Development and Shock Absorption and Dispersion Capability of a Novel Mouthguard Sheet Material Consisting of Two Types of Five-layer Structures

（2種5層構造からなる新規マウスガードシート材の開発と衝撃吸収・分散能）

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I. Abstract

[Objective]

The availability of various types of mouthguard (MG) sheet materials is advantageous as it offers diverse options to sportspersons. In this study, we laminated an ethylene-vinyl acetate (EVA) copolymer and a polyolefin (PO) copolymer resin with different hardness values and fabricated a novel MG sheet material comprising five layers of EVA–PO laminate (newly developed sheet material: ND). Furthermore, we examined the fundamental physical properties and the shock absorption capacity and dispersion capability of ND.

[Materials and Methods]

Research 1: Sheet EVA and PO were laminated to obtain PO-EVA-PO two-material tri-layered sheets, which were further combined to produce a new sheet material consisting of five layers of the as-prepared laminate. In addition to the new sheet material, EVA sheets and PO sheets were used as reference materials in this study. Physical property tests of the materials were performed according to Japanese Industrial Standards (JIS). Sheet materials with a thickness of 3 mm were used for hardness, tensile, elongation, tearing, water absorption, and abrasion resistance tests. All measurements were repeated five times.

Research 2: A free-falling ball shock absorption test was performed for impact testing, and a partially modified DuPont shock absorption tester (IM-201, Tester Sangyo, Saitama, Japan) was used. A total of nine types of test pieces (ND, EVA, PO; thicknesses of 3 and 4 mm) were set. Shock absorption tests were conducted according to ISO 6603-2:2000, Plastics−Determination of puncture impact behavior of rigid plastics−Part 2: Instrumented impact testing (Japanese Industrial Standards K 7211-2). The test pieces comprised 3 and 4 mm thick ND sheets, whereas 3 and 4 mm thick EVA and PO served as controls.

[Results]

Research 1: The basic physical properties of the new composite sheet material were comparable to or better than those of EVA and PO. The new sheet material was harder than existing products, yet it exhibited similar properties. Moreover, it showed good tensile strength, elongation, tear strength, water absorption rate, and abrasion resistance index.

Research 2: Impact testing for the new sheet material showed that the force required to displace

the sheet by 1 mm was significantly higher at all thicknesses ($p<0.001$), whereas the puncture energy and displacement were significantly lower than those for EVA ($p<0.05$).

[Conclusion]

ND, consisting of two types of material (EVA and PO) and five layers, was found to be a hard MG sheet material with physical properties comparable to those of EVA and PO. And the shock absorption and dispersion properties of ND were examined by conducting dual shock absorption tests, and ND exhibited higher shock absorption and dispersion capabilities than conventional products. This new sheet has suitable physical properties and sufficient shock-absorbing capacity to be used in the fabrication of MG.

II. Introduction

Wearing a mouthguard (MG) while playing sports effectively prevents or reduces oral trauma and concussion and fixes the lower jaw in place[1,2]. The material and thickness of MGs significantly affect their safety and efficacy[3]. Custom-made mouthguards (CMGs) fabricated by dentists are widely recommended as they can provide a better fit, contour, and occlusion than commercially available MGs[4].

CMGs are composed of elastic materials that return to their original shape when deformed by external forces. Currently, ethylene-vinyl acetate (EVA) copolymer, polyolefin (PO) copolymer, and styrene-ethylene block copolymer are widely used for fabricating CMGs. EVA is the most commonly used sheet material for sports MGs owing to its low softening temperature, affordability, diverse applications, and availability in multiple colors. PO has good workability, excellent heat adhesion, and weather resistance; however, its insufficient wear resistance restricts its applications. The styrene-ethylene block copolymer is highly flexible and elastic; however, it has a high softening temperature and poor weather resistance[5,6].

