# NATIONAL BUREAU OF STANDARDS REPORT

9039

Progress Report
on
An Evaluation of Complete Dentures
Lined With Resilient Silicone Rubber


U.S. DEPARTMENT OF COMMERCE
NATIONAL BUREAU OF STANDARDS

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# Progress Report on An Evaluation of Complete Dentures Lined With Resilient Silicone Rubber

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# An Evaluation of Complete Dentures Lined with Resilient Silicone Rubber


## Abstract

Twenty four complete dentures which had been in use for at least seven years were lined with a soft resilient silicone rubber (Silastic®-390). The lining did not change the molar-to-molar or flange-to-flange distances significantly. The liner was tasteless, odorless, was well tolerated by the tissues, did not bond well to the periphery of the hard denture base, could not be easily removed for the relief of inflamed mucosa, nor were the stability and the retention of the dentures improved over that expected from repasing or relining a denture with a hard resin. The liner is not a cure all for denture problems as has been reported in the literature and its routine use is not recommended.


Literature Review: During the past three years, several reports cite favorable clinical results with complete dentures, the tissue-bearing surfaces of which were covered with a 1-2 mm thick layer of a silicone rubber, Silastic®-390 (soft liner).[1-5] According to these reports, the silicone rubber retained its resiliency indefinitely and bonded well to the hard denture base resin. It also was most compatible with the mucosa, was tasteless, odorless and was color stable. The silicone rubber liner had a high stain resistance, was dimensionally stable and did not harm the patient or the denture. Patients liked the resilient liner which apparently improved retention of the dentures and consequently the authors[2] recommended its use in 85 percent of newly constructed dentures. Harris[6] predicted this in 1961 when he said, "If there were a material for cushioning dentures (similar to the temporary liner) that would retain those soft, compatible properties as long as 1 year, most of the chronic complaints in denture service would be eliminated."

In laboratory testing, Peyton and Anderson[7] found Silastic®-390 had a low water absorption, was soft, (Shore Durometer reading of 24-23) and retained this softness after soaking in water at body temperature for one month. They also reported that the adhesion between the acrylic resin denture base and Silastic®-390 was greater than its tear strength which was no more than 35 ± 4 pounds per inch.

Sometimes the yeast-like fungi, Candida albicans, is provided a suitable environment by Silastic®-390 according to Gibbons[8].

Introduction: The purpose of this investigation was to measure the dimensional changes in dentures caused by relining them with Silastic®-390; to check some of the previous clinical observations;[1-5] and to provide a greater knowledge about the most widely used resilient liner.

It is estimated that approximately 1.5 to 2 percent of the complete dentures processed in a large commercial dental laboratory have a resilient lining[9]. Almost all of these are lower dentures. The higher cost alone (about $10.00 more per denture) is probably not the main deterrent to a greater use of the resilient liner.

Patients: Thirteen patients (six women and seven men) used in this investigation ranged in age from 46 to 71 and had worn complete dentures from 7 to 39 years. Most types of mouth conditions were present. The largest dentures had projected areas of 36.6 $cm^2$ (upper) and 24.4 $cm^2$ (lower); the smallest, 22.8 $cm^2$ (upper) and 14.5 $cm^2$ (lower).[10] Some ridges were very prominent and high, others were low and flat. Some had broad flat palates, others were V-shaped. There were two cases of papillomatosis which had not changed appreciably in the past five years.

Patients were asked if they would like to have a new soft lining added to their dentures and possibly have the dentures tightened up at the same time, as a compensation for the minor inconvenience of doing without the dentures for two days. No fee was involved and all patients seemed anxious to try out the suggested service.

Dentures: The authors had made complete dentures for all the patients in 1957 and 1958. There was, therefore, available a complete record of the molar-to-molar and flange-to-flange changes during processing and in use. All of these patients had been recalled in 1958, -59, -60, -61, -63 and -64 for an evaluation of retention, stability, occlusal relations, condition of the oral tissues, the satisfactoriness of the dentures to the patient and dentist, and to take color photographs of manually executed pressure-indicator-paste patterns.

Five dentures had bases of vinyl-acrylic resin, four of a polystyrene compound, three of self-curing and thirteen of heat-curing acrylic resin.

