Silicone Rubber Development for Medical Model Production

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ABSTRACT

The silicone rubber casting material is intended for use as a medical model. Muscle skin and fat which mimic the actual amount of the research done by the chemical stability of selected components and many samples of silicone that are generally sold are adapted and defined by four formulas. Each was subdivided into 10 samples. 5 samples were cast thick and the other 5 were cast thin. Altogether 40 samples were used to measure the stability. At day 1, day 5, day 28, and at 180 days throughout the study were noted, and data collected to measure the degree of a semicircle of wood with vernier calipers and measure the elasticity respectively after 5 days and 180 days with a skin cutometer MPA 580. Comparative analysis of the formula was formulated by program SPSS Data Editor.

The results showed that the silicone rubber formula 3 was the most stable formula. At day 180, it had changed into Fixed Stable state by 12.5%, elasticity by 2.7%, and stability was unchanged. In conclusion, the samples of Formula 3 silicone possess three qualifications, stability, steadiness and elasticity, and was suitable to be used as a casting material for our model which was the most practical purpose.

Keywords: Silicone rubber for medical model, mould making

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INTRODUCTION

The Medical Model Production Unit functions to producing medical models which are to be a part of medical personnel education and exhibitions in medical museums.

So far, the Medical Model Production Unit had encountered a lack of materials in the production, especially the simulation of organs such as skin[7], muscles, and fats, which had to be flexible and able to display realistic conditions. By using a common material, rubber,[11] which is easy to come by, affordable, and convenient in production, the result was still unsatisfactory. Industrial model[5] products are commonly made by Thermo Plastic, for instance, Poly Vinyl Chloride (PVC),[5,9] which is able to provide the flexibility and tenderness. However, using the material is costly for the process needs other machines in order to push the plastic into the block.[9] The researchers have attempted to modify and adapt the RTV-2 silicone rubber,[10] a thermo setting[3,9] plastic for mould making[1,6,10] which is commonly available, to make the casting,[9,10] although, there were several limitations. Some common stabilizers[2] were later, used and adjusted in order to generate properly tender and flexible model which best simulates levels of muscles, skins,[7] and fats. The result has been a new satisfactory material for medical model production.

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MATERIALS AND METHODS

Research Methods
Samples creation and Classification

The researcher designed and classified the silicone sample into 4 formulas with 8 types of raw materials as follows: silicone oil, body wash, 5% vinegar, guar gum, thinner, sodium tripolyphosphate [STPP], silicone rubber elastosil M4503 and catalysts T40, with different compositions in each formula.

Method: The silicone sample was modelled into a rectangular shape with two sizes. Firstly, in thick size with dimension of 5x10x5 cm. [width x length x height] and one acute angle. The number from 1 to 21 was assigned to each angle. For formulas, there were 20 samples [5 samples for each formula and there were 4 formulas]. This thick size was for rigidity and stability in measurement. Second;y, in thin size with dimension of 5x10x1 cm. [width x length x height]. This thin size was for elasticity measurement. There were 20 samples [5 samples for each formula and there were 4 formulas].

Measurement

Assign 4 formulas and codes for each of 40 silicone samples. To evaluate these silicone samples, the researcher measured in 3 aspects as follows: rigidity, stability and elasticity. To measure rigidity, assign number on each angle of the silicone sample by starting from 1 to 21 [there were 21 angles] after 1, 5, 28 and 180 days. To measure stability, measurements along X, Y and Z axes were made on the silicone samples after 1, 5, 28 and 180 days. To measure elasticity, measurement was after 5 and 180 days.

Since the research has been conducted in order to create a medical model, the silicone rubber would have to be more flexible than common rubbers. To make them most similar to human skin, levels of muscle, with realistic feeling were created, so the flexibility evaluation of the silicone rubber was the same as the one for human skin.

Formerly, the skin flexibility evaluation in medical research was a subjective evaluation which was highly unstable. Therefore, an 'in vitro test' which was an objective parameter has since been conducted. The subject was cut out of the model patient in order to make the evaluation; tensile strength (load/area), elasticity (end portion of stress-strain curve), strain (extension before rupture). This method, nevertheless, was not widely used as it required expertise, complicated techniques, and most of all, the method created wounds. Also, the 'in vitro test' could only be tested 1 time, since the skin membrane would be destroyed in the first evaluation.[4,8]

Thus, during the past 20 years, the 'in vitro test' has been developed to be more comfortable and create neither wound nor pain. The method is presently widely used.