The sheet material used to manufacture mouthguards should possess the following properties: (1) optimal fit; (2) durability (high abrasion resistance and low water absorption); (3) non-toxicity; (4) high shock absorbency; and (5) excellent shock dispersibility[7]. Currently, most CMGs provided by dentists constitute sheet materials composed of thermoplastic resins, mainly comprising EVA and PO, because they satisfy the aforementioned conditions (1)–(5). However, when considering the prevention of oral trauma, if the thickness of the sheet material cannot be maintained, the applied shock cannot be absorbed and dispersed. Westerman et al.[7] reported that the anterior teeth of the mouthguard should be at least 3–4 mm thick to protect the teeth; however, wearing such a thick mouthguard not only increases discomfort and the feeling of a foreign body but also may affect occlusion. Therefore, mouthguard sheet materials with moderate thicknesses, high shock absorption, and dispersibility are required.

The physical properties of the materials used for fabricating MGs are significant for obtaining effective MGs. In particular, the physical properties of the sheet material, such as hardness, tensile strength, tear strength, elongation, and water absorption, determine the effectiveness of MGs. Currently, various types of CMGs are manufactured mainly using EVA and PO. They exhibit good physical properties, such as biosafety, shock absorption, and durability[8].

Several studies have been conducted to improve mouthguard shock absorption and dispersion effects, mainly using materials such as EVA and PO. For example, various approaches such as combining the sheets of the same material with different hardness values[7)], and laminating EVA and a viscoelastic material with flexible properties have been explored[9)]. Additionally, inserting acrylic material or a buffer space between laminated EVA sheets improves the shock absorption/dispersibility[10)]. However, all these methods involve increasing the thickness of the necessary potions of the mouthguard after formation or inserting different materials, such as hard materials and voids. Therefore, these aspects increase the number of processes required for mouthguard production and lead to concerns related to production issues, such as poor adhesion and peeling between materials, or increase the burden on the producer as well as the production cost.

However, conventional MG sheet materials are designed for general use in sports and have not been studied specifically for each sport or athlete. Expanding the recommended wearing range is essential to promote the widespread use of CMGs. Additionally, to improve athlete satisfaction with CMGs, new sheet materials that differ from those used in conventional MGs must be developed. For example, developing new sheet materials that afford improved comfort by adjusting the hardness using easily processable materials that are familiar to manufacturers is essential.

The aim of the present study was twofold: first, to investigate the basic physical properties of a novel sheet material comprising five layers of EVA and PO, with unique compositions and hardness (newly developed sheet material: ND), and second to examine multiple shock absorption tests were performed to investigate the shock absorption and dispersion properties of ND.

III. Materials and Methods

Research 1: Development of a New Mouthguard Sheet Material Comprising Two Different Five-Layered Structures

EVA and PO were laminated to fabricate ND. A two-type, three-layer tube with PO as the outer layers and EVA as the inner layer was prepared. Thereafter, two sets of two-type, three-layer tubes were co-extruded and interposed between flat molds to form a sheet material for molding a two-type, five-layer MG. Strong adhesion was achieved by the "co-extrusion" of special PO in a molten state between all layers. The final 5-layer structure of the ND comprised 5% PO in the surface layer, 40% EVA, 10% PO in the middle, 40% EVA, and 5% PO. (Fig. 1a, 1b).

The new sheet material was analyzed using various techniques. Additionally, EVA (Erkoflex®, Erkodent Erich Kopp, Germany) and PO (MG21® Regular, CGK Co. Ltd., Hiroshima, Japan) were used as control materials.

Physical property tests were conducted according to Japanese Industrial Standards (JIS)[11] procedures. A sheet material with a thickness of 3 mm was used for testing the hardness, tensile strength, elongation, tear strength, water absorption, and abrasion resistance. Five specimens were prepared for each test.

