The Capability of Multi-layered Design Mouthguards on Impact Absorbing

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Abstract

Mouthguards are devices utilized by athletes on their maxillary teeth to obtain a level of protection from orofacial traumas and injuries. These devises deal the sudden impact by absorbing and distributing the impact energy to the largest possible area to provide protection to their wearers.

This study examined the ability of multi-layered designs to absorb and transmit impact force, also to determine the best arrangement of materials in the multi-layered design that providing the highest level of protection. The studied designs constructed from a shell consisted from

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an outer layer and an inner layer of Poly Ethyl Vinyl Acetate (pEVA) and the middle layer of Poly Methyl Meta Acrylate (PMMA) and Sorbothane in reciprocation between the two last materials.

A small steel ball 2 mm in diameter and 33.36 gm dropped from fixed height of 52 mm, and the rebound height has been measured to calculate absorbed energy.

In addition, the best five resulted absorb energy of different designs have been chosen to make up multi-layered mouthguard, and examine their ability to absorb energy by using Charpy rig. The multi-layered designs employed in the mouthguard just in the extended distance from maxillary canine to canine.

This in-vitro experimental study concluded that design of EVA-Sorbothane- EVA 1-3-3 seems to be the best design and the best thickness could be decrease severity of injuries and has the highest ability to absorb impact shock among the five different designs followed by EVA-Sorbothane- PMMA-EVA 1-3-2-1.

***Key words**: Mouthguard, Multi-layered, Impact force, Shock absorbing.*

1. Introduction

The Mouthguards appliances have been in use since the 19th century, when they were consumed originally by boxers [1, 2]. Later on and due to their significant effect in reducing the incidence and severity of injuries and traumas related to sports, the American Dental Association (ADA) and Academy for Sports Dentistry recommended that the players of 29 sports, including American football, basketball, soccer, volley ball, and baseball, should wear mouthguards during training and competitions [2,3].

In general, mouthguards are classified into three categories: stock mouthguards, mouth formed (boil and bite) mouthguards, and custom mouthguards. Nevertheless, the levels of protection, retention, and comfort are diverse according to the type of mouthguard, the highest level of protection and retention can be provided by custom mouthguards. Moreover, custom mouthguards are more expensive than the other two types [3, 4, 5, 6, 7].

Custom mouthguard can be fabricated by different techniques including vacuum-forming technique using vacuum forming machine, pressure-forming technique which using pressure-forming machine, a combination of both techniques [8, 9, 10], and CAD/CAM technique which is the most recent developed technique [11]. Both vacuum-forming technique and pressure forming techniques are conventional techniques relaying on the dental cast of patient (user) [10].

The vacuum and pressure made mouthguard can be classified into two classes: single and multi-layered mouthguards [12, 13]. However, multi-layered mouthguards are superior to single mouthguards in terms of their flexibility in the used thickness. Multi-layered designs more thick in the labial region where the maximum level of protection is demanded. Also, they are more flexible to use different colours and different insertions (hard, soft, or both) [13, 14].

The used material must be non-toxic and tasteless polymers. Moreover, it should provide high impact resistance to accomplish suitable absorption and shock energy distribution of the over a large area, and subsequently, reduce the possibility of injury [15, 16]. In addition to other properties, for instance water absorption, stiffness, hardness, and material processing should be taken into consideration to match the desired performance of the device [17].

Owing to the absence of international standards for the materials used to fabricate mouthguards, a large variety of materials are used in their construction, including: poly vinyl acetate-polyethylene or ethylene vinyl acetate (EVA) copolymer, poly vinyl chloride, latex rubber, acrylic resin, and polyurethane. However, EVA copolymers are the most commonly used materials because of their physical and mechanical properties and their cost effectiveness [18]. There are many of features may play a role in the final thickness of custom mouthguard, these features include the manufacturer's perception of correct thickness and the user's acceptance of the mouthguard thickness. Furthermore, several specialists recommend different thickness. Australian dental association suggest a thickness of 2 mm for mouthguard [14]. Therefore, the main aims of this study was to examine the ability of multi-layered designs to absorb and transmit impact force, also to determine the best arrangement of materials in the multi-layered design that providing the highest level of protection.

2. Materials and Methods

2. 1. Sample preparation:

EVA copolymer discs (BIOPLAST®, SCHEU; Dental -GmbH, Germany) of diameter 120 mm and thicknesses of (1-5) mm were used for the inner layer which is in contact with the teeth and the outer layer in contact with the upper lip. EVA samples with dimensions of 1.5cm× 6cm (according to the distance from canine to canine, which is the target area for the layered design) were prepared using a heated sharp scalpel and then trimming them with a bar and disc.

PMMA discs (BIOCRYL®, SCHEU; Dental -GmbH, Germany) were obtained from the manufacturer in diameter 120 mm and thicknesses of (1.5-3) mm used as the hard material inserted to eliminate the impact force on teeth by distributing the energy to the largest possible area. The thickness of 4 mm and 5 mm were obtained by laminating two layers (2 mm, 2 mm) and (2 mm, 3 mm) of PMMA sheets. A small diamond slitting disc and hand piece were used to prepare PMMA samples with dimensions of 1.5cm× 6cm.

Meanwhile, all the Sorbothane samples (Sorbothane ®, Leyland Rubber Components Ltd, Preston, UK) had dimensions of 1.5 cm length × 6 cm width × 3 mm thickness and were prepared using a sharp scalpel and scissors. Sorbothane was used as a soft material in the design; this material has been used in orthopaedic as well as in different sport applications because of its ability to absorb the impact of shock. These three materials are used in different arrangements of the hard and soft materials. The prepared materials and multi-layered designs are presented in (table 1).

Table 1: Required materials and thicknesses

Material	Thickness	Function
Bioplast material	1-5mm	Outer and inner shields which contain the layers.
Sorbothane	3 mm	Absorbs the impact shock.
PMMA	1.5-3mm	Distributes the energy to the largest possible area.

2. 2. Multi-layered Designs:

(pEVA- PMMA- pEVA), (pEVA –Sorbothane –pEVA), (pEVA-Sorbothane- PMMA –pEVA), (pEVA-PMMA-Sorbothane–pEVA) (figure 1). The layers were of varying thickness, e.g. 1 2 1; varying thicknesses of the laminates were used for consequent tests and the order of the layering of the various materials in the structure was changed, using up to four laminate materials in each sample.

