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L. C. BALDWIN

3,407,808

DENTAL MOUTHGUARD

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FIG. 1

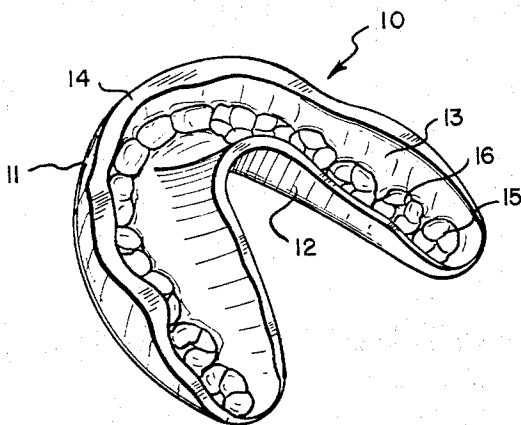


FIG. 2

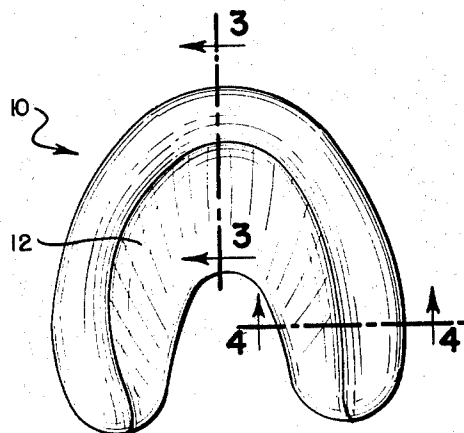


FIG. 3

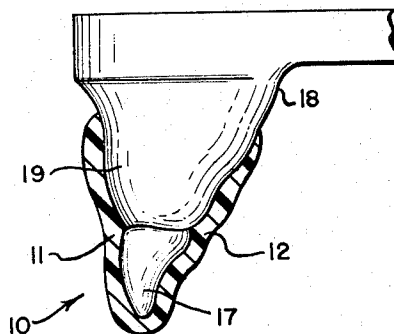
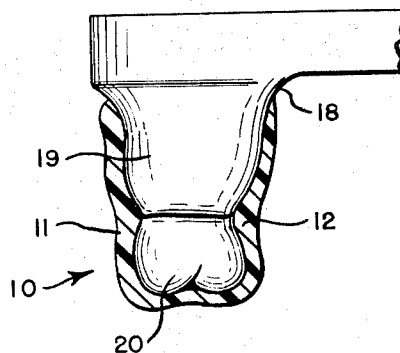


FIG. 4



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3,407,808

DENTAL MOUTHGUARD

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This invention relates to a dental mouthguard characterized by ease of manufacture and having properties conducive to long and continuous use without substantial mechanical or chemical deterioration and without undesirably excessive absorption of mouth fluids.

Dental mouthguards are widely used in contact sports. Fundamentally, the design of a mouthguard must be such as to permit the guard to fit firmly and comfortably upon the upper teeth and dental arch of the wearer; and must, moreover, effectively protect the wearer's teeth, lips and jaw against injury from blows to the jaw and mouth area. There are essentially three major types of mouthguard:

- (1) The "stock" variety, designed to fit any wearer.
- (2) The "mouth-formed" mouthguard which is adapted to fit upon a particular wearer's dental arch. Such guards comprise a relatively firm rubber or plastic shell curved to match the curve of the dental arch and having an inner lining of a soft material or a material softened by boiling. In initial use, the shell containing the impressionable material is pressed against the teeth. After impression, the material is hardened by cooling or by other means and the guard is then in a form suitable for use.
- (3) The "custom-made" mouthguard is fabricated over a cast or model made from a dentist's impression of the prospective wearer's dental arch.

The experience of those familiar with the use of mouthguards reveals that stock and mouth-formed protectors do not fit well. They are bulky, generally uncomfortable and interfere with speech and breathing. Neither stock nor mouth-formed guards are professionally fitted, and the protection offered by these types is less than desirable. Generally, dentists and coaches of contact sports have recognized that custom-made mouthguards are superior to stock and mouth-formed types. They have been proved to be most effective in preventing injuries to the teeth and mouth, and have had greatest player acceptance.