Nine upper and ten lower dentures were rebased and lined with Silastic®-390. Most of the tissue-bearing surfaces of the remaining five dentures (three upper and two lower) were duplicated with the soft liner without making a rebase impression.

One additional patient who had been unable to wear comfortably several different single free-end saddle lower partial dentures was included in the investigation to learn if the resilient liner, when added to a rebase impression of his most recent partial denture, would relieve the discomfort.

Procedure at first appointment: Each patient was questioned about how satisfactory the dentures had been during the last year. The retention, stability, and occlusal relations of each denture were tested as previously described.[11] The supporting oral tissues were examined for color, firmness, health, and signs of irritation as done in other years.[12] After cleaning and drying the denture, manual pressure-indicator-paste patterns were made (Figure 1A), photographed, and compared with those made in previous years. This gave a record of the apposition of each denture to the tissue immediately prior to the rebasing or to the duplication of the tissue-bearing surface of the denture with the silicone rubber.

In the 19 complete dentures, which were rebased, the undercuts were removed with a large vulcanite or fissure bur. Additional room was made for the impression material by removing resin in the rugae of uppers, and on the ridge crest and below the mylohyoid ridges of the lowers as well as in any areas of hard contact as shown in the pressure-indicator-paste patterns. (Figure 1A). Each denture was then dried thoroughly and the reference pins used in the flange-to-flange measurements were covered with a narrow strip of adhesive tape. (Figure 1B). Zinc-oxide and eugenol impression paste was rapidly and uniformly spread over the entire tissue surface and borders of the denture. The denture was then placed in the mouth and positioned somewhat manually using a rotary motion toward the supporting tissues. The patient was instructed to relax his jaw and close gently on his back teeth. The jaw was opened briefly while border molding was accomplished with the fingers and thumb (except for the lingual flange of the lower which was trimmed by having the tongue touch the upper lip or palate); the patient was again instructed to close on his back teeth and hold them together. In every instance the patient had for about 30 seconds an unpleasant burning sensation caused by the zinc-oxide and eugenol paste. The denture with the completed rebase impression was left in the mouth for 2-3 minutes after the apparent initial set of the impression paste.

Photographs (Figure 1C) of the rebase impressions were made and later compared with photographs of the pressure-indicator-paste patterns made in the dentures before (Figure 1A) and after lining (Figure 1D).

Measurements before processing: The molar-to-molar and flange-to-flange distances were measured on all dentures which had been conditioned in distilled water at 23 ± 2°C for 30 minutes and wiped dry with tissue paper to prevent chilling from evaporation. These same measurements were compared with those made on the dentures seven years previously, when each denture had been in service for three months. Thus, the relative dimensional stability of each denture just prior to the rebase procedures was known (Table 1--Columns 2, 4, 9 and 11). These data show the combined effect of more than seven years of service, the removal of a layer of the denture base, and the zinc-oxide and eugenol paste. These changes ranged from 0.00 to 0.28 percent, yet on the average amounted to only 0.06 percent molar-to-molar and 0.13 percent flange-to-flange for upper dentures and 0.11 percent molar-to-molar and 0.09 percent flange-to-flange for lower dentures. Such a small change, even if it occurred suddenly, could not be detected clinically by the dentist or the patient.[13] The effect, when spread over seven years is practically nil. These data support previous evidence that complete dentures, for all practical purposes are very dimensionally stable over long periods of time.[11,13,14]

Immediately after completing the measurements, the dentures containing the zinc-oxide and eugenol impressions were taken to a commerical dental laboratory along with prescriptions which specified processing, posterior palatal seal, relief when desired, and the areas of the tissue-supporting surfaces that were to be covered with the Silastic®-390.

Laboratory procedure*: A dental stone cast was poured into each denture. Then it was mounted on the upper member of a duplicating jig (Figure 2A). An occlusal and incisal index was then made on the lower member of the assembled jig. By so mounting each denture, the occlusal and vertical jaw relations were easily maintained throughout the subsequent procedures (Figure 2B).