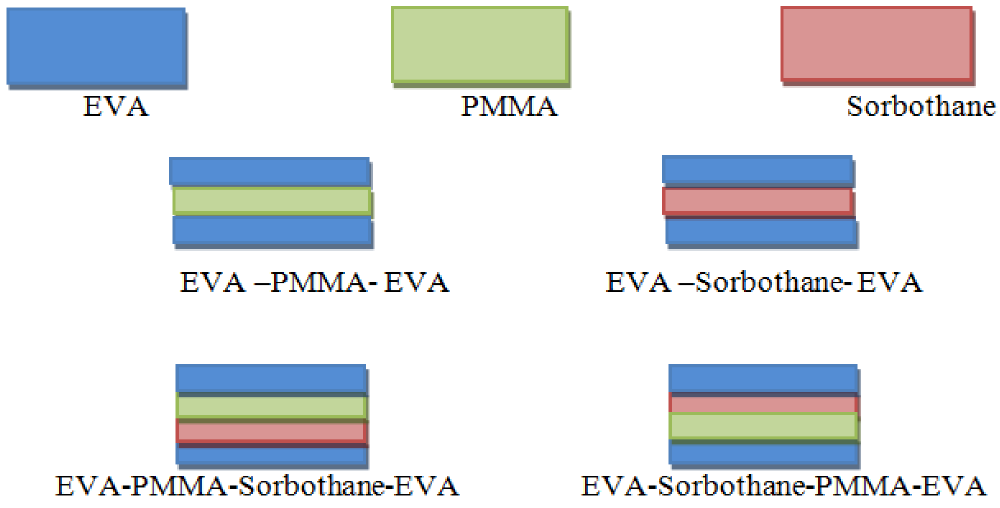


Figure 1: Materials and Different Multi-layered Designs

2. 3. Rebound Impact Testing:

The simple testing rig was constructed from a Perspex tube 100cm in height (figure 2a); the steel ball (2mm diameter and 33.36 gm) was dropped from a height of 50cm (figure 2b). The model shown in (figure 2c) used to hold the specimens, was made by duplicating (4mm high × 2cm width ×6.5cm length) a wax template into which was poured a mixture of high strength stone. The wax template was removed after the stone had set.

The rebound test was conducted at room temperature by placing a calibrated Perspex tube on the model with the specimens (distance between tube and model was 2cm) and allowing a 2.0 mm diameter steel ball (33.36 gm) to drop from a fixed height (50 cm), the rebound height was observed visually and measured. The test was repeated ten times for each specimen. The height of rebound was used to define the absorbed energy for each material and multi-layered design.

The absorbed energy was calculated using a Newton's equation of motion:

Absorbed energy = mass of steel ball ×gravity × (height $_{initial}$ – height $_{rebound}$). Where mass of ball (33.36gm), gravity (9.8 m/s^2), and initial height 52cm (50 cm tube height plus 2cm distance between tube and model).

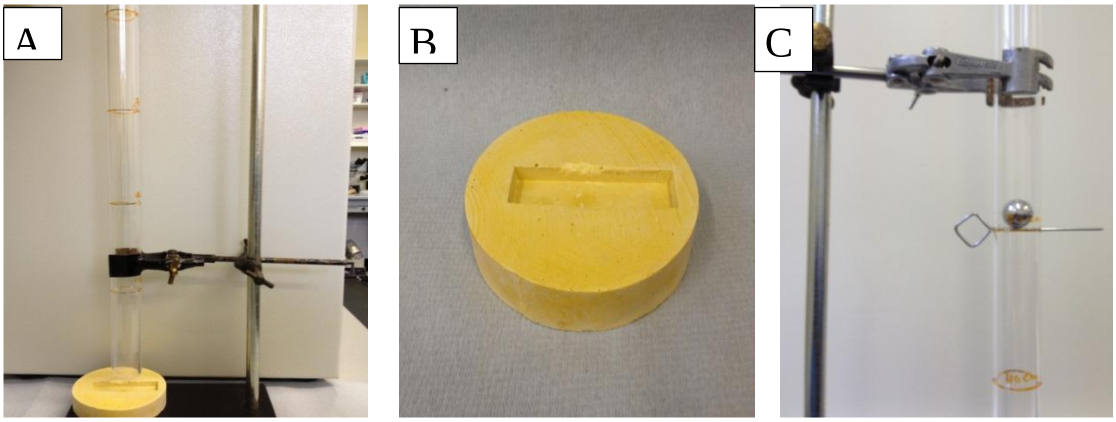


Figure 2 (A-C): Rebound Test Rig

2. 4. Fabrication of Multi-layered Mouthguards:

The best 5 designs were selected based on the basis of height of rebound (table 2).

Table 2: Best 5 Performed Specimens

Design	Thickness (mm)
EVA-PMMA-EVA	1-3-2 respectively
EVA- Sorbothane- EVA	1-3-2 respectively
EVA- Sorbothane- EVA	1-3-3 respectively
EVA-PMMA-Sorbothane-EVA	2-1.5-3-1 respectively
EVA- Sorbothane- PMMA-EVA	1-3-2-1 respectively

The first layer of multi-layered mouthguard was made from (1, 2, or 3 mm) EVA sheets (Bioplast®; SCHEU Dental Technology, Germany). The first and last EVA sheet layers covered the buccal, incisal, occlusal, and palatal surfaces of the arch. The EVA sheets were softened in the thermal forming machine (MINISTAR S® ; SCHEU-Dental, Iserlohn, Germany) (figure 3a,3b) for 40 s, 60 s, and 80 s for 1 mm, 2 mm, and 3 mm thickness sheets, respectively. Next, the sheets were placed on the models under pressure (2 bar) to achieve optimal adaptation. Each design was cut and trimmed facially 3mm away from the sulcus, and 4 mm away from the incisive papillae palatally.

The two EVA layers in the (EVA- PMMA- EVA) and (EVA-Sorbothane- EVA) designs were with different thicknesses. The first layer was 2 mm thick, while the last layer was 1 mm. The middle layers of all designs were made up of different material types and thicknesses. The dimensions of the layers were 6.0 mm length × 1.5 mm height, extending labially from canine to canine. In the (pEVA- PMMA- pEVA) design, the middle layer was 3 mm thickness PMMA. This layer was softened using a medical purposes hot air blower unit (figure 3d) and fixed to the first layer using a temporary adhesive material to facilitate processing of the last layer. The same process was used with the (pEVA-Sorbothane- pEVA) design, using a Sorbothane layer instead of PMMA. However, the (pEVA-PMMA-Sorbothane-pEVA) and (pEVA-Sorbothane -PMMA- pEVA) designs consisted of two different layers in the middle part.

