable in patient treatment for protecting the body of a human or animal against localized pressures.

BACKGROUND OF THE INVENTION

In the course of developing and adapting the cushion structure of my U.S. Pat. No. 3,308,491 to various uses related to patient therapy and treatment, I found that many problems were greatly reduced, but not completely eliminated, by the original design of the cushion structure, which was directed primarily, but not entirely, to the relief of necrosis due to concentrations of weight on pressure points produced by bones located close to the surface of the skin. However, it is well known in the medical profession that necrosis producing substantially the same discomforts can results from pressures produced by prosthetic devices, by corrective appliances and by plaster casts, especially if the patient is ambulatory. Other similar and related conditions develop the same type of pressure necrosis problems.

In addition to the foregoing, there are special weight-producing pressure necrosis conditions, such as those encountered by people having particular foot gear problems which require special adaptation of my cushion structure. Almost all of these special problems have certain common factors which, when understood, render these problems capable of solution by variations in my cushion structure. A principal factor was the need for maintaining the gel in a relatively thin layer so that the cushion could fit into a relatively narrow space and, further, confining the gel against migration under conditions of substantially continuous and relatively high pressure. Yet, on the other hand, where shearing forces tend to develop due to shifting in the position of the patient's body with respect to the pressure creating device, the material confining the gel must be capable of allowing the gel to effect the lateral movement which avoid the necrosis which usually occurs with conventional pads for substantially the same purpose. In other words, the containing material must be capable of holding the gel in a selected position to minimize necrosis and soreness due to excessive pressure without creating necrosis due to the creation of prohibitive shearing forces parallel with the engaged surface of the patient.

It was found that even small amounts of lateral movement provided by the cushion could greatly reduce necrosis due to shearing forces so that the gel could be used in combination with layers of fabric or foamed plastic, for example, which would serve to contain the gel within a selected, desired region.

Under some circumstances, particularly with ambulatory patients, severe pressure conditions exist or occur on a periodic repetitive basis. For example, particular problems may arise wherein the feet may be sensitive in localized areas to the support of weight, such as the metatarsal region, and are not sensitive when no weight is placed upon such spots. Yet, due to the normal buildup of protective calluses on the bottom of the foot, necrosis due to shearing motions are not a problem. However, due to the excessive weight concentrated on such sensitive spots, migration of the gel becomes a far more serious problem. Thus, the containing material must be capable of applying sufficient pressure in its uncompressed condition (due to the weight of the human) to tend to move the gel into a preselected position following each pressure application produced by walking, for example. This type of problem also occurs at the distal end of a stump where it is engaged by a prosthetic device and in other similar circumstances.

During the further development of the cushion structure of my prior U.S. Pat. No. 3,308,491, particularly when the structure was provided in the form of a seat cushion, it was discovered that the cushion was often moved from one place of use to another and, when so moved, was mishandled and thereby damaged. That is, persons without knowledge of the nature of the cushion would grasp it along one edge and suspend it from such edge. Due to the substantial size and weight of the cushion, support thereof in this manner sometimes resulted in the breaking away of pieces of the gel core from the remainder thereof.

Accordingly, it is a primary object of the present invention to provide a cushion structure which overcomes the above-mentioned disadvantages.

Particularly, it is an object of this invention to provide a cushion structure for protecting the body of a human or animal against localized pressures directed against the surface of the body and usually capable of developing pressure necrosis of such pressure concentrations are not eliminated.

A further object of this invention has been the provision of a cushion structure, as aforesaid, which is hypoallergenic, stable over a relatively wide temperature range, which will not support the growth of algae and/or bacteria, which is relatively easy to handle and maintain, which has good properties of moisture and thermal resistance, and which includes a soft, nonfriable and jelly-like material capable of absorbing relatively large shearing forces without fracturing.

A further object of this invention has been the provision of a cushion structure, as aforesaid, which can be used effectively in zones where normal relatively thin padding has heretofore been used while, at the same time, performing the aforesaid protection.