Shore A hardness was measured using a GS-703N durometer (Teclock Co., Ltd., Nagano, Japan) according to JIS K6253-3[12]. Tensile strength and elongation tests were performed in accordance with JIS K6251[13], and the tear strength was evaluated as per JIS K6252[14]. The tear strength refers to the value at which a single specimen (30 mm^2) can be pulled through a cut and torn in opposite directions. A universal testing machine (AGS-500A, Shimadzu Corporation, Kyoto, Japan) was used at a 500 mm/min speed for these measurements. Water absorption was determined according to JIS K7209[15] by preparing a sample with dimensions of 50 φ × 1.5 mm and immersing it in distilled water at 37 °C for 24 h. Thereafter, the rate of weight change was monitored using an electronic balance (AE166, Mettler Toledo, Ohaio, USA). The abrasion resistance test was conducted according to JIS K6264-2[16]. A test piece was punched to a diameter of 15 mm and pressed against a rotating polishing drum to measure the abraded mass.

To analyze, One-way analysis of variance was used to evaluate each physical property of the ND, EVA, and PO sheets, and the Bonferroni method was used for multiple comparisons. A 5% significance level was set for both.

Research 2: Shock Absorption and Dispersion Capability of a Novel five-layer Mouthguard Sheet Material

The test pieces selected were derived from the ND, with EVA and PO as controls similar to Research1. A free-falling ball shock absorption test was performed for impact testing, and a partially modified DuPont shock absorption tester (IM-201, Tester Sangyo, Saitama, Japan) was used according to the method described by Fukasawa et al.[17)]. A total of six types of test pieces (ND, EVA, PO; thicknesses of 3 and 4 mm) were set, and each was molded into a circular shape with a diameter of 50 mm; six sheets were prepared for each set for the experiments. Each test piece was placed on a stainless-steel plate with a thickness of 10 mm, and a 15 mm diameter iron ball (13.8 g) was allowed to freely fall from a height of 600 mm. The load change generated at this time was measured using three pressure sensors (LMA-A-1KN-P, Kyowa Dengyo, Tokyo, Japan) at the bottom of the stainless-steel plate. PC-based recordings were conducted at 20 kHz with a sensor interface (EDS 100A, Kyowa Dengyo), and the sum of the loads detected by the three pressure sensors was obtained. Each measurement was performed thrice, and the average value of the maximum load was calculated. Similar measurements were performed without the test pieces, and the values were used as controls, as shown in Figure 2.

Shock absorption tests were conducted according to ISO 6603-2:200015, Plastics−Determination of puncture impact behavior of rigid plastics−Part 2: Instrumented impact testing (JIS K 7211-2)[18)]. The test pieces comprised 3 and 4 mm thick ND sheets, whereas 3 and 4 mm thick EVA and PO served as controls, and for each sheet material, the following parameters were measured: impact force required to displace sheet by 1 mm after the striker drops and comes into contact with the test piece at a speed of 4.4 m/s (maximum impact (kN)/displacement at maximum impact (mm)), the energy required to reach the puncture displacement (puncture energy (J)), and displacement when the maximum impact was halved (puncture displacement (mm)).

To analyze, the measurements were performed three times, and the average value was calculated. One-way analysis of variance was performed for each thickness in both the impact and shock absorption analyses, and the Bonferroni correction was performed for multiple comparisons. Each sheet material was compared with the control during the impact test, whereas the other specimens were analyzed at each thickness. All statistical analyses were performed using SPSS for Windows version 20 (IBM Corp., Armonk, NY, USA). The significance level was set at 5%.

IV. Results

Research 1: Development of a New Mouthguard Sheet Material Comprising Two Different Five-Layered Structures

The Shore A hardness was 92 for the ND, 85 ± 1 for EVA, and 82 for PO. The hardness of ND was significantly higher than that of EVA and PO. The tensile strength (MPa) was 19.3 ± 0.7 for ND, 16.2 ± 6.8 for EVA, and 8.9 ± 0.7 for PO. The elongation at break (%) was 693.3 ± 5.8 for ND, 823.3 ± 45.1 for EVA, and 756.7 ± 5.8 for PO. ND showed a significantly smaller value than EVA. The tear strength (kN/m) was 58.9 ± 0.6 for ND, 38.6 ± 1.8 for EVA, and 40.9 ± 0.9 for PO. ND showed a significantly higher value than EVA and PO. The water absorption (%) was 0.03 ± 0.01 for ND, 0.11 for EVA, and 0.01 ± 0.01 for PO. ND and PO showed significantly smaller values than EVA. The abrasion weight (g) was 0.01 for ND, 0.12 for EVA, and 0.06 for PO. ND showed a significantly smaller value than EVA and PO (Table 1).