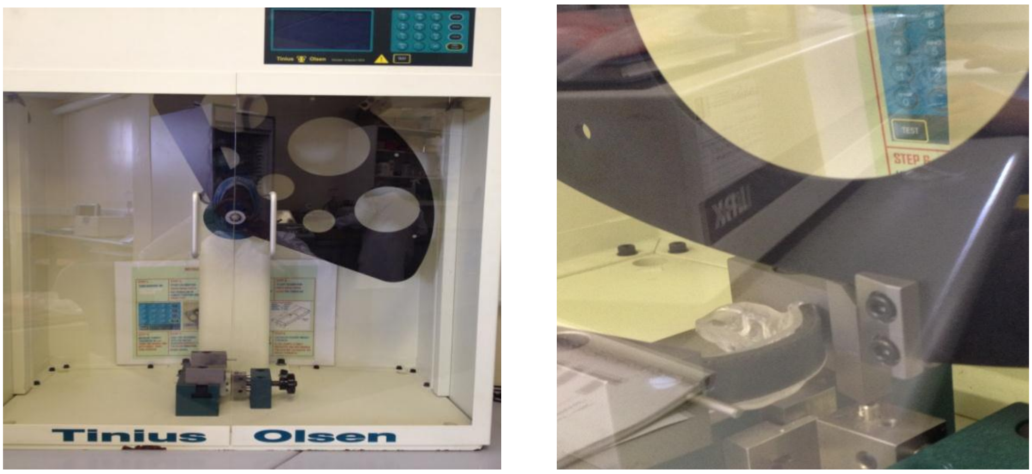
In the pEVA-PMMA-Sorbothane-pEVA) design the thicknesses of PMMA and Sorbothane were 1.5 mm and 3 mm respectively, whereas the Sorbothane and PMMA thicknesses were 3 mm and 2 mm respectively in the (pEVA- Sorbothane- PMMA-pEVA) design.

Figure3 (A-F): process of making multi-layered mouthguards

2. 5. Charpy Impact Test Procedures:

The five multi-layered design specimens and multi-layered mouthguards were tested on a Charpy impact tester (Tinius Olsen; Model Impact IT 503) (figure 4 a). The impact testing was based on test ASTMD standard 6110 and ISO 179.

The multi-layered design specimens and mouthguards were placed in position (figure 5b), and impacted ten times with a 3.2892 J capacity pendulum, to determine the shock absorption ability for each design and mouthguard. To make sure the validity of the data, and the machine was calibrated regularly.



(A) **(B)**

Figure 4(A-B): Charpy Rig and impact testing

3. Results

3. 1. Rebound Test:

The test was repeated ten times for each specimen of different multi-layered designs, the mean of rebound height was used to define the absorbed energy for each material and multi-layered design. The absorbed energy was calculated using a Newton's equation of motion:

Absorbed energy = mass of steel ball ×gravity × (height $_{initial}$ – height $_{rebound}$).

The results obtained from rebound test on different thicknesses of PMMA and pEVA materials showed in tables (3, 4), and figures (5, 6). The results indicated that the amount of energy absorption increased with increasing of the thickness of specimen.

Table 3: Rebound heights, mean of rebound and absorbed energy of PMMA specimens

PMMA												
Thickness (mm)	Rebound height (cm)										Mean of Rebound (cm) ± S.D	Absorbed Energy (mJ)
	R1	R2	R3	R4	R5	R6	R7	R8	R9	R10		
1.5 mm	17	17	17.3	17.2	17.1	17	17.1	17	17.2	17.1	17.1 ± 0.11	111.3
2 mm	19.6	19.8	19.6	19.6	19.7	19.7	19.7	19.9	19.6	19.7	19.7 ± 0.09	103.3
3 mm	19	19	19.2	19.1	19.3	19	19.1	19	19.2	19.1	19.1 ± 0.11	105.3
4 mm	18.5	18	18.4	18.5	18.5	18.5	18.3	18.4	18.4	18.5	18.4 ± 0.16	107.5
5 mm	14.6	14.5	14.6	14.4	14.5	14.5	14.5	14.6	14.8	15	14.6 ± 0.18	119.7

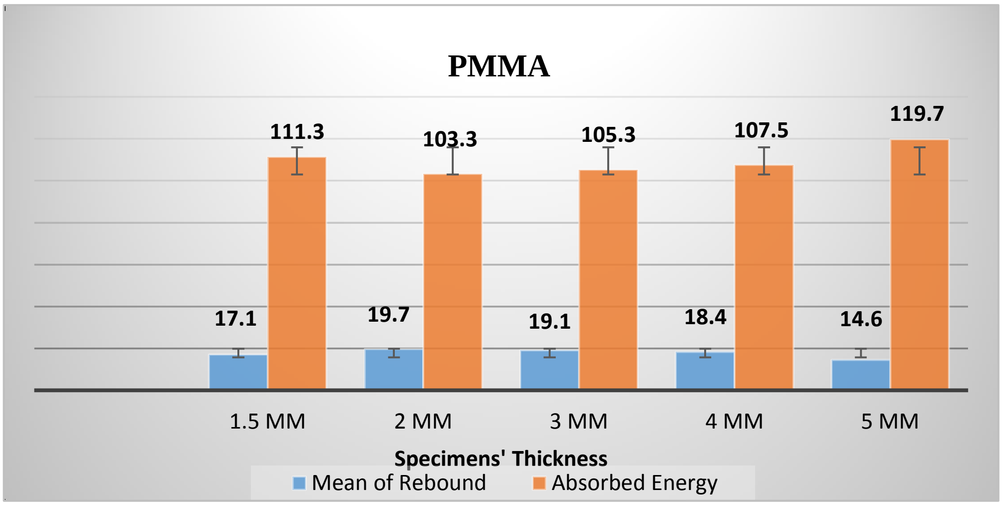


Figure 5: Mean of rebound with standard deviation and absorbed energy of PMMA specimens.

