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Research Article

Innovative Polymers for TMD Rehabilitation Devices

Bertoldi S[1,2], Farè S[1,2]*, Montagna S[3] and Tanzi MC[2]

[1]Biomaterials Laboratory, Department of Chemistry, Materials and Chemical Engineering "G. Natta", Politecnico di Milano, Italy

[2]INSTM, Local Unit Politecnico di Milano, Department of Chemistry, Materials and Chemical Engineering "G. Natta", Milano, Italy

[3]MD, DDS Private Practice in orthodontics and functional problems related to occlusion, Parma, Italy

***Corresponding author:** Farè S, Department of Chemistry, Materials and Chemical Engineering "G. Natta", Politecnico di Milano, P.zza L. da Vinci 32, 20133, Milano, Italy, Tel:+39-0223993389; Fax: +39-0223993360; E-mail: silvia.fare@polimi.it

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Abstract

In diagnostic and training procedures during oral rehabilitation in Temporomandibular Disorders (TMD), the need for devices and materials that can exert the muscular activity, thus improving muscle rehabilitation, is constantly increasing. In this preliminary work, the mechanical behavior of four innovative poly(styrene-block-isobutylene-block-styrene) copolymers (SIBS) was compared to the one of Silasto®, a silicone elastomer already used in TMD rehabilitation. INNOVIA SIBS and the three KANEKA SIBS formulations (Sibstar® 073T, Sibstar® 102T, and Sibstar® 062M) showed a typical elastomeric tensile behavior, (i.e. sigmoid curve), while Silasto® showed a brittle elastic performance. The influence of styrene content, hardness, and molecular weight on the mechanical properties of SIBS copolymers, already highlighted in literature, is in agreement with the results obtained in this work. In the creep/recovery tests and in the stress relaxation/recovery tests, the investigated materials experienced a different time-dependent increase of strain. Silasto® showed a constant linear deformation under the applied load, confirming the result obtained in the tensile test. Instead, SIBS copolymers exhibited a visco-elastic behavior, undergoing increased deformation with time under an applied constant stress. These preliminary results allow assessing the advantages of the SIBS family of materials in respect of the already used Silasto®. In fact, their viscoelastic behavior allows to obtain a slow deformation recovery, that is one of the fundamental requirements for a correct muscle rehabilitation in selected patients.

Keywords: Temporomandibular disorders; Muscle activity; PDMS; SIBS; Tensile properties; Creep

Introduction

Researchers have increasingly recognized the need to evaluate and quantify the material properties of chewing items, to understand jaw kinematic and muscle activity during mastication [1]. As soft foods are progressively reducing muscular force and muscular compliance, function impairment and reduced chewing ability during hard food mastication are increasingly experienced by dental patients [2]. To overcome these complications, devices and materials with elastic properties have been used in diagnostic and training procedures during oral rehabilitation in Temporomandibular Disorders (TMD), as they can exert the muscular activity, thus improving muscle rehabilitation [3].

A mastication test should be adapted to the patient's compromised oral function level [4,5]. The elastic materials used during chewing tests can determine a muscle over-contraction, thus reducing the reliability of the test. At the same time, the elastic materials commonly used for these applications (e.g. polydimethylsiloxane, PDMS), after the chewing stress and deformation have been applied, have a very fast recovery rate, being the elastic recovery immediate, causing the overwork of the muscle.

Considering the above mentioned current limitations of the actual training procedures, the need to find a polymeric material with different mechanical properties, in particular with a viscoelastic recovery behavior, slower and more gradual than the one experienced by elastic materials, is important to reduce the muscular loading, extending the possibilities to test the patient. Considering possible alternative materials for TMD rehabilitation, besides the viscoelastic recovery to applied stresses and deformations, several other requirements should be ideally satisfied. In particular, the material should be biocompatible (or at least food grade), possess tear and wear resistance, liquid impermeability, and stability to the chemical detergent and cleaning substances and to the aggressive environment inside the mouth.

