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International application number:	PCT/US2018/035384
International filing date:	31 May 2018 (31.05.2018)
Document type:	Certified copy of priority document
Document details:	Country/Office: US
	Number: 62/590,627
	Filing date: 26 November 2017 (26.11.2017)
Date of receipt at the International Bureau:	15 June 2018 (15.06.2018)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a),(b) or (b-bis)

931648

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

June 14, 2018

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE.

APPLICATION NUMBER: 62/590,627

FILING DATE: November 26, 2017

RELATED PCT APPLICATION NUMBER: PCT/US18/35384

THE COUNTRY CODE AND NUMBER OF YOUR PRIORITY APPLICATION, TO BE USED FOR FILING ABROAD UNDER THE PARIS CONVENTION, IS US62/590,627



Certified by

Under Secretary of Commerce
for Intellectual Property
and Director of the United States
Patent and Trademark Office

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PROVISIONAL APPLICATION FOR PATENT COVER SHEET – Page 1 of 2

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Priority Mail Express® Label No. _____

INVENTOR(S)		
Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
Ray F	Stewart	Redwood City, CA
John	Lahlouh	San Jose, CA

Additional inventors are being named on the _____ separately numbered sheets attached hereto.

TITLE OF THE INVENTION (500 characters max):

DUAL SHELL DENTAL APPLIANCE AND MATERIAL CONSTRUCTIONS

Direct all correspondence to: **CORRESPONDENCE ADDRESS**

☐ The address corresponding to Customer Number:

OR

☒ Firm or Individual Name **Linda Judge**

Address **807 Toyon Way**

City Redwood City	State CA	Zip 94062
Country USA	Telephone 650-678-3450	Email ljudge@wakeuplegal.com

ENCLOSED APPLICATION PARTS (check all that apply)

☒ Application Data Sheet. See 37 CFR 1.76. ☐ CD(s), Number of CDs _____

☒ Drawing(s) Number of Sheets 5 ☐ Other (specify) _____

☒ Specification (e.g., description of the invention) Number of Pages 27

Fees Due: Filing Fee of \$260 (\$130 for small entity) (\$65 for micro entity). If the specification and drawings exceed 100 sheets of paper, an application size fee is also due, which is \$400 (\$200 for small entity) (\$100 for micro entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

METHOD OF PAYMENT OF THE FILING FEE AND APPLICATION SIZE FEE FOR THIS PROVISIONAL APPLICATION FOR PATENT

☒ Applicant asserts small entity status. See 37 CFR 1.27.

☐ Applicant certifies micro entity status. See 37 CFR 1.29. Applicant must attach form PTO/SB/15A or B or equivalent.

☐ A check or money order made payable to the *Director of the United States Patent and Trademark Office* is enclosed to cover the filing fee and application size fee (if applicable). **130**

☒ Payment by credit card. Form PTO-2038 is attached. **TOTAL FEE AMOUNT (\$)**

☐ The Director is hereby authorized to charge the filing fee and application size fee (if applicable) or credit any overpayment to Deposit Account Number: _____

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 10 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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PROVISIONAL APPLICATION FOR PATENT COVER SHEET – Page 2 of 2

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☒ No.

☐ Yes, the invention was made by an agency of the U.S. Government. The U.S. Government agency name is: _____

☐ Yes, the invention was made under a contract with an agency of the U.S. Government. The name of the U.S. Government agency and Government contract number are: _____

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

SIGNATURE /Linda Judge/ DATE 11/26/17
 TYPED OR PRINTED NAME Linda Judge REGISTRATION NO. 42,702
 (if appropriate)
 TELEPHONE 650-678-3450 DOCKET NUMBER _____

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	
		Application Number	
Title of Invention	DUAL SHELL DENTAL APPLIANCE AND MATERIAL CONSTRUCTIONS		
The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76. This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.			

Secrecy Order 37 CFR 5.2:

☐	Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)
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Inventor Information:

Inventor 1					Remove	
Legal Name						
Prefix	Given Name		Middle Name		Family Name	Suffix
Mr.	Ray		F		Stewart	
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service						
City	Redwood City		State/Province	CA	Country of Residence	US
Mailing Address of Inventor:						
Address 1		807 Toyon Way				
Address 2						
City	Redwood City		State/Province	CA		
Postal Code	94062		Country i	US		
Inventor 2					Remove	
Legal Name						
Prefix	Given Name		Middle Name		Family Name	Suffix
	John				Lahlouh	
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service						
City	San Jose		State/Province	CA	Country of Residence	US
Mailing Address of Inventor:						
Address 1		674 Apache Court				
Address 2						
City	San Jose		State/Province	CA		
Postal Code	95123		Country i	US		
All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the Add button.					Add	

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below. For further information see 37 CFR 1.33(a).

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	
		Application Number	
Title of Invention	DUAL SHELL DENTAL APPLIANCE AND MATERIAL CONSTRUCTIONS		

☐ An Address is being provided for the correspondence information of this application.

Customer Number	77268		
Email Address	rstewart@baymaterials.com	Add Email	Remove Email
Email Address	lrjudge@comcast.net	Add Email	Remove Email

Application Information:

Title of the Invention	DUAL SHELL DENTAL APPLIANCE AND MATERIAL CONSTRUCTIONS		
Attorney Docket Number		Small Entity Status Claimed	☒
Application Type	Provisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	5	Suggested Figure for Publication (if any)	

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

Publication Information:
☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32). Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	☐ Customer Number	☒ US Patent Practitioner	☐ Limited Recognition (37 CFR 11.9)
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Application Data Sheet 37 CFR 1.76		Attorney Docket Number		
		Application Number		
Title of Invention	DUAL SHELL DENTAL APPLIANCE AND MATERIAL CONSTRUCTIONS			
Prefix	Given Name	Middle Name	Family Name	Suffix
Ms.	Linda	R	Judge	
Registration Number		42702		
Additional Representative Information blocks may be generated within this form by selecting the Add button.				

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.

When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status		Remove	
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the Add button.			

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)¹ the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Application Number	Country ¹	Filing Date (YYYY-MM-DD)	Access Code ¹ (if applicable)
Additional Foreign Priority Data may be generated within this form by selecting the Add button.			

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013. ☐ NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.
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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	
		Application Number	
Title of Invention	DUAL SHELL DENTAL APPLIANCE AND MATERIAL CONSTRUCTIONS		

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	
		Application Number	
Title of Invention	DUAL SHELL DENTAL APPLIANCE AND MATERIAL CONSTRUCTIONS		

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

☐ Assignee	☐ Legal Representative under 35 U.S.C. 117	☐ Joint Inventor
☐ Person to whom the inventor is obligated to assign.	☐ Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor:	
If the Applicant is an Organization check here. ☐	

Prefix	Given Name	Middle Name	Family Name	Suffix

Mailing Address Information For Applicant:

Address 1			
Address 2			
City		State/Province	
Country		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button.

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	
		Application Number	
Title of Invention	DUAL SHELL DENTAL APPLIANCE AND MATERIAL CONSTRUCTIONS		

Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

If the Assignee or Non-Applicant Assignee is an Organization check here. ☐

Prefix	Given Name	Middle Name	Family Name	Suffix

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1			
Address 2			
City		State/Province	
Country ¹		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button.

Signature:

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). However, if this Application Data Sheet is submitted with the INITIAL filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).

This Application Data Sheet must be signed by a patent practitioner if one or more of the applicants is a juristic entity (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, all joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of all joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Linda Judge/		Date (YYYY-MM-DD)	2017-11-26
First Name	Linda	Last Name	Judge	Registration Number
				42,702

Additional Signature may be generated within this form by selecting the Add button.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	
		Application Number	
Title of Invention	DUAL SHELL DENTAL APPLIANCE AND MATERIAL CONSTRUCTIONS		

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Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

PROVISIONAL PATENT APPLICATION

Title: DUAL SHELL DENTAL APPLIANCE AND MATERIAL CONSTRUCTIONS

Inventor(s): Ray F. Stewart and John Lahlouh

Assignee: Bay Materials, LLC

Entity: Small

DUAL SHELL DENTAL APPLIANCE AND MATERIAL CONSTRUCTIONS

BACKGROUND

[0001] There is a need for improved orthodontic and dental appliances capable of performing orthodontic tooth movements, stabilizing tooth positions or protecting teeth from potentially damaging outside forces. Existing materials and products are constructed from single layer materials, bi-layer materials or tri-layer materials which have limited functionality and may suffer from performance deficiencies. Aligners are plastic shells which fit over teeth designed to apply translational or rotational forces to teeth. Their ability to accurately move teeth is limited by their effective modulus, elasticity and ability to resist creep and stress relaxation. Additionally, they generally should be resistant to staining and environmental stress cracking.

[0002] Appliances for protection of teeth, for example, sports mouth guards, and dental splints have contradictory requirements. On the one hand, they should be capable of dissipating impact forces and on the other hand should be thin and not interfere with the natural occlusion of a person's teeth, or impede speaking.

BRIEF DESCRIPTION OF THE DRAWINGS

[0003] FIG. 1A is a schematic depiction of a cross sectional view of a three-layer sheet of the invention with a simple ABC construction. Layer A and layer C may be the same or different materials and each layer may be comprised of one or more materials, or blends or alloys. Layer B may be a single material or a blend of materials or alloys.

[0004] FIG. 1B is a schematic depiction of a cross sectional view of a multiple layer sheet. Each layer A, B and C, may be comprised of a single layer or multiple layers and each layer may be comprised of one or more materials or a blend of materials. Layer A may be comprised of layer a and a', layer B may be comprised of layer b and b', and layer C may be comprised of layer c and c', as exemplified in FIG. 1B.

[0005] FIGS. 2A and 2B are schematic depictions of exemplary test samples for determining displacement (FIG. 2A) and restoring force (translational movement; FIG. 2B), of a simple 3-layer sheet comprised of two rigid outer layers and an inner elastomeric layer, where A, B and C are individual layers of the sheet. In this example, layers A and C are reversibly translated relative to

each other and layer B provides a restoring force. In one more specific example, the A B C layers may each be about 250 microns thick, and layers A, B and C may be comprised of one or more materials and may each individually comprise one or more layers.