Table 4: Rebound heights, mean of rebound and absorbed energy of pEVA specimens

pEVA												
Thickness (mm)	Rebound height (cm)										Mean of Rebound (cm) ± S.D	Absorbed Energy (mJ)
	R1	R2	R3	R4	R5	R6	R7	R8	R9	R10		
1 mm	7.9	7.7	8	7.6	7.6	7.9	7.6	7.8	7.9	8	7.8 ± 0.16	141.4
2 mm	8	7.6	7.9	7.5	7.8	7.6	8	7.9	7.8	7.9	7.8 ± 0.18	141.4
3 mm	7.5	7.7	7.6	7.9	7.7	7.6	7.9	7.9	7.7	7.5	7.7 ± 0.16	141.8
4 mm	7	7.5	7.5	8	7	7.5	7.5	7.5	8	7.5	7.5 ± 0.333	142.4
5 mm	7.5	7	8	7.5	7.5	7	8	7	7.5	7	7.4 ± 0.17	145.9

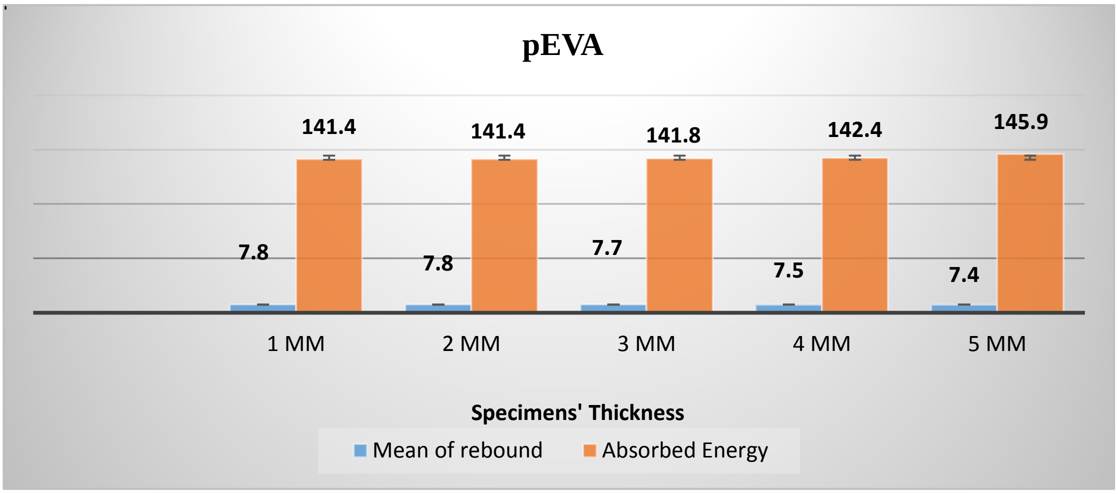


Figure 6: Mean of rebound with standard deviation and absorbed energy of pEVA specimens

The mean of rebound with standard deviation and absorbed energy of pEVA-PMMA-pEVA design specimens presented in (figure 7) and (table 5).

The results exhibited that the greatest amount of absorbed energy obtained by the design of 1-3-2 mm, in which the mean of rebound height of this design was (5.2 ± 0.14) and absorbed energy 149.8 m J.

Table 5: Rebound heights, mean of rebound and absorbed energy of pEVA-PMMA-pEVA design specimens.

pEVA- PMMA-pEVA												
Thickness (mm)	Rebound height (cm)										Mean of Rebound (cm) ± S.D	Absorbed Energy (mJ)
	R1	R2	R3	R4	R5	R6	R7	R8	R9	R10		
2-2-2 mm	7.5	7.7	7.8	7.5	7.3	7.5	7.5	7.5	7.4	7.3	7.5 ± 0.16	142.4
3-2-1 mm	8.3	8	8.2	8.3	8.4	8.2	8.3	8.3	8	8	8.2 ± 0.15	140.2
2-1-2 mm	8.5	8.8	8.7	8.5	8.4	8.5	8.3	8.6	8.4	8.3	8.5± 0.16	139.2
1-3-2 mm	5.1	5.3	5.4	5.1	5.2	5.1	5	5.4	5.3	5.1	5.2 ± 0.14	149.8
1-2-2 mm	7.1	7.2	7	7	7.2	7.1	7	7.1	7.1	7.2	7.1 ± 0.08	144.4

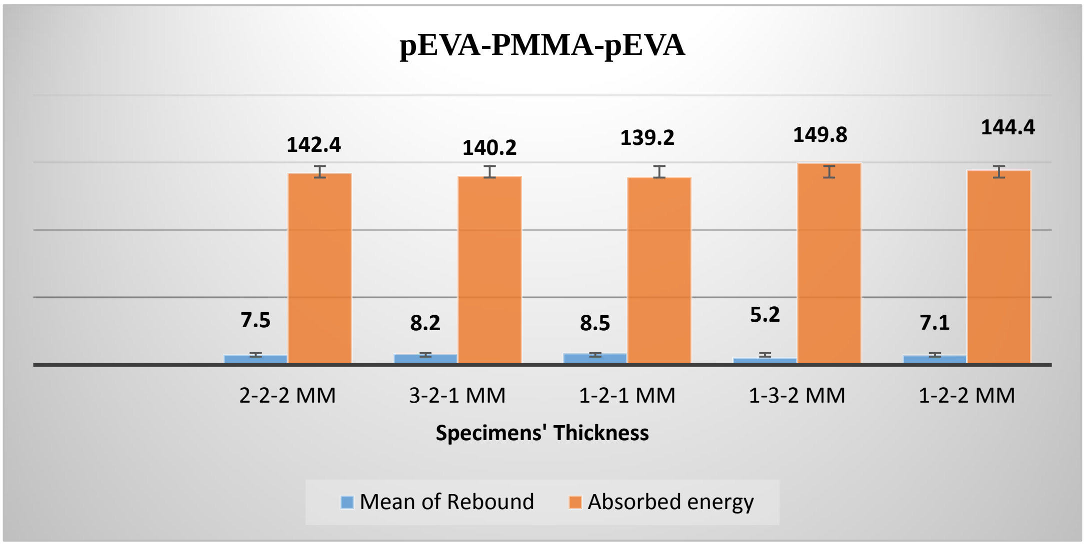


Figure 7: Mean of rebound with standard deviation and absorbed energy of pEVA-PMM-pEVA design specimens.

The rebound test carried out on multi-layered designs of pEVA Sorbothane pEVA, and (table 6) and (figure 8) illustrated the mean &

standard deviation of rebound height and amount of absorbed energy for the different thicknesses of this design. The specimens of 1-3-3 mm and 1-3-2 mm thicknesses showed mean of rebound height of (5.9 ± 0.15) and (5.9 ± 0.11) respectively, in addition to the better ability to absorb impact shock with 147.5 m J.