In selecting a material out of which a custom-made mouthguard is to be fabricated, such a material must have properties conducive to quick and accurate fabrication on a dental model. Moreover, the material should be inexpensive and otherwise convenient to use. Apart from these factors, others relating to the suitability of the material for mouth wear must also be considered. Thus, a material for projected mouthguard manufacture must be dimensionally stable, relatively tough, resistant to mechanical degradation (as a result of chewing), tasteless, odorless and possess a relatively low rate of mouth fluids absorption.

Latex rubber has been one of the most common materials used in mouthguard manufacture. However, it possesses several disadvantages; viz., latex must be painted on the dental model in several layers. This makes the fabrication process rather time-consuming and expensive. Latex mouthguards are also subjected to dimensional change during use, in part due to a relatively high rate of mouth fluids absorption. The resultant distortion interferes with proper fit and adequate protection of the wearer. Fluids absorption is conducive to fouling of the guard, the guard becoming either foul tasting or foul smelling.

More recently, ethylene-vinyl acetate copolymers have been used in mouthguards. These materials are relatively easy to fabricate, tougher than latex rubber and have

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somewhat lower rates of mouth fluids absorption. The vinyl materials soften and distort with continued use, however, and thereby eventually render the initial custom fit valueless. Vinyl mouthguards are permanently distorted by sterilization by boiling.

The dental mouthguard of this invention is of the custom-fitted variety and is composed of a novel thermoplastic composition which may be quickly and accurately fabricated into a mouthguard upon a dental model. The thermoplastic composition herein is also tough and highly resistant to mechanical wear. The toughness of the material does not compromise the comfort of the mouthguard out of which it is made, but it does provide a guard which is more resistant than prior art mouthguards to the chewing, grinding and tearing action of the teeth.

In addition, the mouthguard of the invention has a low rate of mouth fluids absorption; hence, it will not foul, nor will its texture and hardness vary during its use. It will not change its shape and texture (or color) during sterilization in boiling water.

The dental mouthguard of this invention is made of a tough elastomeric material which is resistant to mechanical wear and has a low rate of mouth fluids absorption and which comprises a vinyl resin and a thermoplastic polyesterurethane the molecular structure of which is substantially free of cross-linkages. More particularly the mouthguard herein has preferably a Shore A durometer hardness of from about 50 to 85 and comprises 100 parts by weight of polyvinyl chloride, 75 parts by weight of dioctyl phthalate plasticizer, 1.25 parts by weight of a calcium stabilizer and 100 parts by weight of a thermoplastic polyesterurethane the molecular structure of which is substantially free of cross-linkages. The suitable polyesterurethane, however, has a tensile strength, abrasion resistance and elongation at least equal to that of corresponding vulcanized, cross-linked polyurethanes.

In the drawings which accompany this specification: FIG. 1 is a perspective view of the interior of a typical mouthguard of this invention;

FIG. 2 is a plan view of the exterior of the mouthguard herein;

FIG. 3 is a side elevation view of the mouthguard along the line 3—3 of FIG. 2 showing a section of the guard fitted on the front teeth and palate; and

FIG. 4 is a side elevation view of the mouthguard along the line 4—4 of FIG. 2 showing a section of the guard fitted on the back teeth.

In the drawings, the mouthguard 10 is curved to conform to the curve of the dental arch. It has an outer wall 11, an inner wall 12 and a hollowed-out portion or channel 13 to receive the teeth of the wearer. In the embodiment shown in the drawings, the hollowed-out portion 13 is adapted to receive the upper teeth of the wearer, but it is possible and of course fully within the scope of this invention, to design a guard which may also receive the wearer's lower teeth. Outer wall 11 is fabricated so that its upper edge 14 is contoured to conform to the configuration of the juncture of the gum and interior upper lip area. In FIG. 1, the indentations 15, 16 (etc.) within the hollowed-out portion 13 are visible. These indentations will of course receive the wearer's teeth; they are produced from an accurate dental model of the prospective wearer's dental arch. The thermoplastic material of this invention, usually in sheet form, is softened and pressed over the dental model and trimmed to form the type of guard illustrated in the drawings. The accurate fit obtainable is reflected in FIGS. 3 and 4. There, the guard 10 fits snugly and firmly around the front teeth 17, palate 18 and gums 19, and the back teeth 20 and gums 19 of the wearer.