[0006] FIG. 3A is a graphic depiction of displacement/force curves for elastomers having different degrees of hardness. The graph demonstrates the restoring force (N) generated from translational movement of Layer A relative to Layer C, having a middle B layer with different hardness TPU elastomers, and that the hardness of the elastomer impacts displacement and restoring force. A harder thermoplastic urethane (TPU) will generate a greater restoring force, but may limit the amount of movement.

[0007] FIG. 3B is a graphic depiction of the restoring force (N) as a function of time (0 to 48 hours) for a given displacement between an A layer and a C layer having a middle B layer with different hardness TPU elastomers in the B layer. TPU 75A has a low compression set and shows the least initial force, but the force decays very little over time. TPU 75D has a high compression set, and while it shows a much higher initial restoring force, the force decays rapidly over time.

[0008] FIG. 4 is a graphic depiction of the retained force at 5% stress for different constructions exposed to 37 C and water over a 48-hour time period.

[0009] It should be appreciated that the constructions and properties illustrated in FIGS. 1-4 are specific examples and not intended to limit the scope of constructions and testing that may be used. Other materials, constructions and sequences of steps may also be performed according to alternative embodiments. For example, alternative embodiments may contain additional layers including tie layers, pigments, optical additives or reinforcing agents and may be constructed in any manner known in the art such as flat sheet extrusion, coextrusion blown film, calendaring, laminating and adhesive bonding. The structures (or polymer sheets) and devices may in some embodiments be made by 3D printing or dip coating. One of ordinary skill in the art would recognize and appreciate many variations, modifications, and alternatives of the constructions.

[0010] The specification and drawings are, accordingly, to be regarded in an illustrative rather than a restrictive sense. It will, however, be evident that various modifications and changes may be made thereunto without departing from the broader spirit and scope of the disclosure as set forth in the claims.

[0011] Other variations are within the spirit of the present disclosure. Thus, while the disclosed embodiments are susceptible to various modifications and alternative constructions, certain

illustrated embodiments thereof are shown in the drawings and are described herein. It should be understood, however, that there is no intention to limit the disclosure to the specific form or forms disclosed, but on the contrary, the intention is to cover all modifications, alternative constructions and equivalents falling within the spirit and scope of the disclosure, as defined in the appended claims.

DETAILED DESCRIPTION

[0012] Current orthodontic aligners have a very limited elastic range (typically 4% to 7%) and when deformed exhibit a rapid decay of recovery force. As a result, it may be necessary to change appliances frequently, increasing manufacturing cost, teeth may not move as desired, and the patient may experience discomfort from excessively high initial forces. Attempts to improve elastic range by providing a thin outer layer of elastomer (typically a polyurethane, as described for example in US 9,655,693 B2), can result in a tooth contact surface which is readily deformed, reducing accuracy of tooth movement, and may increase the propensity for unsightly staining by common foods, beverages or cigarettes. US Patent No. 6,524,101 describes dental appliances having regions with different elastic modulus and appliances having added stiffening elements. Non-staining polyurethanes used for fabricating dental appliances such as Zendura® A available from Bay Material, LLC (Fremont, CA), have excellent properties but are very hygroscopic and requires rigorous drying prior to thermoforming, and thus may not be ideal for some applications.

[0013] Many other polyurethanes must also be dried prior to thermoforming, adding time and cost to the manufacturing process. Aromatic polyesters or copolyesters may be used to form aligners, however, they exhibit poor chemical resistance and low impact and tear strength. Aligners constructed from stiff materials such as polyesters or rigid polyurethanes have a high modulus, for example greater than about 1,000 or 1,500 MPa, and when deformed can exert excessive forces on teeth causing discomfort and potential damage to tooth roots. Highly elastomeric polymers such as thermoplastic polyurethane elastomers (TPU), styrenic elastomers (such as SBS, SEBS, SIS for example) have low modulus (typically less than 100 or 200 MPa), which may be insufficient for moving teeth and are readily stained making them of limited utility for producing aligners.

[0014] The present disclosure is based on the discovery that many of the deficiencies in prior materials and dental appliances constructed from them can be reduced or eliminated with a sheet or device having outer layers comprised of a material having a modulus of greater than about 1,000 MPA up to 2,500 MPA and an inner elastomeric layer or core comprised of elastomeric

material or materials having a modulus of from about 50 MPa to 500 MPa, which can be non-staining, lower cost than rigid urethanes, exhibits improved elastic properties, and has surprisingly greater environmental stress cracking resistance.

[0015] A polymeric sheet or device may be comprised of more than two rigid layers, for example a third rigid layer may be disposed between two or more elastomeric layers. The multilayer construction provides a dual shell dental appliance which may be adapted to moving teeth, retaining teeth in an existing position, or protecting teeth from impact. As disclosed herein, the outer shell material that contacts the teeth may be substantially rigid to accurately mate with the teeth providing precise forces while maintaining the ability to exert a more nearly constant force over longer distances.

[0016] By selecting appropriate outer and inner materials modulus and thickness, two or more substantially rigid shells may be reversibly displaced relative to each other to a greater extent than a rigid material of comparable thickness and shape providing a dental appliance that can apply desired forces to teeth with a greater range of movement while not creating excessive forces or exhibiting excessive stress relaxation when deformed. While not limiting the disclosure to specific constructions, a sheet or dental appliance may be referred to herein as a “dual shell” sheet or appliance. A “dual shell” sheet or appliance may comprise two or more shells. A series of dental appliances comprised of this “dual shell” construction may be used to move teeth in incremental stages wherein two or more appliances may be constructed of the same or different materials. Dental appliances may be constructed by thermoforming a dual shell material over a model of one or more teeth, or may be constructed by sequentially thermoforming rigid and elastomeric precursor sheets or by sequentially dip coating a model with polymer solutions or polymer forming monomers or oligomers which may optionally cured or otherwise post processed. The inventors have discovered that this unique construction can significantly reduce the amount of stress cracking that a shell or materials exhibits, thereby expanding the range of materials which can be used in the sheets or appliance.

DEFINITIONS

[0017] The use of the terms “a” and “an” and “the” and similar referents in the context of describing the disclosed embodiments (especially in the context of the following claims) are to be construed to cover both the singular and the plural, unless otherwise indicated herein or clearly contradicted by context. The terms “comprising,” “having,” “including,” and “containing” are to be

construed as open-ended terms (i.e., meaning “including, but not limited to,”) unless otherwise noted. The term “connected” is to be construed as partly or wholly contained within, attached to, or joined together, even if there is something intervening. The phrase “based on” should be understood to be open-ended, and not limiting in any way, and is intended to be interpreted or otherwise read as “based at least in part on,” where appropriate. Recitation of ranges of values herein are merely intended to serve as a shorthand method of referring individually to each separate value falling within the range, unless otherwise indicated herein, and each separate value is incorporated into the specification as if it were individually recited herein. All methods described herein can be performed in any suitable order unless otherwise indicated herein or otherwise clearly contradicted by context. The use of any and all examples, or exemplary language (e.g., “such as”) provided herein, is intended merely to better illuminate embodiments of the disclosure and does not pose a limitation on the scope of the disclosure unless otherwise claimed. No language in the specification should be construed as indicating any non-claimed element as essential to the practice of the disclosure.

[0018] The term “dental appliance” is used herein with reference to any device placed in or on the teeth of a subject. Dental appliances include but are not limited to orthodontic, prosthetic, retaining, snoring/airway, cosmetic, therapeutic, protective (e.g., mouth guards) and habit-modification devices.

[0019] The term “ASTM D638”, is used herein with reference to the test for Plastics Tensile Strength.

[0020] The term “ASTM D1876”, is used herein with reference to the test for inter layer peel strength.

[0021] The term “compression set” is used herein with reference to the permanent deformation of a material when a force applied and removed.

[0022] The term “flexural modulus” is used herein with reference to the rigidity of a material and/or resistance of the material to deformation in bending. The higher the flexural modulus of the material, the more resistant to bending it is. For an isotropic material the flexural modulus and elastic modulus are nearly the same.

[0023] The term “hardness” is used herein with reference to a Shore hardness scale. Shore hardness and modulus are generally correlated and can be converted by approximation is only one value is known.

[0024] The term “modulus” or “tensile modulus” is used herein with reference to the rigidity of a material and/or resistance of the material to stretching. The higher the modulus of the material,

the more rigid. The flexural modulus and modulus of a material may be the same or different. For isotropic materials such as A, B and C, flexural modulus and modulus (which may also be referred to as tensile modulus) are substantially the same and one or the other may be measured dependent upon the circumstances.

[0025] The term "polymeric sheet" is used interchangeably herein with the term "plastic sheet".

[0026] The term "lateral restoring force" with respect to A and C layers of a polymeric sheet is used with reference to the force which may be exerted by one layer which has been translated relative to another layer which is fixed in position. If the A and C layers are caused to move independently of each other they will subsequently return to their original positions if not restrained.

[0027] The term "shearing force", as used herein means the translational force applied to two surfaces which are connected by an elastic material.

[0028] The term "shell" is used herein with reference to polymeric shells which fits over the teeth and are removably placeable over the teeth.

[0029] The term "stain resistant" is used herein with reference to a material designed to be resistant to being stained.

[0030] The term "thermoplastic polymer" is used herein with reference to a polymer is a polymer that becomes pliable or moldable above a specific temperature and solidifies upon cooling, provided that the heat and pressure do not chemically decompose the polymer.

[0031] The terms "tooth" and "teeth" include natural teeth, including natural teeth which have been modified by fillings or by crowns, implanted teeth, artificial teeth that are part of a bridge or other fitting secured to one or more natural or implanted teeth, and artificial teeth that are part of a removable fitting.

[0032] In the following description, various embodiments of the invention will be described. For purposes of explanation, specific configurations and details are described in order to provide a thorough understanding of the embodiments. However, it will also be apparent to those skilled in the art that the embodiments may be practiced without the specific details. Furthermore, well-known features may be omitted or simplified in order not to obscure the embodiment being described.

