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Pre-Stretching of Elastic Modules

Robert Leroy McClurg
Loyola University Chicago

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PRE-STRETCHING OF ELASTIC MODULES

By

Robert L. McClurg, B.S., D.D.S.

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VITA

Robert Leroy McClurg was born on March 28, 1950 in Delta, Colorado.

He received a Bachelor of Arts degree with a major in Biology from the California State University at Chico in 1972.

He began his dental studies at Loyola University School of Dentistry in Chicago and graduated in 1976 with the degree of Doctor of Dental Surgery.

In September of 1976 he began graduate studies in the Department of Oral Biology at Loyola University of Chicago. Specialty training was begun in the Department of Orthodontics under the Director of Graduate Orthodontics, Doctor Milton L. Braun in 1976.

DEDICATION

To Mother and Father for their many years of guidance, encouragement and support. And to my loving wife, Janine for her devotion and patience.

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CHAPTER I

INTRODUCTION

The purpose of this study is to improve the use of elastic polymers in the practice of orthodontics. Elastic polymers are one of many mechanics and materials used by the orthodontist to close spaces between teeth. The ideal appliance must be easy to manipulate, reasonable in cost, compatible with the oral cavity, esthetic, and produce the necessary force to accomplish the goal of space closure between teeth. The elastic module satisfies the afore mentioned criteria, except the capability of providing a continuous, predictable force over a useful time span.

The Alastik CK force module by Unitek Corporation is one of the most popular elastic polymers used by orthodontists for consolidation or stabilization of space between teeth. In treating an orthodontic case where the first premolar is extracted, the Alastik CK chain is stretched from the canine to the molar on the same side and left there for the duration of three to four weeks, which is the usual time period between orthodontic appointments.

There is an initial loss of force exhibited by the CK chain. Most of the force loss occurs during the first day (74.21 per cent).[1] After this extreme rate of decay, the forces tend to stabilize more in the remainder of the three week period with an additional loss of 8.2 per cent. For all practical purposes, after the first day there is a reasonably constant force throughout the three week period. To overcome this force lost, Andreasen suggested to have initial forces about four times greater than the forces desired to accomplish tooth movement.[1] Young devised a way to improve the power of the elastic module by stretching the CK chain to a specific length, immediately relaxing it and then using the module in the usual manner.[2]

This experiment involves the technique of stretching the elastic module to a specific length and holding it in this stretched position for one day outside the mouth, and then utilizing it in the usual manner. Hopefully, in doing so, the largest percentage of force loss is done before use and a more continuous, accurage and predictable force can then be utilized for the entire three week period.

CHAPTER II

REVIEW OF LITERATURE

There is not an abundant amount of literature published on elastic polymers as they are used in orthodontics. Various tests of the material have been done to evaluate their usefulness, but the methods, equipment, and environment have varied so much between tests that direct comparisons are impossible.

The elastic polymers are made from polyurethane materials but their exact chemical composition is a proprietory secret. Polyurethane rubber is a generic term given to the elastic polymers which contain the urethane linkage. They can be synthesized by extending a polyether glycol or polyhydrocarbon diol with a diisocyante and joining these together in a urethane linkage.[2]

Synthetic elastic polymers excel in strength and resistance to abrasion when compared to natural rubber. They tend to permanently distort, however, following long periods of time in the mouth and often lost their elastic properties. Clinical observations show that the elastomeric materials have permanently elongated and undergo plastic deformation. This deformation is related to the amount of time as well as the amount of stretch given to the materials. The elastic return curve, or resiliency recovery of the sample, does not necessarily follow the same slope. If the same sample is stretched again, the slope will be slightly different. This effect is the property of plastic deformation. The cross linkings of the molecular units and polymer chains, as well as the extent and time of elongation, are affected by heat and fluids.

A few studies have been conducted on Unitek's Alastik products. Bishara[4] compared Alastiks to latex elastics, investigating the relationship between time and force. They used 90 Alastiks from the "K" group. Standard K1, Heavy K2 and Standard K3 were all tested. They were placed over a metal frame in a stretched length varying from 22 to 40 mm. at 6 mm. intervals. Correx gauges were used at various time periods to measure the force levels. The Alastiks were tested at 37°C. in water. After the first hour the force lost was 45.3 per cent, after the first 24 hour period, 54.7 per cent, after one week, 60.5 per cent, and after a three week period the remaining force was 32.5 per cent of the original force level, with 67.5 per cent of the force lost. The Alastiks were also observed to have undergone plastic deformation.

Andreasen et al.[1] compared Alastik chains to elastics involving intra-arch molar-to-molar forces. The Alastik chains and 5/8 and 3/4 inch surgical bonded latex elastics were stretched for distances ranging from 65 to 105 mm., which were found to be the minimum and maximum distances from the molar of one side to the molar of the other side of the arch. The total time on the test was three weeks. The force was measured at the start, 1 hour, 8 hours, 24 hours, 1 week, 2 weeks, and 3 weeks in order to learn the relative changes occurring throughout the whole time period.

Andreasen et al. did a study to determine different environmental conditions of both materials. It was found that to simulate mouth conditions Alastiks are best tested in water at 37°C. Alastik chains were deformed by approximately 50 per cent of their original length measured at the maximum

105 mm. stretch. A Correx gauge was used to measure the force levels. There was an initial decay of 74.21 per cent the first day. After this extreme rate of decay, the forces tended to stabilize more in the remainder of the three week period. The Alastiks lost an additional 8.2 per cent during the remaining time period after the first day.

Bergman[5] compared elastomeric thread to Unitek's K modules. He found the initial drop in load relaxation to be similar. However, after 24 hours, the load relaxation of the elastomeric thread was projected to be 10 per cent higher and after one week its load relaxation was 12 per cent higher. Bergman stated that if "Duraflex" elastomeric thread was used to give a 100 gram force to a tooth for a three week period, an initial force of 408 grams would be necessary.

Loyola[6] tested CK Clear regular Alastik chain, CK Gray medium Alastik chain, and the Spool Gray Chain. He found that most of the load relaxation in all the Alastik modules occurs within the first 24 hours. Under water at 37^{o}C, the Alastik modules underwent twice as much relaxation as that at room temperature. There was no significant difference in the per cent of load relaxation when the Alastiks were tested at a low or high initial load. There was a significant difference between the CK groups (Clear and Gray) and the Spool Chain in the percentage of load relaxation, being about 69 per cent for the CK groups and 92 per cent for the Spool Chain after three weeks time.