The 'Cutometer MPA 580 (Courage & Khazaka, Koln, Germany)' is a tool which is able to portray functional data and kinetic transformation of mechanical property of the whole. Nowadays, the equipment has taken part in various clinical skin researches: skin flexibility evaluation in skin diseases, and efficiency evaluation of skin flexibility recovery by various method of treatments, for instance. In conclusion, the equipment uses negative pressure in a vacuum chamber to suck the skin in order to create skin deformity. LED and photoreceptor cells are then used to measure the skin deformity. After being digitally displayed in the Cutometer, the result is transmitted to the computer in order to generate graphic results. The evaluated parameters were varied (R0-R9) which demonstrated various characteristics of skin; stretch capacity (R0, R3, R6), skin return (R1, R4, R7), fatigue (R9), and skin elasticity (R2, R5, R8). The important result which has often been used in skin elasticity or skin flexibility is R2 (gross elasticity). The result is around 1 (100%) displayed high skin flexibility. According to the research, the R2 result from the Silicone rubber subject using various methods and times were compared with each other and with the R2 result of humans in various positions, as formerly evaluated,[8] in order to find a formula which creates highly flexible silicone rubber for medical model production.

Evaluating equipment

Several pieces of equipment employed for measurement by research employers are vernier calipers to evaluate stability, semicircular protractor to evaluate rigidity, and skin cutometer MPA 580 evaluate elasticity. The data from these three types of measurement were record in Microsoft Excel and the SPSS Data Processing was employed for evaluation.

RESULTS

After the test with each formula entered in the stability average chart, it could be concluded that the evaluation of formula 3 on day 5 decreased 4.9 % in change and the stability was stable on day 28. On day 180, the figure changed 12.5 %. In conclusion, formula 3 was the best when compared to formulas 1, 2, and 4.

After the test with each formula in the rigidity average chart (average of 21 angles), it could be concluded that formula 1, 2, and 3 are definitely rigid.

After the test with each formula in the gross elasticity (R2) chart, it could be concluded that formula 3 of the evaluation on day 5 was the closet to 1 (100%) at 0.98 %. On day 180, the result was 0.96% which was merely slightly different from that on day 5 at 2.7%. Therefore, formula 3 is the best elastic silicone rubber sample.

DISCUSSION

All four formulas of silicone were compared amongst each other and their rigidity, stability, and elasticity measured. From the table with the mean values of all measurements, it was found that the rigidity of Formula 3 silicone changed only 4.9% when measured on day 5 and there was no further change after that. For Formulas 1, 2, and 4, there was a 12.5% change in their rigidity after day 180. In terms of stability, the obtained data remained constant for Formulas 1, 2, and 3. In addition to those data, the mean value of elasticity of Formula 4 silicone as measured by Cutometer MPA 580 (a graphic digital device displaying the results according to the measured R2 gross elasticity) was 0.96 after 180 days. The mean elasticity for Formula 1, Formula 2, and Formula 4 silicones were 0.92, 0.88, and 0.30, respectively. Based on the data measured in vitro

TABLE 1. The average of volume (stability) of the sample models.

	Mean±SD , cm^3				
	Formula 1 (N=5)	**Formula 2 (N=5)**	**Formula 3 (N=5)**	**Formula 4 (N=5)**	**p-value***
Day 1	247.5±0	247.5±0	247.5±0	247.5±0	
Day 5	245.0±0	247.5±0	235.3±0 [a, b, c]	218.8±3.3	<0.001
Day 28	235.3±0	235.3±0	235.3±0 [c]	193.7±4.7	<0.001
Day 180	209.9±3.2	209.9±0	216.6±0 [a, b, c]	186.2±4.2	<0.001
% decrease Day 5	-1.0±0	.0±0	-4.9±0 [a, b, c]	-11.6±1.3	<0.001
% decrease Day 28	-4.9±0	-4.9±0	-4.9±0 [c]	-21.7±1.9	<0.001
% decrease Day 180	-15.2±1.3	-15.2±0	-12.5±0 [a, b, c]	-24.8±1.7	<0.001

*Significant difference by Kruskal-Wallis Test

[a]Significant difference from Formula 1, [b]Significant difference from Formula 2, [c]Significant difference from Formula 4 by Mann-Whitney Test : p =0.008

TABLE 2. The average of angles (rigidity) of the sample models.