Embodiments

[0033] In some embodiments (referred to herein as embodiment #1), a thermoformable polymeric sheet, is comprised of at least two outer layers A and C, and a middle layer B, wherein the A and C layers are individually comprised of a thermoplastic polymer having a

modulus of greater than about 1,000 MPa, for example 1,000 MPa to 1,500 MPa; 1,100 MPa to 1,600 MPa; 1,200 MPa to 1,700 MPa; 1,300 MPa to 1,800 MPa; 1,400 MPa to 1,900 MPa; 1,500 MPa to 2,000 MPa; 1,100 MPa; 1,200 MPa; 1,300 MPa; 1,400 MPa; 1,500 MPa; 1,600 MPa; 1,700 MPa; 1,800 MPa, 1,900 MPa; 2000 MPa; or up to 2,500 MPa; and a glass transition temperature (T_g) and/or melting point from about 80 C to 180 C; 90 C to 170 C; 100 C to 160 C; 110 C to 150 C; 120 C to 150 C; 130 C to 170 C; 140 C to 180 C; 80 C; 90 C; 100 C; 110 C; 120 C; 130 C; 140 C; 150 C; 160 C; 170 C; or 180 C.

[0034] In such embodiments, the middle B layer is comprised of at least an elastomer having a modulus of from about 50 MPa to about 500 MPa; 60 MPa to 470 MPa; 70 MPa to 440 MPa; 80 MPa to 400 MPa; 100 MPa to 350 MPa; 150 MPa to 300 MPa; 200 MPa to 400 MPa; 60 MPa, 70 MPa; 80 MPa, 90 MPa; 100 MPa; 110 MPa; 120 MPa; 130 MPa; 140 MPa; 150 MPa, 160 MPa; 170 MPa; 180 MPa; 190 MPa; 200 MPa, 250 MPa, 300 MPa, 350 MPa, 400 MPa, 450 MPa, or up to 500 MPa, and one or more of (a) a glass transition temperature, or (b) a melting point of from about 90 C to about 220 C; from 100 C to about 200 C; from 120 C to about 180 C; from 140 C to 220; or from 160 C to about 220 C.

[0035] In embodiment #1, layers A and C may comprise a polyester or co-polyester, a polyurethane, a polyamide, a polyolefin, a (meth) acrylic polymer, a polycarbonate, a vinyl polymer such a polyvinyl chloride, or a fluoropolymer.

[0036] In embodiment #1, layer B may comprise a polyurethane elastomer, a polyester elastomer, a styrenic elastomer, a polyamide elastomer, a siloxane elastomer, a polyether elastomer a polyolefin elastomer, an olefin copolymer, an acrylic elastomer or a fluoroelastomer.

[0037] In embodiment #1, the B layer material has a 22 hr. @ 25 C compression set of less than about 35%, 30%, 25%, 20% 10%, less than 35%, 34%, 33%, 32%, 31%, 30%, 29%, 28%, 27%, 26%, 25%, 24%, 23%, 22%, 21%, 20%, 19%, 18%, 17%, 16%, 15%, 14%, 13%, 12%, 11% or 10%. In contradiction to the findings of US 9,655,693 B2 where an elastomer is used as an outer layer, we have found that a lower compression set rather than higher compression set is more effective.

[0038] In certain aspects of embodiment #1, the sheet has an overall thickness of from about 250 microns to about 2,000 microns.

[0039] In certain aspects of embodiment #1, the combined thickness of the A and C layers is from about 25 microns to about 1000 microns, 50 microns to 750 microns, 100 to 750 microns, 250 microns to 750 microns, or 250 microns to about 600 microns.

[0040] In certain aspects of embodiment #1, the thermoformable sheet has a flexural modulus of from about 100 MPa to about 2,000 MPa, from about 250 MPa to about 2,000 MPa, from about 500 MPa to 1,500 MPa, from about 750 MPa to about 2,000 MPa, or from about 750 microns to about 1,500 MPa.

[0041] In certain aspects of embodiment #1, the A and C layers have a Tg of between about 80 and 150 C, and the B layer has a Tg or melting point of between about 180 C and 220 C and a heat of fusion of from about 5 Joules/g to about 20 Joules/g, or 5 Joules/g to 15 Joules/g.

[0042] In certain aspects of embodiment #1, the inter layer peel strength of an A layer is greater than about 50 N/inch (Newtons/inch), greater than about 60 N/inch, greater than about 70 N/inch.

[0043] In certain aspects of embodiment #1, the A and C layers each have a thickness of 25 microns to about 1000 microns, 50 microns to 750 microns, 100 to 750 microns, 125 to 300 microns, 250 microns to 750 microns OR 250 microns to about 600 microns and may have a combined thickness of about 250 microns to about 600 microns being comprised of a rigid co-polyester or polyurethane having a modulus of from 1000 MPa to 2,500 MPa with Tg of between 95 C and 150 C, the elastomeric B layer having a thickness of from about 200 microns to about 1000 microns or 200 to 500 microns is comprised of a polyether or polyester polyurethane having a hardness of from about D 35 to about D 65, and a 22 hr. at 25 C compression set of less than about 35%, 30%, 25%, 20%, 10%, less than 35%, 34%, 33%, 32%, 31%, 30%, 29%, 28%, 27%, 26%, 25%, 24%, 23%, 22%, 21%, 20%, 19%, 18%, 17%, 16%, 15%, 14%, 13%, 12%, 11% or 10%, and an A layer that has an inter layer peel strength of greater than about 50 N/inch, greater than about 60 N/inch or greater than about 70 N/inch, wherein the polymer sheet has flexural modulus of from about 750 MPa to about 1,500 MPa; from about 100 MPa to about 2,000 MPa; from about 250 MPa to about 2,000 MPa; from about 500 MPa to 1,500 MPa; or from about 750 MPa to about 2,000 MPa.

[0044] In some aspects of embodiment #1 thin layers of additional polymers (tie layers) may be present to improve the adhesion of polymer layers that are not naturally adhesive to each other for example a layer of maleic anhydride grafted polypropylene may be used to increase the adhesion between a polypropylene A layer and polyester or polyamide B layer.

[0045] In some embodiments (referred to herein as embodiment #2), the A and C layers of the sheet or device can reversibly move relative to each other (for example translationally) from about 0.05 mm to about 0.1mm with a force of less than 100 N per cm², 50 N per cm², 25 N per cm², or 10 N per cm².

[0046] In some aspects of embodiment #2, the A and C layers of the sheet or device have a total thickness of from about 500 microns to 1,000 microns and can reversibly move relative to each other by a distance of from 0.05mm to 0.1mm with a force of less than 100 N per cm², 50 N per cm², 25 N per cm², or 10 N per cm².

[0047] In some aspects of embodiment #2, the B layer material has a 22 hr. @ 25 compression set of less than about 35%, 30%, 25%, 20%, 10%, less than 35%, 34%, 33%, 32%, 31%, 30%, 29%, 28%, 27%, 26%, 25%, 24%, 23%, 22%, 21%, 20%, 19%, 18%, 17%, 16%, 15%, 14%, 13%, 12%, 11% or 10%.

[0048] In some embodiments (referred to herein as embodiment #3), one or more of the A and C layers comprises a microcrystalline polyamide comprised of from 50 to 100, 50 to 90, 50 to 80, 50 to 70, 60 to 90, 60 to 80, or 70 to 90 mole % of C6 to C14 aliphatic diacid moieties, and about 50 to 100, 50 to 90, 50 to 80, 50 to 70, 60 to 90, 60 to 80, or 70 to 90 mole % of 4,4'-methylenebis(cyclohexylamine) (CAS [1761-71-3]), having a glass transition temperature of between about 100 C and 180 C, a heat of fusion of less than 20 J/g, e.g., 5 Joules/g to about 20 Joules/g, or 5 Joules/g to 15 Joules/g. See, e.g., DE Application No. 43 10 970 (embodiment 3). In some aspects of embodiments #3, the combined thickness of the A and C layers is less than about 500 microns, less than about 400 microns, less than about 300 microns.

[0049] In some embodiments (referred to herein as embodiment #4), a dental appliance conformal to one or more teeth comprises at least two outer layers A and C, and a middle layer B wherein the A and C layers, are individually comprised of a thermoplastic polymer having a modulus of greater than about greater than 1,000 MPA, for example 1,000 MPA to 1,500 MPA; 1,100 MPA to 1,600 MPA; 1,200 MPA to 1,700 MPA; 1,300 MPA to 1,800 MPA; 1,400 MPA to 1,900 MPA; 1,500 MPA to 2,000 MPA; 1,100 MPA; 1,200 MPA; 1,300 MPA; 1,400 MPA; 1,500 MPA; 1,600 MPA; 1,700 MPA; 1,800 MPA, 1,900 MPA; 2000 MPA; up to 2,500 MPA, in certain aspects greater than 1,500 MPa, and a glass transition temperature and/or melting point from about 80 C to 180 C; 90 C to 170 C; 100 C to 160 C; 110 C to 150 C; 120 C to 150 C; 130 C to 170 C; 140 C to 180 C; 80 C; 90 C; 100 C; 110 C; 120 C; 130 C; 140 C; 150 C; 160 C; 170 C; or 180 C, in certain aspects 80 to 150 C or 95 to 150 C. In such embodiments, the middle B layer

is comprised of at least an elastomer having a modulus of from about 50 MPa to 500 MPa; 70 MPa to 450 MPa; 80 MPa to 400 MPa; 100 MPa to 350 MPa; 150 MPa to 300 MPa; 200 MPa to 400 MPa; 60 MPa, 70 MPa; 80 MPa, 90 MPa; 100 MPa; 110 MPa; 120 MPa; 130 MPa; 140 MPa; 150 MPa, 160 MPa; 170 MPa; 180 MPa; 190 MPa; 200 MPa, up to 250 MPa, and one or more of a glass transition temperature or melting point of from about 90 C to about 220 C.