Table 6: Rebound heights, mean of rebound and absorbed energy of pEVA-Sorbothane- pEVA design Specimens.

pEVA- Sorbothane - pEVA												
Thickness (mm)	Rebound height (cm)										Mean of Rebound (cm) ± S.D	Absorbed Energy (mJ)
	R1	R2	R3	R4	R5	R6	R7	R8	R9	R10		
1-3-1 mm	6.3	6.2	6.5	6.4	6.1	6.4	6.2	6	6.5	6.4	6.3 ± 0.17	146.2
1-3-2 mm	5.9	5.8	6	5.7	5.9	6	6	5.8	6	5.9	5.9 ± 0.11	147.5
2-3-1 mm	7.5	7.5	7.2	7.4	7.4	7.1	7	7.2	7.4	7.3	7.3 ± 0.17	143
3-3-1 mm	7.9	7.8	8	7.7	7.9	8	8	7.8	8	7.9	7.9 ± 0.11	141.1
1-3-3 mm	5.9	5.9	5.8	5.9	5.7	6.1	6.2	5.8	5.8	5.9	5.9 ± 0.15	147.5

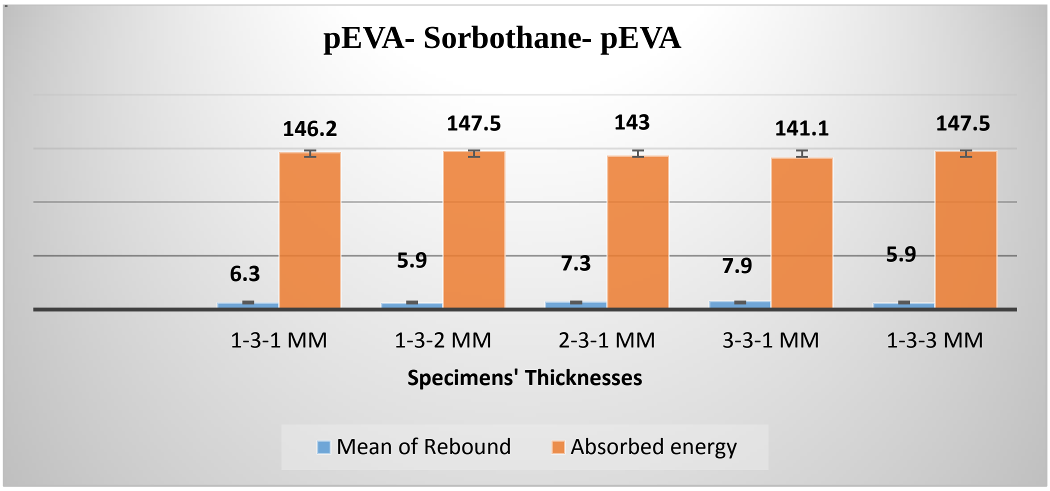


Figure 8: Mean of rebound with standard deviation and absorbed energy of pEVA-Sorbothane-pEVA design.

The mean of rebound with standard deviation and absorbed energy of pEVA Sorbothane PMMA pEVA) design is shown in (table 7) and (figure 9). The design of pEVA Sorbothane PMMA pEVA at the thicknesses of 1 3 2 1 mm attained mean of rebound about (5.7 ± 0.18) and the calculated absorbed energy at 147.5 m J, followed by the design of 1-3-1.5-2 pEVA Sorbothane pEVA with mean of rebound of (6 ± 0.19) and absorbed energy of 146.2m J.

Table7: Mean of rebound and absorbed energy of pEVA - Sorbothane-PMM - pEVA design specimens.

pEVA- Sorbothane - PMMA- pEVA												
Thickness (mm)	Rebound height (cm)										Mean of Rebound (cm) ± S.D	Absorbed Energy (mJ)
	R1	R2	R3	R4	R5	R6	R7	R8	R9	R10		
1-3-1.5-2	6.2	6	6.3	5.9	6	6	5.8	6.2	5.9	5.7	6 ± 0.19	147.2
1-3-2 -1	6	5.7	5.5	6	5.6	5.8	5.7	5.6	5.5	5.6	5.7 ± 0.18	148.2
2-3-1.5-1	6.5	6.3	6.4	6.8	6.5	6.6	6.5	6.4	6.5	6.5	6.5 ± 0.13	145.6
2-3-1.5-2	6.9	6.7	6.8	7	6.6	7	6.7	6.9	6.8	6.6	6.8 ± 0.15	144.6

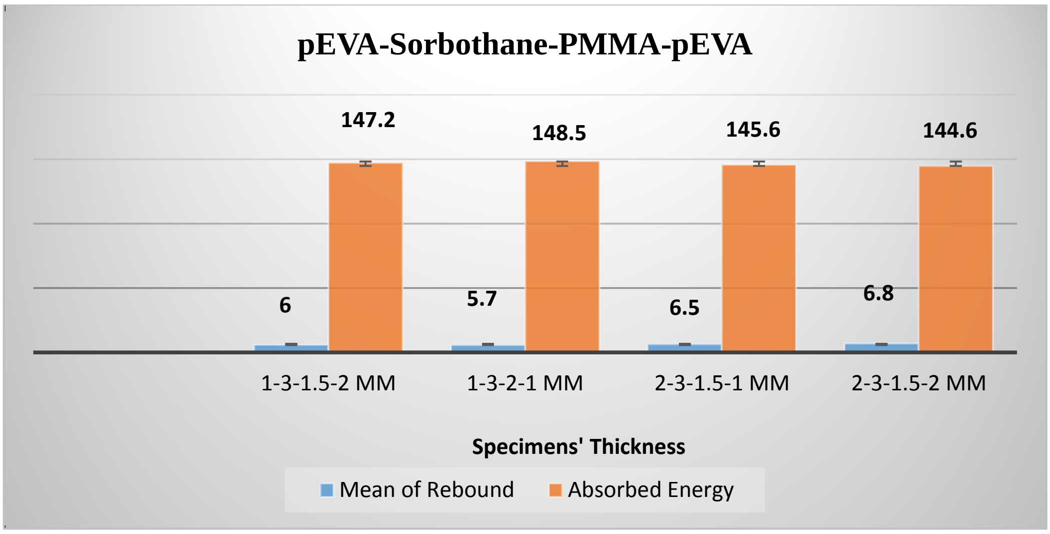


Figure 9: Mean of rebound and absorbed energy of pEVA-Sorbothane-pEVA design Specimens.