The elastomeric material out of which mouthguard 10 is made broadly comprises an intimate blend of approximately equal parts by weight of a vinyl resin, preferably vinyl chloride, and a polyesterurethane the molecular structure of which is substantially free of cross-linkages. Polyesterurethane may also be used alone with fully adequate results. Various combinations of vinyl and urethane are possible; all of which yield a mouthguard which is tough and reasonably hard but nonetheless comfortable, resistant to mechanical wear, has a low rate of mouth fluid absorption and may be used for a relatively long time.

The compounded material of which the guard is made should have a Shore A durometer hardness of generally between 35 and 95 but more preferably from about 50

75 parts by weight of dioctyl phthalate and 1.25 parts by weight of calcium stearate (as a stabilizer). If desired, pigment may be added (about 8 parts by weight); and additional processing aids, lubricants and stabilizers may also be used in the blend. Some other calcium salt stabilizer may be used in place of the stearate salt if desired.

After compounding, the above or a similar blend is used in producing a mouthguard by vacuum or by pressure forming a preformed sheet of the above-described material over a cast obtained from an impression of the prospective wearer's dental arch.

The following table presents data comparing several factors of importance in mouthguards made of latex rubber, ethylene-vinyl acetate copolymer and the vinyl polyesterurethane blends described herein.

TABLE I

Test Description	Vinylpolyesterurethane	Ethylenevinyl acetate copolymer	Latex rubber
(1) Water absorption (immersion in water):			
30 min. at 37° C. (wt. percent change) -----	0.10	0.09	9.1.
1 hour at 37° C. (wt. percent change) -----	0.18	0.12	11.6.
2 hours at 37° C. (wt. percent change) -----	0.24	0.14	13.2.
5 min. at 100° C. (wt. percent change) -----	0.19	0.12	4.4.
(2) Dimensional change: Linear change after 2 hours in 37° C. water (percent). -----	No change	No change	4.5.
(3) Hardness (Shore A durometer):			
Dry at 20° C. -----	80.	60.	50.
Wet at 37° C. (after 2 hours immersion) -----	80.	55.	35.
(4) Sterilization: 5 min. in boiling water. -----	No change in characteristics.	Became soft, gummy and sticky; was completely deformed.	Some swelling; became spongy soft; color change evident.

to 85. To insure adequate physical properties in the finished mouthguard, it may be desirable to insure quality control of the polyesterurethane component. Thus, the particular polyesterurethane, although thermoplastic, essentially linear and thus substantially free of cross-linkages should preferably have a tensile strength, abrasion resistance and elongation at least equal to that of vulcanized, cross-linked polyurethanes. Optimally, the polyesterurethane out of which the guard may be wholly or partially made has a tensile strength of at least 6000 p.s.i., an abrasion resistance such that in a Taber Abrasion Apparatus, the weight loss of a sample is immeasurable, an elongation of from 500% to 650% and a 300% moduli of about 1000 to 1600 p.s.i.

The polyesterurethanes employed in producing the mouthguard of this invention are thermoplastic and linear but nevertheless exhibit the physical properties of cross-linked vulcanized polyurethanes. The class of polyesterurethanes efficacious herein exhibiting the physical characteristics delineated in the preceding paragraph are those disclosed for example in United States Patent No. 2,871,218. They are produced by reacting a diphenyl diisocyanate having an isocyanate group on each phenyl nucleus; a saturated aliphatic free glycol containing from 4 to 10 carbon atoms and having hydroxyl groups on its terminal carbon atoms; an essentially linear hydroxyl terminated polyester of a saturated glycol having from 4 to 10 carbon atoms and having hydroxyl groups on its terminal carbon atoms; and a dicarboxylic acid. The molar ratios of the various components are critical and after reaction, no free, unreacted diisocyanate or glycol must remain in the elastomeric mixture. Otherwise, cross-linked urethanes will be produced, and these will not be entirely satisfactory for use in dental mouthguards. One of the most common, commercially available polyesterurethanes is produced by reacting a hydroxyl terminated polytetramethylene adipate, butanediol-1,4, and diphenyl methane-p,p'-diisocyanate. The critical molar ratios of components may be obtained by consulting standard handbooks or formularies or the above-mentioned patent.

