〔**Original**〕 Matsumoto Shigaku 30：143~153, 2004

key words：soft lining materials - tensile testing - tear testing - hardness testing - clinical observation

Laboratory evaluation of 10 permanent soft lining materials and some clinical observations

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Summary

Ten commercial soft lining materials were selected to be representative of the types currently available including plasticised acrylic, silicone and fluorine-containing materials. These have been investigated in terms of their tensile, tear and hardness properties. With the exception of tear strength, where silicone materials had the lowest values, there appeared to be no correlation between material type and property. All but two of the materials had hardness values in the range of 30.3 to 43.7. The general conclusion was that the materials selected showed a large variability in the properties investigated. Regarding clinical aspects of some soft lining materials used for acrylic resin denture bases, it was appeared that colour change and deterioration occurred.

Introduction

The success of complete and partial dentures depends comfort, esthetics and function. One of the fundamental principles of these prostheses is the prevention of undue movement of the denture during function ; in an effort to reduce movement it is generally recognized that a rigid denture base is desirable. There are, however, cases when the denture-bearing area is of such a nature as to make coverage by a rigid denture intolerable to the patient. Many patients experience pain and difficulty using dentures constructed with hard denture bases. The soft denture-bearing mucosa is confined between the hard denture base and the bone, and during normal function damage can occur to the tissues, resulting in chronic soreness. This problem is even more pronounced for those patients who have diabetes or other debilitating diseases or for geriatric patients[1,2].

Denture soft lining materials are widely used as aids for the treatment and prevention of localized

(recieved June 21, 2004 ; accepted August 25, 2004)

areas of painful tissue irritation under dentures. These materials provide a cushion for the denture-bearing mucosa, and this provides comfort for patients[3]. Denture soft lining materials are also valuable when treating patients with ridge atrophy or resorption, bony undercuts, congenital or acquired oral defects requiring obturation and xerostomia[1].

There is a wide range of materials currently on the market with the majority being based wholly or partly on methacrylate (so-called soft acrylics) or silicone chemistry. The large number of materials available indicates that none have proved fully satisfactory but does show a need. Commonly observed deficiencies include poor adhesion to the denture base, poor tear resistance, difficult finishing and polishing, excessive hardness, gradual hardening with time, and excessive fluid absorption with resultant distortion and fouling[4-6]. Failures are associated with poor physical and mechanical properties and fouling or colour changes of the liners by fungal growth, processing variables or cleansing agents. Although the physical and mechanical data of these materials are indicated by a manufacture, we have never seen it that was obtained by the same researcher and the same laboratory conditions such as room temperature, room humidity and/or experimental equipment for each material. For the reason of this point, the authors thought that the physical and mechanical measurements of these materials are significant. The aim of this study was to evaluate the physical and mechanical properties of 10 commercial long-term soft lining materials, selected to represent the different types currently in use. Since many of these products have been recently introduced to the dental profession, a comparison of materials will provide clinicians with useful data when choosing materials for their patients and will serve as a benchmark when new or experimental elastomers are evaluated.

Materials and Methods

A series of 10 soft lining materials were selected as representative of the types in wide spread current use. Details of the materials tested are listed Table 1, which also includes powder/liquid ratio