The mean of rebound height with standard deviation and absorbed energy of pEVA PMMA Sorbothane pEVA) design is shown in (table 8) and (figure 10). The mean of the best rebound result was obtained by the design of pEVA PMMA Sorbothane pEVA at thicknesses of 2 1.5 3 1 mm which is (5.4 ± 0.19) and achieved absorbed energy of 147.5 m J.

Table 8: Rebound heights, mean of rebound and absorbed energy of pEVA-PMM- Sorbothane-pEVA design specimens.

pEVA- PMMA- Sorbothane - pEVA												
Thickness (mm)	Rebound height (cm)										Mean of Rebound (cm) ± S.D	Absorbed Energy (mJ)
	R1	R2	R3	R4	R5	R6	R7	R8	R9	R10		
1-2-3-2	6.7	6.7	6.6	6.5	6.5	6.4	6.7	6.5	6.6	6.8	6.6 ± 0.12	145.3
2-1.5-3-1	5.5	5.4	5.2	5.3	5.5	5.6	5.4	5.5	5.6	5	5.4 ± 0.19	149.1
3-1.5-3-2	7.8	7.5	7.7	7.8	8	7.8	7.9	8	7.7	7.8	7.8 ± 0.15	141.4
1-2-3-1	6.7	6.5	6.7	6.5	6.4	6.5	6.8	6.6	6.5	6.8	6.6 ± 0.14	145.3
2-2-3-1	7	6.7	6.7	6.9	6.8	7	7.1	6.7	6.9	7.2	6.9 ± 0.18	144.3

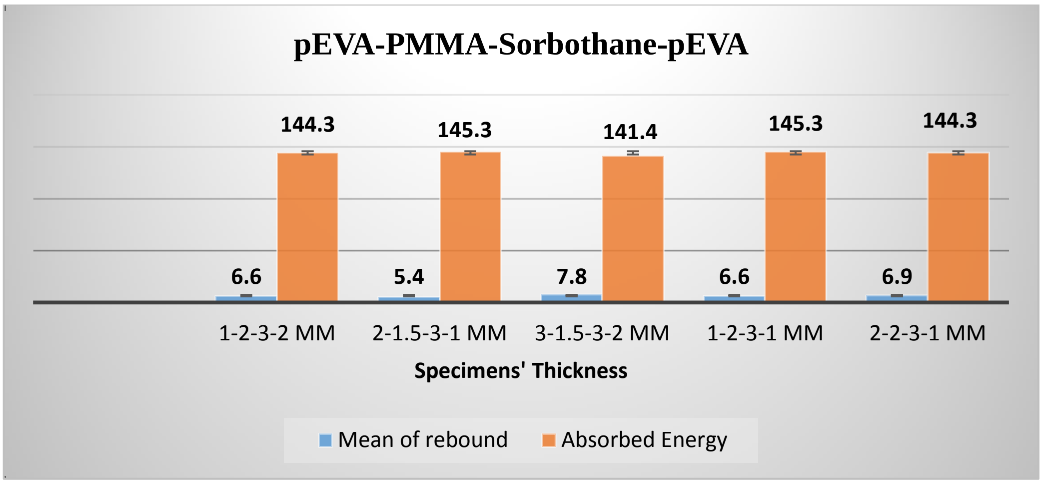


Figure 10: Mean of rebound and absorbed energy of pEVA-PMM- Sorbothane-pEVA design specimens.

3. 2. Mouthguard designs:

The best 5 absorbed absorb energy of different designs have been chosen to make up multi-layered mouthguard to produce different designs of mouthguards as shown in (figure 11) from left to right**:**

Design 1- pEVA- Sorbothane- pEVA with thickness of 1-3-3.

Design 2- pEVA- Sorbothane- pEVA with thickness of 1-3-2.

Design 3- pEVA-PMMA-pEVA with thickness of 1-3-2.

Design 4- pEVA- PMMA-Sorbothane- pEVA with thickness of2-1.5-3-1.

Design 5- pEVA-Sorbothane-PMMA-pEVA with thickness of 1-3-2-1.

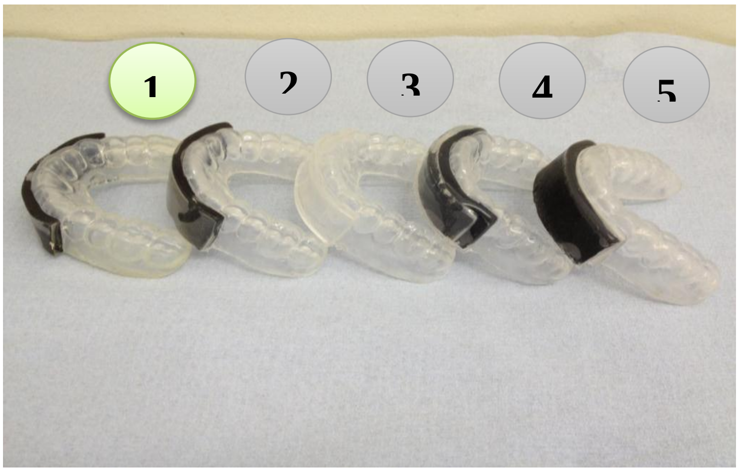


Figure 11: The 5 Mouthguard designs

3. 3. Charpy Impact Test:

The best five resulted absorb energy from rebound test of different designs have been chosen to examine their ability to absorb energy by using Charpy rig. The multi-layered specimens were subjected to Charpy tester (Charpy, Tinius Olsen, IT 503) once and the absorbed energy is shown in (table 9). The specimen of design of pEVA- Sorbothane- pEVA with thicknesses of 1-3-3 showed the best result of absorbed energy with 862 m J. followed by the design of pEVA- Sorbothane- pEVA with thicknesses of 1-3-2 with mean absorbed energy 585 m J**.**

Table 9: Absorbed Energy for Multi-layered Specimens (Charpy impact test)

Design	Absorbed Energy (mJ)
pEVA- Sorbothane- pEVA (1-3-3)	862
pEVA-PMMA-pEVA (1-3-2)	317
pEVA- Sorbothane- pEVA (1-3-2)	585
pEVA-PMMA-Sorbothane-pEVA (2-1.5-3-1)	388
pEVA- Sorbothane- PMMA-pEVA (1-3-2-1)	442

The multi-layered design mouthguards (figure 11) were subjected to the impact test ten times, and the mean of absorbed energy for each mouthguard was calculated as it displayed in (table 10), there were similarities with the Charpy test results for the multi-layered specimens.