Research 2: Shock Absorption and Dispersion Capability of a Novel Five-layer Mouthguard Sheet Material

In Ball drop shock absorption test, the loading capacity of the control without the test specimen was 660.1 ± 3.9 N. For the 3 mm sheets, the impact values were 461.9 ± 6.3 N for ND, 426.3 ±11.5 N for EVA, and 389.7 ± 6.0 N for PO. All the sheets showed significantly lower impact values than the control ($p < 0.001$) (Table 2); among the test pieces, PO had a significantly lower value, and ND had the highest value ($p < 0.001$) (Table 3). For the 4 mm sheets, the impact values were 455.0 ± 1.9 N for ND, 363.0 ± 6.3 N for EVA, and 377.9 ± 4.0 N for PO. All the sheets showed significantly lower impact values than the control ($p < 0.001$) (Table 2); among the test pieces, EVA had a significantly lower value, and ND had the highest value ($p < 0.001$) (Table 3). In Puncture impact test, the impact values needed for displacing 1 mm in 3 mm sheets were 0.044 ±0.002 kN for ND, 0.023±0.001 kN for EVA, and 0.019±0.001 kN for PO, with ND exhibiting significantly high impact values ($p < 0.001$). The puncture displacement values were 20.33±0.58 mm for ND, 23.67±2.08 mm for EVA, and 36.01±0.01 mm for PO, with ND possessing significantly lower puncture displacement values than EVA and PO ($p < 0.001$) Meanwhile, The puncture energy values were 0.338 J±0.001 J for ND, 0.312±0.02 J for EVA, and 0.332 J±0.001 J for PO, with ND exhibiting a significantly higher puncture energy value than EVA ($p < 0.001$) (Table 4). The impact values needed for displacing 1 mm in 4 mm sheets were 0.044±0.01 kN for ND, 0.025±0.01 kN for EVA, and 0.027±0.001 kN for PO, with ND exhibiting significantly higher values than EVA and PO ($p < 0.001$). The puncture energy values were 0.491±0.01 J for ND, 0.399±0.01 J for EVA, and 0.498±0.001 J for PO, with ND possessing a significantly higher puncture energy value than EVA and a significantly lower value than PO ($p < 0.001$). Meanwhile, the puncture displacement values were 21.33±0.58 mm for ND, 26.33±2.52 mm for EVA, and 37.00±0.01 mm for PO, with ND exhibiting significantly lower puncture displacement values than EVA and PO ($p < 0.001$) (Tables 5).

V. Discussion

Research 1: Development of a New Mouthguard Sheet Material Comprising Two Different Five-Layered Structures

The stomatognathic region is a site that cannot be covered and protected and is easily damaged owing to its anatomical shape. Furthermore, the stomatognathic region plays an essential role in the aesthetics and functioning of the human body. However, trauma to this area often leads to an irreversible healing process accompanied by morphological changes, which is accompanied by a risk of significantly reducing the quality of life of the injured person19). Consequently, numerous studies have focused on the effectiveness of MGs in preventing oral trauma during sports since the World Dental Federation (Fédération Dentaire International; FDI) proposed their use20). In recent years, MGs have been reported effective in alleviating concussion21) and fixing the jaw in place2). Even non-contact sports players have experienced situations where wearing a CMG is necessary. However, whether conventional CMGs are suitable for them remains unclear. Despite a growing demand for appropriate and efficient materials for CMGs, the options available for sheet materials remain limited.