Hershey and Reynolds studied plastic modules taking into consideration simulated tooth movement. A stainless steel framework with edgewise brackets welded on it was constructed so that simulated tooth movement of .25

and .50 mm. per week were studied. Carpo gauges were used to take the measurement of force. Two independent observers were used to measure the force levels. Products by several manufacturers were studied: Unitek's Alastiks, both clear and gray, Power Chain and Links by Ormco Corporation, and Elast-O Chain manufactured by TP Laboratories. The modules were aged in triple distilled water at 37°C. The average force remaining by all modules without tooth movement was 75 per cent at 10 minutes, 64 per cent at one hour, 47 per cent at 24 hours, 40 per cent at 4 weeks, and 42 per cent at the end of six weeks. When tooth movement of .25 mm per week was simulated, approximately one third the initial force was left after four weeks. One-fourth the initial force was found when tooth movement of .50 mm. per week was simulated. It was concluded that as the rate of closure increased, the rate of decay in force also increased. Gray Alastiks were found to be more consistent in the amount of force produced than the clear Alastik. They also found that when the modules were stretched to high and low initial forces that the percentage of force lost was similar. It was not reported if the elastic limit of the modules was exceeded.

Young[2] studied the influence of pre-loading on the stress relaxation of elastic modules. Four module units of Unitek CK and C2 gray were used. The Alastik CK control was initially loaded at 90.7 gms and had an average of 63.4 per cent force remaining after the first hour. The force decayed to 43.6 per cent at the end of the 24th hour. The experimental CK samples pre-stretched to 23 mm. were found to have 67.8 per cent force remaining at the end of the first hour and 54.8 per cent at the end of the 24 hour period. The pre-stretched chains at 23 mm. showed 11.2 per cent less stress relaxation than the unstretched control group.

The second group of CK Alastiks were pre-stretched to 14 mm., and after the first hour had 69.4 per cent force remaining, and at the end of one day had 51 per cent of the original force left. Compared to the control group this represented 7.4 per cent more force remaining at the end of 24 hours. When the two experimental pre-stretched CK groups were compared, it was noted that the 24 mm. group had the best improvement. However, it was concluded that high or low initial forces had no effect on the rate of force decay as long as it was within the elastic limit.

Pre-stretching the C2 chains did not show any difference in the control group. The improvement in force levels in the CK group was probably attributed to the rearrangement of the molecular structures from an unarranged to an arranged pattern, thus increasing the interaction covalent bond reactions.

Wong[3] found in his studies that elastomeric materials should be pre-stretched one third of their length to stress the molecular polymer chain, thus increasing the strength of the material. If the material is overstretched, a slow set will occur but in time it will return to its original state. If the material is repeatedly overstretched to near its breaking point, and remains fixed in its extension, permanent plastic deformation will occur. The extent of resilience and plastic deformation also depends on how fast and how long the material is stretched.

Time and force are the two most important variables in studying elastic modules. Young[2] limited his pre-stretching to as short a time as possible. There is no literature on pre-stretching for a 24 hour period.

From the above it was seen that the best force to test the stress relaxation was not easily decided. In order for the test to be clinically applicable, the literature was reviewed in order to determine the most desirable force needed to retract canines. The ideal force required to retract canines is not known, but several comparisons between heavy and light forces and the rational of the results has been published. The rate of tooth movement and the extent of anchorage loss are the indicators of whether the optimal force is utilized.

"Light" forces have become increasingly popular based on the classic studies done by Storey and Smith, and Reitan.[8] It is generally thought that light forces are somewhat more efficient and somehow more biologically acceptable, and less painful. Hixon[9] reported that there is so great a variation in individual response that there is doubt of the differential concept of forces. However, he found that in canine retraction the higher the forces the more efficient.

Boester and Johnston[10] compared forces used in canine retraction to see if there was a difference between light and heavy forces. He utilized .016 x .016 Rickets sectional retraction springs to retract upper and lower canines. Ten patients in all were tested. A force of two ounces, as recommended by Paulson,[11] Reitan,[8] and Stoner,[12] was used in one test. In another test, eleven ounces was used as recommended by Storey and Smith.

The results of the study by Boester and Johnston suggested that the two ounce force-level produced significantly less movement than did five, eight, and eleven ounces. Relative anchorage loss was independent of the forces employed and there was no significant difference in tooth discomfort between any of the forces.

There is still a lot of controversy on the optimal force used in canine retraction. When deciding upon the force to use, orthodontists must consider the variation in root size, the age of the patient, the biologic response, the difference between bodily and tipping movement, the difference between intermittent and continuous forces, and the various densities in bone structure.

CHAPTER III

METHODS AND MATERIALS

Unitek Corporation's CK Alastiks were used throughout the experiment (catalog number 406 036). The CK chain features no intermodular link between rings. This design provides flexibility in use by skipping rings when required by bracket spacing. It is then pre-cut for application to a specific segment of the arch. Each chain was randomly selected from the same shipment of sealed plastic packages. The chains come in two colors, clear and gray. Gray Alastiks were selected over clear because they are more consistent in the amount of force produced when a given module is stretched a given distance.[7] The chain was cut into segments consisting of four rings at random. Ideally, this length should apply approximately 90 grams of force when used to retract canines. When a chain is used on the buccal side of the tooth and another chain is used on the lingual side, a total of 180 grams should be applied to the canine.

The modules were pre-stretched at room temperature in a dry environment. A plexiglass frame was constructed with round metal rods having a diameter of .015 inches (Figure 1). This diameter was selected as it is slightly smaller than the inside diameter of the rings and would not cause distortion of the modules, yet provided a smooth regular surface. Several sets of rods were placed on the framework to allow more than one module to be stretched at the same time.

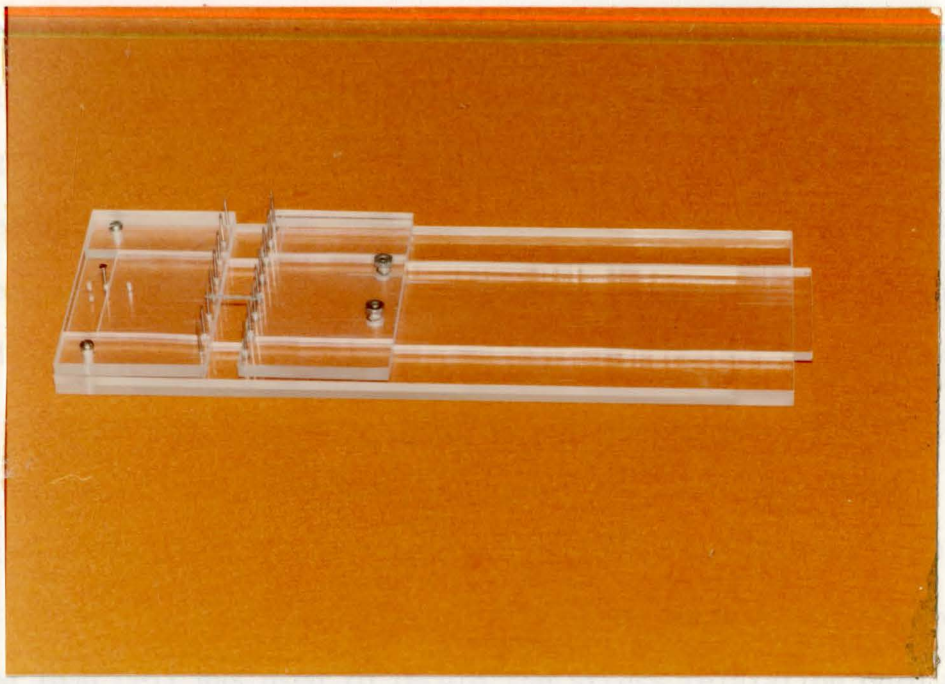

Figure 1. Pre-Stretching Framework.