The denture was separated from its cast and all of the impression material was removed except for a small amount on the ridge crest, which was removed later. The border areas of the denture were then reduced, roughened and cleaned. An alginate separating agent was painted on the cast and a mix of cold-curing acrylic resin was poured into the entire border region on the cast. The denture was then correctly oriented in the occlusal-incisal index and the jig was tightly closed with the two screws until the resin dough hardened. Thus, the original borders and the posterior extent of the denture were now duplicated in hard acrylic resin. This partially re-based denture was removed from its cast and the remaining impression material was cleaned out. From 1 to 2 mm of the resin was cut from the tissue-bearing surface with a vulcanite bur. Whenever the resilient reliner would have a common border with the hard acrylic resin base, a step or ledge was cut in the base. This made a butt joint and avoided a flash of resilient reliner on the base.

A primer or coupling agent was then sprayed on the clean roughened surface and the denture was placed under a jar for 10 to 15 minutes.

The Silastic®-390 was squeezed out of a freshly uncapped tube and an excess amount carefully spread on the entire prepared surface. The denture was again correctly positioned in the jig, and securely bolted (Figure 2B). This assembly was placed in a pressure-cooker at about 30 psi air pressure for three hours at 155°F. No separating medium was used on the cast. After cooling, the denture was easily removed from its cast because of its resilient lining. Thin flash was removed with a knife and any other undesired bulk was cut away with scissors, arbor band or a very course but soft carborundum stone running at a high speed. The tongue side of the denture was polished in the conventional manner. The resilient liner, Silastic®-390, has a matte finish and cannot be polished.

Measurements after relining: After conditioning the denture as previously described, the molar-to-molar and flange-to-flange distances were measured to determing if any change had occurred during the laboratory procedures.

These changes (Columns 3, 5, 10 and 12 in Table 1) were generally small and on the average amounted to 0.16 percent molar-to-molar and 0.14 percent flange-to-flange on the upper dentures and 0.33 percent and 0.22 percent for the same respective distances on the lower dentures. These changes were slightly greater on the lower dentures which usually shrank. The clinical fit and occlusal relations were not affected by these small changes.

Procedure at second appointment: Pressure-indicator-paste patterns were made on the relined dentures when they were first inserted (Figure 1D). Without exception, the patterns of the 24 dentures showed uniform contact of the tissues with the areas of the dentures covered by the Silastic®-390.

Previous experience using pressure-indicator-paste patterns in dentures with hard bases showed that hard areas of contact were easily and reliably located over firm tissue but not over soft moveable tissue. It is possible that the resiliency of the Silastic®-390 renders the pressure-indicator-paste patterns ineffective so far as determining actual degrees of apposition between the denture and the mucosa. Sore spots (Table 1--Columns 8 and 15) which subsequently occurred beneath the Silastic®-390 lining could not be located in the pressure-indicator-paste patterns. These inflamed mucosal areas were marked with purple indelible pencil and transferred to the denture.

*Procedure followed by Rothstein Dental Laboratory, Silver Spring, Maryland.

Occlusal relations were corrected by drying the posterior teeth and having the patient close several times on a thin sheet of blue articulating paper. None of the rebased dentures were remounted at the time of insertion. One set of dentures was remounted a week later in an attempt to correct their poor stability during function. This patient had not recently experienced such a difficulty prior to having her dentures rebased and lined with the Silastic®-390.

The retention and stability of each denture was tested at the time of insertion and one week later there was no appreciable change. Numerical values given for the retention and stability are as follows: excellent 4, good 3, fair 2 and poor 1.[11] These values are shown in columns 6 and 7 of Table 1 for upper dentures and columns 13 and 14 for lower dentures. The retention of the dentures was about what would be expected normally with a rebase, but the stability of a number of the dentures was somewhat disappointing. Each patient was given an appointment to return one week later for examination and adjustments.

Subsequent appointments: The liner apparently was well tolerated by the oral tissues. Three patients required adjustment of their dentures to relieve discomfort after only two days whereas four others required no post insertion adjustments. Two patients said they were sorry they had had their dentures rebased and lined with the Silastic®-390 because they had been more comfortable previously and thought their dentures had been more stable in function before.

The number of places on each denture which was adjusted to relieve tissue abrasion is shown in column 8 of Table 1 for uppers and column 15 for lowers. Most of the sore places occurred on the hard borders of the rebased denture or at the margin of hard and soft denture base material. Twelve of the 31 sore spots occurred in regions covered solely by the Silastic®-390. These were not the typical white lesions normally caused by a hard denture base, but were redder and less abraded, easy to locate on the mucosa and were quite sore to pressure from an instrument.