Because they are used in the oral cavity, the properties required for CMG materials include a non-irritating nature, tastelessness, and odorlessness. Additionally, they must exhibit excellent durability and adhesiveness and low water absorption (low absorption of saliva) to remain clean7). The main purpose of using MGs is to provide shock absorption and dispersion effects for mitigating trauma from external forces; therefore, they must possess good hardness. When manufacturing a CMG, the material, hardness, thickness, and other essential properties of the sheet should be selected based on the intended application.

The key aspects of this study are as follows:

1. Existing sheet materials (EVA and PO) were used to reduce development and production

costs.

2. A single-sheet material, including the technical operation, was used to simplify CMG production.
3. In contrast to existing products, in the newly developed product, materials of different hardness values were combined to absorb and disperse force.
4. The required properties of the CMG were completely retained.
5. Customization, such as heat welding, was conducted.

As stated in the first point of the list above, EVA and PO were selected as commonly used materials familiar to manufacturers. Considering the second point, the technical operation was simplified by using a single-sheet material. Furthermore, a two-type, five-layer single-sheet material was fabricated through extrusion molding. Because the manufacturing method employed in this study was identical to the conventional method, no specific issues related to operability were observed.

As stated in the third point, laminating materials with different hardness levels results in improved shock absorption and dispersion effects[22)]. Thus far, MGs have generally been manufactured using sheet materials. However, recent advancements have made it possible to successfully bind several technically difficult materials, such as EVA and PO[23)]. Consequently, ND has a Shore A hardness of 92 and is harder than conventional sheet materials. The hardness of a CMG sheet is primarily indicated by the Shore A hardness, which determines the shape stability (maintenance force and occlusion stability), shock absorption, and durability (deformation and wear resistance). The Shore A hardness of CMG sheet materials typically falls within a range of 75 to 90, rendering ND harder than conventional products. Because MGs disperse and absorb impact to provide shock absorption, a harder sheet material offers a higher force dispersion effect[24)]. Hence, we plan to conduct further studies on the impact absorption capacity of the as-developed material.

As per the fourth point, the new material should possess basic physical properties comparable to those of EVA and PO. However, the characteristic results observed in this study suggest a higher hardness of the new sheet material compared to that of the existing products.

Tensile strength refers to the maximum tensile stress a material can withstand before breaking. Elastic and plastic regions were observed, and the size of the elastic region is related to durability. No significant differences were observed between ND, EVA, and PO, indicating similar physical properties. Conversely, elongation represents the plastic deformation region in the tensile test and is a measure of ductility. A large elongation value indicates an easy deformation of the material. ND showed a smaller elongation value than PO and a significantly smaller value than EVA, suggesting its resistance to deformation.

Tear strength refers to the maximum force a material can withstand before tearing when pulled in opposite directions. A higher tear strength indicates higher durability. ND demonstrated a significantly higher tear strength than EVA and PO, suggesting high durability.

Water absorption is an indicator of the ability of a material to absorb water within a given period. High absorption leads to contamination and deterioration; therefore, low absorbency is desirable. The absorbency of PO was lower than that of EVA6), and although the water absorption of ND was higher than that of PO, it was significantly lower than that of EVA. This is attributed to the lower absorbency of the PO in the surface layer and the EVA being exposed only on the sides of the ND layer. However, the absorbency of ND is sufficient to withstand contamination and deterioration.

The abrasion resistance indicates the degree of wear caused by the impact from an external force applied to the MG and occlusal contact owing to the fixation of the lower jaw. An abrasion resistance test determines the ability of a product to withstand harsh environments and conditions in the oral cavity and its long-term durability. A smaller abrasion resistance value indicates a better performance. ND showed a significantly smaller abrasion weight than EVA and PO, indicating high durability.

As per the fifth point, EVA and PO were combined as the surface layer. EVA and PO can be heat-welded to customize the MGs. However, using EVA requires cleaning material for adhesion, whereas PO can be employed without this requirement[8]. Therefore, PO was used as the surface layer in this case.

Research 2: Shock Absorption and Dispersion Capability of a Novel Five-layer Mouthguard Sheet Material

This study examined the shock absorption characteristics of a newly developed two-component, five-layer structure mouthguard sheet material, ND, manufactured using the comparative control materials of EVA and PO based resins, which are the most frequently used material types for MGs.