Table 1 : List of materials, manufacturers and curing methods

Brand	Type	Batch No.	Manufacturers	Powder/Liquid	Curing methods
MOLTENO	Polyorefin	21003	Molten Medical Co.	Single component	Manufacturer made
MOLLOSIL	Silicone	940401	Molloplast Regneri GmbH & Co. KG	2 cm Mollosil 1 drop catalyst	Dry heat 30 min-40 C
MOLLO-PLAST-B	Silicone	940962	Molloplast Regneri GmbH & Co. KG	Single component	Dry heat 20 min-60 C 60 min-100 C
EVATOUCH	Silicone	Base FG 02 Cat. FI 01	Neo Dental Chemical Products Co., Ltd	Base 1 cc Cat.1 cm	Dry heat 10 min-40 C
SIMPA	Silicone	Base 129222 Cat. 129212	Kettenbach Dental	Base 1 scale Cat.2 drops	Dry heat 30 min-40 C
TOKUSO SR	Silicone	91066 D	Tokuyama Corp.	Mixing dispenser	Water bath 20 min-40 C
KUREPEET	Polyfluoro-ethylene copolymer	93702	Kreha Chemical Industrial Co	Single component	Water bath 40 min-70 C 40 min-100 C
NOVUS	Poly phosphazene fluoroelastomer	6195 A	The Hygenic Co.	Single component	Dry heat 2 h.30 min-70C 30 min-100 C
SUPER SOFT	Acrylic resin	Pol. 010492 K Mon.012792 A	Coe Laboratories. Inc.	Powder 5 g Liquid 4 cc	Dry heat 30 min-70 C 10 min-40 C
SOFTEN	Acrylic resin	Pol.1028 Mon.1028	Kamemizu Chemical Ind. Co., Ltd	Powder 3.4 g Liquid 3.0 ml	Dry heat 10 min-40 C

used and curing time. All specimens were prepared according to the manufacture's instructions except Molteno, this material was fabricated by manufacturer.

Specimen Preparation

A specially constructed two-piece metal mould (120 mm x 120 mm x 2.0 mm) (Kobunshikeiki Co. Kyoto, Japan) was used to fabricate sheets of the materials. The mould was sealed and placed in a dry heat and pressure instrument SA 302-11 (Tester Industry Co. Tokyo, Japan). The mould was pressed under a force of approximately 1,800 kg and curing was carried out according to each manufacturers instructions (see Table 1). Each cured sheet was stored in a humidor for 24 hours before testing. Test specimens were punched out of the cured sheets of each material using standard die cutters by using a cutting machine S 400 (Yoshimitsu Seiki Co., Tokyo, Japan). Care was taken to ensure that samples were free of surface irregularities, tear or nicks at the edges, and internal defects. Seven specimens were used for each test. Testing was carried out in a temperature controlled room at 23℃ ± 1℃ and 55% ± 1% humidity.

Tensile Test

Tensile properties were determined using a Shimadzu universal testing machine (Shimadzu Co. Kyoto, Japan) according to ASTM Specification No. D 412. The seven dumb-bell shaped specimens were marked with bench marking stamps and were tested at a crosshead speed of 500 mm/min. Tensile stress at 100% strain, tensile stress and elongation at break were determined.

Tensile stress (MPa) is defined as the formula : Fn/A

Where Fn is the force required to produce 100% elongation and A is the cross-sectional area of the unstretched specimen.

Tensile strength (MPa) is defined by the formula : F/A

Where F is the force required to break the specimen and A is the cross-sectional area of the unstretched specimen.

Elongation to break is defined by the formula : %elongation = (L-Lo) /Lo x 100

Where L is the observed distance between bench marks on the stretched specimen and Lo is the original distance between the bench marks.

Tear Test

Tear resistance was determined using ASTM Specification No. D 624 with tear test die C used to produce the specimens. At least 2.5 cm of each tab end were placed in the grips of the machine and the specimen was tested at a crosshead speed of 500 mm/min. Breaking force was recorded on a chart and fractured specimens were evaluated to determine if failure correlated with defects in the specimen.

Tear resistance (kg/cm) is defined by the formula : T = F/D

Where T is tear resistance, F is the force required to break the specimens, and D is the thickness of the specimen.

Hardness Test

Hardness was determined by using a Shore-A hardness instrument CI-10 (Kobunshikeiki Co. Kyoto, Japan) on three specimens stacked to produce a thickness of approximately 6 mm thick.

Statistical Analysis of Data

Means and standard deviations were determined, and Bartlett's test for homogeneity of variance was applied to the data. If the resultant test value was less than the critical X^2 value at the 0.10 level of significance, and analysis of variance (ANOVA) was greater than the critical value (sample variance not homogeneous), the Welch test was substituted for the ANOVA. When there was a significant difference among the means, multiple comparisons using Tukey's test were performed.

