The Development of Facial Prosthetics and Adhesives in Plastic and Reconstructive Surgery

A study in the application of prosthetic materials and devices used in plastic and reconstructive surgery together with tissue adhesives as an alternative to conventional ligation

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submitted for the degree of Doctor of Philosophy

Postgraduate School in Biomedical Sciences
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CONTENTS

To Margaret

We restore, repair and make whole those parts of the face which nature has given but which fortune has taken away, not so much that they may delight the eye, but that they may buoy up the spirit and help the mind of the afflicted.

Gaspare Taglacozzi
AD 1546–1599

PREFACE

The whole of the experimentation described in this thesis was carried out in the Department of Plastic and Maxillo-Facial Surgery, St. Lukes Hospital, Bradford and the School of Biomedical Sciences, University of Bradford, between November 1983 and May 1988.

The thesis consists of my own research and development and is believed to be original except where acknowledgement and reference is made. The elastomer materials testing was in co-operation with J. Leadbetter Esq., while on undergraduate attachment to me from the Undergraduate School of Material Sciences, University of Bradford.

The construction and development of the adhesive instrumentation was undertaken in co-operation with Loctite U.K. Engineering. The conclusions in this thesis are my own reached after considerable consultation with my supervisor, Professor T.G. Baker.

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ABSTRACT

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Keywords:-

FACIAL PROSTHESIS | SILICONE ELASTOMER | PHYSICAL PROPERTIES | SKIN
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APPLICATOR SYSTEM | SURGEON'S SURVEY

Various silicone elastomers have been evaluated for use in the prosthetic reconstruction of facial defects. Their strength, texture, flexibility, hardness, ease of preparation, pigment receptivity and retention, and their resistance to cleaning were compared and the data consulted when an elastomer was chosen to restore defects, improve aesthetics and re-establish the confidence of a selection of patients. Detailed case reports are provided, together with information on the adhesives or mechanical methods available for retaining the facial prosetheses.

Cyanoacrylate adhesives for use on skin surfaces and as tissue adhesives have been studied in detail. A novel n-butyl 413 cyanoacrylate has been developed with a viscosity, haemostatic property and stability to make it particularly suitable for use in skin grafting and tissue repair. It has already been used with good results on patients with severe burns. An improved formulation, containing a fluorescent dye, can be precisely applied through a specially constructed foot-controlled dispenser illuminated by a fibre-optic supplying UV-light.

Cyanoacrylates are already being used as tissue adhesives in place of the conventional but potentially disfiguring suture. The availability of improved, imperceptible adhesives and a precision applicator, which can be used in a modern operating theatre, will extend their effectiveness and satisfy some of the needs of Plastic, and Oral and Maxillo-Facial Surgeons. Portable applicators have potential use in battlefield and in veterinary surgery and overcome the imprecision characteristic of earlier methods.

INTRODUCTION

Ever since man began to live in organized groups which marked the beginning of civilization the desire to be of acceptable appearance became as basic as the will to live. The face with its expressions of all human emotions is a vital means of communication and represents the centre point of attention in human relationships with particular emphasis placed on cosmetic acceptance.

Many patients who have facial or body defects resulting from cancer surgery, trauma or congenital anomalies benefit from prosthetic rehabilitation. Plastic and reconstructive surgery has developed to the point where gross deformity, both congenital and acquired, can be corrected or improved by surgical means.

The use of the patient's own tissues is far more desirable than employing synthetics. However reconstructive surgery produces satisfactory results only if the case is suitable. In many cases there is a period between the establishment of the deformity and the commencement of surgical procedures, and the provision of a temporary prosthesis is of considerable psychological as well as practical value.

There are also cases which are considered inoperable due to the possibility of recurring disease and general health of the patient. In such cases the provision of a permanent prosthetic reconstruction is essential. Patients who have suffered extensive burns to the face and body of a severity requiring skin cover often have insufficient tissue locally available for reconstructive procedures.

A feature of cancer surgery is the requirement to remove an extensive section of tissue adjacent to the tumour which can result in considerable post-operative deformity. The immediate result of this necessary surgery is that the patient has completely changed facial features: what was once an acceptable and familar face to family and friends is different and often not readily accepted by society in general.

Advances in materials science have illustrated that synthetic materials can be developed and applied to the human body in support of surgery. Attempts to substitute materials for defective or missing organs or parts have been made throughout the history of medicine but only in the last 20 years have techniques met with consistent success.

Few materials qualify for clinical application to humans. The polymer industry has developed many new materials, most of these for intended industrial applications. From time to time a particular polymer has been found to have some properties which might apply to clinical prosthetics or surgery but all too often the seemingly ideal material fails to meet the demanding specifications required. There is a definite need for a resilient polymer for prosthetic reconstruction and simulation of human tissue together with a reliable and effective means of attachment of the material to the body surface.