[0050] In some aspects of embodiment #4, the A and C layers have a combined thickness of about in certain aspects 25 microns to about 600 microns, e.g., 250 microns, 300 microns, 350 microns, 400 microns, 450 microns, 500 microns, 550 microns or 600 microns, being comprised of a rigid co-polyester or polyurethane having a modulus of greater than 1,000 MPa, for example 1,000 MPa to 1,500 MPa; 1,100 MPa to 1,600 MPa; 1,200 MPa to 1,700 MPa; 1,300 MPa to 1,800 MPa; 1,400 MPa to 1,900 MPa; 1,500 MPa to 2,000 MPa; 1,100 MPa; 1,200 MPa; 1,300 MPa; 1,400 MPa; 1,500 MPa; 1,600 MPa; 1,700 MPa; 1,800 MPa, 1,900 MPa; 2000 MPa; or up to 2,500 MPa with a Tg of from 80 C to 180 C; 90 C to 170 C; 100 C to 160 C; 110 C to 150 C; 120 C to 150 C; 130 C to 170 C; 140 C to 180 C; 80 C; 90 C; 100 C; 110 C; 120 C; 130 C; 140 C; 150 C; 160 C; 170 C; or 180 C, e.g., 80 to 150 C or 95 to 150 C.

[0051] In some aspects of embodiment #4, the elastomeric B layer has a thickness of from about 200 microns to about 1,000 microns, e.g., 100 microns, 200 microns, 250 microns, 300 microns, 350 microns, 400 microns, 500 microns, 750 microns or 1,000 microns, is comprised of a polyether or polyester polyurethane having a hardness of from about D 35 to about D 65 and a 22hr @ 25 C compression set of less than about 35%, 34%, 33%, 32%, 31%, 30%, 29%, 28%, 27%, 26%, 25%, 24%, 23%, 22%, 21%, 20%, 19%, 18%, 17%, 16%, 15%, 14%, 13%, 12%, 11% or 10%, and an A layer with an inter layer peel strength of greater than about 50 N/inch, greater than about 55 N/inch, greater than about 60 N, greater than about 70 N, wherein the polymeric sheet has flexural modulus of from about from about 100 MPa to about 2,000 MPa, from about 250 MPa to about 2,000 MPa, from about 500 MPa to 1,500 MPa, from about 750 MPa to about 2,000 MPa, e.g., from about 750 microns to about 1,500 MPa.

[0052] In some aspects of embodiment #4, the A and C layers have a lateral restoring force of 0.05 mm to 0.1mm with a force of less than 100 N per cm², 50 N per cm², 25 N per cm², or 10 N per cm².

[0053] In some embodiments (referred to herein as embodiment #5), a dental appliance is formed by thermoforming a multilayer sheet over a model of teeth wherein thermoforming is performed at a temperature that is at least greater than the glass transition temperature and/or melting point

of the outer layers and less than the upper glass transition temperature and/or melting point of at least an inner layer elastomer material.

[0054] In one embodiment of embodiment #5, a dental appliance is prepared by thermoforming a multilayer sheet having least an A and C layer having a T_g from about 80 C to 180 C; 90 C to 170 C; 100 C to 160 C; 110 C to 150 C; 120 C to 150 C; 130 C to 170 C; 140 C to 180 C; 80 C; 90 C; 100 C; 110 C; 120 C; 130 C; 140 C; 150 C; 160 C; 170 C; or 180 C, and the B layer has a glass transition temperature and/or melting point from about 90 C and 220 C, e.g., 180 C to 220 C and a heat of fusion of from about 5 J/g to about 20 J/g, e.g., about 5 J/g to about 20 Joules/g, or 5 Joules/g to 15 Joules/g.

[0055] In one aspect of embodiment #5 the A and C layers comprise a copolyester or polyurethane having a T_g from about 90 C to about 120 C, the B layer is comprised of a polyurethane having a modulus of from about 50 MPa to 500 MPa and a glass transition temperature and/or melting point of from about 170 C to about 220 C and thermoforming is performed at a temperature between about 150 C and 200 C.

[0056] It should be understood that elements of two or more embodiments may be combined.

Construction Methods

[0057] Multilayer sheets of the invention may be prepared by a number of means including without limitation, hot or cold lamination, adhesive lamination, melt lamination, coextrusion multilayer extrusion or other known methods. Sheets may be fully prepared before forming into an orthodontic appliance, or an appliance may be produced using a sequence of individual thermoforming steps to create multiple layers.

[0058] Thermoforming of sheets to produce test samples or dental appliances may performed using a "Biostar" pressure former available from Great Lakes Orthodontics using procedures commonly used in the industry. Alternatively, thermoforming may be performed using a roll fed thermoformer, a vacuum former or other known thermoforming techniques. Thermoforming may be conducted using different conditions, forms or models to vary draw ratio and part thickness. Multilayer appliances may be fabricated through one or more 3D printing processes or by sequential dip coating, spray coating, powder coating or similar processes known for producing films, sheets and 3D structures.

[0059] Sheet temperature during thermoforming can be measured using an infrared thermometer or a surface thermocouple.

Utility

[0060] The sheets and materials described herein have utility as thermoformable materials having superior dimensional stability, impact cushioning, and restorative forces. The sheets may be converted into a number of types of orthodontic appliances, for example for moving teeth, for use as a sports mouth guard with improved impact resistance and for use as an orthodontic retainer.

Test Methods

[0061] Tensile properties were measured using an Instron Universal Materials Tester. The procedures of ASTM D638 were employed unless otherwise noted. Color and transparency were measured using a BYK Gardner Spin colorimeter.

[0062] Impact resistance was measured using a Gardner impact tester. Tear strength was measure using an Materials Tester at a rate of 50 mm per minute.

[0063] Stress relaxation of samples at 37 C in water were measured by the method described in US Patent No. 8,716,425 B2.

[0064] Resistance to staining was measured by exposing test articles to a staining medium such as mustard or coffee for 24 hours at 37 C and measuring color on a white color tile before and after exposure.

[0065] Translational recovery force was measured by constructing a three-layer structure (or polymer sheet) as shown in Figs. 1 and 2. Samples were displaced from 0 to 0.5 mm and the force reported in N/cm².

[0066] Inter layer peel strength is measured at a rate of 50 mm/min and may be reported as Newtons (N) per inch or per 2.54 cm (N). Details may be found in test method ASTM D1876.

[0067] Thermal testing to determine glass transition temperatures, melting, and freezing points were measured using a differential scanning calorimeter at a heating and cooling rate of 10 C per minute unless indicated otherwise.

[0068] Resistance to environmental stress cracking may be determined by fixturing a sheet sample around a cylindrical mandrel to induce a specified strain on the outer surface, for example

3% or 5%, and exposing the samples to a specified environment for a specified time, for example a saliva mimic solution, mouth rinse or other solution of interest. The response can be measured semi quantitatively by visual observation of type and amount of cracks, or quantitatively by subsequently measuring a mechanical property such as tear strength.

Materials and Methods.

[0069] Materials of construction. A large number of commercially available materials can be utilized in producing the sheets and appliances described herein. Table 1 provides a listing of exemplary materials for use in the A or C component. Table 2 provides a listing of exemplary materials for use in the B component. Similar or related materials can be obtained from other manufacturers or produced by known methods

[0070] Table 1. Exemplary Materials Useful as Primary Components of A or C Materials.

Trade Name	Supplier	Chemical Composition	Tg or Tm	Modulus Range (MPa)	Hardness Range
Tritan MX 710, MX 810, MP 100 MP 200	Eastman Chemical	Co-polyester of terephthalic acid, cyclohexane dimethanol, and 2,2,4,4-tetramethyl-1,3-cyclobutanediol.	Tg 100 to 120 C	1,000 to 1,500 MPa	R 100 to 115
Eastar 6763	Eastman Chemical	Co-polyester of terephthalic acid, ethylene glycol and diethylene glycol	Tg 80 C	2,000 to 2,100 MPa	R106
Isoplast 2530	Lubrizol	Aromatic polyurethane based on MDI and hexanediol	Tg 85 -95 C	1,900 MPa	R 121
Isoplast 2531	Lubrizol	Aromatic polyurethane with aliphatic diols	Tg 95 – 110 C	2,100 MPa	R 121
Polypropylene co-polymer	Generic	Co-polymer of propylene, ethylene and C4 to C8 alpha olefin	Tm 135 to 160	1,000 to 1,500 MPa	D 55-65
Trogamide CX7323	Evonik	Cycloaliphatic polyamide	Tg 140 C Tm 250 C	1,400 MPa	D 81

[0071] Table 2. Exemplary Materials Useful as Primary Components of B Materials.

Trade Name	Supplier	Chemical Composition	Tg or Tm C	Compression set 23 C @ 22 Hr	Modulus* MPa	Hardness Range
Elastollan 1195A	BASF	Aromatic polyether polyurethane	Tm 180 – 200	30%	10 @ 100% E	95 A
Texin RxT 50D	Covestro	Aromatic polyether polyurethane	Tm 180 – 200	20%	151	50 D

Elastollan 1185 A	BASF	Aromatic polyether polyurethane	Tm 180 – 200	14%	57	85 A
Texin 985	Covestro	Aromatic polyether polyurethane	Tm 180 – 200	17%	60	85 A
Pebax Clear 300	Arkema	Polyether polyamide	TM 160	< 20%	183	53 D
Kraton FG 1901	Kraton Polymers	Maleated SEBS	Tg 90 - 100	15%	25	71 A
Noito	Mitsui Chemical	Propylene – ethylene microcrystalline elastomer	Tm Est 120 C	20%	30 MPa	75 A
Vestamide E or ME	Evonik	Polytetramethylene ether polyamide block polymer	Tm Est. 170 to 220 C	25 to 40%	50 to 500 MPa	D40 to D70

* Modulus from vendor literature or estimated based on Shore hardness

[0072] Additional suitable materials for the A, B or C layers can include compatible or incompatible blends, for example blends of two or more co-polyesters, blends of polypropylene and polyethylene and ethylene propylene elastomers, fluoropolymers, such as polyvinylidene fluoride or its co-polymers, styrene acrylonitrile resins, acrylonitrile styrene butadiene resins (ABS), polyurethanes containing polycarbonate soft blocks, siloxane soft blocks, silicone elastomers such as Geniomer TM, a siloxane urea co-polymer, and cyclic olefin co-polymers and cyclic olefin elastomers.