Clinical observations

The concerned materials were the four type of materials, silicones (Silicone A after 5 years and Silicone B after 2 years), acrylic soft resin after 3.5 years, Polyorefin after 1.5 years and Polyphosphazene Fluoroelastomer after 1 year were observed respectively.

Results and Discussion

Table 2 and Figs.1 to 5 show the means and standard deviations for each of the properties measured. Those means that were not statistically different from one another (Tukey's procedure for multiple comparisons, $p \leq 0.05$) have been designated the same letter in Table 2 and are joined by a horizontal line in the Figures. Except of these lines, the data were statistically different.

Table 2 : Mean and standard deviation of physical and mechanical properties

Materials	Tensile stress (Mpa)	% Elongation at break	Tensile strength (Mpa)	Tear resistance (Kg/cm^2)	Shore A hardness
MOLTENO	2.8(a)* ± 0.07	892.9(a) ± 87.45	6.8(a) ± 0.58	45.3(a) ± 1.65	69.9(a) ± 2.33
EVATOUCH	2.3(b) ± 0.07	110.2(b) ± 10.52	2.3(b) ± 0.47	5.1(b) ± 1.29	40.7(b, c) ± 1.93
MOLLOSIL	0.4(c) ± 0.05	376.8(c) ± 23.31	3.2(c,d) ± 0.28	8.0(c, d) ± 0.69	11.2(d) ± 0.39
MOLLOP–B	1.0(d) ± 0.06	367.9(c) ± 27.82	3.8(c) ± 0.30	11.9(e, f) ± 1.96	36.4(b, e) ± 0.87
SIMPA	1.0(d) ± 0.10	141.1(b) ± 17.25	1.3(e, f) ± 0.16	6.6(b, c) ± 1.47	30.3(f) ± 0.64
TOKUSO SR	0.9(d) ± 0.07	578.3(d) ± 26.40	1.6(e, f) ± 0.19	6.8(b, c) ± 0.74	33.4(e, f) ± 3.08
KUREPEET	1.8(e) ± 0.13	139.3(b) ± 20.95	2.5(b, d) ± 0.25	8.4(c, d) ± 0.98	31.6(e, f) ± 5.70
NOVUS	3.1(f) ± 0.29	226.8(e) ± 21.64	4.8(g) ± 0.11	10.8(d) ± 0.54	43.7(c) ± 2.59
SUPER SOFT	1.2(d) ± 0.15	324.6(c) ± 12.30	5.1(g) ± 0.43	14.1(f) ± 2.89	33.8(e, f) ± 3.08
SOFTEN	0.8(d) ± 0.09	260.0(e) ± 28.50	1.4(e, f) ± 0.24	6.7(b, c) ± 0.37	37.6(b, e) ± 1.28

* Multiple comparisons using Tukey's procedure. At $p \leq 0.05$, groups means designated by the same letter are not statistically different.

Generally, the materials tested exhibited a wide range of values in the properties measured. However we must assume that, as they are commercially available, their performance as soft lining materials is satisfactory.

All the materials were tested in tension and tensile stress at 100% extension, ultimate tensile strength and elongation at break were determined (Figs.1–3 respectively). The tensile stress results provide a direct comparison between the materials at levels of strain that they may experience in use. This is important especially where the lining material has been used to engage undercuts and the material will be required to deform easily to facilitate insertion and removal of the denture. As shown in Fig.1, with the exception of Mollosil and Evatouch, the silicone and acrylic–based materials gave the same level of stress at almost 1 MPa ($p \leq 0.05$), Mollosil had the lowest at 0.04 MPa and

Novus the highest at 3.1 MPa.