The bonding of synthetic devices to the skin has constituted a major problem in prosthetic rehabilitation. The use of adhesives in medicine and surgery is an area of rapid development with important consequences to the future progress in surgical practice.

This study is concerned with the development of a structured silicone elastomer formulated for prosthetic reconstruction in plastic surgery, together with tissue adhesives. The prosthetic elastomer concerned in the study has been developed to meet the specification required of the ideal prosthetic tissue substitute and has found comprehensive clinical application in the department of Plastic and Maxillo-Facial Surgery at St. Luke's Hospital, Bradford.

The development of adhesives in this study has complemented the prosthetic elastomer in the attachment of prostheses and devices to the skin together with the bonding of tissue and precision application of the adhesive as an alternative to conventional ligation.

PART I FACIAL PROSTHETICS

HISTORICAL REVIEW

The Royal Library Copenhagen records that a Danish astronomer Tycho Brahe (1546-1601) lost his nose in a duel over a woman's favours. He lost the dual, the woman and his nose. A resourceful gentleman he constructed a new prosthetic nose for himself from silver and gold. WHYPER (1832) recorded in the London Medical Gazette, the case of the Gunner with the silver mask - a complex mechanical facial restoration for a young French soldier with an extensive facial defect acquired in battle. Whyper describes the prosthesis as weighing some three pounds and costing £12 sterling. Skin colour simulation was by means of oil paint "analagous to his complexion so that the illusion was so strong that unless forewarned the man might be steadfastly examined at a short distance without betraying his misfortune."

TETAMORE (1899) used Celluloid painted to a flesh colour in ten cases of patients with nasal defects. UPHAM (1901) describes his work constructing noses and ears. He comments on the materials available for his work ... "Vulcanized rubber is the best material to use. It is more easily worked, has no odour and is not easily broken. I find Celluloid hard to work, it gets broken and has the misfortune to catch fire if the wearer is an absent-minded smoker! Aluminium and silver are too hard and do not keep the enamel flesh colour on the surface."

WOOD (1917) an artist and captain in the Royal Army Medical Corps attached to the 3rd London Military Hospital at Wandsworth records his construction of prostheses. His facial prostheses were

in the form of 'masks' cast in copper and silver plated, after which they were realistically painted in oil paints to reproduce as faithfully as possible the former appearance of the patient. Wood devised these permanent prostheses to take the place of the soft vulcanised rubber and gelatin mixtures currently used at that time, which he describes as of "minimal success in the many cases of facial disfigurement sent to me from the battle front. My work begins where the work of the surgeon is completed. The surgeon does all he can to restore function by bone grafting and skin grafting. I then endeavour by means of the skill I possess as a sculptor to make a man's face as near as possible to what it was before he was wounded."

The use of facial prostheses through the ages illustrates man's ingenuity and application of materials to replace lost anatomical tissue.

The origins and first use of prostheses to reconstruct facial and body defects are lost in antiquity. Some appreciation of man's earliest attempts have been seen from excavated remains, together with illustrative carvings, sculptures and paintings. The Chinese are known to have made facial restorations using waxes and tree resins.

GRAY (1967) in a radiographic study of Ancient Egyptian mummies refutes the long standing hypothesis of BULBULIAN (1945) and perpetual by CHALIAN et al. (1972) that the ancient Egyptians used facial prostheses such as noses, ears, and eyes. Gray's study shows that the prostheses were used solely in a post-mortem role.

As early as the Fourth Dynasty (2613-2492 B.C.) mummification was used with particular attention being paid to the face. Mud or sand was packed under the facial skin and linen placed in the mouth to restore contour. Artificial eyes were inserted into the orbits, made of materials such as limestone, calcite or bone (Fig. 1). Balls of linen were also used, the pupil represented by a spot of black paint. These eyes were considered an innovation from the Twenty-first Dynasty.

This restoring procedure was further complementedby facial painting with ochre red for a man and yellow for a woman. The process of mummification was an expensive procedure mostly confined to the aristocracy.

Ambrose Pare (1510-1590) can be described as the founding father of facial and body prosthetics. His construction of prostheses and, in particular, facial prosthetics did much to form the basis of future development in the field of reconstructive prosthetics (Fig. 2). The materials used by Pare were gold, silver, paper and linen enamelled to create the illusion of skin colour (PARE, 1579).