	Mean±SD, Degree				
	Formula 1 (N=5)	**Formula 2 (N=5)**	**Formula 3 (N=5)**	**Formula 4 (N=5)**	**p-value***
Day 1	90±0	90±0	90±0	89.9±0.1	0.211
Day 5	90±0	90±0	90±0	89.7±0.2 [a, b, c]	<0.001
Day 28	90±0	90±0	90±0	87.2±0.5 [a, b, c]	<0.001
Day 180	90±0	90±0	90±0	86.1±0.7 [a, b, c]	<0.001

*Significant difference by Kruskal-Wallis Test

[a]Significant difference from Formula 1, [b]Significant difference from Formula 2, [c]Significant difference from Formula 3 by Mann-Whitney Test : p =0.008

TABLE 3. The average of elasticity of the sample models.

	Mean±SD, %				p-value*
	Formula 1 (N=5)	Formula 2 (N=5)	Formula 3 (N=5)	Formula 4 (N=5)	
Gross elasticity (R2)					
Day 5	0.97±0.01	0.95±0.03	0.98±0.01	0.57±0.31	
Day 180	0.92±0.04	0.88±0.08	0.96±0.01	0.30±0.29	
% change R2 Day 180	-5.9±4.2	-7.9±8.9	-2.7±1.2	-51.1±38.3 [b, c]	
Net elasticity (R5)					
Day 5	1.29± 0.04	1.29±0.15	1.31±0.05	1.76±1.17	
Day 180	1.47±0.16	1.60±0.22	1.31±0.11	0.10±0.32	
% change R5 Day 180	14.0±9.1	24.6±15.0	-0.2±5.9 [a, b, c, d]	-102.7±29.6 [a,b,c]	<0.001

*Significant difference by Kruskal-Wallis Test

[a]Significant difference from Formula 1 ; p=0.008, [b]Significant difference from Formula 2,

[c]Significant difference from Formula 3, [d]Significant difference from Formula 4 by Mann-Whitney Test : p =0.008

by Cutometer MPA 580, the well-approved device widely used in dermatological research and clinics, it could be concluded that Formula 3 silicone was the most elastic. The measurements made by the device were accepted as more precise than the ones made manually. Thus, the data gathered via Cutometer were conducted by one of the best and most standardized methods available today.[8]

Judging from the data table, Formula 3 silicone had the best average values in terms of rigidity, stability, and elasticity. To make the product that could be incorporated into the making of medical models, the amount of ingredients and the catalyst had to be in the right ratio in order to achieve the likeness of human skin, fat tissues, muscles, and internal organs. The findings indicated that Formula 3 silicone had the suitable elasticity value, the most important trait of silicone made for medical purposes, closest to 100%. However, the researches in the past found that the skin at the forearms of all age groups had R2 (gross elasticity) values of 59-70%.8 Such values were smaller than Formula 3 silicone, but very close to R2 value as measured in Formula 4 silicone on day 5.

For making medical models, it is necessary to use the silicone with high softness and elasticity for their skins which would simulate the feelings of actual human skin from dermis to fat layer and muscles. The similarity was especially beneficial for manikin traditional therapy.