Still a further object of the present invention is the provision of a cushion structure, as aforesaid, provided with a gel core having a flexible mesh-like fabric disposed centrally within and completely surrounded by the gel, the fabric being disposed approximately midway between the upper and lower surfaces of the core for providing the core with additional resistance against damage while at the same time permitting the core to be effectively formed as a single monolithic mass and without restricting materially the capability of both sides of the gel core to absorb pressures and minimize shearing forces.

Other objects and purposes of this invention will become apparent to persons familiar with this type of structure upon reading the following descriptive material and examining the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a plan view of a cushion structure embodying the invention.

FIG. 2 is an enlarged, broken, sectional view taken along the line II—II in FIG. 1.

FIG. 3 is a plan view of a alternate cushion structure.

FIG. 4 is an enlarged, broken, sectional view taken along the line IV—IV in FIG. 3.

FIG. 5 is an enlarged broken, sectional view similar to that appearing in FIG. 4 and including protective cover sheets on the opposite sides thereof.

FIG. 6 is a broken, cross-sectional view of the cushion structure of FIG. 4 disposed between the outer surface of a human body and a plaster cast.

FIG. 7 is a broken, partially sectioned view of another alternate cushion structure.

FIG. 8 is a fragmentary sectional view taken along the line VIII—VIII in FIG. 7.

FIG. 9 is a broken, partially sectioned view similar to FIG. 7 and disclosing modified cushion structure.

For convenience in description, the terms "top," "bottom" and words of similar import will have reference to the front and rear sides, respectively, of the cushion structures appearing in FIGS. 1 and 3, for example. The terms "inner," "outer" and derivatives thereof will have reference to the geometric center of a said cushion structure and parts thereof.

DETAILED DESCRIPTION

As shown in FIGS. 1 and 2, which illustrate one embodiment of the invention, the cushion structure 11 is comprised of a relatively flat and thin, self-contained, semisolid core 12 and a pair of resiliently flexible sheets 13 and 14 disposed on opposite sides of said core. Although the cushion structure 11 (FIG. 1) is shown as being substantially rectangular in outside shape, it could be otherwise if so desired. The core 12 is preferably made from an organosiloxane gel, substantially of the type disclosed and described in U.S. Pat. No. 3,020,260. Thus, said core will have a soft, slightly tacky, nonfriable and jelly-like consistency in its cured condition. Specific reference is made herein to the use of a gel and, more specifically, to those gels known as organosiloxane gels, because this particular material has been found especially suited to the purposes of the invention. However, it may be found that other gels and/or colloids, including jelly-like substances which, strictly speaking, are not colloids, can serve satisfactorily in carrying out the purposes of the invention.

The elastic, flexible sheets 13 and 14 may be fabricated from a foamed material such as polyurethane or from any other elastic, flexible material. Although such material should be of a type that is reasonably soft and resilient, it should also to a certain degree resist stretching. Sheets 13 and 14 may be secured together wherever they are in contact with each other, as distinguished from contact with core 12, by an adhesive material 16 such as, for example, zinc oxide. As shown in FIG. 1, the zone of engagement occurs along the entire periphery 14 of the cushion structure 10.

The particular embodiment of the cushion structure 11 described in especially suitable for use with corrective appliances, such as a Milwaukee Brace. In such an application the cushion 11 may be disposed between the appliance and the patient's body in all areas where pressure is apt to exist.

The laminated cushion structure 31 (FIGS. 3 and 4) is well adapted for use between a patient and a plaster cast 43 (FIG. 6). Cushion structure 31 has a central member 32 which is comprised of a porous material, such as a sheet of foamed polyurethane or a fibrous fabric, which is impregnated with a gel, such as the gel 12 in cushion 11. The gel is applied to the central member 32 so as to form layers 33 and 34 of gel disposed on either side of the central member 32. In some cases, the gel which impregnates fabric and the gel layers 33 and 34 are integral parts of a single mass in which the fabric is embedded. Although the cushion structure 31 is illustrated in a rectangular shape, it may be provided in various shapes including long strips which, for example, may be rolled up on a spool.