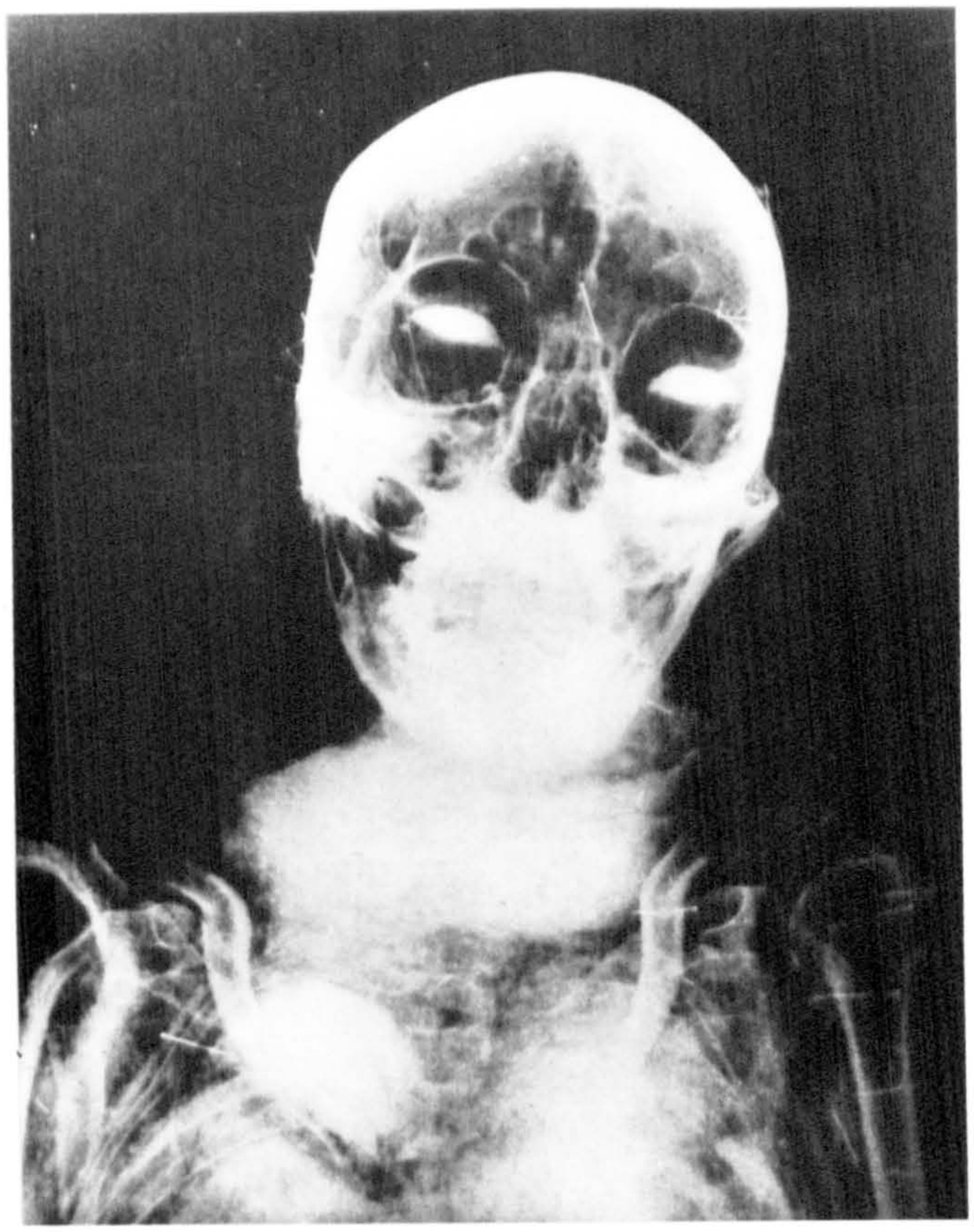