Tensile strength results show a different pattern (Fig.2) with values in 5 different groups ($p \le 0.05$) : 1) Simpa, Soften, Tokuso SR, 2) Evatouch, Kurepeet, 3) Mollosil, Molloplast B, 4) Novus, Supersoft, 5) Molteno. The range is 1.3 MPa for Soften to 6.8 MPa for Molteno and there appeared to be no correlation with material type. There is a different pattern again with elongation at (Fig.3) and again there appears to be no correlation with material type. Values vary from 110.2% for Evatouch to 892.9% for Molteno. Energy to break is the area under the stress/strain curve so is influenced by tensile strength and elongation, as such Molteno will have by far the highest as it has the highest value for both parameters. The importance of considering both parameters is shown by looking at the results for Simpa, Tokuso and Soften, they have similar tensile strength values but their elongation to break values are very different (141.1, 578.3 and 260% respectively), giving Tokuso the highest energy to break.

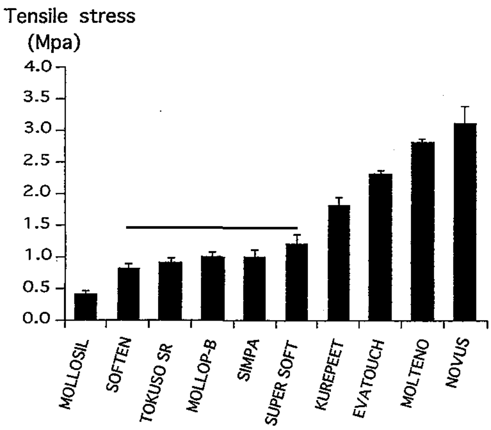

Fig.1 : Tensile stress values. Connecting bars indicate no significant difference ($p \le 0.05$) with use of analysis of variance (ANOVA) with Tukey's procedure.

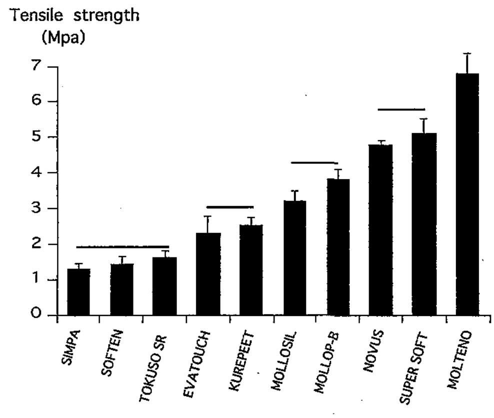

Fig.2 : Tensile strength values. Connecting bars indicate no significant difference ($p \le 0.05$) with use of ANOVA with Tukey's procedure.

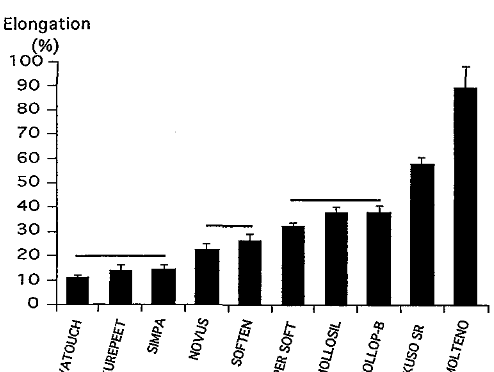

Fig.3 : Elongation values. Connecting bars indicate no significant difference ($p \le 0.05$) with use of ANOVA with Tuley's procedure.

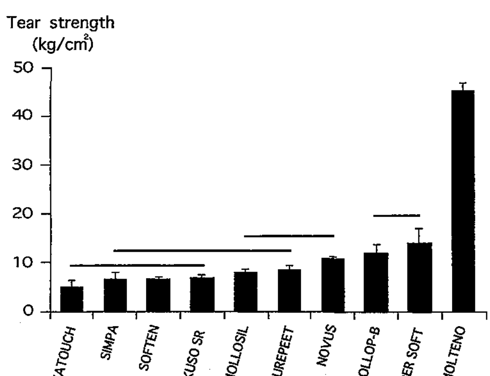

Fig.4 : Tear strength (kg/cm^2). Connecting bars indicate no significant difference ($p \le 0.05$) with use of ANOVA with Tuley's procedure.