In this perspective, a novel family of polymeric materials can be considered for the devices used in TMD oral rehabilitation, namely the poly(styrene-block-isobutylene-block-styrene) copolymers (SIBS). SIBS are biostable thermoplastic elastomers with physical properties overlapping silicone rubber and polyurethanes [6]. The development of SIBS for medical devices evolved from limitations encountered with the long-term *in vivo* performance of polyurethanes (i.e. oxidative degradation and inflammatory and fibrotic reactions). Their structure and chemical composition lead to important properties for biomedical applications, such as bio- and hemo- compatibility, and long-term stability. In addition, SIBS properties can be tailored by varying chemical composition and structure [6]; in particular, their mechanical properties are correlated to their molecular weight, hardness and styrene content [6,7]. Therefore, by varying these parameters, SIBS with different properties can be synthesized. SIBS are actually under investigation for several biomedical applications, such as stent-grafts [8], drug carrier in drug-eluting coronary stent [9,10], glaucoma shunt in ophthalmology [11], and synthetic trileaflet aortic valve [12,13].

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Table 1: Properties of the investigated materials.

Material	062M	073T	102T	Innovia
Molecular Weight (10^3 g/mol)	35	65	100	60
Styrene % [wt%]	22.5	30	15	17.5
Hardness Shore A	20A	45A	46A	55A

All the favorable SIBS properties above discussed, in particular their biocompatibility, tunable mechanical properties and chemical and *in vivo* stability, make them possible candidates for the production of devices for TMD rehabilitation. Keeping in mind the material requirements for the proposed applications, the aim of this preliminary work is the characterization of four SIBS materials, provided by two different manufacturers, to evaluate the tensile mechanical behavior and viscoelastic properties, by creep/recovery and stress relaxation/recovery tests, and to assess their potentiality in this field of application.

Materials and Methods

Film preparation

The considered SIBS materials were provided as pellets by two companies. The INNOVIA LCC (Miami, Florida, USA) provided the INNOVIA SIBS (lot n° MRR322), and the KANEKA (Westerlo-Oevel, Belgium) provided three different SIBS formulations: Sibstar® 073T, Sibstar® 102T, and Sibstar® 062M. The properties of the investigated materials, according to the manufacturers, are reported in Table 1.

Films of the different SIBS were obtained by solvent casting from the pellets. A 25% w/v solution was prepared by dissolving the SIBS pellets in chloroform (cod. 32211, Sigma-Aldrich), at room temperature. The solution was cast in a glass Petri dish (Ø = 10 cm), allowing the solvent to evaporate, until complete evaporation. Films 0.3 mm thick were obtained. Specimens with two different shapes and dimensions were punched out from the obtained films for the mechanical characterization. In particular, rectangular (l = 20 mm, w = 5 mm) specimens were obtained for DMA analysis and Dumbbell shaped specimens were cut with a manual die from the films, according to the ASTM D638 for the mechanical tensile tests.

As control for all the characterization tests, rectangular samples (l = 20 mm, w = 5 mm) were obtained cutting a device used for the specific application in Silasto® 50 Shore A (Dr. Hinz Dental, Germany). Silasto® is an A-silicon (addition cross-linked with a platinum catalyst), vulcanized at a temperature of 225°C.

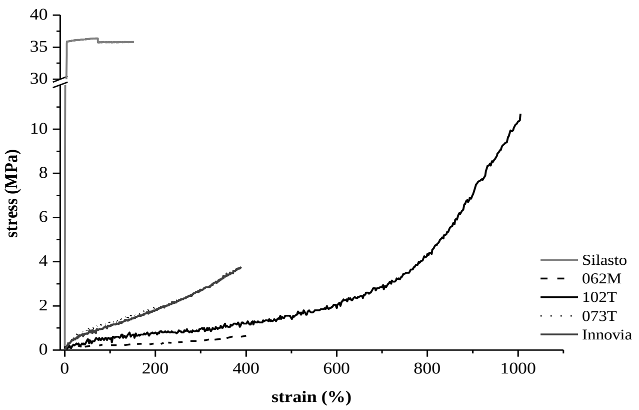

Figure 1: Uniaxial tensile mechanical tests: stress/strain curves.

Tensile mechanical tests

Uniaxial tensile tests were performed with a MTS 1/MH electromechanical system (MTS System Corporation, USA) equipped with a 5 kN load cell, at 37°C, at a crosshead speed of 200 mm/min, after a preload at 0.5 N applied with a crosshead speed of 100 mm/min. Dumbbell specimens (n = 3 per each SIBS films) and rectangular samples for Silasto® (n = 3) were tested. High capacity pneumatic grips, allowing a correct specimen alignment and removing the bending effects, were used. Tensile test results were recorded and elaborated with Testworks® software. From the stress/strain curves, the following mechanical parameters were considered: elastic modulus (E), secant moduli at different strain values (E_{100}, E_{200}, and E_{300}), stress (σ_b) and strain (ε_b) at break.