The best absorption capability of 637 mJ was demonstrated by the EVA Sorbothane EVA specimen with thicknesses of 1 3 3 mm, while the lowest capability of 199 m J, was demonstrated by the multilayered mouthguard made up of pEVA PMMA Sorbothane pEVA with thicknesses of 2 1.5 3 1 mm.

Design	Absorbed Energy of specimens (mJ)										Mean of A. E
	A.E1	A.E2	A.E3	A.E4	A.E5	A.E6	A.E7	A.E8	A.E9	A.E10	
pEVA-Sorbothane-pEVA (1-3-3)	733	731	733	734	730	732	733	732	732	730	**732**
pEVA-PMMA-pEVA (1-3-2)	636	639	638	636	637	637	635	638	638	636	**637**
pEVA- Sorbothane-pEVA (1-3-2)	430	433	430	433	435	434	432	435	433	435	**433**
pEVA-PMMA-Sorbothane-pEVA (2-1.5-3-1)	200	198	200	197	198	200	203	198	198	198	**199**
pEVA-Sorbothane-PMMA-pEVA (1-3-2-1)	698	700	699	697	697	696	697	699	699	698	**698**

Table 10: Mean of Absorbed Energy for multi-layered mouthguards (Charpy impact test).

4. Discussion

The current study is *in-vitro* experimental study aimed to examine the ability of multi-layered designs to absorb and transmit impact force, also to determine the best arrangement of materials in the multi-layered design that offering the maximum level of protection. The study employed a simple rebound test, as the idea was that the test would give a clear concept about how the material behaves in relation to the impact force on the basis of Newton's third law: "to every action there is always opposed an equal reaction". In the rebound test, the material that rebounds the ball to the maximum height has very low impact energy absorption, and vice versa.

In addition, this test can clarify what kinds of properties are required for materials used to manufacture athletes' mouthguards. A number of earlier studies [4,19,20] have investigated the properties of materials for use in the manufacture of mouthguards utilizing the rebound test, and these tests obtained valid results.

By using the same procedures that carried in the study of Parker *et al* [4], the present study found that the rebound test gave valuable information on amount of energy absorbed. The study of Parker *et al* [4] was carried out by dropping two stainless steel balls (a small ball and a big ball) from a pre-determined height, heir finding concluded that thicker mouthguards provided greater protection. However, they did not specify the ideal thickness in terms of energy absorption.

As a result of a necessity of developing the ability of impact absorption through developments in the mouthguard design, many studies had examined the improvement in the capability of impact absorption by improving in the mouthguard material itself or using of different types of insertions.

Regarding to the improvement in the p EVA material itself, a study conducted by Bishop et al. [18] examined the static and dynamic absorbed energy of nine combinations of pEVA containing various percentages of poly vinyl acetate (PVA). The finding concluded that the material which performed best in the dynamic absorbing energy test was pEVA mouthguard material with content of 18 % PVA which recorded 31.8 m J.

In the present study, the effect of materials and thickness on absorbed energy was examined by the mean of rebound and standard deviation. The absorbed energy for each specimen was calculated as is shown in (figure 5). And as the (table 3) illustrated, the samples of 1.5 mm and 2 mm thickness showed more ability to absorb energy than the specimens of 3 mm or 4 mm thickness. However, in absorbing maximum energy the PMMA material tended to crack and deform. Therefore, PMMA would not on its own be a suitable material for mouthguard manufacture.

In contrast to the PMMA samples, the pEVA samples showed good ability to absorb energy (figure 6) without any deformation, and that refers to the elasticity and flexibility of the material. It could be observed that as the thickness of the pEVA samples increased, the height of the ball's rebound decreased. In other words, as the thickness increased the ability of the pEVA to absorb impact increased (table 4), and this finding was with agreement with the most studies in literature [4, 26, 27].

One of these approaches involved utilizing air cell insertion to 4 mm thick EVA mouthguard, which decreased the transmission of forces by 32% as compared with the conventional EVA mouthguard of the same thickness. Another approach was that foam insertion to bi-layered mouthguard, which showed the greatest shock absorption as 49% [24]. Another study undertaken by Kataoka *et.al* [25] on EVA material with and without Titanium wire mesh insertion and examine the effect on shock absorption, the results showed that Titanium insertion did not have a significant effect on impact force absorption.

Whereas Going *et al.* [20] analyzed the physical and mechanical properties of a number of materials used for manufacturing mouthguards. The tests included hardness, impact energy absorption, and resistance to impact penetration. However, the weakness of this study was that the researchers provided no suggestions about the most suitable material.

According to Girase *et al* [28], there is need for detailed study using different materials, designs with different combinations because this kind of studies is not conducted. Therefore, the current experimental *in-vitro* study designed to examine multi-layered designs which made up from different materials including (pEVA, PMMA, and Sorbothane), designs, and thicknesses.

The results of rebound test exhibited that the insertion of PMMA or Sorbothane between two pEVA layers had a more effect on the amount of absorbed energy than the use of 5 mm thickness pEVA samples without any insertions, and that could be due to the effect of insertions to absorb and transmit more amount of energy than p EVA material alone.

In the combination of pEVA PMMA pEVA, where PMMA used as hard insertion. The absorbed energy of different thicknesses of this combination ranged between 140 and 150 m J, as shown in (table 5) and (figure 7), and the greatest absorption of energy was demonstrated by the combination of PMMA with thickness of 3 mm between 1 and 2 mm thicknesses of pEVA. Next was the composite with 2 mm thickness PMMA between 1 and 2 mm thicknesses of pEVA. This finding was unexpected, as the assumption had been that the combination of 3 2 1 would provide maximum absorption. The explanation could be that a thinner upper layer of pEVA allows the inserted material to have a more dominant effect on the composite as a whole.

On one hand, the study of Greasley & Karet [21] stated that employing thinner, hard insertions with a thickness of 1.5 mm or 2 mm would not affect the impact absorption of the mouthguard because PMMA as a hard material, tends to crack at the site of the impact in order to absorb energy, and so mouthguards with this design require frequent maintenance or replacement. In addition, Westerman *et al*., [22] believed that there's no any advantages obtained from hard insertion in mouthguard. Moreover, they thought that hard insertion increases the risk of mouth injuries.

On the other hand, Takeda *et al.* [23] found that mouthguards with a hard insertion offered high capability of absorbing the impact shock. Considering that controversy findings of both studies based on the differences of designs, the results of Greasley and Karet [21] based on testing mouthguard design with hard insertion; however, Takeda *et al.* [23] conclusion based on testing mouthguard design with hard insertion and the presence of air space.