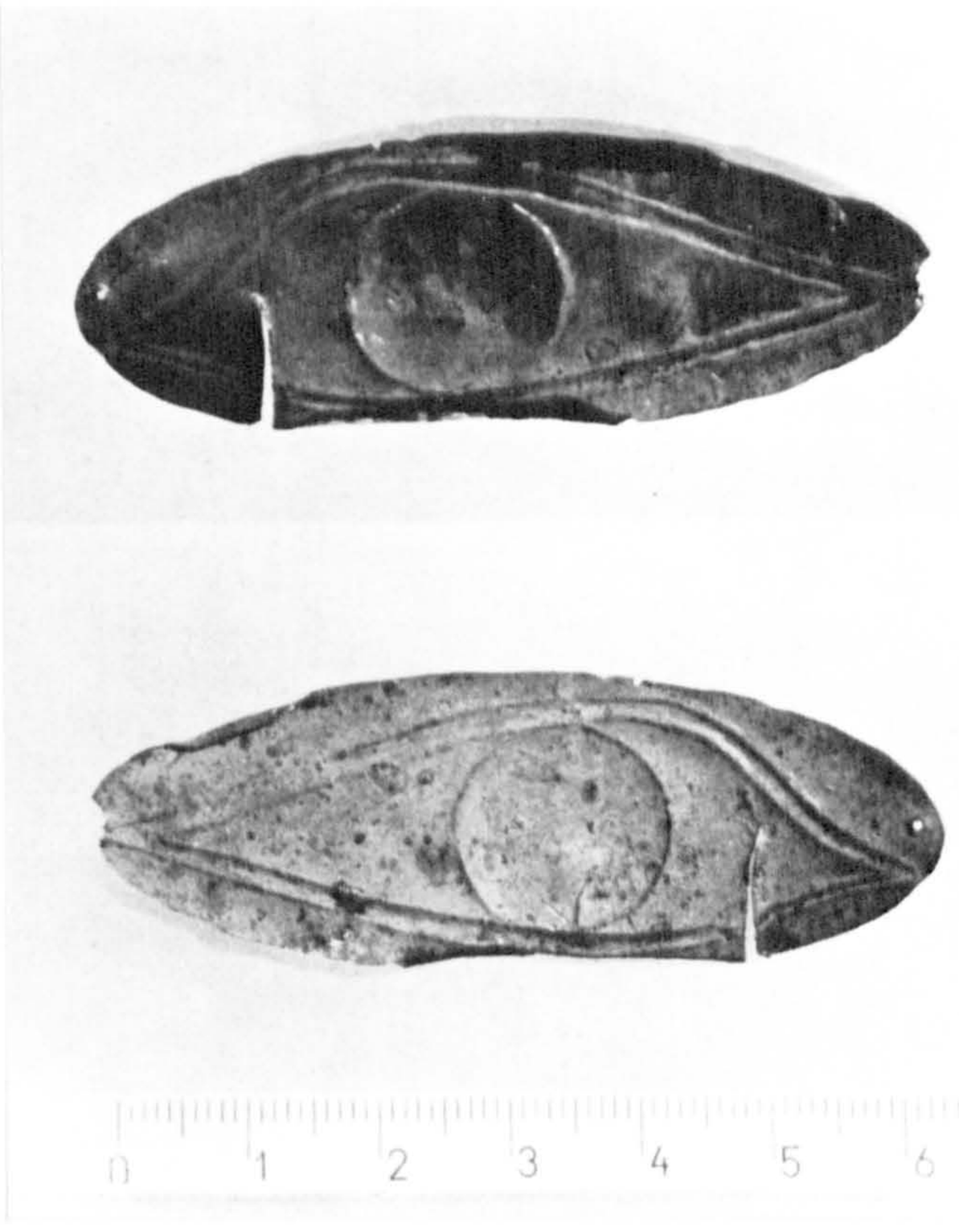