Creep and recovery tests

The creep and recovery tests were performed using a Dynamical Mechanical Analyzer (TA Q800 DMA, TA Instruments), testing rectangular specimens (n = 3 per each SIBS films and for Silasto®). Considering the proposed application in TMD rehabilitation, three stress values were tested, namely 0.5, 1 and 2 MPa. The tests were carried out at 37°C, with a preload of 0.01 N, applying the stress for 10 minutes with a recovery time of 10 minutes.

Stress relaxation and recovery tests

The stress-relaxation and recovery tests were performed using the DMA TA Q800 at 37°C, with a preload of 0.01 N, applying a constant deformation of 100% for 10 minutes and a recovery time of 10 minutes, testing rectangular specimens (n = 3 per each SIBS films and for Silasto®).

Results and Discussion

Tensile mechanical tests

Figure 1 shows representative stress-strain curves of SIBS and Silasto®, obtained by tensile mechanical test. All the SIBS exhibited the σ/ε curves typical of elastomeric materials, (i.e. sigmoid curve), while Silasto® shows a brittle elastic behavior. In fact, Silasto® samples reached very high values of stress at break with low deformation. The difference in tensile properties between Silasto® and SIBS are highlighted observing the values of the considered mechanical parameters (Table 2). Significant differences ($p < 0.05$) in all the mechanical parameters (E, E_{100}, σ_b and ε_b) are evidenced comparing Silasto® with all the tested SIBS. Besides, among the SIBS materials some differences in the mechanical properties can be detected and correlated to their properties (Table 1). Actually, Innovia and 073T SIBS, being characterized by high hardness (55A and 45A, respectively) together with a high styrene content (17.5% and 30%, respectively), show higher stiffness (i.e. elastic modulus, E) if compared to 102T and 062M ($p < 0.05$). On the contrary, the lower hardness value of 062M SIBS (i.e. 20 Shore A) leads to a low value in the elastic modulus. The influence of styrene content and hardness on the mechanical properties of SIBS has been already highlighted in literature [6,7], in agreement with the results obtained in this work. Another chemical parameter affecting the mechanical properties of SIBS is the molecular weight; in general, an increase in molecular weight leads to an increase in elongation at break [7]. This statement is verified also by the results here obtained; in fact, a significant

Table 2: Uniaxial tensile mechanical tests: values of the considered mechanical parameters.

Materials	E (MPa)	E_{100} (MPa)	E_{200} (MPa)	E_{300} (MPa)	σ_b (MPa)	ε_b (%)
Innovia	4.08 ± 1.17	1.18 ± 0.19	0.93 ± 0.11	0.91 ± 0.05	3.70 ± 0.31	384.70 ± 20.78
102T	0.62 ± 0.27	0.21 ± 0.11	0.17 ± 0.02	0.14 ± 0.01	4.45 ± 0.79	948.50 ± 59.72
073T	3.66 ± 0.38	1.24 ± 0.05	0.95 ± 0.03	n.d.	2.89 ± 0.52	352.99 ± 88.63
062M	0.43 ± 0.19	0.16 ± 0.04	0.13 ± 0.01	0.13 ± 0.01	0.81 ± 0.30	414.57 ± 64.46
Silasto	967.04 ± 229.33	29.10 ± 15.64	n.d.	n.d.	29.55 ± 15.94	139.67 ± 29.44