EXAMPLES

[0073] The invention is further illustrated by the following examples. The examples are provided for illustrative purposes only. They are not to be construed as limiting the scope or content of the invention in any way.

EXAMPLE 1

[0074] A series of monolayer and multilayer sheets of nominal total thickness 0.76 mm were prepared as shown in Table 3. Test samples 1-4 were prepared by compression molding and heat laminating individual films or by extrusion lamination. Examples of prior art materials, P1, P2 and P3, were prepared by compression molding films and optionally heat laminating them.

[0075] Press lamination was conducted at 200 to 220 C, extrusion lamination was done using a polyurethane melt temperature of 210 to 240 C, and coextrusion was done with a polyester melt temperature of 240 C to 260 C, and a polyurethane melt temperature of 210 to 240 C. Conditions

of time, temperature and pressure were varied to maximize structure (polymer sheet) quality, thickness and adhesion.

[0076] Mechanical properties, optical properties, stress relaxation and shape recovery were measured to compare the suitability of resulting structures (polymer sheets).

[0077] Table 3. Monolayer and Multilayer Sheets.

Material / Property	P1	P2	P3	1	2	3	4
Construction	Monolayer	Monolayer	ABA	ABC	ABC	ABC	ABC
P1 layer / microns	Isoplast 2530	Polyester A* 250	Texin 950 75	Polyester A 250	Polyester A 250	Isoplast 2531	Polyester A 175
P2 layer / microns	Isoplast 2530	Polyester A 250	Polyester A 600	Elastollan 1185A	Texin RxT 50D	Texin RxT 65D	Texin 950 LW
P3 layer / microns	Isoplast 2530	Polyester A 250	Texin 950 75	Polyester A 250	Polyester A 250	Isoplast 2531	Polyester A 175
Flexural Modulus	1910 Mpa	1750 Mpa	675 MPa	824 Mpa	968 Mpa	729 Mpa	575 Mpa
Elongation to break %	100 - 130	100 - 130	100 - 130	100 - 130	100 - 130	100 - 130	100 - 130
Impact Strength J/mn	15.2	6.9	----	----	9.2	14	----
Trouser Tear Force (N)	18	48	51	156	165	187	170
Load Retention g (1)							
0 days	4244	3956	1664	2638	2739	2567	1598
1 days	707	853	875	1329	1469	1534	1232
2 days	498	601	823	1257	1389	1398	1247
Color Change dB (2)	0.97	2.1	44	2.6	2.3	1.1	2.2
* Polyester A is a cycloaliphatic copolyester marketed by Eastman Chemical under the tradename Tritan.							
1- 5% strain / 37C / water							
2- Mustard / 24 hr / 22C							

[0078] Prior art material P1, is a commercial thermoformable aligner material supplied by Bay Materials, LLC, Fremont Ca. Prior art material P2, is a polyester having a glass transition temperature of 110 C manufactured by Eastman Chemical sold under the trade name Tritan made from an aromatic di-acid and cyclohexyl and cyclobutane diols. Prior art material P3, is described in US 9,655,693 B2. Test samples 1-4 are multilayer laminates (as described herein), demonstrating improved stress relaxation properties, increased tear strength and excellent stain resistance.

[0079] Compared to the prior art materials, test samples 1-4 exhibited a number of unexpected properties. Comparing test samples 1-4 and prior art materials P1 and P2, it can be seen that test samples 1-4 exhibit substantially lower initial forces in the stress relaxation test (believed to translate to greater user comfort), but surprisingly, maintain the forces for a longer time. This is in contradiction to the teachings of US 9,655,693 B2, which claims an outer layer of elastomer is

required to prevent loss of force. The ability of the multilayer sheets of the invention to maintain appropriate force levels for long time periods under demanding conditions can readily be seen in Figure 4.

[0080] Tear strength is an important property of dental appliances. Materials with low tear strength have low durability and may crack at locations where stress is concentrated. Comparing the tear strength of prior art materials P1, P2 and P3, with test samples 1-4 show that such multilayer structures (or polymer sheets) with an elastomeric B layer have significantly greater tear strength than comparable monolayer structures or prior art multilayer structured.

[0081] To further investigate the effect of construction on tear strength, another laminate (#5) was prepared with 0.25 mm A and C layers comprised of Eastar 6763, a copolyester available from Eastman Chemical. having a Tg of 86 C and a 0.2 mm B layer of shore 50 D urethane elastomer to give a total thickness of 0.7 mm. Tear strength of this sample was compared to prior art materials P1, P2 and P3. Sample #5 exhibited a tear strength of 120 N, more than 200% of the value of prior art material P3, while having similar ratios of polyurethane and polyester.

EXAMPLE 2 (Measurement of Translational Force)

[0082] A three-layer sheet was prepared as described in Example 1 for test material 2. A strip of the sheet 2.54 cm x 1 cm was bonded between two strips of rigid polyester 2.54 cm wide to create 0.5 cm overlap ("multilayer sample A2"). A control test sample was prepared using the same size and thickness of polyester A (prior art) between two strips of rigid polyester. The displacement / force response was measured at a rate of 0.04 MPa/min and results are reported in Table 4. The multilayer construction allows the two outer layers (or the two shells) of an appliance to accommodate greater elastic movement with appropriate forces than the prior art constructions.

[0083] Table 4. Controlled Elastic Movement of Multilayer Material.

Displacement (mm)	Force (N)/Cm2		
	Polyester A	95 A	50 D
0	0	0	0
0.1	43	8	12
0.25	106	20	31
0.5	249	50	71

[0084] Orthodontic devices were made using the materials and methods of the invention and compared to devices of the same shape and thickness made from Zendura A and Essix Plus. The devices of the invention were substantially more elastic and more comfortable to wear. Because the inner and outer shells can deform independently from each other, they can accommodate a greater offset between the actual teeth and the appliance without causing undue discomfort to the patient and exert a near constant force for long time periods to accurately move teeth.

EXAMPLE 3

[0085] A clarified polypropylene film designated BFI 257 supplied by Blue Ridge Films (Petersburg, Virginia), with a thickness of 0.25 mm was laminated to both sides of 0.25mm thick film prepared from Kraton GF (maleated SEBS, available from Kraton Polymers) in a hot press at 180 F, cooled and cut into a 125 mm circle. The modulus of the polypropylene is reported at 1,100 MPa. The SEBS elastomer has a reported hardness of 71 A and a modulus of 25 MPa. The multilayer film exhibited low staining and was thermoformable over a dental model to produce a retainer with excellent elastic recovery properties.

EXAMPLE 4.

[0086] The durability of sheet materials in the presence mouthwash was investigated since it is known that dental appliances may be readily damaged by alcohols and /or surfactants. Test sheets with a thickness of 0.75 mm were prepared 2.54 cm wide X 12 cm length. Prior art materials P1, P2 and P3, and multilayer sheet (test material) #2 were wrapped on a mandrel of sufficient diameter to produce a strain of 5%. The samples were immersed in mouth rinse and maintained at 37 C. This environment is known to promote environmental stress cracking and to induce set causing the materials to be in a hoop shape instead of flat. After 24 hours, the samples were rinsed with deionized water and the amount of recovery was measured immediately and again after 24 and 48 hours at ambient temperature. Subsequently, the samples were viewed under a microscope to determine the amount of stress cracking on the side which was under extension. A sample which returned to completely flat is scored to have 100% recovery. Stress cracking was rated from 1 to 5, with 5 being no visible cracking and 1 being severe cracking. Shape recovery for the samples is given in Table 5. The multilayer sheet (#2) recovered more rapidly and more completely than prior art materials P1, P2 and P3.

[0087] Table 5. Shape Recovery of Samples.

Minutes	% Recovery			
	P1	P2	P3	#2
0.01	53	34	51.6	66
60	54	49	53.8	69
1440	61	65	59.4	77

EXAMPLE 5

[0088] Three laminates were prepared as in Example 1, sample 2 and designated as samples #6, #7 and #8. Sample #6 was extrusion laminated using untreated polyester film at a roll temperature of 40 C, sample #7 was extrusion laminated using corona treated polyester film at a roll temperature of 60 C and sample #8 was extrusion laminated using corona treated film at a roll temperature of 80 C. Corona treatment is commonly used to activate film surfaces to increase their polarity. A control sample of polyester A was designated sample #9. The mechanical properties and environmental stress cracking resistance of the three samples are given in Table 6.

[0089] Table 6. Effect of Inter Layer Peel Strength on ESC Resistance of A Layer.

Property	#6	#7	#8	#9
Modulus (Mpa)	1,490	1,572	1,589	2,700 Mpa
Elongation at Yield (%)	6.1	5.8	6.1	6.2
Elongation at Break (%)	124	131	129	131
Inter Layer Peel Strength Newtons (N)/inch	35	53	137	NA
Tear Strength	55	117	179	48
ESCR / Mouthrinse / 37 C	1	2.5	4	1

[0090] The dramatic improvement in environmental resistance for samples #7 and #8 compared to samples #6 and #9 are unanticipated and unexpected. In each case the material exposed to the environment is chemically identical and under equal amounts of stress. While not wishing to be bound by theory we hypothesize that some concentrated strain induced stress present in the outer polyester layer may be transferred to the elastomeric material and the force transfer is more efficient in the materials having higher interlayer bond strength. However, we are not aware of any precedent for this result.

EXAMPLE 6

[0091] Testing was conducted to investigate the effect of thermal treatment and thermoforming conditions on the performance of devices made from the sheets. Three sheets (2A, 2B and 2C) of test material 2 (three-layer, polyester, polyurethane, polyester), were dried at 60 C under vacuum for 12 hours. The samples were put in moisture barrier bags and subjected to the thermal treatment and thermoforming conditions shown in Table 7. Sample 2A was maintained at 22 C and samples 2B and 2C were annealed at 100 C for 24 hours. The samples were then thermoformed to produce flat sheet using different thermoforming temperatures. Samples 2A and 2B were thermoformed at a temperature below the high end of the melting range of the polyurethane while 2C was thermoformed at a temperature above the melting range of the polyurethane.