The framework was constructed, so that the modules could be stretched in the linear direction. The two variable distances that the modules were pre-stretched to were 20 mm. and 30 mm. The CK module with four rings has a length of 10 mm. when lying flat and relaxed. When stretched to 20 mm., the length of the chain was increased 100% of its original length (Figure 2). At 30 mm., it was increased 200% more than the original length. Previous research showed that when modules were pre-stretched briefly to 23 mm. there was an increase in the force remaining at the end of 24 hours when compared to those pre-stretched to 14 mm.[2] This led to the decision of using the longer distances to pre-stretch the modules. It was hoped that by stretching to the longer length of 30 mm., the rearrangement of molecules would occur in a favorable manner.

The Instron Universal Testing Instrument, table model 1130, was used to record the stress relaxation of the Alastik modules (Figure 3). A ten pound load cell was used to record the stress relaxation onto a chart that had a speed of two inches per minute (Figure 4). The gears selected for this were 26 EX and 26 EY. A Cole Parmer interval timer, model 8606, was used to control the readout of the Instron. Every 15 minutes, the timer would have the Instron record data for a period of 1.5 minutes. This cycle was repeated throughout the 24 hour time period that all samples were tested on the Instron.

The CK chains were placed in a water bath of de-ionized water at 37 degrees Centigrade, while being tested with the Instron machine for 24 hours (Figure 5). The environment of the water bath was controlled to obtain a minimum of fluctuation in water temperature. An external temperature

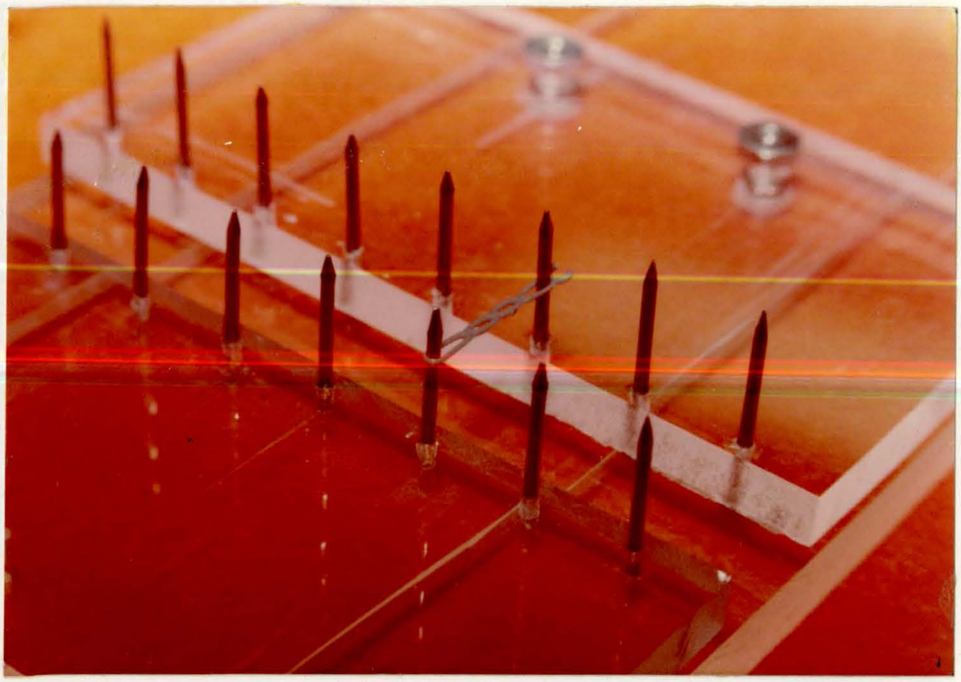

Figure 2. Pre-Stretching Alastik CK Chain.

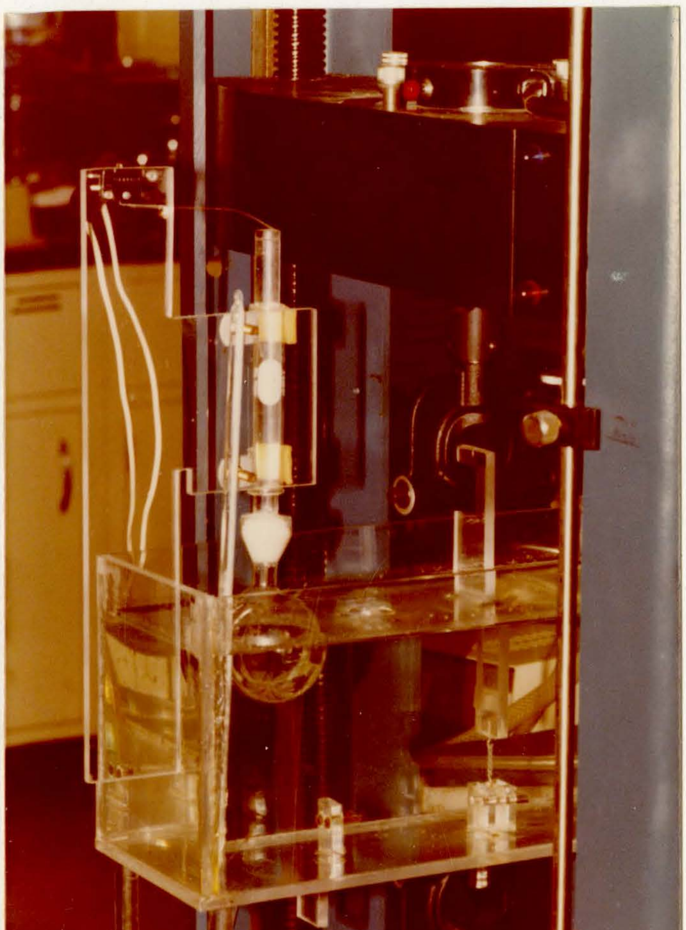

Figure 3.