The hard resin was very easy to relieve and polish. The Silastic®-390 was most difficult to relieve and in every instance after adjustment of it a somewhat roughened or porous surface remained. Many methods of removing small amounts of the silicone rubber were attempted: conventional and high speed burs and stones (course and fine); abrasive rubber wheels, arbor bands, scissors, knives, and hot spatulas. Two technic dentures lined with Silastic®-390 were placed in liquid nitrogen at about minus 195°C for ten minutes in an attempt to temporarily harden the rubber so that it could be cut with a diamond stone in an air driven handpiece. Unfortunately, however, the chilled Silastic®-390 would soften immediately from the heat of friction when contacted with the rotating stone. The least unsatisfactory method of relieving the resilient rubber employed a spherical diamond stone or the edge of a wheel-shaped diamond stone driven by a turbine handpiece. Very quick, light, intermittent contacts with the rubber were used. The rubber would frequently tear several times before adequate relief was achieved and the relieved surface was invariably rough . When the area to be relined was at the margin of hard and soft denture base material, the bond between the two materials loosened or separated slightly during the adjustment, in spite of the utmost care. Actually, even though laboratory tests[7] have shown the bond strength to be greater than the tear strength of Silastic®-390, it is relatively easy to separate Silastic®-390 lining from an acrylic resin denture with the fingernail. It is far too easy to separate when separation is undesired, as in executing a denture adjustment. It is hoped that further investigation may discover a satisfactory method or system for removing a thin layer of resilient denture liner without tearing the surface, loosening the bond, or leaving a rough surface.

Patient acceptance of the material was, with the two exceptions mentioned, adequate, but certainly not enthusiastic. All of these patients were well prepared from a psychological standpoint to expect something very good because they had received good denture service without fee previously. Each patient was told that, if he desired, his dentures would be rebased with a resilient lining which would both tighten and make them more comfortable.

After wearing the dentures for one week, each patient was asked if he or she was aware (while wearing the dentures) of the fact that the dentures had a soft lining. The investigators had anticipated an almost unanimously affirmative reply. However, only four of the patients said they could tell their dentures had a soft inner surface except when they were out of the mouth, such as in cleaning the dentures. Four of the patients were most happy with the success of their rebased dentures; one said the dentures felt like a part of him; another said the "give" in the material made his dentures comfortable and the dentures were easy to keep clean; another said his dentures fit better and were more comfortable than when first made;

and another said he could really use his teeth without getting anything under them. The one patient for whom the partial denture saddle was rebased and lined with Silastic®-390 was much more comfortable than before but only after several rather extensive border adjustments which left the edges of the resilient material quite roughened. Five of the patients complained that they were afraid to brush the inside of their dentures for fear of ruining the soft lining or scratching it and consequently felt that they were unable to clean their dentures adequately. None of the patients complained of any unpleasant taste or odor associated with Silastic®-390. The color was pleasant and the detailed configuration of the cast was well produced in this resilient liner.

Observations at the three month recall: The lingual slope of the lower ridge posteriorly seemed more than usually inflamed in 8 out of 11 patients. This may have been caused by the increased flexure of the denture whose cross-sectional area of the hard resin base was reduced considerably to make room for the soft reliner.

Papillomatosis, which had been present previously in three of the patients, seemed more inflamed than formerly.

The lower denture of one patient had a strong tobacco odor which was not present before relining. This was one of two lower dentures whose lining had darkened markedly in the mouths of heavy smokers, who practiced good oral hygiene.

Inspection of 21 out of the 24 dentures showed circular white area on 12 of them. On one upper and four lowers the white areas covered most of the soft relining. An enlargement of one area near a reference pin is shown in Figure 3. These are colonies of Candida albicans as reported by Gibbons.[8] The illustration in Figure 3 appears very similar to illustrations in Gibbons' report. Some of the white areas could not be removed by scrubbing with soap and water or by gentle scraping.

The soft lining on the lower denture of another patient was blanched, wrinkled and appeared to be deteriorating (Figure 4B). Similar smaller areas were on the upper denture.