[0092] Table 7. Effect of Thermal Treatment/Thermoforming Conditions on Retained Stress.

Sample / Treatment	Sample Treatment and Performance		
	#2A	#2B	#2C
Temperature	22 C	100 C	100 C
Time	24 hrs.	24 hrs.	24 hrs.
T _m	160-190	170 - 195	170 - 195
J/g	6.8	12.4	12.6
Thermoforming temperature	180	180	200
T _m	160-190 C	160 - 210	160 - 200
J/g	6.3	8.3	6.4
Retained Stress 24 Hr	51%	72%	47%

[0093] Test samples were cut from thermoformed samples, analyzed by DSC and subjected to stress relaxation testing at 37C in water. DSC showed that the melting point and heat of fusion of the samples were increased by annealing at 100 C and that the thermoforming reduced the amount of heat of fusion and melting range. However, the sample thermoformed below the upper melting range of the polyurethane retained more crystallinity and performed better in the stress relaxation test. The conditions for sample 2B in Table 7 were used to fabricate a dental appliance.

EXAMPLE 7

[0094] Additional compositions can be made by selection of suitable layer materials having differences in modulus and elasticity as shown in Table 8.

[0095] Table 8. Exemplary Multilayer Sheet Materials.

Layers	Sample #6		Sample #7		Sample #8	
	Material	Thickness	Material	Thickness	Material	Thickness
A	Trogamide CX 7323	0.125 mm	Trogamide CX 7323 / Polyamide 614 Blend 90:10	0.2 mm	Altuglas Luctor CR 13	0.125 mm
A'					Altuglas SG10	0.125 mm
B	Pebax Clear 300	0.5 mm	Pellethane 2373 55D	0.3 mm	Kurarity LA4285	0.25 mm
B'						
C'	Trogamide CX 7323	0.125 mm	Trogamide CX 7323 / Polyamide 614 Blend 90:10	0.2 mm	Altuglas SG10	0.125 mm
C					Altuglas Luctor CR 13	0.125 mm

Altuglas SG10 is a transparent impact modified polymethyl methacrylate sold by Arkema

Altuglas Luctor CR13 is a transparent impact modified polymethyl methacrylate sold by Arkema

Kurarity LA4285 is an acrylic ABA block co-polymer of methyl methacrylate and butyl methacrylate

EXAMPLE 8

[0096] A 2mm thick sheet was prepared by laminating two outer films of polypropylene homopolymer 0.250 mm thick (Blue Ridge Films BFI 3270, modulus 1,200 MPa) and an inner layer of 1.50 mm thick ethylene propylene microcrystalline elastomer (Noito PN 2070, Mitsui Chemical) modulus 150 MPa. The sheet was cut into a disc 125 mm in diameter and thermoformed over a model of the maxillary teeth of an individual and trimmed to make a highly impact resistant sports mouth guard. Surprisingly, the mouth guard provides better impact protection and comfort than a standard device fabricated from 4 mm thick ethylene vinyl acetate copolymer marketed by Dreve under the Tradename Drufosoft.

EXAMPLE 9

[0097] An aligner was made by thermoforming a three-layer sheet over a model of teeth. Two outer layers were comprised of a rigid polyurethane having a Tg of about 120 C and an inner B layer comprised of a Shore A 85 aromatic polyether polyurethane having a hard block melting point of 160 to 195 C and heat of fusion of 8 J/gram. The appliance was annealed at 100 C for 24 hours which is below the Tg of the outer layer. No deformation was observed. Testing

demonstrated that this appliance was more elastic and exhibited less creep under load than the before annealing at 100 C. The improvement is thought to be due to improvement in the microstructure of the polyurethane elastomer.

[0098] In a second test, a comparison was made between a multilayer device and a single layer device where in each case Zendura A materials was used as the A/C material or as the A/B/C material respectively. The devices were annealed at 90 C for 24 hours. It was observed that the monolayer device extensively deformed while the multilayer maintained its shape. It is hypothesized that in the multilayer device the elastomer maintains a stabilizing force on the more rigid material during annealing to prevent undesired dimensional changes.

WHAT IS CLAIMED IS:

1. A polymeric sheet, comprising at least two outer layers A and C and a middle layer B, wherein the A and C layers individually comprise a thermoplastic polymer having a modulus of from about 1,000 MPa to 2,500 MPa and a glass transition temperature and/or melting point of from about 80 C to 180 C and the middle B layer is comprised of at least an elastomer having a modulus of from about 50 MPa to about 500 MPa and one or more of a glass transition temperature and/or melting point of from about 90 C to about 220 C.

2. The sheet of claim 1, wherein the A and C layers are comprised of one or more of a co-polyester, a polycarbonate, a polyester polycarbonate blend, a polyurethane, a polyamide or a polyolefin.

3. The sheet of claim 1, wherein the middle B layer is comprised of one or more of a polyurethane elastomer, a polyolefin elastomer, a polyester elastomer, a styrenic elastomer, a polyamide elastomer, a cyclic olefin elastomer and an acrylic elastomer.

4. The sheet of claim 1, wherein the middle B layer material has a compression set of less than 35%, 30%, 25%, 20% or 10% after 22 hr. at 25 C.

5. The sheet of claim 1, wherein the A and C layers have a lateral restoring force of less than 100 N (Newtons) per cm², 50 N per cm², 25 N per cm², or 10 N per cm², when displaced by 0.05mm to 0.1mm relative to each other.

6. The sheet according to claim 2, wherein one or more of the A and C layers comprises a co-polyester comprised of:

(a) a dicarboxylic acid component comprising 70 mole % to 100 mole % of terephthalic acid residues, and

(b) a diol component comprising

i) 0 to 95% ethylene glycol

ii) 5 mole % to 50 mole % of 2,2,4,4-tetramethyl-1,3-cyclobutanediol residues, and

iii) 50 mole % to 95 mole % 1,4-cyclohexanedimethanol residues,

iv) 0 to 1% of a polyol having three or more hydroxyl groups

wherein the sum of the mole % of diol residues i) and ii) and iii) amounts to 100 mole % and the copolyester exhibits a glass transition temperature T_g from 80° C. to 150° C.

7. The sheet according to claim 2, wherein one or more of the A and C layers comprises a polyurethane comprised of:

(a) a di-isocyanate comprising 80 mole % to 100 mole % of methylene diphenyl diisocyanate residues and/or hydrogenated methylene diphenyl diisocyanate and

(b) a diol component comprising

- i) 0 to 100 mole % hexamethylene diol
- ii) 0 to 50 mole % 1,4-cyclohexanedimethanol

wherein the sum i) and ii) amounts to greater than 90 mole % and the polyurethane has a glass transition temperature T_g from about 85 C to about 150 C.

8. The sheet according to claim 2, wherein one or more of the A and C layers comprises a microcrystalline polyamide comprised of from 50 to 100 mole % of C6 to C14 aliphatic diacid moieties, and about 50 to 100 mole % of 4,4'-methylene-bis(cyclohexylamine) (CAS [1761-71-3]), having a glass transition from about 100 C to 180 C, a heat of fusion of less than 20 J/g, and a light transmission of greater than 80%.

9. The sheet according to claim 1, wherein the combined thickness of the A, B and C layers is from about 500 microns to about 2,000 microns and the combined thickness of the A and C layers is from 25 microns to 750 microns, from 25 microns to 1000 microns, from 50 microns to 750 microns, from 100 microns to 750 microns, from 250 microns to 750 microns, or from 250 microns to 600 microns.

10. The sheet of claim 3, wherein the middle B layer comprises an aromatic or aliphatic polyether or polyester polyurethane.

11. The sheet of claim 2, wherein the A and C layers comprise a blend of a co-polyester, a polycarbonate, a polyester polycarbonate blend, a polyurethane, a polyamide and a polyolefin.

12. The sheet of claim 3, wherein the elastomeric B layer comprises a blend of one or more of a polyurethane elastomer, a polyolefin elastomer, a polyester elastomer, a styrenic elastomer, a polyamide elastomer, a cyclic olefin elastomer and an acrylic elastomer.

13. A dental appliance conformal to one or more teeth made from a polymeric sheet according to claim 1.

14. The appliance of claim 13, wherein the A and C layers are comprised of one of more of a co-polyester, a polycarbonate, a polyester polycarbonate blend, a polyurethane, a polyamide or a polyolefin.

15. The appliance of claim 13, wherein the middle B layer is comprised of one or more of a polyurethane elastomer, a polyolefin elastomer, a polyester elastomer, a styrenic elastomer, a polyamide elastomer, a cyclic olefin elastomer or an acrylic elastomer.

16. The appliance of claim 15, wherein the middle B layer material has a compression set of less than 35%, 30%, 25%, 20% or 10% after 22 hr. at 25 C.

17. The appliance of claim 13, wherein the A and C layers have a lateral restoring force of less than 100 N per cm², 50 N per cm², 25 N per cm², or 10 N per cm², when displaced by 0.05mm to 0.1mm relative to each other.

18. The appliance of claim 14, wherein one or more of the A and C layers comprises a copolyester comprised of:

(a) a dicarboxylic acid component comprising 70 mole % to 100 mole % of terephthalic acid residues, and

(b) a diol component comprising

i) 0 to 95% ethylene glycol

ii) 5 mole % to 50 mole % of 2,2,4,4-tetramethyl-1,3-cyclobutanediol residues, and

iii) 50 mole % to 95 mole % 1,4-cyclohexanedimethanol residues,

iv) 0 to 1% of a polyol having three or more hydroxyl groups

wherein the sum of the mole % of diol residues i) and ii) and iii) amounts to 100 mole % and the copolyester exhibits a glass transition temperature T_g from 80° C. to 150° C.