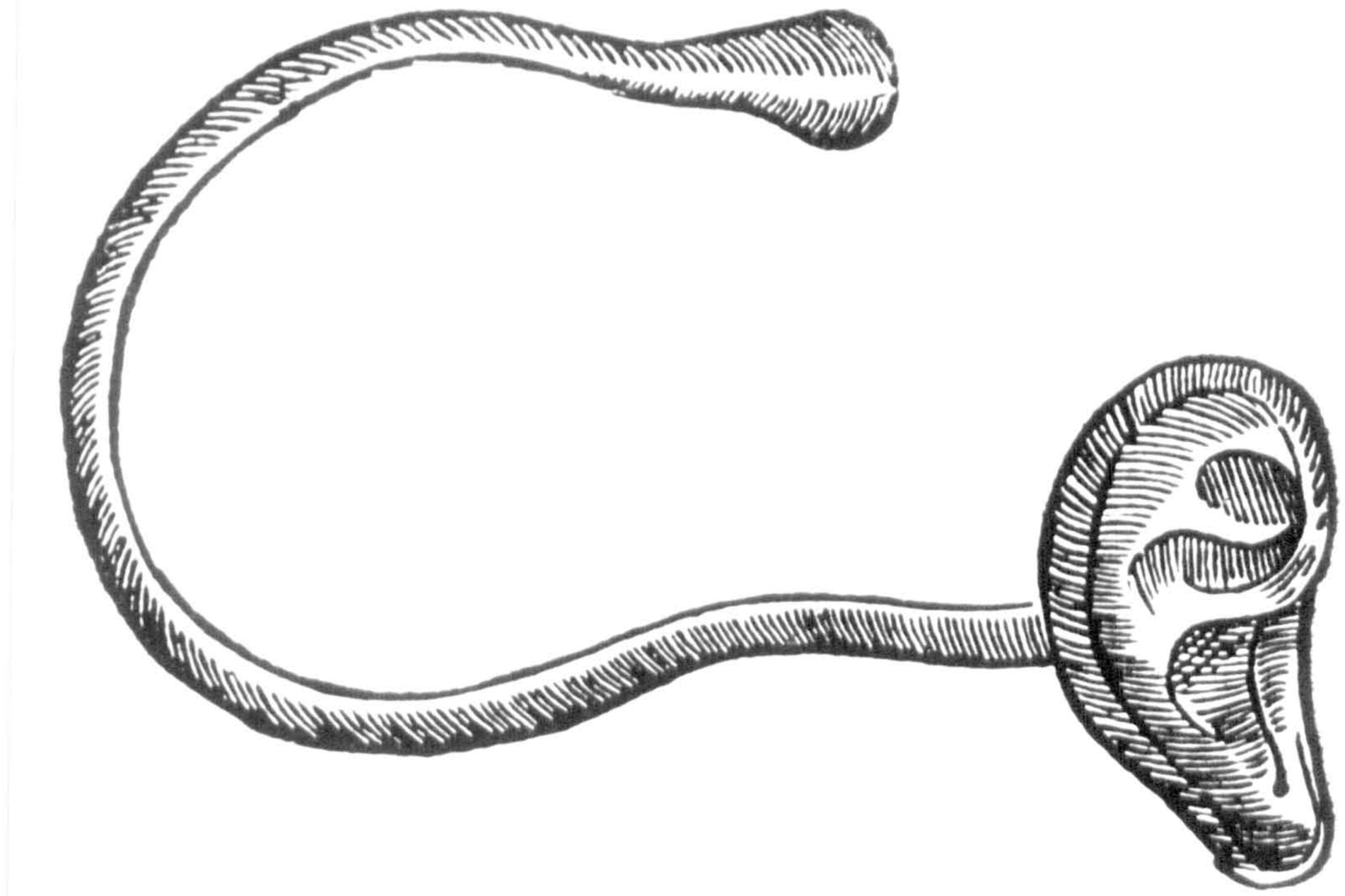