Water Bath

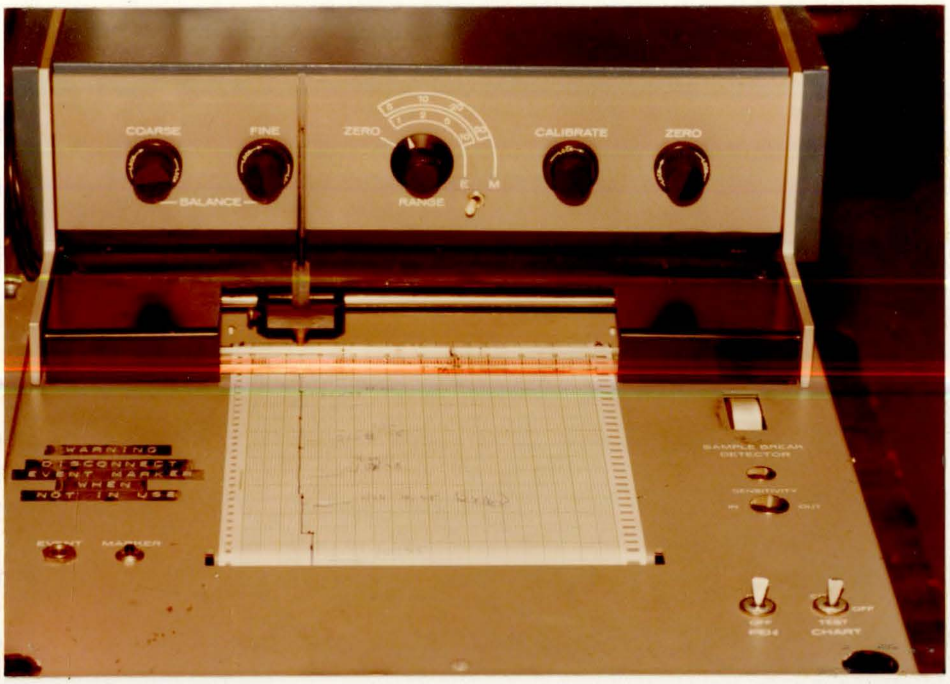

Figure 4. Chart Recording Readout of Instron

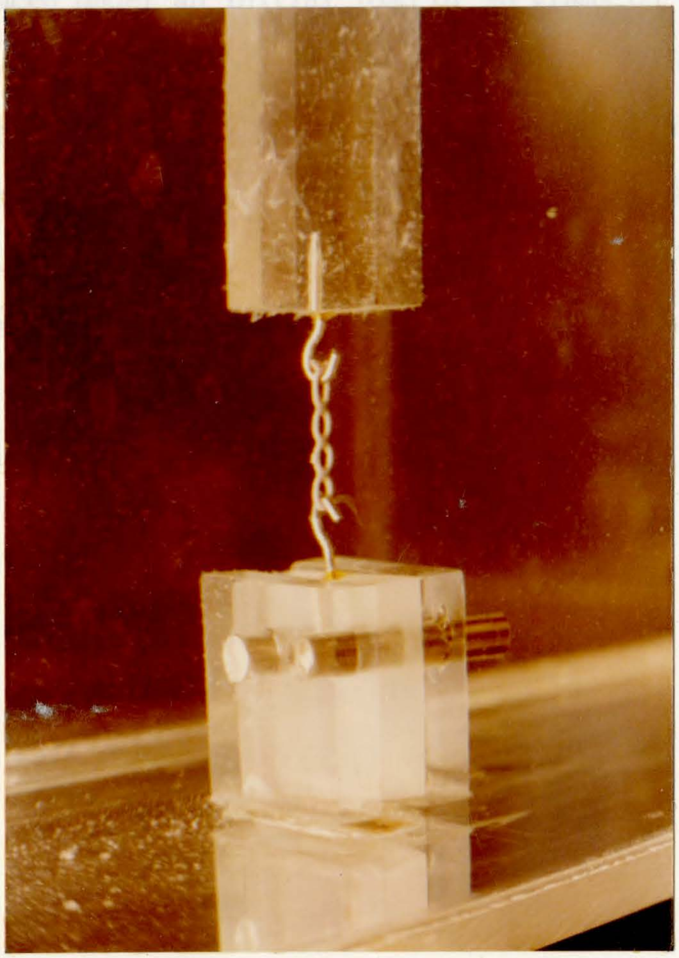

Figure 5.

Alastik CK Chain

controlled water bath provided water via a pump to accomplish this. The water level in the testing tank was controlled by a micro-switch activated by a float.

The experiment was comprised of one control group and four different experimental groups. Five samples of CK chains were utilized for each group. All modules were randomly cut into chains composed of four rings before testing began. The control group did not undergo any pre-stretching. All other groups were pre-stretched for 24 hours. In experiment A, the modules were pre-stretched to a length of 20 mm., and held there for 24 hours. After pre-stretching, group A was relaxed for five minutes before being placed under an initial load of 90 grams on the Instron machine. Group B was pre-stretched to 20 mm., and relaxed for a period of 30 minutes before being placed on the Instron with 90 grams of initial load. Experiments C and D were pre-stretched to a length of 30 mm. and held there for 24 hours. Group C was then relaxed for 5 minutes before being placed under an initial load on the Instron of 90 grams. Group D was pre-stretched for 24 hours and relaxed for 30 minutes before having 90 grams initial load placed on it with the Instron machine.

CHAPTER IV

RESULTS

With an initial force of 90.7 grams, the Alastik CK control modules lost an average of 37.4 per cent of its original force after one hour, leaving 63.6 per cent (Table 1). The remaining force at the end of 6 hours was an average of 48.8 per cent and it continued to lose force through the 24th hour at which time it had an average of 43.0 per cent of the original force. The greatest loss observed occured during the first hour, with much less occuring throughout the experiment.

In experiment A, the modules were pre-stretched 20 mm., and then relaxed for five minutes before subjected to an initial load of 90.7 grams for a 24 hour period. The stress relaxation observed in the control was also seen, but to a much smaller extent. At the end of one hour, the remaining force was 88.0 per cent of the original force (Table II). The force remaining at the end of six hours was 81.0 per cent of the original showing much less loss of force between the first hour and the sixth hour than the control did. The control lost 14.8 per cent of the original force between this time period, and Experiment A had an average loss of only 6.2 per cent. Experiment A had an average force remaining at the end of 24 hours of 74 per cent of the original. This was very significant since there was 31 per cent more force remaining at the end of one day compared to the control modules which averaged 43 per cent.

This data was evaluated with a t test to see what the statistical difference was between the control group and the experimental group A.

TABLE I.