Several researchers have conducted shock absorption tests to confirm the effectiveness of MGs using the ball drop test25); however, it is difficult to make simple comparisons because of the difference in conditions, such as the size and weight of the iron ball and the height from which it is freely dropped. However, in actual sports contexts, the conditions change depending on the sporting event type and specific circumstances as well as the size of the impacting object26). Therefore, examining these aspects under various conditions is beneficial. Reza et al. conducted a similar shock absorption test of MGs materials by comparing the same load cell and film sensor systems and reported that the load cell system was useful for determining the load change for the entire test piece27). Additionally, in this study17), tests similar to those reported in the past were conducted under the condition of approximately 660 N for the control without the test piece. The value of 660 N was chosen because it is the minimum resistance value of the maxillary bone based on the reports by Hodgson and McElhaney et al.28,29), wherein cadavers were used to examine the shock resistance of facial bones. This value is considered a highly appropriate shock value. All the ND sheets showed significantly lower values than the control, indicating sufficient shock absorption. A comparison with commercially available sheet materials showed that ND had higher values than EVA and PO, as reported by Fukasawa et al.17). The impact test results were almost identical to those of the commercially available MGs material, and therefore, it was inferred that ND exhibited sufficient shock absorption.

The shock absorption test was performed according to ISO 6603-2:2000, Plastics−Determination of puncture impact behavior of rigid plastics−Part 2: instrumented impact testing. In this test, a striker moving at a constant shock speed of 4.4 m/s provides a shock to the test piece, and the energy required to puncture the test piece was calculated. Several types of shock absorption tests have been proposed. However, the puncture test method can numerically evaluate the behavior of the material until failure; accordingly, it can calculate the impact as well as the force that resists the applied shock (dispersion force). Therefore, this method was adopted as the test method in the experiment. In the present study, the test piece was a soft material with elastic properties; therefore, the following three evaluation parameters were used: maximum impact needed to displace the sheet by 1 mm/displacement at maximum impact; puncture energy, which is the energy required to reach a puncture displacement (puncture); and puncture displacement, which is the displacement at which the maximum impact is reduced by half. Compared with that of other samples, the impact required to displace the sheet by 1 mm (maximum impact/displacement at maximum impact) was significantly higher for ND for each thickness. This is the result of expending a large amount of force for displacement because of the high shock absorption of ND. Additionally, the significantly higher expended energy (puncture energy/puncture displacement) than that of EVA is considered to be the result of continued absorption while dispersing the force because the dispersion capability of ND is high. The similar or lower value than that of the polyolefin is assumed to be because of the PO surface layer. Additionally, the significantly low sheet displacement when the maximum impact was reduced by half (puncture displacement) can be attributed to the high shock dispersion capability of ND.

Thus far, several attempts have been made to improve shock absorption and dispersion effects, mainly using materials such as EVA and PO. These approaches have been divided into different types based on various considerations: (1) combinations of sheet materials[6,30)], (2) combinations of properties other than the sheet material with the sheet[31)], and (3) the use of alternative materials excluding EVA and PO[32)]. ND is a combination of sheet materials in the form of a sheet that bonds existing EVA and PO sheet materials together. Westerman et al. [3)] reported that when combining EVA materials with different hardness values, if the material with the same thickness is combined with a high-hardness EVA material, the hardness and rigidity will increase, without any change in shock absorption, suggesting that even if the hardness values are different, improvement in shock absorption cannot be expected from the same combination. ND, which combines different types of materials with different hardness values and material components, is a new sheet material with a Shore A hardness of 92, demonstrating high shock absorption and dispersion capabilities.