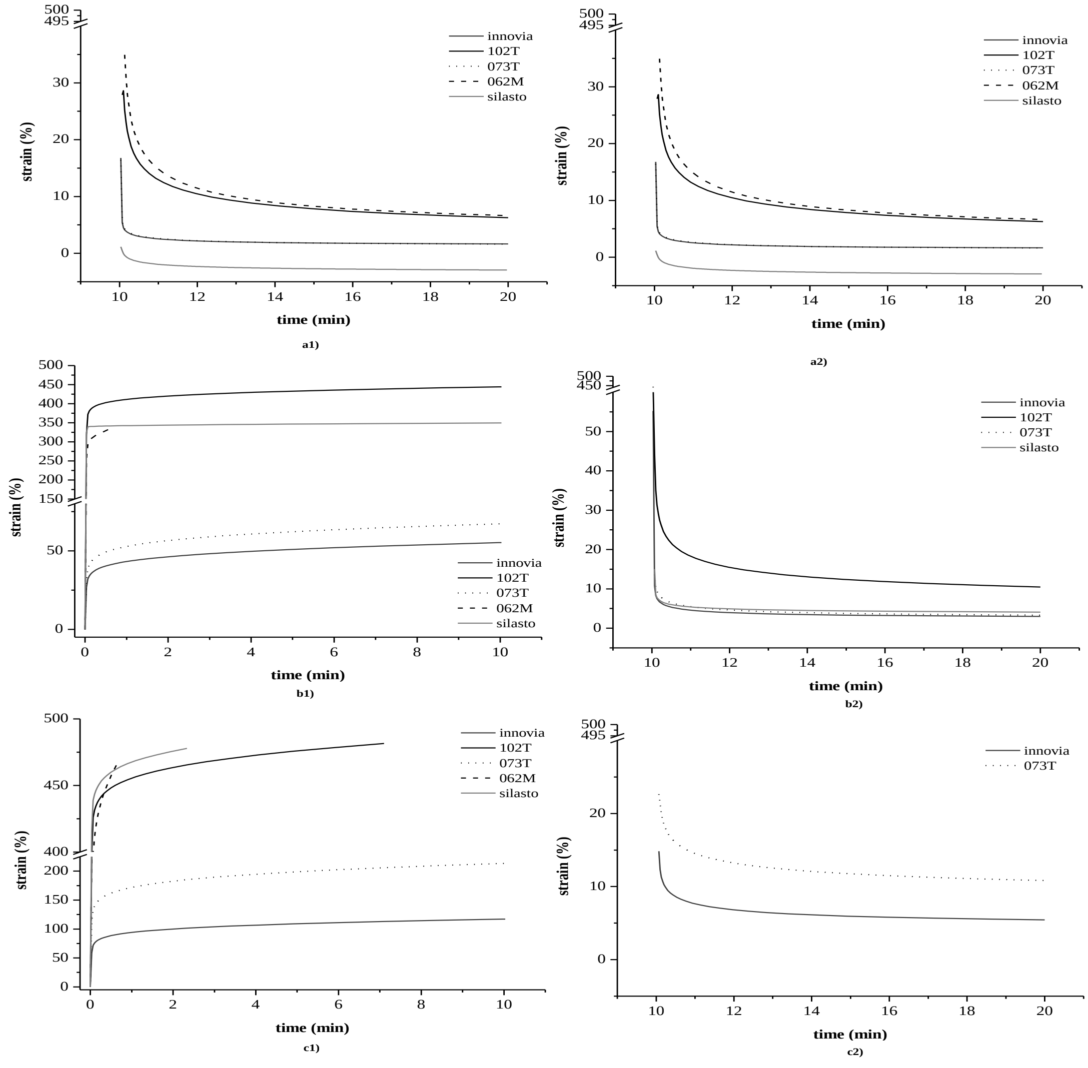

Figure 2: Creep and recovery curves: a1) creep @stress = 0.5 MPa, a2) recovery @stress = 0.5 MPa, b1) creep @stress = 1 MPa, b2) recovery @stress = 1 MPa, c1) creep @stress = 2 MPa, c2) recovery @stress = 2 MPa.

difference ($p < 0.05$) in ε_b has been detected between 062M and 102T, that showed the lowest and highest molecular weight values (35 and 100 × 10^3 g/mol, respectively). In addition, the 102T SIBS is found to be more flexible than the other tested SIBS, possibly correlated to the major length of the macromolecules (i.e. high molecular weight).