19. The appliance of claim 14, wherein one or more of the A and C layers comprises a polyurethane comprised of:

(a) a di-isocyanate comprising 80 mole % to 100 mole % of methylene diphenyl diisocyanate residues and/or hydrogenated methylene diphenyl diisocyanate and

(b) a diol component comprising

i) 0 to 100 mole % hexamethylene diol

ii) 0 to 50 mole % 1,4-cyclohexanedimethanol

wherein the sum i) and ii) amounts to greater than 90 mole % and the polyurethane has a glass transition temperature T_g from about 85 C to about 150 C.

20. The appliance of claim 14, wherein one or more of the A and C layers comprises a microcrystalline polyamide comprised of from 50 to 100 mole % of C₆ to C₁₄ aliphatic diacid moieties, and about 50 to 100 mole % of 4,4'-methylene-bis(cyclohexylamine) (CAS [1761-71-3]), having a glass transition of between about 100 C and 180 C, a heat of fusion of less than 20 J/g and a light transmission of greater than 80%.

21. The appliance according to claim 13, wherein the combined thickness of the A, B and C layers is from about 500 microns to about 2,000 microns and the combined thickness of the A and C layers is from 25 microns to 750 microns, from 25 microns to 1000 microns, from 50 microns to 750 microns, from 100 microns to 750 microns, from 250 microns to 750 microns or from 250 microns to about 600 microns.

22. The appliance of claim 15, wherein the middle B layer comprises an aromatic or aliphatic polyether or polyester polyurethane.

23. A reversibly deformable dental appliance comprised of an inner shell and an outer shell, wherein the inner and outer shell are connected by an elastomeric middle layer, wherein the inner and outer shells can reversibly move relative to each other have and a lateral restoring force of less than 100 N per cm², 50 N per cm², 25 N per cm², or less than 10 N per cm² when displaced by 0.05mm to 0.1mm relative to each other.

24. The appliance of claim 23, wherein the inner and outer shells have a total thickness of from about 250 microns to about 2,000 microns.

25. The appliance of claim 23, wherein the elastomeric middle layer comprises a polyurethane having a hardness from about A 80 to D 75.

26. The appliance of claim 23, wherein an outer shell comprises one or more of a polyurethane, a polyester, a polycarbonate, a polyolefin, or an acrylic or methacrylic polymer.

27. The appliance of claim 23, wherein an inner shell or outer shell comprises a blend of a co-polyester, a polycarbonate, a polyester polycarbonate blend, a polyurethane, a polyamide and a polyolefin.

28. The appliance of claim 23, wherein the elastomeric middle layer comprises a blend of one or more of a polyurethane elastomer, a polyolefin elastomer, a polyester elastomer, a styrenic elastomer, a polyamide elastomer, a cyclic olefin elastomer and an acrylic elastomer.

29. A sheet or dental appliance having improved environmental stress resistance comprised of at least two outer layers and an elastomeric inner layer, wherein one or more of the outer layers is a polyester or co-polyester or polyurethane having a modulus of from about 1,000 MPa to 2,500 MPa, and the inner layer comprises an elastomer having a modulus of from about 50 MPa to about 500 MPa, wherein the inter layer peel strength between at least one outer layer and the elastomer is greater than about 50 N /inch.

30. The sheet or dental appliance of claim 29, wherein at least one outer layer has a thickness of less than about 500 microns, 400 microns, 300 microns, 250 microns, or 200 microns.

ABSTRACT

The invention provides improved polymeric sheets and dental appliances having outer layers comprised of a material having a modulus of from about 1,000 MPA to 2,500 MPA and an inner core comprised of elastomeric material or materials having a modulus of from about 50 MPa to 500 MPa, which have improved flexibility and strength relative to currently available materials.