In this study, the as-obtained findings were compared with several previous reports on mouthguard materials to ensure the validity of the results. The experiments were performed at room temperature in a dry state; therefore, the physical properties of an actual oral cavity were not examined. By conducting experiments within oral cavities or in a biomimetic environment, the mouthguard characteristics can be accurately determined. Furthermore, from the perspective of durability, observing the changes in physical properties over a long period, such as 1 day, 1 week, or 1 month, following a period of immersion in water, is essential. Significantly, in addition to its utility in sports MGs, ND can be applied in occlusal splints for temporomandibular disorder treatment, night guards to prevent teeth grinding, and oral appliances for sleep apnea, which will be investigated in future studies.

VI. Conclusion

In conclusion, a newly developed sheet, ND, consisting of two types of material (EVA and PO) and five layers, was found to be a hard MG sheet with physical properties comparable to those of EVA and PO. And the shock absorption and dispersion properties of ND were examined by conducting dual shock absorption tests, and ND exhibited higher shock absorption and dispersion capabilities than conventional products. This new sheet has suitable physical properties and sufficient shock-absorbing capacity to be used in the fabrication of MGs.

VII. References

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Tables

Table 1 Physical data for hardness, tensile strength, elongation, tear strength, water absorption, and abrasion resistance of each material.

	ND		EVA		PO		*F*	*p*	multiple comparison
	M	SD	M	SD	M	SD			
Hardness (Shore A)	92	0.0	85	1.0	82	0.0	351.0	<.001	ND>EVA>PO
Tensile strength (Mpa)	19.3	0.7	16.2	6.8	8.9	0.7	5.4	.045	ND>EVA>PO
Elongation (%)	693.3	5.8	823.3	45.1	756.7	5.8	18.1	.003	ND<EVA
Tear strength (kN/m)	58.9	0.6	38.6	1.8	40.9	0.9	259.2	<.001	ND>PO, ND>EVA
Water absorption %)	0.03	0.01	0.11	0.0	0.01	0.01	140.6	<.001	ND<EVA, PO<EVA
Abrasion weight (g)	0.01	0.0	0.12	0.0	0.06	0.0	3762.7	<.001	ND<PO<EVA

ND; Newly developed sheet material, EVA; ethylene vinyl acetate; PO; polyolefin copolymer. $P < 0.05$.

Table 2 Results of the impact test: comparison with control

Test sample	Thickness (mm)	Mean ± SD (N)	F	P
Control	na	660.1 ± 3.9	1258.83	<0.001
ND	3	461.9 ± 6.3		
	4	455.0 ± 1.9		
EVA	3	426.3 ± 11.5		
	4	363.0 ± 6.3		
PO	3	389.7 ± 6.0		
	4	377.9 ± 4.0		

ND; Newly developed sheet material, EVA; ethylene vinyl acetate; PO; polyolefin copolymer, SD; standard deviation.

Table 3 Impact test: comparison between sheets

	ND	EVA	PO	F	p	Bonferroni's Multiple Comparison
	Mean ± SD	Mean ± SD	Mean ± SD			
3mm (N)	461.9 ± 6.3	426.3 ± 11.5	389.7 ± 6.0	130.47	<.001	PO<EVA<ND
4mm (N)	455.0 ± 1.9	363.0 ± 6.3	377.9 ± 4.0	715.68	<.001	EVA<PO<ND

ND; Newly developed sheet material, EVA; ethylene vinyl acetate; PO; polyolefin copolymer, SD; standard deviation.

Table. 4 Shock absorption test of 3 mm sheet material

	ND	EVA	PO	F	p	Multiple Comparison
	Mean ± SD	**Mean ± SD**	**Mean ± SD**			
The impact values needed for displacing 1 mm (kN)	**0.044 ± 0.002**	**0.023 ± 0.001**	**0.019 ± 0.001**	**715.43**	**<.001**	**PO<EVA<ND**
The puncture energy values (J)	**0.338 ± 0.001**	**0.312 ± 0.02**	**0.027 ± 0.001**	**6.04**	**<.001**	**EVA<ND**
The puncture displacement values (㎜)	**20.33 ± 0.58**	**23.67 ± 2.08**	**36.01 ± 0.01**	**131.36**	**<.001**	**ND<EVA<PO**

ND; Newly developed sheet material, EVA; ethylene vinyl acetate; PO; polyolefin copolymer, SD; standard deviation.