PERCENTAGE OF FORCE REMAINING FOR ALASTIK CK CONTROL

(NO PRE-STRETCH)

SAMPLE	PERCENTAGE OF INITIAL FORCE REMAINING				
	TIME - HOURS				
	1	6	12	18	24
I	62	48	44	40	46
II	63	48	43	40	40
III	65	50	46	42	41
IV	67	52	50	44	45
V	61	46	42	42	43
AVERAGE	63.6	48.8	45.0	41.6	43.0
± STANDARD DEVIATION	2.41	2.28	3.16	1.67	2.55

TABLE II.

PERCENTAGE OF FORCE REMAINING FOR ALASTIK CK EXPERIMENT A

(PRE-STRETCHED 20MM - RELAXED 5 MINUTES)

SAMPLE	PERCENTAGE OF INITIAL FORCE REMAINING				
	TIME - HOURS				
	1	6	12	18	24
I	86	76	74	69	71
II	88	84	75	72	73
III	87	80	75	75	73
IV	85	78	74	71	69
V	94	91	85	84	84
AVERAGE	88.	81.	76.6	74.2	74.0
± STANDARD DEVIATION	3.54	5.93	4.72	5.89	5.83

The t value at the 99 per cent confidence level to be statistically significant must be above 3.36. The value of t in this test was 12.75, thus showing a very high statistical difference between the control and experiment A (Table III).

The third group of modules tested, experiment B, was pre-stretched for 24 hours at 20 mm. and then relaxed for 30 minutes. The average force remaining after one hour was 85 per cent (Table IV). This showed almost as much force remaining at one hour as experiment A (88 per cent), and 63.6 per cent compared to the control. The t test between the control and experiment B for the loss in the first hour showed it to be very significant at the 99 per cent confidence level with a value of 11.50 (Table V). After the 24th hour, experiment B had 73.8 per cent of the original 90.8 grams load applied to it. This too, was statistically different at the 99 per cent confidence level when compared to the control group. The t test between these groups was 7.19.

The comparison between experiment A and experiment B showed little difference (Table VI). The t test at the first hour showed them to be statistically similar. The t value was 1.37 and to be statistically different at the 95 per cent confidence level it had to be larger than 2.31. Comparing the remaining force between experiment A and experiment B after 24 hours, there was no statistical difference at the 95 per cent confidence level with a t value of only .04.

The value of t is seen to have an inverse relationship with time in comparing experiments A and B. After one hour t is 1.36 but it drops to

TABLE III.

t Test of Means Between Control and Experiment A

	HOUR	N	MEAN (% FORCE REMAINING)	STANDARD DEVIATION	T-VALUE	DEGREE OF FREEDOM	SIGNIFICANT DIFFERENCE P=.05/P=.01
CK CONTROL	1	5	63.6	2.41	12.75	8	YES YES
EXPERIMENT A			88.0	3.54			
CK CONTROL	6	5	48.8	2.28	11.61	8	YES YES
EXPERIMENT A			81.8	5.93			
CK CONTROL	12	5	45.0	3.16	12.43	8	YES YES
EXPERIMENT A			76.6	4.72			
CK CONTROL	18	5	41.6	1.67	11.90	8	YES YES
EXPERIMENT A			74.2	5.89			
CONTROL A	24	5	43.0	2.55	10.89	8	YES YES
EXPERIMENT A			74.0	5.83			

TABLE IV.

PERCENTAGE OF FORCE REMAINING FOR ALASTIK CK EXPERIMENT B

(PRE-STRETCHED 20MM. - RELAXED 30 MINUTES)

SAMPLE	PERCENTAGE OF INITIAL FORCE REMAINING				
	TIME - HOURS				
	1	6	12	18	24
I	83	70	68	64	61
II	90	90	86	85	85
III	81	75	75	74	75
IV	86	81	77	72	69
V	85	79	75	74	79
AVERAGE	85.0	79.0	76.2	73.8	73.8
$\pm$STANDARD DEVIATION	3.39	7.44	6.46	7.50	9.23

TABLE V.

t Test of Means Between Control and Experiment B

	HOUR	N	MEAN (% FORCE REMAINING AT 24 HOURS)	STANDARD DEVIATION	T-VALUE	DEGREES OF FREEDOM	SIGNIFICANT DIFFERENCE P=.05/P=.01
CK CONTROL EXPERIMENT B	1	5	63.6 85.0	2.41 3.39	11.50	8	YES YES
CK CONTROL EXPERIMENT B	6	5	48.8 79.0	2.28 7.45	8.68	8	YES YES
CK CONTROL EXPERIMENT B	12	5	45.0 76.2	3.16 6.46	9.70	8	YES YES
CK CONTROL EXPERIMENT B	18	5	41.6 73.8	1.67 7.50	9.37	8	YES YES
CK CONTROL EXPERIMENT B	24	5	43.0 73.8	2.55 9.93	7.19	8	YES YES

TABLE VI.

t Test of Means Between Experiment A and Experiment B

	HOURS	N	MEAN (% FORCE REMAINING AT 24 HOURS	STANDARD DEVIATION	T-VALUE	DEGREES OF FREEDOM	SIGNIFICANT DIFFERENCE P=.05/P=.01	
EXPERIMENT A	1	5	88.00	3.54	1.37	8	NO	NO
EXPERIMENT B	1	5	85.00	3.39	1.37	8	NO	NO
EXPERIMENT A	6	5	81.78	5.93	0.66	8	NO	NO
EXPERIMENT B	6	5	79.00	7.45	0.66	8	NO	NO
EXPERIMENT A	12	5	76.60	4.72	0.11	8	NO	NO
EXPERIMENT B	12	5	76.20	8.46	0.11	8	NO	NO
EXPERIMENT A	18	5	74.20	5.90	0.09	8	NO	NO
EXPERIMENT B	18	5	73.80	7.50	0.09	8	NO	NO
EXPERIMENT A	24	5	74.00	5.83	0.04	8	NO	NO
EXPERIMENT B	24	5	73.80	9.23	0.04	8	NO	NO

less than one-half this number at the end of six hours with a value of .66. At the end of twelve hours, the t value between these is .11 and it continues to drop to .09 at the end of 18 hours, and as reported earlier, .04 after the 24th hour.

In experiment C, the modules were pre-stretched 30 mm. for 24 hours and then relaxed 30 minutes. The average force remaining at the end of one hour was 77 per cent (Table VII). The average per cent force remaining at 6, 12, 18 and 24 hours respectively were 71.4, 68.8, 68.2 and 67.2. When compared to the control group, there was a very significant increase in the average force remaining at every six hour interval recorded. The greatest difference was recorded after the first hour with a t test value of 11.50, and the least amount of difference was observed at the end of 24 hours with a t value of 7.17 (Table VIII). The t values were all significantly larger than the 3.36 value required at the 99 per cent level of confidence.

To see if there was a difference between experiment C and experiments A and B, another t test was done for each 6 hour interval. The only significant difference between experiment A and experiment C was after the first hour. The t value was 3.94 making it statistically different at the 99 per cent level (t equals 3.36). Experiment A had a mean force remaining at 99 per cent compared to 77 per cent in experiment C. The t test after the first hour showed no significant difference at the 95 per cent level.