Three patients complained of an after taste caused by the cleaning agents. In two instances, the taste was chlorine from the Calgon®-Chlorox® solution recommended by the manufacturer of the liner.

One lower denture fractured near the midline as the patient was eating a candy bar. Another lower denture had two cracks which were in the same vertical place but which were not joined. One upper denture developed a typical midline fracture. No breakage occurred on these dentures in the previous seven years of use. The breakage may have been caused by the reduction in the cross-sectional area of the hard acrylic resin in order to make space for the soft reliner.

When the patients were asked, "How do you like the soft liner?" seven said they liked it very much, two thought they liked it, one said there was no difference and three said they did not like it.

The patients were also asked, "If you were having new dentures made, would you prefer a hard or a soft material?" Eight chose the soft and five the hard material.

Summary: Twenty-four complete dentures which had been in use for at least seven years by 13 patients were lined with Silastic®-390, a soft resilient silicone rubber.

The molar-to-molar and flange-to-flange distances on the dentures were not seriously changed during relining.

The resilient liner reproduced the detailed configuration of the cast, was odorless, tasteless, and pleasantly colored. The mucosa tolerated it well. Some sore spots on the mucosa developed beneath the liner. Inflammation of the tissue on the lingual slope of the lower ridge was more extensive in the lined dentures which were more flexible than they were previously. This greater flexibility, caused by a reduction of the cross-sectional area of the dentures by removal of the hard denture resin to make space for the resilient liner, probably caused this inflammation as well as the fracturing of two lower and one upper dentures.

Sometimes an after taste caused by tobacco or by cleaning agents persisted. The resilient liner was more difficult to clean than the hard denture base. ~~Twelve~~ TWENTY OF the ~~24~~ 24 lined dentures showed circular white areas which appear to be penetrating

the liner as they could not be brushed off or removed entirely by gentle scraping.

The liner on one lower denture became blanched, wrinkled and appeared to be deteriorating.

The liner did not bond well to the hard denture base near the peripheral boundary of the soft and hard materials.

Comfort to the patient, retention and stability were not improved over that expected from the rebasing or relining of a denture with a hard resin.

The liner could not be ground or cut without tearing, having a rough surface or loosening the bond. Hence, it was most difficult to make proper adjustments for the relief of inflamed areas. This fault is a major drawback in the use of the liner.

Eight of the 13 patients preferred the soft lining to hard resin base when asked, "If you were having new dentures made, would you prefer a hard or soft material?"

The resilient silicone liner is not a cure-all for denture problems. In some instances its use may even cause difficulties not ordinarily encountered when a hard base is used.

The routine use of a resilient lining in all complete dentures is not recommended.