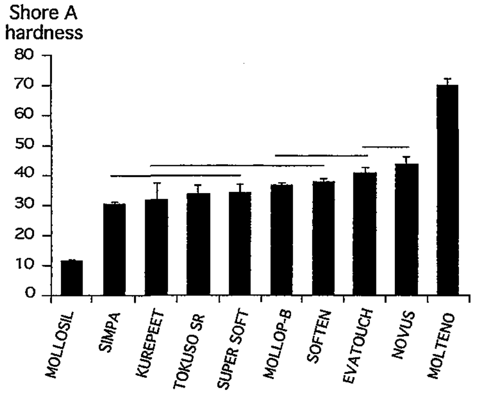

Fig.5 : Hardness values. Connecting bars indicate no significant difference ($p \leq 0.05$) with use of ANOVA with Tukey's procedure.

Assessment of tear characteristics (Fig.4) is important in that they are more commonly the forces that a soft lining will experience in use. Molteno proved to have by far the highest tear strength at 45.3 kg/cm, a factor of 9 higher than the lowest, 5.1 kg/cm for Evatouch. With the exception of Molloplast B, the silicone-based materials had similar tear strength, lower than that of the other types of material. Poor tear property is a common problem with silicone-based materials[7-9]. Likewise there was no significant difference ($p \leq 0.05$) in the values for the two fluorine-containing materials. However, the two acrylic-based materials differ widely with Supersoft having a tear strength more than twice that of Soften.

Soft lining materials are required to have sufficient compliance to provide adequate cushioning of the mucosa. Shore 'A' hardness is one of the indentation methods commonly used as a measure of compliance of soft lining materials[8,9]. With the exception of Molteno (the highest at 69.9) and Mollosil (the lowest at 11.2) the materials all have similar hardness values in the range 30.3 for Simpa to 43.7 for Novus. There was no obvious relationship with type of material within that grouping.

There have been several other studies comparing the various properties of soft lining materials,[7-20] however comparison of results is difficult where testing methods differ. Specimen size speed of testing etc. can have a significant affect on properties and even the ranking order may be different. A study by Dootz et al[9] compared the physical properties of 11 different commercial soft lining materials using the same ASTM test for tensile, tear (although specimen size was modified) and hardness as this study. Of the materials tested Molloplast B, Novus and Supersoft were common to this study and Table 3 compares the results. In most cases the results given from the Dootz et al[9] study are estimations from the figures in their paper. Tensile strength and elongation to break were similar for Molloplast B and Novus but this study found a higher tensile strength (almost double) for Supersoft. Tear resistance was also higher in this study, double for Molloplast B and Supersoft. In this case, although the test method was the same, Dootz et al[9] used a modified tear test die C for the specimens which could help explain the difference in results. Shore 'A' hardness results were slightly lower for Molloplast B and Novus but less than half for Supersoft. This difference in hardness values for Supersoft is a little puzzling. There is a difference in specimen thickness between the two studies but that used by Dootz et al was 10 mm, compared to 6 mm, which should result in a higher result in the present study. The only suggestion is that Supersoft has been reformulated in recent years resulting

Table 3 : Comparison of results from Dootz et al[9] (1) with the present study (2)

	Molloplast B		Novus		Supersoft	
	(1)	(2)	(1)	(2)	(1)	(2)
Tensile strength (Mpa)	4.2	3.8	3.6	4.8	2.6	5.1
% Elongation at break	325	367	240	227	230	260
Tear resistance (kg/cm^2)	5.5	11.9	8	10.8	7	14.1
Shore A hardness	43	36.4	50	43.7	80	33.8

in a higher modulus material[21] and the material used in this was used in the Dootz et al[9] study. This would also help explain their higher tensile strength and lower elongation to break values.