The t test between experiment B and C showed similar results with the average remaining force being significantly greater at the 95 per cent

TABLE VII.

PERCENTAGE OF FORCE REMAINING FOR ALASTIK CK EXPERIMENT C

(PRE-STRETCHED 30MM - RELAXED 30 MINUTES)

SAMPLE	PERCENTAGE OF INITIAL FORCE REMAINING				
	TIME - HOURS				
	1	6	12	18	24
I	73	71	67	69	66
II	69	58	60	58	58
III	78	75	69	70	68
IV	85	80	76	74	73
V	80	73	72	70	71
AVERAGE	77	71.4	68.8	68.2	67.2
±STANDARD DEVIATION	6.20	8.20	5.94	6.02	5.81

TABLE VII.

t Test of Means Between Control and Experiment C

	HOURS	N	MEAN (% FORCE REMAINING AT 24 HOURS)	STANDARD DEVIATION	T-VALUE	DEGREES OF FREEDOM	SIGNIFICANT DIFFERENCE P=.05/P=.01
CONTROL	1	5	63.60	2.41	4.50	8	YES YES
EXPERIMENT C			77.00	6.20			
CONTROL	6	5	48.80	2.28	5.94	8	YES YES
EXPERIMENT C			71.40	8.20			
CONTROL	12	5	46.00	3.16	7.87	8	YES YES
EXPERIMENT C			68.80	5.97			
CONTROL	18	5	41.60	1.67	9.52	8	YES YES
EXPERIMENT C			68.20	6.02			
CONTROL	24	5	43.00	2.55	8.53	8	YES YES
EXPERIMENT C			67.20	5.81			

TABLE VIII.

t Test of Means Between Experiment A and Experiment C

	HOURS	N	MEAN (% FORCE REMAINING AT 24 HOURS)	STANDARD DEVIATION	T-VALUE	DEGREES OF FREEDOM	SIGNIFICANT DIFFERENCE P=.05/P=.01	
EXPERIMENT A	1	5	88.00	3.54	3. 44	8	YES	YES
EXPERIMENT C			77.00	6.20				
EXPERIMENT A	6	5	81.80	5.93	2.30	8	NO	NO
EXPERIMENT C			71.40	8.20				
EXPERIMENT A	12	5	76.60	4.72	2.29	8	NO	NO
EXPERIMENT C			68.80	5.97				
EXPERIMENT A	18	5	74.20	5.89	1.59	8	NO	NO
EXPERIMENT C			68.20	6.02				
EXPERIMENT A	24	5	74.00	5.83	1.85	8	NO	NO
EXPERIMENT C			67.20	5.81				

level only after the first hour. (Table IX).

In experiment D, the modules were pre-stretched for 24 hours at 30 mm. and then relaxed for 5 minutes before a load of 90.7 grams was placed on them. The average force left at the end of one hour was 81.6 per cent of the original force (Table X). This was not as much as experiment A or B had at this time but it was more than experiment C exhibited. It was significantly more than the control at the 99 per cent confidence level with a t value of 7.88 (Table XI). It was not significantly different compared to experiment A at the 99 per cent level of confidence, but it was significantly less at the 95 per cent level (Table XII). The first hour was not significantly different from experiment B or C at the 95 per cent confidence level (Tables XIII, XIV).

The t test at the end of the 24th hour showed that the 72.60 per cent average force remaining in experiment D was significantly more than the control at the 99 per cent confidence level. The t value was 15.47. There was no statistically significant difference at the 95 per cent level between experiment D and experiments A, B and C.

In order to determine the force remaining at the end of the first, second, third and fourth weeks, a regression analysis was calculated on the results of the 24 hour time period. The force predictions were calculated for the control group and all the experimental groups (Table XV). There is a very high linear relationship between the amount of force remaining and the log of time. The coefficient of correlation was -.96 or better in all the tested groups. The high negative correlation coefficient

TABLE IX.

t Test of Means Between Experiment B and Experiment C

	HOURS	N	MEAN (% FORCE REMAINING AT 24 HOURS)	STANDARD DEVIATION	T-VALUE	DEGREES OF FREEDOM	SIGNIFICANT DIFFERENCE P=.05/P=.01
EXPERIMENT B EXPERIMENT C	1	5	85.00 77.00	3.39 6.20	2.53	8	YES NO
EXPERIMENT B EXPERIMENT C	6	5	79.00 71.40	7.45 8.20	1.53	8	NO NO
EXPERIMENT B EXPERIMENT C	12	5	76.20 68.80	6.46 5.97	1.88	8	NO NO
EXPERIMENT B EXPERIMENT C	18	5	73.80 68.20	7.50 6.02	1.30	8	NO NO
EXPERIMENT B EXPERIMENT C	24	5	73.80 67.20	9.23 5.81	1.35	8	NO NO

TABLE X.

PERCENTAGE OF FORCE REMAINING FOR ALASTIK CK EXPERIMENT D

(PRE-STRETCHED 30MM. - RELAXED 5 MINUTES)

SAMPLE	PERCENTAGE OF INITIAL FORCE REMAINING				
	TIME - HOURS				
	1	6	12	18	24
I	77	73	72	71	70
II	80	75	70	69	70
III	80	74	75	71	74
IV	82	74	72	70	71
V	89	84	80	78	78
AVERAGE	81.6	76.0	73.8	71.8	72.6
±STANDARD DEVIATION	4.51	4.53	3.90	3.56	3.44

TABLE XI.

t Test of Means Between Control and Experiment D

	HOURS	N	MEAN (%FORCE REMAINING AT 24 HOURS)	STANDARD DEVIATION	T-VALUE	DEGREES OF FREEDOM	SIGNIFICANT DIFFERENCE P=.05/P=.01
CONTROL	1	5	63.60	2.41	7.88	8	YES YES
EXPERIMENT D			81.60	4.51			
CONTROL	6	5	48.80	2.28	11.99	8	YES YES
EXPERIMENT D			76.00	4.53			
CONTROL	12	5	45.00	3.16	12.83	8	YES YES
EXPERIMENT D			73.80	3.90			
CONTROL	18	5	41.60	1.67	17.15	8	YES YES
EXPERIMENT D			71.80	3.56			
CONTROL	24	5	43.00	2.55	15.47	8	YES YES
EXPERIMENT D			72.60	3.44			

TABLE XII.