Table 5 Shock absorption test of 4 mm sheet material

	ND	EVA	PO	F	p	Multiple Comparison
	Mean ± SD	**Mean ± SD**	**Mean ± SD**			
The impact values needed for displacing 1 mm (kN)	**0.044 ± 0.01**	**0.025 ± 0.01**	**0.027± 0.001**	**6.39**	**<.001**	**EVA<ND, PO<ND**
The puncture energy values (J)	**0.491 ± 0.01**	**0.399 ± 0.01**	**0.498 ± 0.001**	**70.77**	**<.001**	**EVA<ND<PO**
The puncture displacement values (㎜)	**21.33 ± 0.58**	**26.33 ± 2.52**	**37.00 ± 0.01**	**86.45**	**<.001**	**ND<EVA<PO**

ND; Newly developed sheet material, EVA; ethylene vinyl acetate; PO; polyolefin copolymer, SD; standard deviation.

Figure legends

Figure 1a

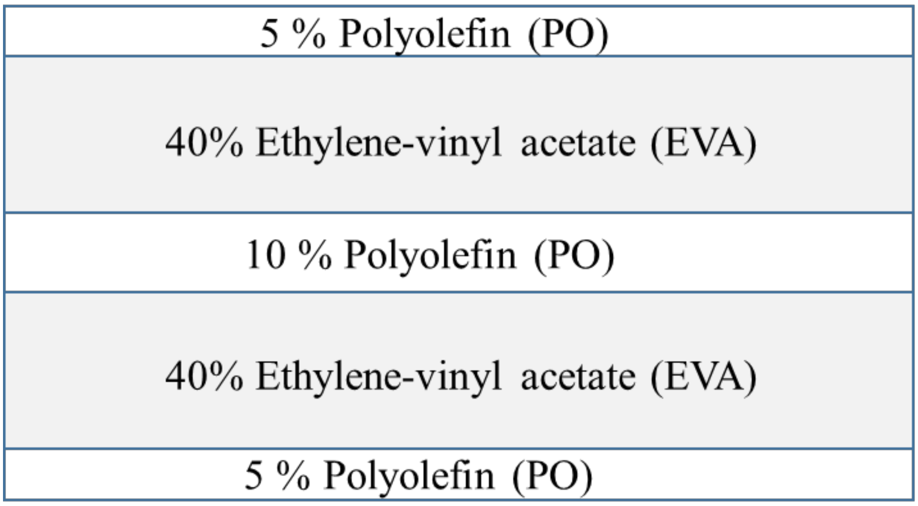

Figure 1b

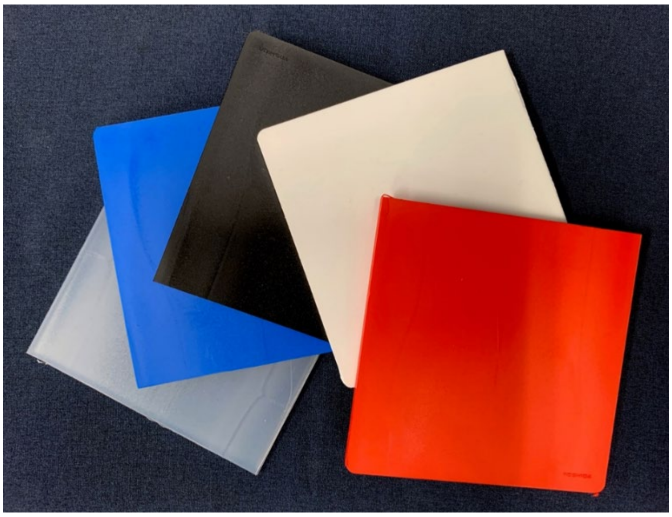

Figure 1 Schematic (1a) and photograph (1b) of the composition of the new mouthguard sheet material comprising two different five-layered structures.