The rebound test was carried out on other multi-layered designs of pEVA Sorbothane pEVA, and (table 6) and (figure 8) illustrated the mean & standard deviation of rebound height and amount of absorbed energy for the different thicknesses of this combination. The samples of 1 3 3 mm and 1 3 2 mm thicknesses exhibited rebound mean and standard deviation of (5.9 ± 0.11), (5.9 ± 0.11) respectively and better ability to absorb impact shock with 147.5 m J. The results showed that the amount of energy absorption increased with the increased thickness of the samples; nevertheless, the samples with a thickness of more than 7 mm showed lower ability to absorb impact energy than the samples of 6 mm thickness. This finding supports the results of a previous study conducted by Meada *et al*. [24]. Using the same pEVA Sorbothane pEVA combination, Bulsara & Matthew [29] carried out a test at room temperature by dropping a weight and measuring the peak of impact force (PIF) with a peizoelectric transducer. This study concluded that the ability of the pEVA mouthguard material to absorb impact energy improved significantly on modification of their design by incorporation of Sorbothane material. However, Bulsara and Matthew did not specify how the Sorbothane material was held in place or how the piezoelectric transducer was mounted on the samples.

The multi-layered structure of the (pEVA Sorbothane PMMA pEVA) design is shown in (table 6). As with the other multi-layered designs, the combinations were of different thicknesses of pEVA and PMMA, while the thickness of Sorbothane was standard at 3 mm. The mean & standard deviation of rebound and the amount of absorbed energy are illustrated in (figure 9). The results showed a 7 mm layered composite made up of 1-3-2-1 mm thicknesses achieved mean of rebound with standard deviation (5.4 ± 0.19) and maximum absorbed energy was the 149.1 m J. The next best result was gained with the 7.5 mm multi structure of 1- 3- 1.5- 2 mm, with absorbed energy of 147.2 m J. Once again the findings from this group were unexpected in that the lower thicknesses exhibited better capability of absorption. Moreover, the absorption capability of the multi-layered composite decreased with an increase in the thickness, and the specimens with an upper pEVA layer of 1 mm thickness gave better results than those of 2 mm thickness.

The design of pEVA PMMA Sorbothane pEVA, the layered composites were made up of different thicknesses of pEVA and PMMA, as listed in (table 7). (Figure 10) showed the ability of each group to absorb the shock impact. The result demonstrated that the use of hard and soft insertions in the mouth guard, with an upper PMMA layer, had a significant effect on absorption ability. The results of this group were in contrast to those gained with the pEVA Sorbothane PMMA pEVA composite structure, with the 7.5 mm specimen exhibiting more ability to absorb energy than the composite of 7 mm thickness. However, increasing the thickness of the specimens beyond 7.5 mm had an adverse effect on energy absorption ability. The modified designs of mouthguard material achieved better results than the 5 mm thickness pEVA mouthguard material. The multi-layered composite designs that exhibited improvement in their performance recorded very similar results. The best results were achieved with the composite of pEVA PMMA pEVA of thicknesses 1 3 2 mm, which absorbed 149.8 m J of energy. The combinations of pEVA Sorbothane PMMA pEVA at 1 3 2 1 mm and pEVA PMMA Sorbothane pEVA at thicknesses of 2 1.5 3 1 mm achieved the second best result, at 148 m J. pEVA Sorbothane pEVA with thicknesses of 1 3 3 and 1 3 2 absorbed 147.5 m J.

The best five performing specimens from the simple rebound test were made up into mouthguards and impacted in a Charpy rig.

The results of this test were little different from those obtained from the rebound test. The maximum absorbed energy was 862 m J, achieved by the multilayered mouthguard made of pEVA Sorbothane pEVA with thicknesses 1 3 3 mm, whereas the composite of pEVA PMMA Sorbothane pEVA and thicknesses of 2 1.5 3 1mm showed the lowest absorption ability. The explanation for this result could be that the application of temperature and pressure to process the mouthguard may had an effect on the performance of the multi-layered design.

The best absorption capability of 637 m J was demonstrated by the pEVA Sorbothane pEVA specimen with thicknesses of 1 3 3 mm, and the lowest capability of 199 m J was demonstrated by the multi-layered mouthguard made up of pEVA PMMA Sorbothane pEVA with thicknesses of 2 1.5 3 1 mm. The results of this test contradict the finding of a previous study carried out by Kim and Mathieu [30] in their study, they found that when the soft layer was in contact with the indenter there was no significant effect on stress distribution, whilst when the hard layer was in contact with the indenter this had a significant effect on stress distribution. Although, the researchers didn't mention the thickness of the samples.

However, the present study showed that this combination (hard material most upper layer) had the lowest ability to absorb impact energy and had a tendency to fracture. On the other hand, the current results support the results of another previous study that demonstrated that increasing the thickness beyond 7 mm decreased the ability of the mouthguard to absorb impact shock [23].Further study is required to examine the forces that generated by deferent force stimulators such as cricket ball or baseball on frontal and frontal/side of mouthguard.

For this stage, the mouthguard designs has been tested *in vitro*. For next step, these designs could be investigated *in vivo* to examine the ability of impact absorption and degree of comfort.

5. Conclusions:

The current study was experimental *in-vitro* based on the implementation of a simple rebound test followed by Charpy testing.

With limitations in terms of the sample size was relatively small. In addition to the sensitive sensor device wasn't used to measure the amount of absorbed force in the rebound test and the absorbed energy was based on using a Newton's equation of motion, the study concluded the followings:

The thickness of the laminated mouthguard design has a crucial influence on its energy absorption: the energy absorption of the mouthguard increases with an increase in thickness. However, further increases in the thickness beyond 7 or 7.5 mm have adverse effect on the ability of the mouthguard to absorb impact shock.

The nature of the material receiving the impact has an effect on the impact absorption ability. Exposure of mouthguard materials to heat and pressure during processing had an effect on the obtained results.

Results from both tests suggested that the laminated mouthguard with incorporation of the soft material pEVA- Sorbothane- pEVA 1-3-2 in the anterior region from canine to canine provides the best level of protection to athletes, followed by sandwiching soft and hard materials in a pEVA- Sorbothane- PMMA-pEVA 1-3-2-1 combination.

6. Acknowledgment:

The authors would like to thank Dr. David G. Patrick for many helpful comments and discussions

7. References

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