Figure 1 Calcite artificial eyes. Fourth Dynasty (2613 - 2492 BC)
used in mummification





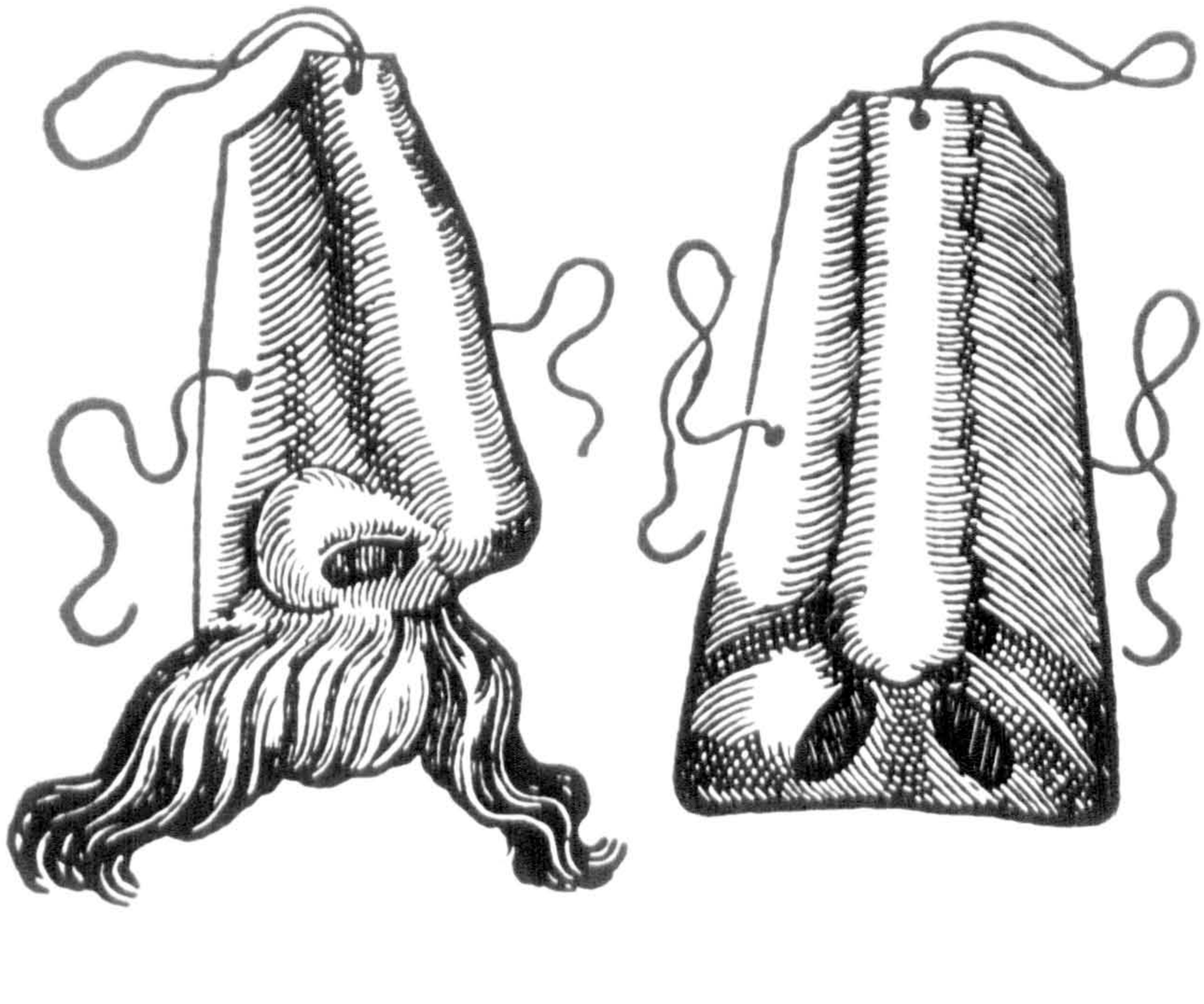


Figure 2 Ambrose Pare prostheses (1510-1590)

THE SKIN

Colour

Many factors make up the quality of human skin described as 'life-like'. Colour is one of the main important factors in patient acceptance in a facial prosthetic material.

The object of workers in the field of prosthetic restoration has been to duplicate and simulate normal human skin so that the prosthetic restoration will appear realistic.

The absolute covering material for the human body has yet to be defined, however for the task it has to do the skin is worthy of examination to form an understanding of the many problems of finding a prosthetic substitute.

Human skin is resistant to wear. It replaces itself. It is warm in winter yet cool in summer. It has a resistance to damp, corrosive elements and micro-organisms and its aesthetic properties can much influence the social acceptance of its owner. HARRY (1962) gives the total area of skin covering a six foot 70 kg male as 1.9 m^2 and the weight as approximately 2100 g.

In its ideal state the skin appears perfectly smooth. However, as skin ages, it is more exposed to heat and cold, pressure and abrasion. In order to reproduce skin colour to an acceptable degree in a prosthetic material it is necessary to examine briefly the structure of human skin with regard to pigmentation.

The aesthetic colour of a translucent surface like that of human skin results from the scattering of unabsorbed spectral regions throughout the heterogenous surface and substrate layers with highly diffuse reflectance by the internal dermal structure. Human skin comprises a series of translucent layers (Fig. 3), the outer epidermis, the dermis and the subcutaneous tissues, each containing various pigments contributing to the sensible colour of skin. When seen in light some of the incidental rays are reflected from the surface unchanged contributing to that quality of human skin termed gloss, often thought to be only shine. The remaining light enters the epidermis and is either absorbed, transmitted or reflected with diffuse scattering depending upon the spectral colour characteristics of the pigments in the dermal layers. The total reflection, both direct and diffuse, contributes to the visual stimulus with the process continued in the dermis and subcutaneous tissue layers. The overall visible sensible colouration of human skin is therefore a complexity of absorption, transmission and reflection, depending upon the location, depth and amount of colour particulate producing pigments and upon the diffuse nature of the skin layers.

Previous workers in skin colour, SCHULTZE (1926) and WILLIAMS (1933) considered only specific pigments namely melanin and haemoglobin. No consideration was given to reduced haemoglobin and neither carotene nor melanoid was recognised as a normal constituent (EASTWOOD, 1978). The epidermis was considered a screening factor for underlying blood. Roberts, in the study of skin pigmentation, describes human skin colour as attributable to five prevailing pigments - Melanin, Melanoid, Haemoglobin, reduced Haemoglobin and carotene.