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TABLE 1

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | UPPER DENTURES | | | | | | | LOWER DENTURES | | | | | | |
| | Dimensional Change | | | | Evaluation[2] | | | Dimensional Change | | | | Evaluation[2] | | |
| | Molar-to-Molar | | Flange-to-Flange | | | | | Molar-to-Molar | | Flange-to-Flange | | | | |
| Denture Code[1] | 3 mo. thru 7 yrs. use | Silastic® Rebase | 3 mo. thru 7 yrs. use | Silastic® Rebase | Retention | Stability | Number of Sore Spots | 3 mo. thru 7 yrs. use | Silastic® Rebase | 3 mo. thru 7 yrs. use | Silastic® Rebase | Retention | Stability | Number of Sore Spots |
| | % | % | % | % | | | | % | % | % | % | | | |
| A-167-H-6&7 | +0.10 | +0.14 | -0.18 | +0.12 | 3 | 2 | 0 | +0.22 | -0.07 | +0.09 | -0.14 | 4 | 4 | 1† |
| A-167-L-6&7 | -0.03 | -0.15* | -0.09 | -0.02* | 4* | 4* | 0* | -0.10 | -0.1[illegible] | -0.09 | -0.21 | 4 | 3 | 2 |
| A-149-J-5&6 | -0.05 | 0.00 | -0.11 | 0.00 | 3 | 3 | 1† | +0.04 | -0.01 | -0.01 | -0.01 | 3 | 2 | 3† |
| A-167-V-6&7 | 0.00 | -0.19 | +0.01 | -0.11 | 3 | 2 | 3 | -0.10 | -0.70 | -0.10 | -0.12 | 3 | 3 | 3†† |
| A-167-T-9 | +0.08 | -0.12 | -0.15 | -0.12* | 4* | 4* | 0* | | | | | | | |
| A-167-A-8 | | | | | | | | +0.06 | -0.39 | -0.05 | -0.11 | 2 | 3 | 0 |
| A-149-H-1&2 | +0.14 | +0.01 | -0.03 | -0.11 | 2 | 3 | 1 | +0.18 | -0.24* | +0.12 | -0.34* | 2* | 2* | 0* |
| A-167-D-6&7 | +0.05 | -1.00 | -0.04 | -0.29 | 2 | 2 | 2 | +0.04 | -0.79* | +0.01 | -1.03* | 3* | 3* | 1*† |
| A-167-H-9*10 | +0.09 | -0.05 | -0.02 | +0.11 | 3 | 2 | 3 | -0.04 | -0.74 | -0.11 | -0.11 | 4 | 2 | 5†† |
| A-149-J-1&2 | -0.07 | +0.13 | -0.14 | +0.32 | 4 | 4 | 2†† | -0.12 | -0.11 | -0.08 | 0.00 | 3 | 2 | 2† |
| A-149-L-1 | -0.02 | -0.05* | -0.13 | +0.12* | 4* | 4* | 0* | | | | | | | |
| A-149-L-2&3 | -0.04 | -0.11 | -0.09 | -0.16 | 2 | 4 | 0 | -0.01 | -0.17 | -0.06 | +0.12 | 2 | 2½ | 0 |
| A-167-A-6&7 | +0.05 | -0.03 | -0.63 | +0.21 | 2 | 2½ | 1† | -0.26 | -0.63 | -0.28 | +0.06 | 3 | 3 | 1 |
| A-363-115 | | | | | | | | | +0.02 | | | 4 | 2½ | 0 |
| Partial Lower Denture | | | | | | | | | | | | | | 4†† |
| Average | 0.06‡ | 0.16‡ | 0.13‡ | 0.14‡ | 3.0‡ | 3.0‡ | 1.0‡ | 0.11‡ | 0.33‡ | 0.09‡ | 0.22‡ | 3.1 | 2.7 | 1.6 |

* Existing tissue-bearing surface of denture was copied or duplicated into Silastic®-390 without making a rebase impression inside the denture.
† Indicates one sore spot entirely beneath resilient lining material. †† Indicates two sore spots entirely beneath resilient lining material.
‡ Plus or minus signs were ignored in calculating average.
1. The first letter and three numerals designate the data book. The next letter refers to the hard denture base -- A-Acralite 88, D-Duraflow, H-Hydro-Cast, J-Jectron, L-Luxene 44, T-Tilon and V-Vernonite. The last number or numbers identify the denture in each series of base material used.
2. Criteria used in the evaluation will be found in reference 12.

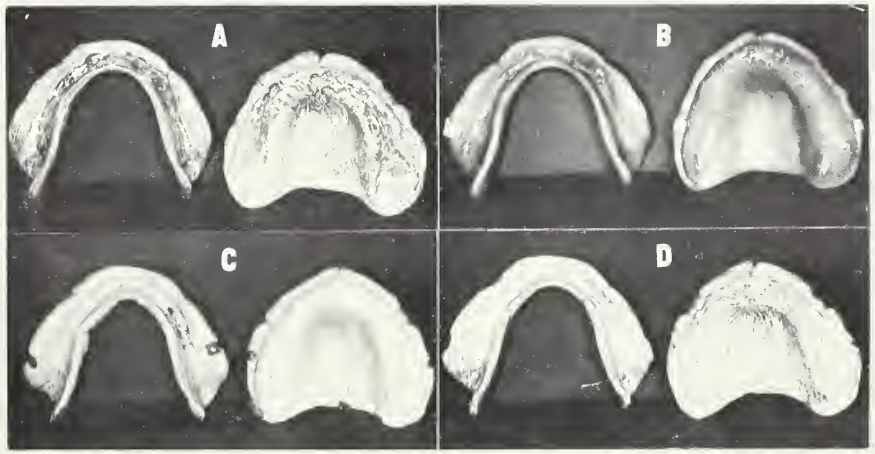


Figure 1. (A) Photograph of a manually made pressure-indicator-paste pattern prepared August 11, 1965 prior to rebasing upper and lower dentures. Dentures were made by Hydro-cast process on May 20, 1958. There is relatively good apposition after 7 years of service. Notice the stainless steel reference pins on the flanges. These were used in measuring dimensional changes on the denture. These reference pins were covered over (B) prior to making the rebase impressions of zinc oxide-eugenol paste (C). (D) shows the pressure-indicator-paste patterns made on the dentures after relining with Silastic®390 (Aug. 13, 1965).