A pair of protective sheets 37 and 38 (FIG. 5) of material such as paper may be provided adjacent the layers 33 and 34, respectively, thereby preventing damage to or contamination of said layers during handling. Immediately prior to use, the paper sheets 37 and 38 are removed from the cushion structure 31. It is known that casts are often located in regions where the adjacent surface 39 of the patient's body can move excessively with respect to the cast in a direction parallel with the surface 39. However, under normal conditions, the cast will often be urged strongly against such surface. The gel layers 33 and 34 may have a slightly tacky texture which would normally cause them to stick to the surface 39 and the cast 43, which would be undesirable in regions where said excessive movement occurs. Thus, to provide for pressure protection and excessive lateral movement, a layer of lubricant 42, such as talc, is placed between the surface 39 of the patient and cushion structure 31 before the plaster cast 43 is applied to the patient over the cushion structure 31.

FIGS. 7 and 8 illustrate a further cushion structure 51 which is specifically desirable when the cushions are of rather larger size since the cushion structure possesses the necessary strength and durability to permit ease of handling without fear of tearing or otherwise damaging the gel core. The cushion 51 includes a core 52 which is formed from a gel, such as the gel 12 used in the cushion 11. The core 52 includes a thin central member 53 which comprises a flexible, mesh-like sheet or fabric, such as a dacron mesh or net. The mesh-like member 53 is disposed within the core 52 so that the gel effectively forms layers 56 and 57 of gel disposed on opposite sides of the fabric 53. However, due to the porosity of the member 53, the gel forming the core 52 effectively impregnates and totally surrounds the member 53 so that the gel layers 56 and 57 are in fact integrally bonded together and the layers 56 and 57 thus effectively form a single monolithic mass of gel.

The cushion structure 51 is normally provided in the form of a seat cushion having substantially parallel major surfaces 54 and 55, and the mesh 53 is preferably disposed substantially midway between and substantially parallel to the surfaces 54 and 55. Although the gel of the core 52 is normally of such shape and strength that it is capable of maintaining its own continuity, nevertheless the type of use to which it is exposed generally dictates the use of some form of container. For this purpose, the core 52 is preferably placed in a resiliently flexible envelope 58 which may be made from a stockinette material. The combined core 52 and envelope 58 are then preferably inserted into a waterproof casing, such as a pure latex rubber cover 59.

The provision of the intermediate fabric 53 impregnated and bonded within the central portion of the core 52 is highly desirable since it substantially strengthens the core 52 and thus reduces the possibility of damage to the core 52 without restricting materially the capability of the cushion 51 to absorb pressures and minimizing shearing forces. Particularly, cushions of the type illustrated in FIGS. 7 and 8, when used as a seat cushion, are generally of substantial size and weight. Further, when the cushions are being handled, there is a tendency to grasp the cushion by a corner thereof, which can cause a piece of the gel to separate from the remainder of the gel core. This type of damage is virtually eliminated in the present invention since the fabric 53 provides substantial strength to the overall cushion 51, particularly when the cushion is being suspended vertically, as by being grasped adjacent one edge thereof.