Creep and recovery tests

The results obtained in the creep/recovery tests (Figure 2) show a load-dependent behavior for all the tested materials (both SIBS and Silasto®). Besides, only two materials, Innovia and 073T SIBS, can sustain an applied stress of 2 MPa for 10 minutes, in agreement with the results obtained in the uniaxial tensile characterization: Innovia and 073T exhibit a higher value of elastic modulus, i.e. higher stiffness, compared to 062M and 102T ($p < 0.05$). In addition, either Innovia and 073T have an E value and a stress at break over the 2 MPa fixed as stress value in the creep run. The 062M SIBS, having a lower stiffness (E < 1 MPa), cannot bear a stress value of 1 MPa during the creep run, probably due to the low mechanical strength of this SIBS formulation (σ_b < 1 MPa). SIBS 102T and Silasto® experience the break few minutes after the application of a constant stress value of 2 MPa. The creep behavior of Silasto® is mainly related to the elastic component of the material (correlated to the elastic behavior

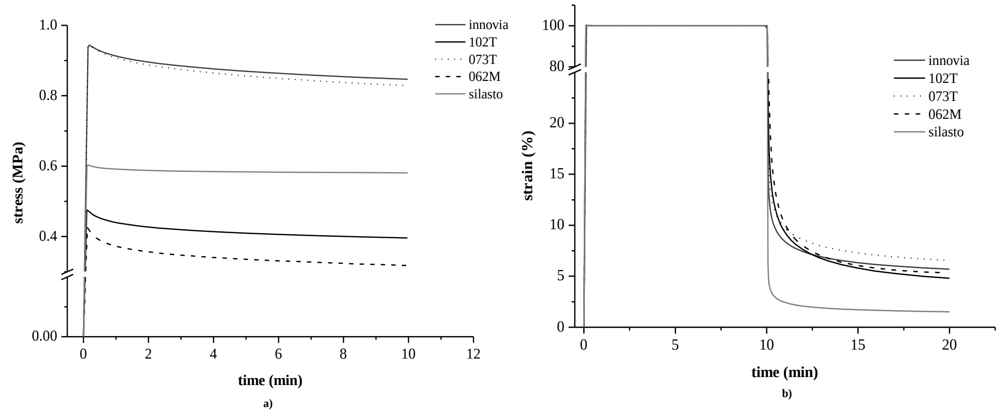

Figure 3: (a) Stress relaxation and (b) recovery curves.

evidenced in the tensile test), whereas SIBS copolymers exhibited a visco-elastic behavior, undergoing increased deformation under the applied constant stress.

Considering the recovery phase, all the SIBS show a recovery rate slower than the one of Silasto® for all the tested stress values, denoting their viscoelastic behavior, in contrast to the almost completely elastic behavior of the control material. In particular, a different recovery for the SIBS highlight an influence of the styrene content and molecular weight in the deformation recovery.

Stress relaxation and recovery tests

The representative stress relaxation and recovery behavior of the SIBS and the control material is reported in Figure 3. The viscoelastic behavior of the SIBS confirm the consideration highlighted for the creep/recovery test. In fact, also in this case Innovia and 073T prove to be stiffer than the other materials. Furthermore, both stress relaxation and recovery curves very well show the viscous behavior of SIBS, in contrast with the pure elastic response of Silasto®. In addition, Silasto® recovers the deformation, reaching its initial dimension, as soon as it is removed exhibiting a quasi-perfect elastic behavior, while the viscous component of the deformation recovery is evident for all SIBS. In fact, the deformation is recovered increasing the recovery time (t = 10 min).

Conclusions

The research work here presented is focused on the study of novel materials, the SIBS, to be possibly used in devices for TMD rehabilitation, overcoming the limitation experienced by the current used material (i.e. Silasto®). The SIBS proposed and characterized in this work demonstrated to possess mechanical properties that can fulfill the requirements of materials that have to be used in temporomandibular rehabilitation. In fact, they are biocompatible, stable *in vivo* and in contact with different chemical substances, and with mechanical properties tunable by varying their chemical composition. In particular, the main requirement for this application is the capability to present a viscoelastic recovery in response to applied stress and deformation. The preliminary results obtained in this work allow assessing the advantages of this family of materials in respect to the commonly used Silasto®. In fact, their viscoelastic behavior allows obtaining a slow recovery of the deformation, which is fundamental for a correct muscle rehabilitation.

Future studies assessing their properties in physiological-like environments (i.e. mouth fluids, different pH), together with abrasion tests simulating the parafunction of the teeth in physiological and pathological movements (i.e. bruxism), are needed to better assess their promising application in the TMD rehabilitation.

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