To produce the elastomer mixture preferable for use herein, a vinyl resin, preferably polyvinyl chloride, is blended with the polyesterurethane. A particularly economical and useful blend comprises 100 parts by weight of any one or combination of the polyesterurethanes described above, 100 parts by weight of polyvinyl chloride,

The swelling of a dental mouthguard is undesirable because the accuracy of fit is correspondingly affected. High water absorption has been correlated with mouth fluids absorption. (The greater the mouth fluids absorption, the greater the fouling.) It is often desirable to sterilize the mouth-guard in hot water after each use. The rate of water absorption of latex renders it undesirable; and its sponge-like character makes cleaning difficult. Other mouthguard materials, such as ethylene-vinyl acetate copolymers as indicated earlier and as shown in Table I, become soft and distort with use. They are therefore not as advantageous as the material out of which the mouthguard herein is made. The polyester-urethane-vinyl compound described herein has the advantage of remaining structurally static during sterilization. Coupled with these advantages, as well as the others related earlier, the mouthguard of this invention has been found to possess the qualities of resilience and shock-absorptive capacity necessary for safety. It has held up under conditions of wear (biting and chewing stress, contact with mouth fluids, etc.) for periods well in excess of a football season.

I claim:

1. A dental mouthguard made of a tough elastomeric material resistant to mechanical wear and having a relatively low rate of mouth fluids absorption comprising a blend of a vinyl resin and thermoplastic polyesterurethane which is substantially free of cross-linkages.

2. A dental mouthguard made of a tough elastomeric material resistant to mechanical wear and having a relatively low rate of mouth fluids absorption comprising an intimate blend of approximately equal parts by weight of a vinyl resin and a polyesterurethane which is substantially free of cross-linkages.

3. The dental mouthguard of claim 2 in which the vinyl resin is polyvinyl chloride.

4. A dental mouthguard according to claim 2 having a Shore A durometer hardness of from 35 to 95.

5. A dental mouthguard made of a tough elastomeric material resistant to mechanical wear and having a relatively low rate of mouth fluids absorption comprising a thermoplastic polyesterurethane which is substantially free of cross-linkages.

6. A dental mouthguard made of a tough elastomeric material resistant to the chewing action of the teeth and having a relatively low rate of mouth fluids absorption comprising 100 parts by weight of a vinyl resin, 100 parts

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by weight of an essentially linear polyesterurethane which is substantially free of cross-linkages, 75 parts by weight of dioctyl phthalate plasticizer and 1.25 parts by weight of a calcium stabilizer.

7. The dental mouthguard of claim 6 wherein the vinyl resin is polyvinyl chloride and the calcium stabilizer is calcium stearate.

8. A dental mouthguard having a Shore A durometer hardness of from about 50 to 85 made of an elastomeric material resistant to the chewing action of the teeth and having a relatively low rate of mouth fluids absorption comprising 100 parts by weight of polyvinyl chloride, 75 parts by weight of dioctyl phthalate plasticizer, 1.25 parts by weight of calcium stearate and 100 parts by weight of a thermoplastic polyesterurethane which is substantially free of cross-linkages but which has a tensile strength, abrasion resistance and elongation at least equal to that of a vulcanized, cross-linked polyurethane.

9. The dental mouthguard of claim 8 wherein the polyesterurethane has a tensile strength of at least 6000 p.s.i., the abrasion resistance is such that in a Taber Abrasion Apparatus the weight loss of a sample of said polyesterurethane is immeasurable, the elongation is from 500% to

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650% and said polyesterurethane has a 300% moduli of about 1000 to 1600 p.s.i.

10. A dental mouthguard made of a tough elastomeric material resistant to the chewing action of the teeth and having a relatively low rate of mouth fluids absorption comprising a non-vulcanized thermoplastic polyesterurethane which is substantially free of cross-linkages but which has a tensile strength, abrasion resistance and elongation at least equal to that of a vulcanized, cross-linked polyurethane.

11. The dental mouthguard of claim 10 wherein the polyesterurethane has a tensile strength of at least 6000 p.s.i., the abrasion resistance is such that in a Taber Abrasion Apparatus the weight loss of a sample of said polyesterurethane is immeasurable, the elongation is from 500% to 650% and said polyesterurethane has a 300% moduli of about 1000 to 1600 p.s.i.

References Cited

UNITED STATES PATENTS

2,755,552	7/1956	Brandau	32—2
3,103,217	9/1963	Butler et al.	128—136

ADELE M. EAGER, *Primary Examiner.*