FIG. 9 illustrates a further cushion structure 61 which is similar to the cushion structure illustrated in FIGS. 7 and 8. Particularly, the cushion structure 61 is also provided in the form of a seat cushion and includes a core 62 consisting of a gel which may be of the same type used in the core 12. While the gel of core 62 is normally of such thickness that it is capable of maintaining its own continuity, nevertheless the type of use to which the cushion 61 is exposed also dictates the use of some form of container. Thus, the core 62 is also preferably placed within a resiliently flexible envelope 66, which may be of a stockinette material, with the combined core 62 and envelope 66 then preferably being inserted into a waterproof casing, such as a pure latex rubber cover 67. The rubber cover 67 tends to strengthen the seat cushion 61 and further reduce the possibility of damage to the gel core 62 without restricting materially the capability of the pad to absorb pressures and minimize the shearing force. The gel core 62 is also preferably provided with a thin, flexible, mesh-like sheet or fabric 63 securely bonded to and impregnated with the gel of the core 62. The fabric 63 is disposed adjacent one of the surfaces of the core (the bottom surface in FIG. 9) so as to provide the core with additional resistance against damage.

The gel portions or cores 12, 33, 34, 56, 57 and 62 are preferably made from the reaction product of an intimate mixture consisting essentially of (1) an organosiloxane having a viscosity of from 100 to 10,000 centistokes at 25° C. and being a copolymer consisting essentially of units of the formula $RViSiO$, R_2SiO and $CH_3R_2SiO_{.5}$ where each R individually is selected from the group consisting of methyl and phenyl radi-

cals and Vi represents a vinyl radical, at least 0.174 molar percent of the units in said copolymer being the said RViSiO units, (2) a liquid hydrogenosiloxane of the average general formula $HRCH_3SiO(R_2SiO)_nSiCH_3RH$ where each R is as above defined and n has an average value such that the viscosity of the hydrogenosiloxane is no more than 10,000 cs. at 25° C., no more than 25 molar percent of the total R radicals present in (1) and (2) being phenyl and (3) a platinum catalyst in an amount sufficient to furnish at least 0.1 part per million of Pt based on the combined weight of (1) and (2); the proportions of (1) and (2) being such that prior to reaction there is an average of from 1.4 to 1.8 grams atoms of the silicon-bonded H atoms in (2) per gram molecular weight of (1) and there being at least one RViSIO unit in (1) for every silicon-bonded H atom in (2), the molecular weight of (1) being calculated by the equation:

$$\log \text{visc.} = 1.00 + 0.0123M^{.5}$$

where M is the molecular weight and "visc." is the viscosity of (1) in cs. at 25° C.

The above-described gel possesses very desirable hydrostatic properties in that the gel is capable of easily flowing laterally under pressure, the gel being capable of returning toward its original shape as a result of its internal restoring force when the external pressure is removed.

While the gel portions **12**, **33**, **34**, **56**, **57** and **62** may be made of a pure reaction product as described in the preceding paragraph, it may be found desirable in some cases to incorporate a quantity of a filler or extender material in the reaction product in order to minimize cost. It has been found satisfactory to use a filler consisting essentially of dimethyl polysiloxane fluid which can be uniformly mixed in the reaction mixture before the reaction begins. The dimethyl polysiloxane fluid may be of viscosity of about 1,000 cs. at 25° C. It has been found quite desirable to use about 25 percent by weight of the filler material, but approximately 10 percent up to 50 percent by weight can be used for some applications.

Although a particular preferred embodiment of the invention has been described above in detail for illustrative purposes, it will be recognized that variations or modifications of such disclosure, which lie within the scope of the appended claims, are fully contemplated.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. A cushion structure for protecting a mammal body against the application on the body of injurious localized pressures, comprising:

a cushion made of an elastic, nonfriable, nonporous, semisolid gel of a synthetic organic material, said gel having a hydrostatic property so that it is capable of easily flowing laterally under pressure and is capable of returning toward its original shape as a result of its internal restoring forces when the pressure is removed:

said cushion having two substantially parallel major surfaces whose dimensions are substantially larger than the dimensions of the minor surfaces of said cushion, one of said major surfaces forming a mammal-supporting surface so that when a mammal contacts the mammal-supporting surface, the gel comprising the cushion will flow laterally in order to avoid injurious concentrations of supporting pressure in the area of support of said mammal by said cushion; and

a thin, flexible and substantially flat sheet of porous mesh-like material disposed within said cushion in substantially parallel relation to said major surfaces whereby substantial quantities of gel are disposed in layers on opposite sides of said sheet, said sheet having sufficient porosity to permit the gel to penetrate therethrough whereby the gel layers are integrally connected so as to form a single mass of gel.