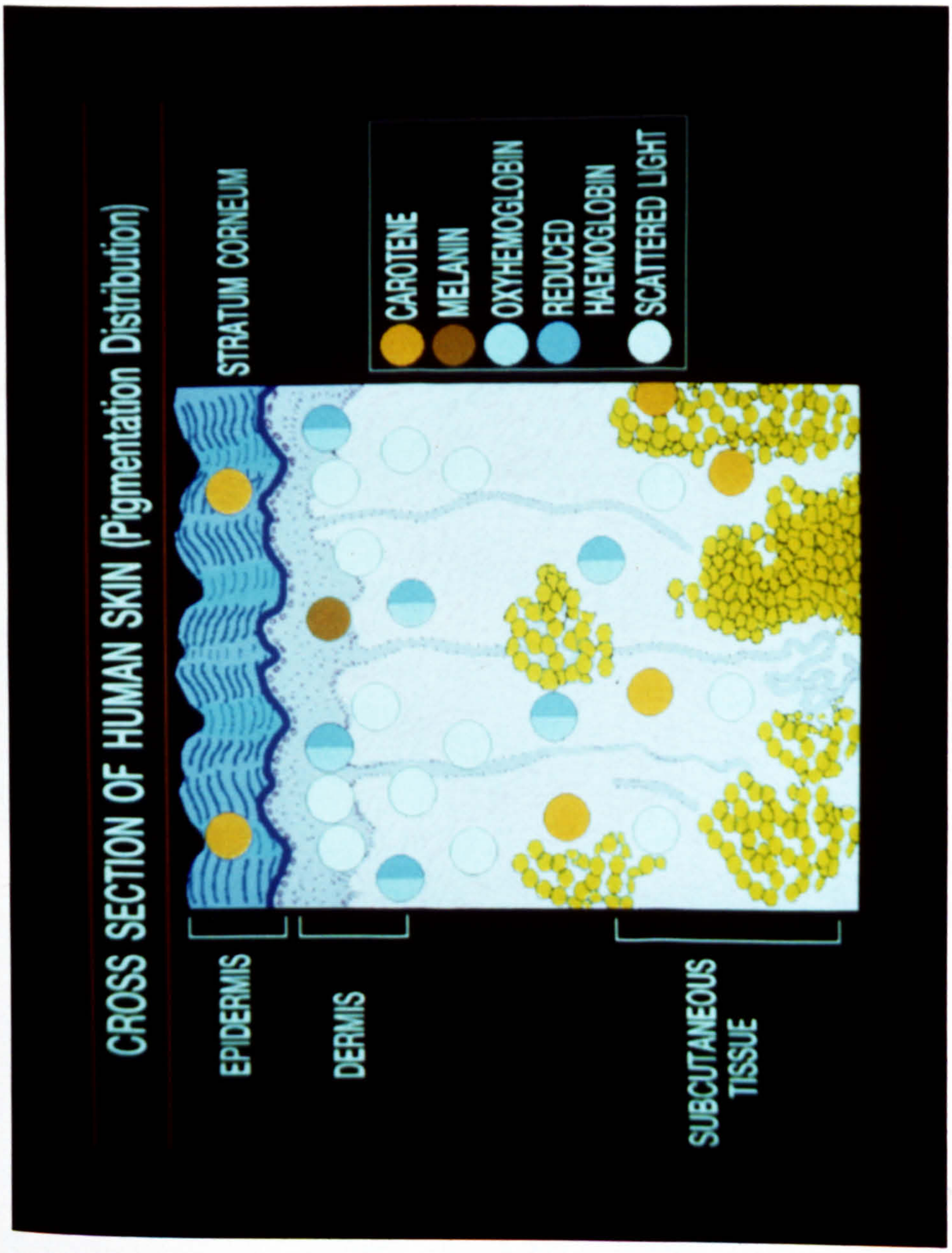

CROSS SECTION OF HUMAN SKIN (Pigmentation Distribution)
STRATUM CORNEUM
CAROTENE
MELANIN
OXYHEMOGLOBIN
REDUCED HAEMOGLOBIN
SCATTERED LIGHT
EPIDERMIS
DERMIS
SUBCUTANEOUS TISSUE

Figure 3

These pigments (Table 1) absorb specific spectral regions and reflect colour characteristics. Melanin, found principally in the epidermis, is the basic dark pigmentation and is responsible for the yellow and brown effects of the skin. McANDREW (1963) in an investigation of skin pigmentation, describes melanin as a coloured protein complex indicating "tinctorial" differences that are seen in the skin, hair and eyes of man. A microquantitive study of human dermis established that the variation in the hue of the skin in Caucasian, Negro and Mongolian (racial groups described as having white, brown-black and yellow skins respectively) is not related to the number or distribution of pigment producing cells which appear to be the same for all races, but to the content of melanocytes. The melanocyte beingthe pigment bearing cell which secretes melanin. SZARBO (1959) determined that the epidermis is on average 10 cells in depth, the melanocytes being situated in the lowermost epidermal cell layer of the epidermis (Figs. 4 & 5).