Although there is considerable variability in the physical/mechanical properties of the materials tested there are some conclusions to be made. Hardness is perhaps the most clinically relevant property determined in this study with most of the materials having values in the range 30 to 40. Whereas materials with lower values would be acceptable, in fact preferable in some situations, those with higher values may well not be sufficiently compliant to adequately cushion the mucosa. So although Molteno proved to have the highest values in all except tensile stress however it is felt that it is too hard to provide sufficient cushioning for the mucosa.

In the second part of this study, the applied soft lining materials for removable acrylic resin dentures were observed. Figs.6 to 10 show the clinical observations. Severe colour change and/or deterioration of materials showed, it thought depend on bacterial influences are observed in these materials. These are room temperature vulcanized (RTV) silicones. Also these room temperature vulcanized silicones are available for heat vulcanizing. In these cases, both are made with room temperature. The colour change of the Silicone A is smaller than Silicone B and some abrasions are observed as shown in Fig.6. The flexibilities of Silicone A soft lining materials are harder than 5 years ago by

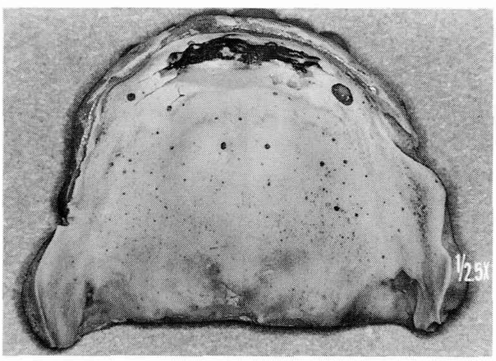

Fig.6 : after 5years (Silicone A)

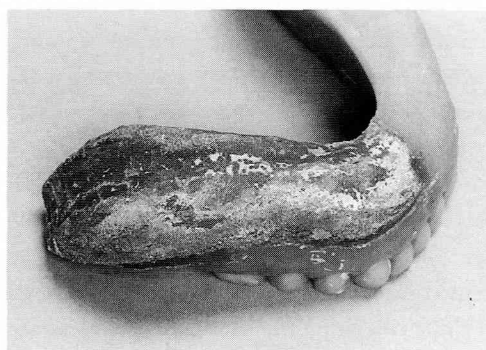

Fig.7 : after 2years (Silicone B)

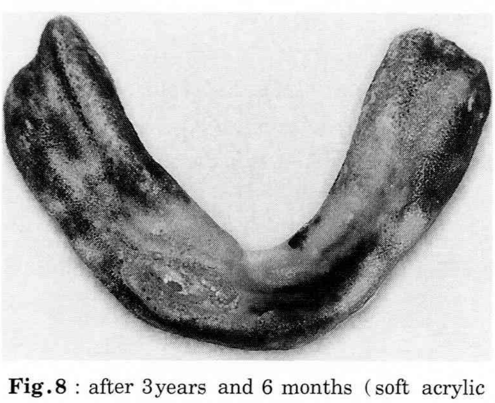

Fig.8 : after 3years and 6 months (soft acrylic resin)

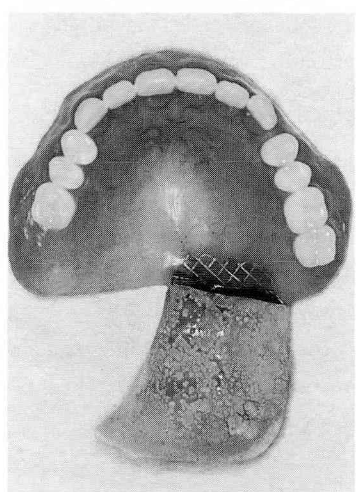

Fig.9 : after 1year and 6months (Polyorefin)