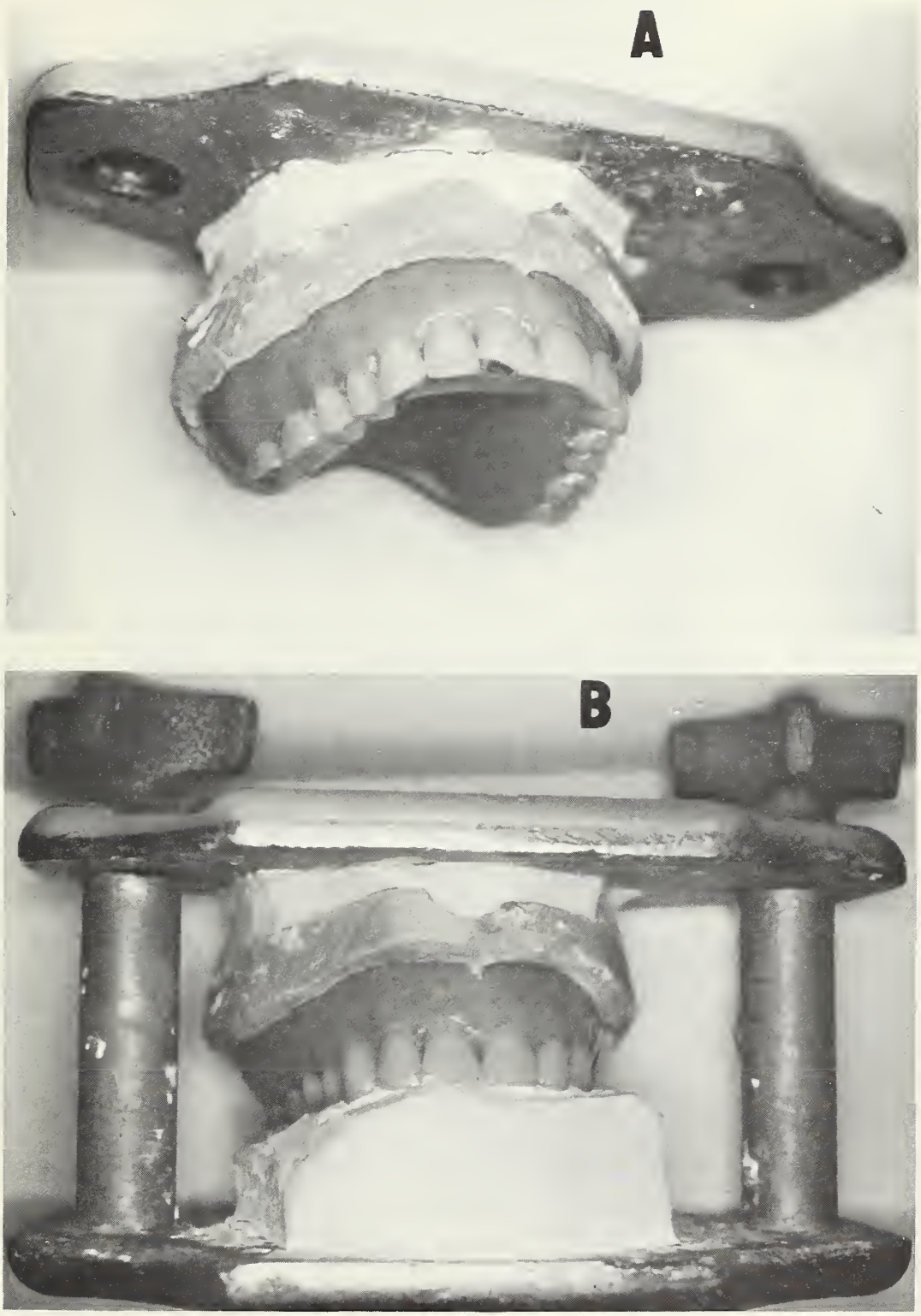


Figure 2. (A) Photograph of an upper denture with zinc oxide-eugenol paste impression wash into which a artificial stone cast has been poured and then the whole assembly attached to the upper member of a duplicating jig. (B) The assembled jig with the plaster of paris occlusal-incisal index on the lower member.