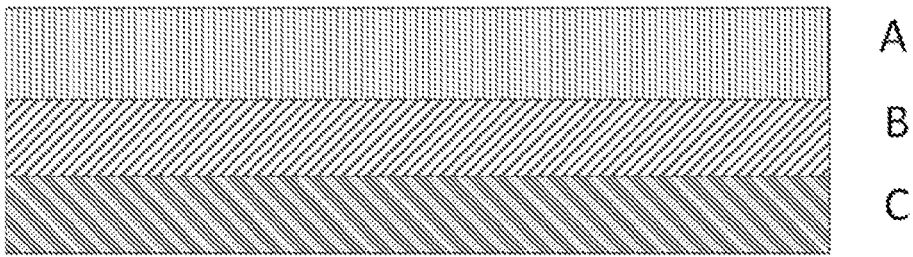


Fig. 1A

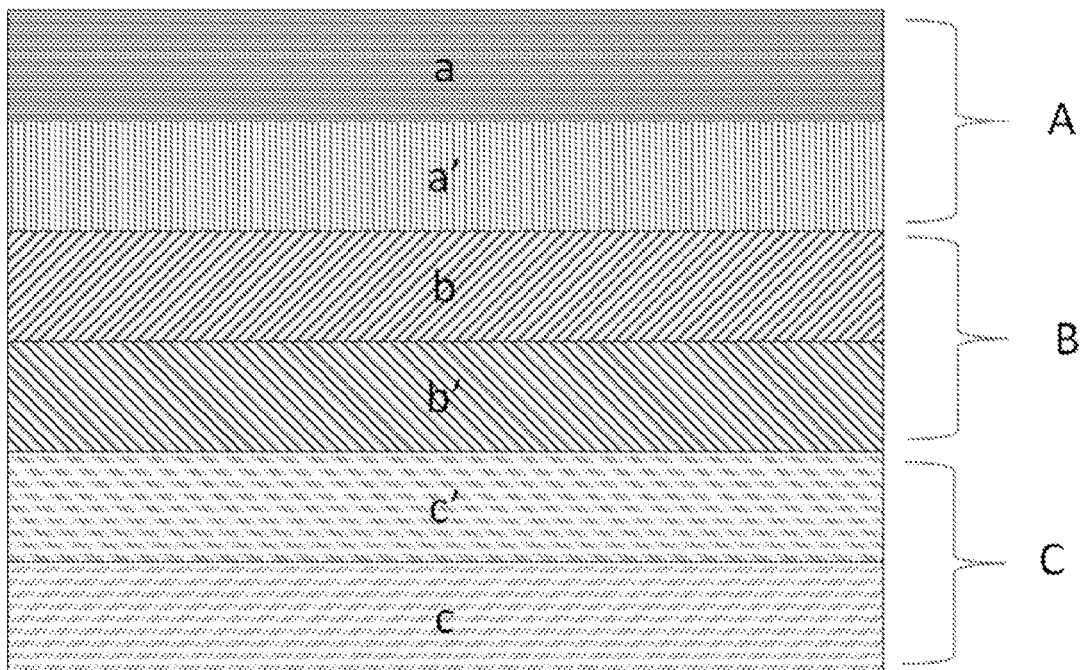


Fig. 1B

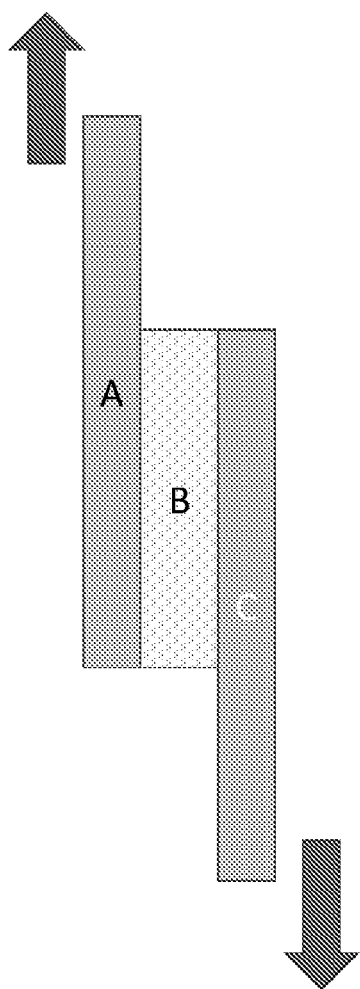


**Fig. 2a Displacement
Force**

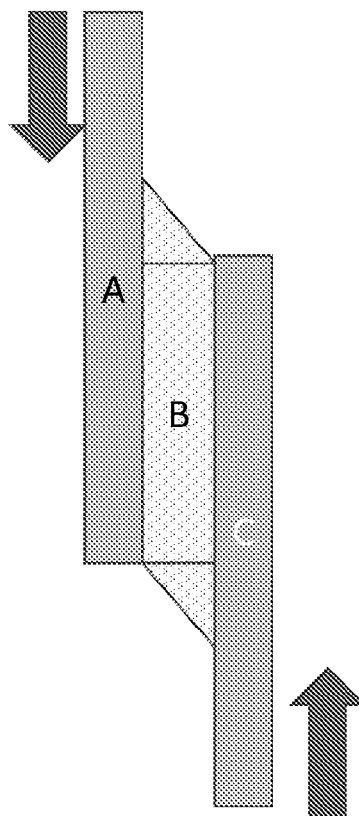


**Fig. 2b Restoring
Force**

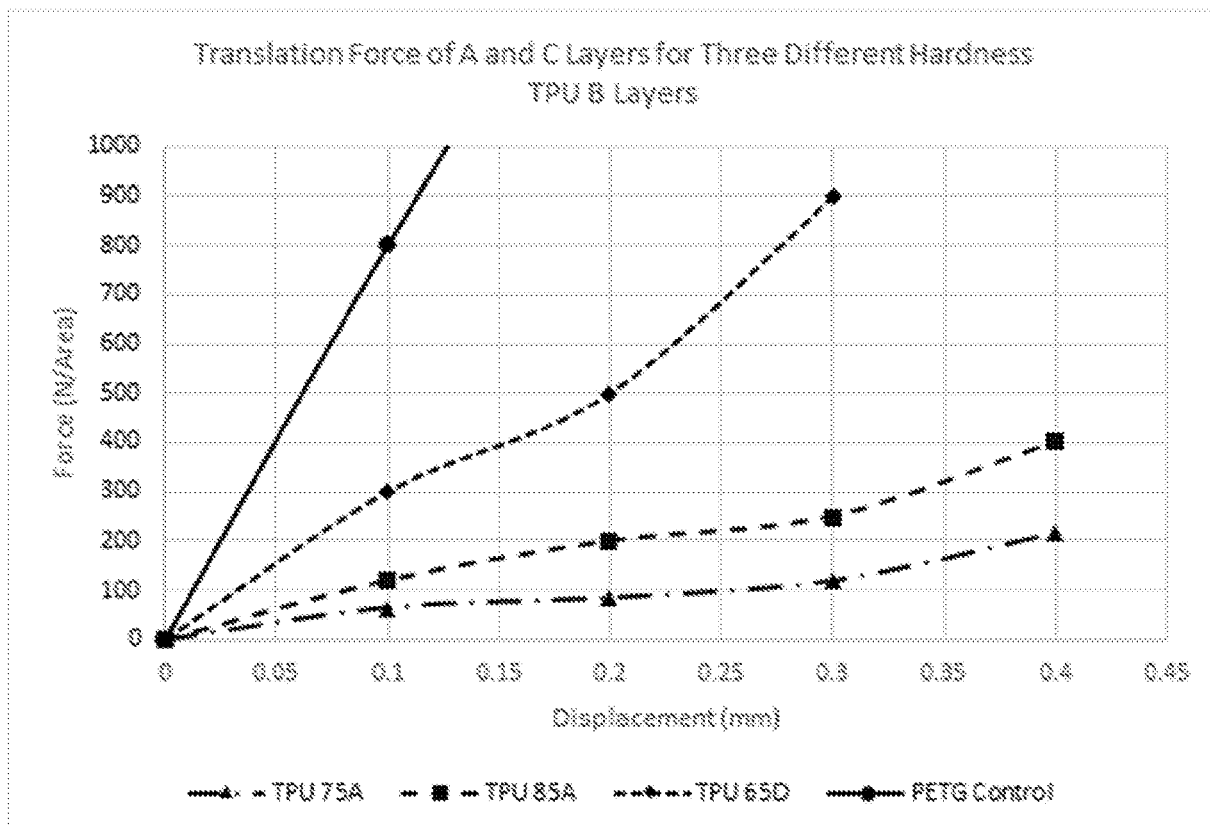


Fig. 3A

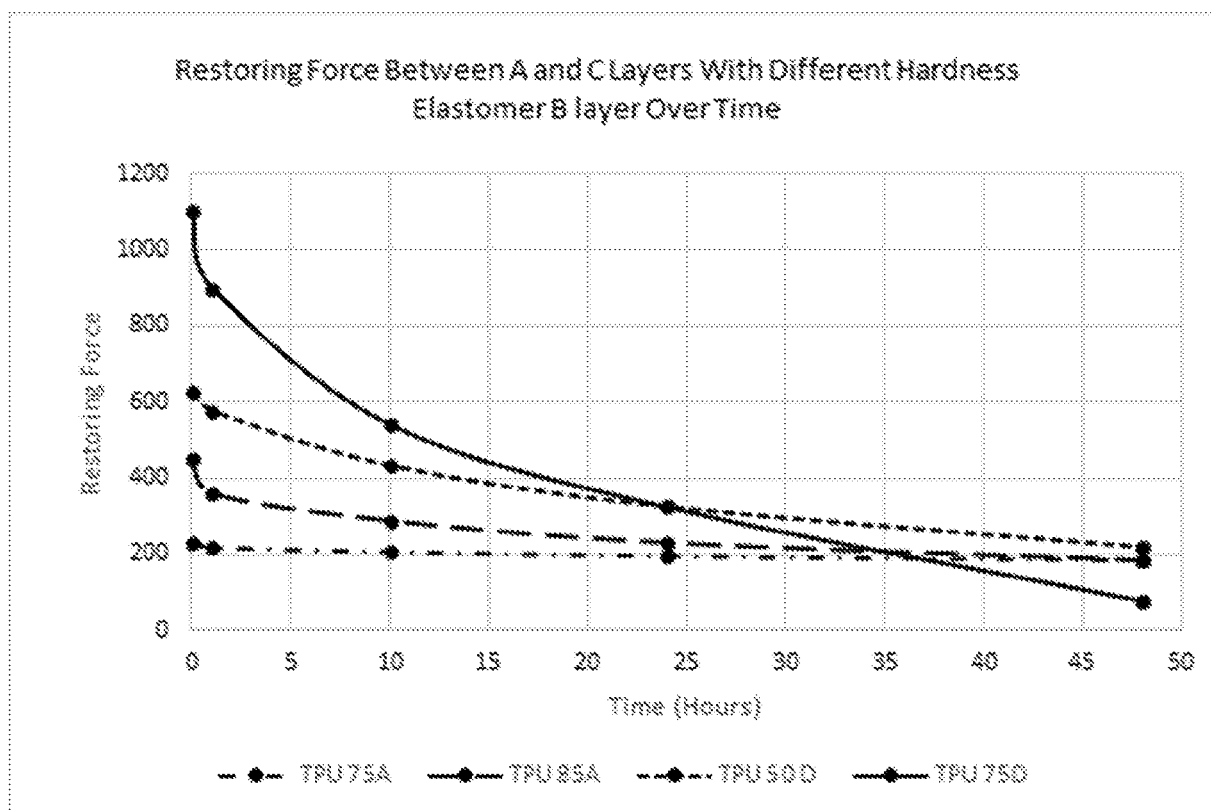


Fig. 3B

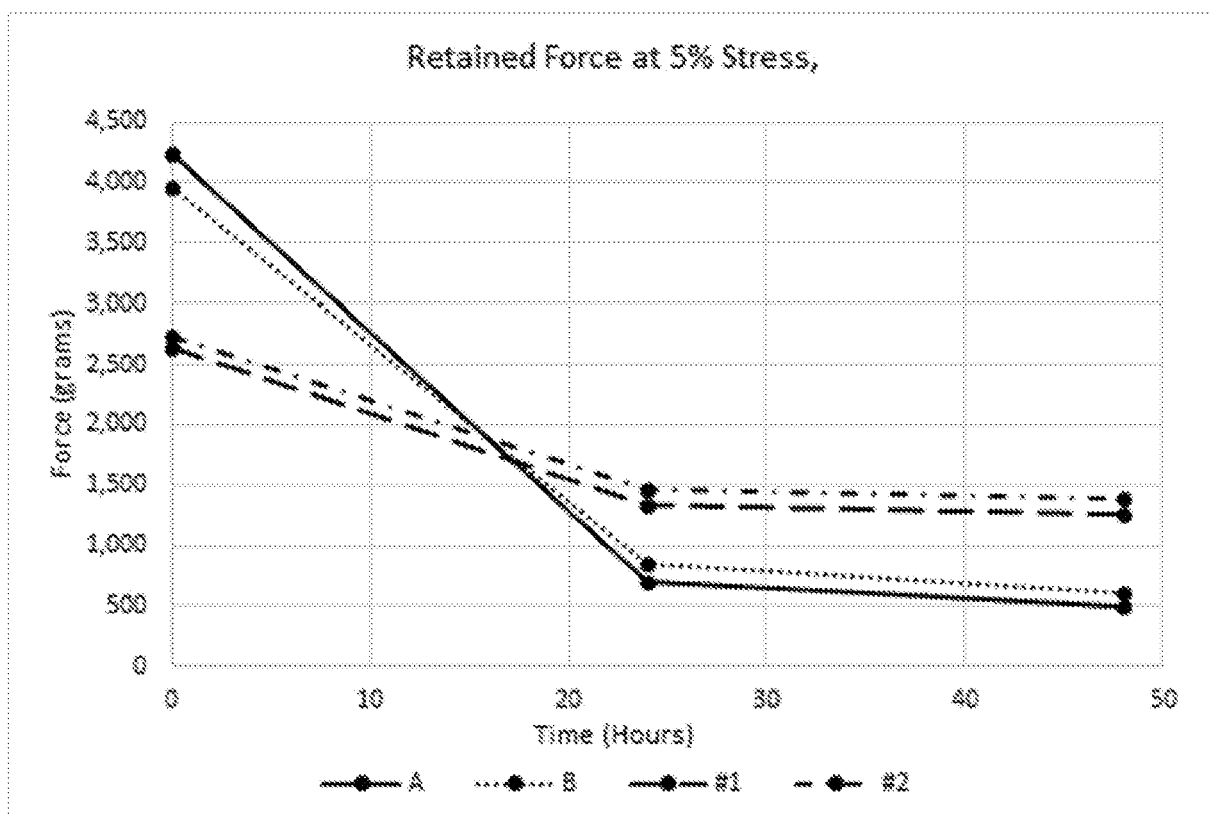


Fig. 4

Electronic Acknowledgement Receipt	
EFS ID:	31040048
Application Number:	62590627
International Application Number:	
Confirmation Number:	8845
Title of Invention:	DUAL SHELL DENTAL APPLIANCE AND MATERIAL CONSTRUCTIONS
First Named Inventor/Applicant Name:	Ray F. Stewart
Customer Number:	77268
Filer:	Linda R. Judge
Filer Authorized By:	
Attorney Docket Number:	
Receipt Date:	26-NOV-2017
Filing Date:	
Time Stamp:	21:31:30
Application Type:	Provisional

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$ 130
RAM confirmation Number	112717INTEFSW21333000
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Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Provisional Cover Sheet (SB16)	sb0016ZenduraXL26Nov17.pdf	320505	no	3
			ff77292c2b9def7539d5655632cd32f714fe2a5b		
Warnings:					
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2	Application Data Sheet	ADSZenduraXLProvisional26NOV17.pdf	324593	no	8
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3	Specification	SpecZenduraXLProvisional26NOV17.pdf	173380	no	27
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Warnings:					
Information:					
4	Drawings-only black and white line drawings	DrawingsZenduraXLProvisional26NOV17.pdf	1893516	no	5
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Warnings:					
Information:					
5	Fee Worksheet (SB06)	fee-info.pdf	29304	no	2
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