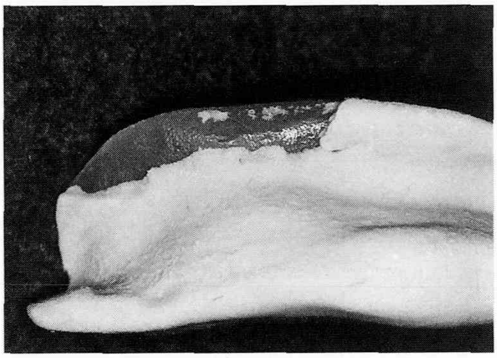

Fig.10 : after 1year (Polyphosphazene Fluoroelastomer)

judgment of finger pressure. In comparison with the physical and mechanical properties of RTV and HTV silicone materials, the HTV silicone is better than RTV silicone[11]. However, the application for acrylic resin dentures with RTV silicone is easier handling than HTV silicone because of their chair time. Fig.8 shows soft acrylic resin for mandibular complete denture and the deteriorations have been occurred. Fig.9 shows speech aid attached to the maxillary complete denture made from Polyorefin soft lining materials after one year and half. The rough of surface, colour changes and the deteriorations were observed. The peeling off of the soft lining materials from acrylic resin were also observed in Polyphosphazene Fluoroelastomer (Fig.10). This case is used for mandibular complete denture after one year. Even this material contain the acrylic component[12] and an expecting the chemical bonding, the result was as Fig.10.

It was considered that the all observed materials influenced by bacteria and patient's handling and storage method at their home are important. From a point of clinical view, the materials have to have resistance to peel off from acrylic resin and need to have antibacterial effect. And also, the education for the patient how to handling their soft lining materials in their home is important.

It might be provided clinicians with useful data when selecting the soft liner, especially Shore A hardness value (Table 2, Fig.5) depend on patient who have weak residual ridge. When the patient have a weak and soft alveolar ridge in his and/or her, it is better to choose a softer material than a hard material like Molteno. However, there are many points which are uncertain between the patient's oral condition and the physical and mechanical properties of soft liners.

While it is acknowledged that the success or failure of a soft denture liner also dependant other factors (e.g. creep compliance[14-16], dynamic modulus and resilience[18], bond strength to acrylic[22-26], water sorption[27-30], stain resistance[31-33], and a propensity for fungal/microbial accumulation and growth[34-36], the properties measured in this study provide an initial screening to ensure that the materials are sufficiently compliant and mechanically robust to function.

Conclusions

1. There is considerable variability in the physical and mechanical properties of the soft denture liners examined in this study.
2. With the exception of tear strength there appeared to be no correlation between material type and property.
3. With the exception of Molteno and Mollosil, the hardness values were in a similar range.
4. It was appeared that the colour change and the deterioration of clinical examined materials were occurred.

Acknowledgement

The author appreciates the support of the research by Ministry of Education, Culture, Sports, Science and Technology grant No.05671642.

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抄録：市販軟質裏装材10種類の物理・機械的性質と臨床的観察

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軟質義歯裏装材を臨床に応用するに際して，その選択の一つの目安として物理・機械的数値を得る目的で，市販されている10種類の義歯床用軟質裏装材（シリコーン系５種類，アクリル系２種類，フッ素樹脂系１種類，ポリフォスファザン系１種類，ポリオレフィン系１種類）を用いて，各種の物理・機械的試験を行い，比較検討を行った．また，実際臨床に応用した軟質義歯裏装材の内，シリコーン系（２種類），アクリル系（１種類），ポリフォスファザン系（１種類）について，１年から３年の経過観察を行った．物理・機械的試験では各項目共通して，ジンパ（シリコーン系）の値が低く，モルテノ（ポリオレフィン系）が大きな値を示した．これらのデータは，患者の顎堤粘膜の状態によって，材料を選ぶ際に参考になると考えられる．しかし，物理・機械的性質によってのみ選択基準にすることは異論のあるところでもあり，今後のさらなる研究が必要である．経過観察では，いずれの材料も，変色，レジン義歯床からの剥離，表面の粗造化が見られ，口腔内細菌の影響が強く作用しているものと考えられ，また患者自身の清掃・取り扱い方が重要であることが示唆された．