2. A cushion structure according to claim **1**, including resiliently flexible envelope means enclosing said cushion and closely engaging same; and

a thin resiliently flexible and extensible casing loosely and completely enclosing said envelope means and said cushion.

3. A cushion structure according to claim **1**, in which the gel is a reaction product of a methyl polysiloxane containing silicon-bonded vinyl groups and a methyl polysiloxane containing SiH groups in which said reaction is catalyzed by platinum.

4. A cushion structure according to claim **1**, wherein said sheet of material comprises a plastic, mesh-like fabric.

5. A cushion structure according to claim **4**, wherein said sheet of material comprises a dacron mesh.

6. A cushion structure according to claim **4**, wherein said sheet of fabric is disposed approximately midway between the major surfaces and extends substantially coextensively with said major surfaces.

7. A cushion structure according to claim **4**, in which the cushion consists essentially of an organosiloxane gel which is the reaction product of an intimate mixture consisting essentially of (1) an organosiloxane having a viscosity of from 100 to 10,000 cs. at 25° C. and being a copolymer consisting essentially of units of the formula RViSiO, R_2SiO and $CH_3R_2SiO_{.5}$ where each R individually is selected from the group consisting of methyl and phenyl radicals and Vi represents a vinyl radical, at least 0.174 molar percent of the units in said copolymer being the said RViSiO units, (2) a liquid hydrogenosiloxane of the average formula $HRCH_3SiO(R_2SiO)_niCH_3RH$ where each R is as above defined and n has an average value such that the viscosity of the hydrogenosiloxane is no more than 10,000 cs. at 25° C., no more than 25 molar percent of the total R radicals present in (1)and (2) being phenyl: the proportions of (1) and (2) being such that prior to reaction there is an average of from 1.4 to 1.8 gram atoms of the silicon-bonded H atoms in (2) per gram molecular weight of (1) and there being at least one RViSiO unit in (1) for every silicon-bonded H atom in (2), the molecular weight of (1) being calculated by the equation:

$$\log \text{visc.} = 1.00 + 0.0123M^{.5}$$

where M is the molecular weight and "visc." is the viscosity of (1) in cs. at 25° C., and (3) a dimethyl polysiloxane fluid having a viscosity of about 1,000 cs. at 25° C. and comprising from approximately 10 percent to 50 percent by weight of said cushion.

8. A cushion structure according to claim **4**, wherein said gel is hypoallergenic, stable over a selected temperature range and incapable of supporting the growth of bacteria.

9. A cushion structure for protecting a mammal body against the application on the body of injurious localized pressures, comprising:

a one-piece cushion made of an elastic, nonfriable, nonporous, semisolid gel of a synthetic organic material, the gel having a hydrostatic property so that it is capable of easily flowing laterally under pressure and is capable of returning toward its original shape as a result of its internal restoring force when the pressure is removed;

a thin, flexible sheet of mesh-like fabric securely bonded to the gel of said cushion, said sheet of fabric being substantially coextensive with one of the external surfaces of said cushion, whereby said sheet of mesh-like fabric resists damage to the gel cushion due to forces applied to said cushion in a direction substantially parallel with said fabric; and

flexible cover means surrounding and totally enclosing said cushion and said sheet of fabric.

10. A cushion structure according to claim **9**, wherein said sheet of fabric is disposed totally within the gel cushion so as to form gel layers on opposite sides of the sheet of mesh-like fabric with the porosity of the mesh-like fabric permitting the gel layers to be integrally interconnected so that the gel of the cushion is effectively a single monolithic mass.

* * * * *