t Test of Means Between Experiment A and Experiment B

	HOURS	N	MEAN (%FORCE REMAINING AT 24 HOURS)	STANDARD DEVIATION	T-VALUE	DEGREES OF FREEDOM	SIGNIFICANT DIFFERENCE P=.05/P=.01
EXPERIMENT A EXPERIMENT D	1	5	88.00 81.60	3.54 4.51	2.50	8	YES NO
EXPERIMENT A EXPERIMENT D	6	5	81.80 76.00	5.93 4.53	1.74	8	NO NO
EXPERIMENT A EXPERIMENT D	12	5	76.60 73.80	4.72 3.90	1.02	8	NO NO
EXPERIMENT A EXPERIMENT D	18	5	74.20 71.80	5.89 3.56	0.78	8	NO NO
EXPERIMENT A EXPERIMENT D	24	5	74.00 72.60	5.83 3.43	0.46	8	NO NO

TABLE XIII.

t Test of Means Between Experiment B and Experiment D

	HOURS	N	MEAN (% FORCE REMAINING AT 24 HOURS)	STANDARD DEVIATION	T-VALUE	DEGREES OF FREEDOM	SIGNIFICANT DIFFERENCE P=.05	P=.01
EXPERIMENT B	1	5	85.00	3.49	1.35	8	NO	NO
EXPERIMENT D			81.60	4.51				
EXPERIMENT B	6	5	79.00	7.45	0.77	8	NO	NO
EXPERIMENT D			76.00	4.53				
EXPERIMENT B	12	5	76.20	6.46	0.71	8	NO	NO
EXPERIMENT D			73.80	3.90				
EXPERIMENT B	18	5	73.80	7.50	0.54	8	NO	NO
EXPERIMENT D			71.80	3.56				
EXPERIMENT B	24	5	73.80	9.23	0.27	8	NO	NO
EXPERIMENT D			72.60	3.43				

TABLE XIV.

t Test of Means Between Experiment C and Experiment D

	HOURS	N	MEAN (% FORCE REMAINING AT 24 HOURS)	STANDARD DEVIATION	T-VALUE	DEGREES OF FREEDOM	SIGNIFICANT DIFFERENCE P=.05/P=.01	
EXPERIMENT C	1	5	77.00	6.20	1.34	8	NO	NO
EXPERIMENT D			81.60	4.50				
EXPERIMENT C	6	5	71.40	8.20	1.10	8	NO	NO
EXPERIMENT D			76.00	4.53				
EXPERIMENT C	12	5	68.80	5.97	1.57	8	NO	NO
EXPERIMENT D			73.80	3.90				
EXPERIMENT C	18	5	68.20	6.02	1.15	8	NO	NO
EXPERIMENT D			71.80	3.56				
EXPERIMENT C	24	5	67.20	5.81	1.79	8	NO	NO
EXPERIMENT D			72.60	3.44				

TABLE XV.

STATISTICAL RESULTS AND PREDICTIONS

SAMPLE	STATISTICAL PARAMETERS						FORCE PREDICTIONS-WEEKLY			
	r	r^2	A	B	S.E.E.	F-VALUE	1st	2nd	3rd	4th
CK CONTROL	-0.96	0.95	60.18	-13.81	1.19	419.84	29.43	25.28	22.84	21.12
EXPERIMENT A	-0.98	0.97	89.28	-11.58	0.74	725.36	63.50	60.01	57.97	56.52
EXPERIMENT B	-0.99	0.99	85.69	- 9.04	0.36	1842.60	65.32	62.84	61.25	60.12
EXPERIMENT C	-0.99	0.97	77.15	- 7.53	0.46	812.05	60.39	57.85	56.78	55.86
EXPERIMENT D	-0.98	0.97	81.73	- 7.34	0.49	670.38	65.39	62.91	61.89	60.97

r = correlation coefficient
r^2 = coefficient of determination
A = intercept at Y
B = slope

S.E.E. = standard error of estimate
* Predications are percentage of force remaining

c.c. refers to correlation between force remaining and log of time.

indicates that low and high values of the remaining force are respectively associated with high and low values of the time.[13] The coefficient of determination, r^2, was also very close to 1.0 with values of .95 or higher. In all the tests done, 95 per cent or more of the variation in the dependent variable (percentage of force remaining), can be explained by the independent variable (time).

The standard error of estimate was the highest in the control group at 1.19 which is still very good. This is a measure of the general reliability of the estimates and not a specific measure. It is based on the difference between each reported "y" value and the calculated "y" value from the paired x value using the semi-log regression equation of $Y = A + B \log X$, (Y being remaining force and X being time). A is the intercept point along the Y axis. B is the slope and was negative in the control and all experiments.

To be statistically significant at the 99 per cent level of confidence, the F value had to be greater than 7.9 for the regression coefficient on all the tested groups. The lowest calculated F value of all the groups was the CK control group, and it had a value of 419.84, which is much larger than the critical limit.

CHAPTER V

DISCUSSION

The Alastik CK control module showed the greatest reduction in force of any group tested. (Table 1). The average remaining force at the end of 24 hours was 43.0 per cent of the original 90.7 grams load that was placed on it. This is slightly less than the 43.6 per cent amount reported by Young[2] in previous research. The exact same materials and methods were used in the control group as Young and the similar results places confidence in the testing procedures utilized in both studies.

The greatest force loss occured in the first hour with an average loss of 36.4 per cent. The following 23 hours showed an additional loss of 20.6 per cent. The statistical parameters of the experiment were highly accurate and consistent enough that the force predictions for one, two, three, and four weeks were done utilizing the results from the first 24 hours. A semi-logarithmic equation was derived and with regression analysis the calculations for these time periods were determined. The results of the force predictions showed that 70.57 per cent of the original load could be predicted to be lost at the end of one week. Only 4.15 per cent additional force was predicted to be lost in the following week. This is only 5.88 per cent of what was lost the first week. The third week, 2.44 per cent of the original force was predicted to be lost, and the fourth week, 1.72 per cent additional force was predicted to be lost.

The results that were observed in the control group confirmed the need in the original plans to pre-stretch the Alastik modules for a 24 hour period before placing a load of 90.7 grams on them. The control group lost 57 per cent of their original force during the 24 hour period. The experimental groups attempted to overcome this large force decay which is very undesirable in clinical use.

The results of all the experimental groups showed marked improvement over the control CK group (Tables I - XV). There was only 12.0 per cent average force lost after the first hour in the experimental group A (Table II). This is only 33.0 per cent of the force lost in the control group for the same time period. Since the Alastik CK module is usually placed for a time period of three to four weeks, the force predictions from the regression analysis for the longer time periods is more useful.

The average force remaining in the Experiment A group after one week was 63.59 per cent of the original 90.7 grams. This is 116 per cent more force remaining than the control group with no pre-stretching. The calculated remaining force at two weeks for Experiment A was 60.01 per cent of the original force. Only 3.49 per cent of the original force was lost between the first week and the second week. Another 2.04 per cent was lost between the second and the third week. The force prediction between the third and the fourth week showed only 1.45 per cent more force lost. The force loss is seen to gradually diminish with very little change in the last weeks that the force predictions were calculated for.