The researchers have used Formula 3 silicone as the substitution for making medical models instead of the old formula and production. The types of model that had been made were two types of breast models, for breastfeeding practice and tumor detection practice, and the hip model for practicing therapeutic massage. As a result, the texture of breast models made from Formula 3 silicone felt elastic and more natural than the

Stability Average, cm^3

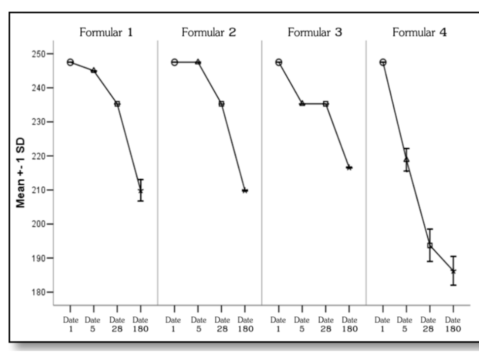

Fig 1. Portrays the average of stability in each formula. (N=5)

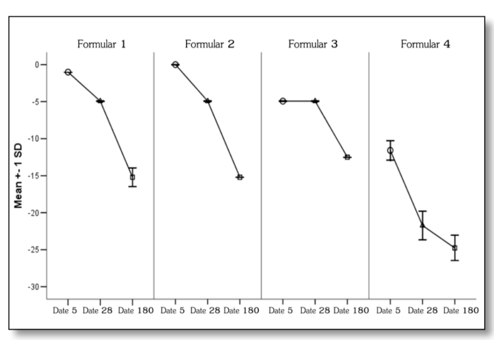

Fig 2. Portrays the average of decreasing stability in each formula. (N=5)

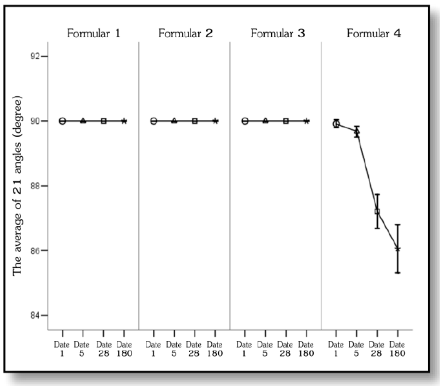

Fig 3. Portrays the average of Rigidity in each formula. (N=5)

Gross elasticity (R2)

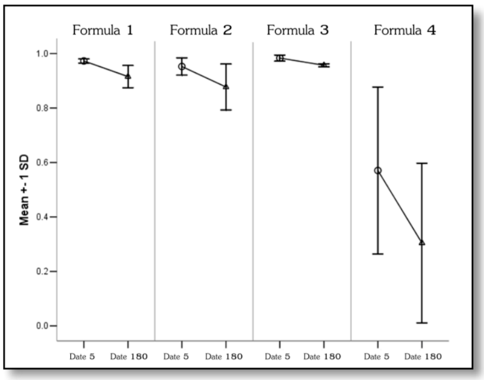

Fig 4. Portrays the average of Gross elasticity (R2) in each formula. (N=5)

Net elasticity (R5)

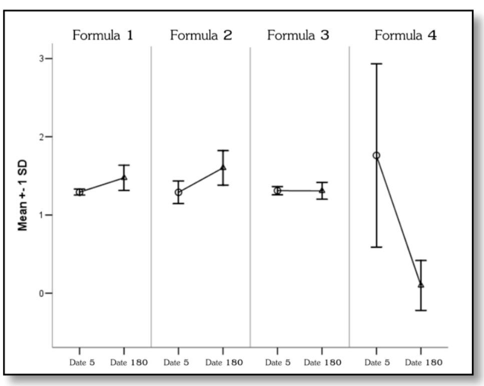

Fig 5. Portrays the average of Net elasticity (R5) in each formula. (N=5)

traditional rubber. Also, the new material simplified the production by making water bag insertion unnecessary due to the softness and elasticity of the compound that simulated the texture of real human flesh. For the models made for practicing therapeutic massage on a specific place, the new type of silicone made the product more flesh-like compared to the older way of embedding springs under the surface to simulate the elasticity of human flesh. However, durability of the product remains the significant problem. The formula needs to be developed further to make the silicone work with different types of applications.

CONCLUSION

The Formula 3 silicone was more superior to the others in terms of rigidity, elasticity, and stability. During the period of 180 days, there was a 12.5% change in rigidity, 2.7% change in elasticity, and no change in stability. Thus, Formula 3 silicone was the most suitable material for molding models bearing similar characteristics to human flesh, muscles, fat layer, and internal organs.

Note: In this research for the present we will use silicone “SiLM” (Siriraj lim model) as the formula 3 silicone.

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