Figure 3. An enlargement of an area of the tissue-bearing surface of a denture near the reference pin used in measuring the flange-to-flange dimension. White areas are colonies of Candida albicans as described by Gibbons[8] and confirmed by Dr. E. G. Hampp, Research Associate of the American Dental Association at the National Institute of Dental Research.

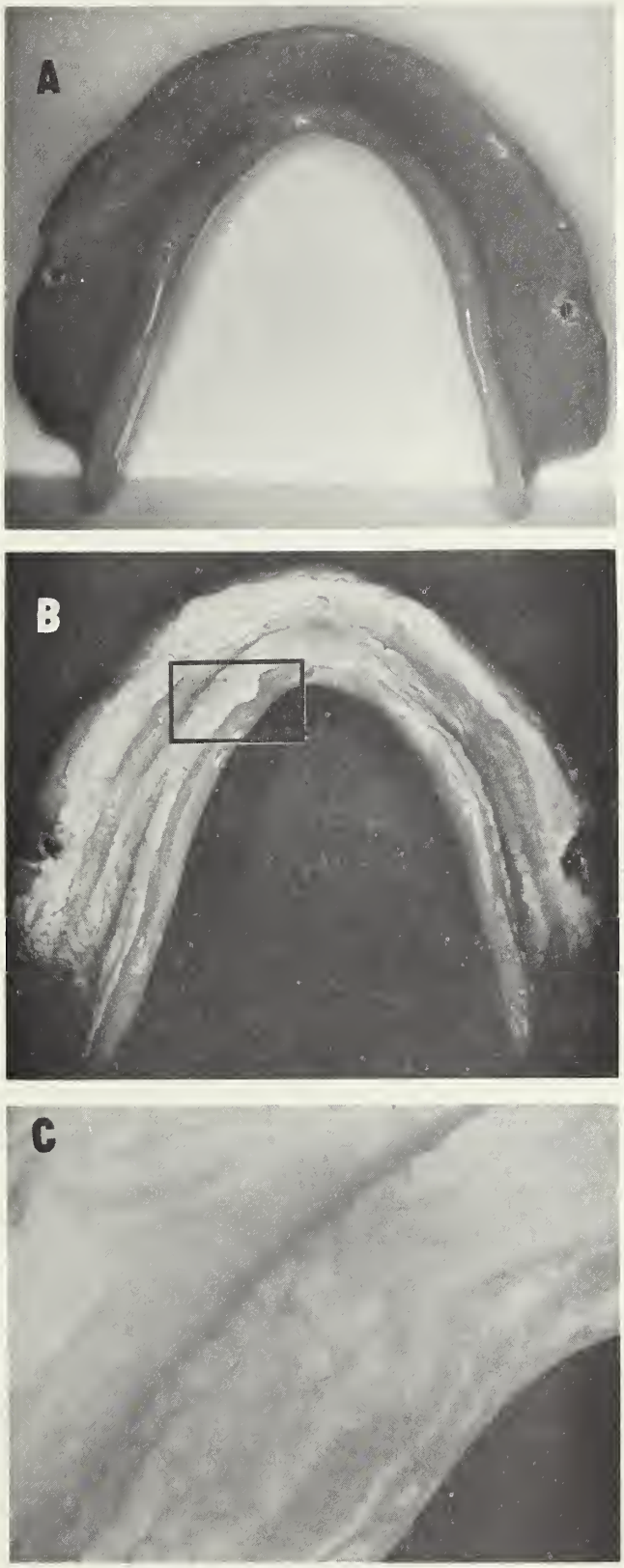


Figure 4. (A) The lower denture of one patient after lining with Silastic®390 just prior to insertion. (B) The relining has blanched, wrinkled and is deteriorating. (C) A close-up view of a typical area shown grossly in (B).


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