The predicted force lost in the control group was 4.15 per cent between the first and second week, 2.44 per cent more between the second and third week, and 1.72 per cent additional loss of force between the third and fourth week. When these amounts are compared to the per cent losses of the experiment A group, it is seen that they are very similar. The largest difference was between the first and second week.

A t test was done to evaluate the statistical significance of the different results between the various groups. The t value between the control group and the Experiment A group after the first hour was 12.75 (Table III). This far exceeded the critical value of t (3.36) at the 99 per cent confidence level. The remaining hours tested showed similar values, going down to 10.89 at the end of 24 hours. This value still represents a large statistical difference between the control group and the Experimental group A. Pre-stretching for a period of 24 hours, as done in Experiment A, had 116 per cent more remaining force at the end of one week than the control group with no pre-stretching. At the end of the fourth week it had 167 per cent more force remaining than the control group.

Experiment A showed that in pre-stretching the Alastik modules, the amount of force remaining was increased significantly. Experiments B, C, and D were done to see if the force remaining could be further improved by variations in the pre-stretching procedures. In Experiment B, the Alastik modules were also pre-stretched 20 mm. for 24 hours, but they were relaxed 30 minutes before having a load of 90.7 grams placed on them. It was thought that the shorter time period between pre-stretching and placement of the modules under the 90.7 gram load would give a better result due to the molecules not having time to reorganize into their original configuration. The t test between Experiment A and Experiment B showed that there was no significant difference between the two groups at the 95 per cent level of confidence (Table IV). The critical value of t at the 95 per cent level is 2.31 and the largest value in this comparison was 1.37, which was after the first hour of loading. The t value continued to get smaller during the remainder of the 24 hour test period, showing that there was less difference between the two groups as time passed. Apparently in both groups the "memory" of the Alastik modules was recovered to about the same extent within 24 hours.

The next variable tested was the length that the module was pre-stretched. In Experiments A and B the modules were pre-stretched to 20 mm. In Experiments C and D the modules were pre-stretched to 30 mm. In Experiment C the modules were allowed to relax 30 minutes before being loaded with the 90.7 grams and in Experiment D, five minutes. Experiment C was significantly different from the control group for all time periods at the 99 per cent level of confidence (Table IV). There was less force remaining in the modules of Experiment C for all time periods as compared to all the other experimental groups (Tables VIII, IX, XIV). It was significantly less than A at the 99 per cent level of confidence for only the first hour (Table VIII). At the 95 per cent level of confidence, it was only different from Experiment B for the first hour. During the 24 hour test period, the t value between Experiment C and Experiment A and B, progressively declined in value. The passage of time again led to a decrease in the effects the introduced variable had on the remaining forces.

The results of Experiment D were also significantly greater than the control group for all time periods at the 99 per cent level of confidence (Table XI). The t test between all the experimental groups and Experiment

D showed there to be no significant differences except between Experiment A and Experiment D (Table XII, XIII, and XIV). At the 95 per cent level of confidence there was more force remaining at the end of one hour in Experiment A. Here again the important observation to be made is that with the passage of time the difference between Experiment D and Experiments A and B declined. The two experiments that were pre-stretched 20 mm. had more force remaining than those stretched 30 mm. at the end of 24 hours, indicating that the "memory" was regained faster with the shorter pre-stretched groups, but that eventually the results were the same.

At the end of the first week, and through the fourth week, the modules in Experiment D were predicted to have more remaining force than any other experimental group, or the control (Table XVI). It had 189 per cent more force than the control group at the end of four weeks. The recovery of the modules in Experiment D was slower than Experiment A or Experiment B, but eventually the force remaining was the best.

It was interesting to note that when comparing the t value between the control group and the experimental groups, that in Experiments A and B, the t value declined from the first hour to the 24th hour and in Experiments C and D it increased. When the modules were pre-stretched to 20 mm. the initial increase in remaining force over that remaining in the control group was high but it steadily declined. However, when the modules were pre-stretched 30 mm., the initial increase in force was not as large, but there was a definite improvement in the remaining force over the control. In these, the molecules were strained so much initially that they were slower in reorganizing. This is a very desirable property clinically. This keeps the force applied initially more equal to the final force.

The improvement of 189 per cent over the control that was obtained in Experiment D is significant. The force remaining at the end of four weeks was 60.97 per cent of the original force, but only when it is 100 per cent will the ideal module exist. Further testing that would extend the range of time and distance should be done so that this goal may be met.

CHAPTER VI

SUMMARY

The effects on stress relaxation by pre-stretching Unitek's Gray Alastik CK modules were tested. CK chains of four modules were pre-stretched to 20 mm. for 24 hours. In Experiment A they were relaxed 5 minutes then placed under a load of 90.7 grams. In Experiment B they were allowed to relax 30 minutes before being loaded. In Experiment C and D the modules were pre-stretched 24 hours at 30 mm. Experiment C was then relaxed 30 minutes before being loaded, and Experiment D, 5 minutes before being loaded. The control group was not pre-stretched. 90.7 grams was the load placed on all modules. All modules were tested at 37°C. in de-ionized water.

The control group had 43 per cent of its original force remaining after the first 24 hours. The rate of force decay then slowed down, and at the end of four weeks the remaining force was predicted to be 21.12 per cent of the original force. The pre-stretched groups were statistically (P=.01) greater than the control in the amount of force remaining for all time periods.

All experimental results were the same at the P=.05 level except Experiment A and B were greater than Experiment C for the first hour only, and Experiment A was greater than Experiment D for the first hour only. After six hours, all pre-stretched groups had the same results at the P=.01 level.

Experiment D had the most force remaining at the end of the first week, with 65.39 per cent of the original force. The additional force lost from the first week to the fourth week was only 4.42 per cent of the original. At the end of the fourth week, Experiment D had the most remaining force with 60.97 per cent of the original force.

At the end of four weeks, the force remaining in Experiment D was 189 per cent more than the control group.

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APPROVAL SHEET

The thesis submitted by Robert L. McClurg has been read and approved by the following committee:

Doctor James L. Sandrik, Director
Associate Professor, Chairman Department of Dental Materials,
Loyola

Doctor Joseph M. Gowgiel
Associate Professor, Chairman Department of Anatomy,
Loyola

Doctor James Young
Assistant Professor, Orthodontics,
Loyola

The final copies have been examined by the director of the thesis and the signature which appears below verifies the fact that any necessary changes have been incorporated and that the thesis is now given final approval by the Committee with reference to content and form.

The thesis is therefore accepted in partial fulfillment of the requirements for the degree of Master of Science.

April 12, 1978
DATE

James L. Sandrik
SIGNATURE OF DIRECTOR