Table 1 Principal Pigments in Living Tissue

Pigments	Location	Qualitative Colour
Melanin	Basal layer	Brown and yellow bluish tinge
Melanoid (sol.)	Basal layer	
Oxyhemoglobin	Capillary tips	Red
Hemoglobin	Capillary tips	Blue red Pink tone
Carotene	Tissues and stratum corneum	Yellow and red

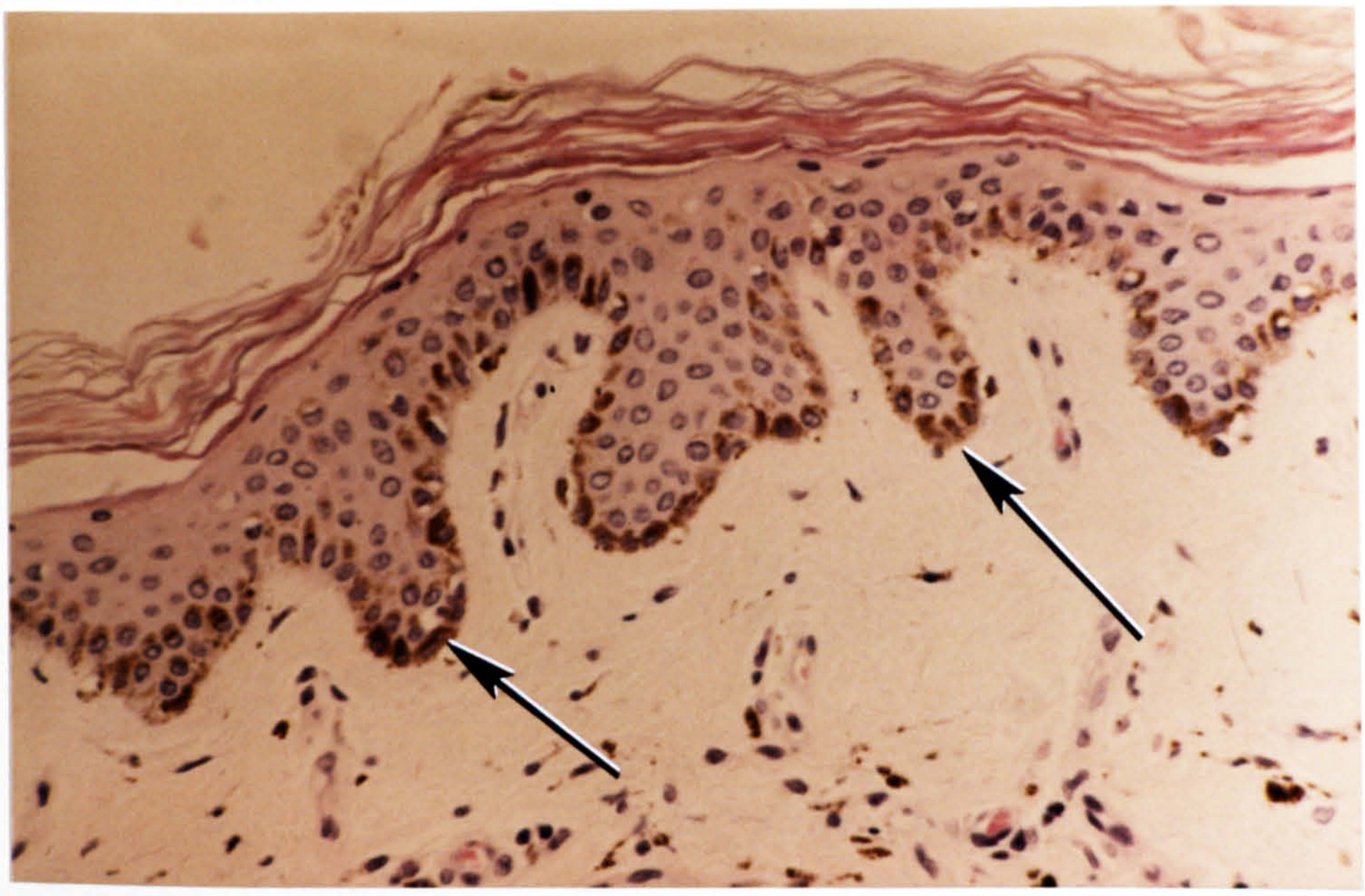


Figure 4 Section showing normal epidermis of a negro. The upper black zone in the prickle cell layer is the normal granular layer, with granules composed of keratohyalin - not melanin. The basal layer shows intense pigmentation with caps composed of melanin granules above the nuclei.

(H & E X 250)

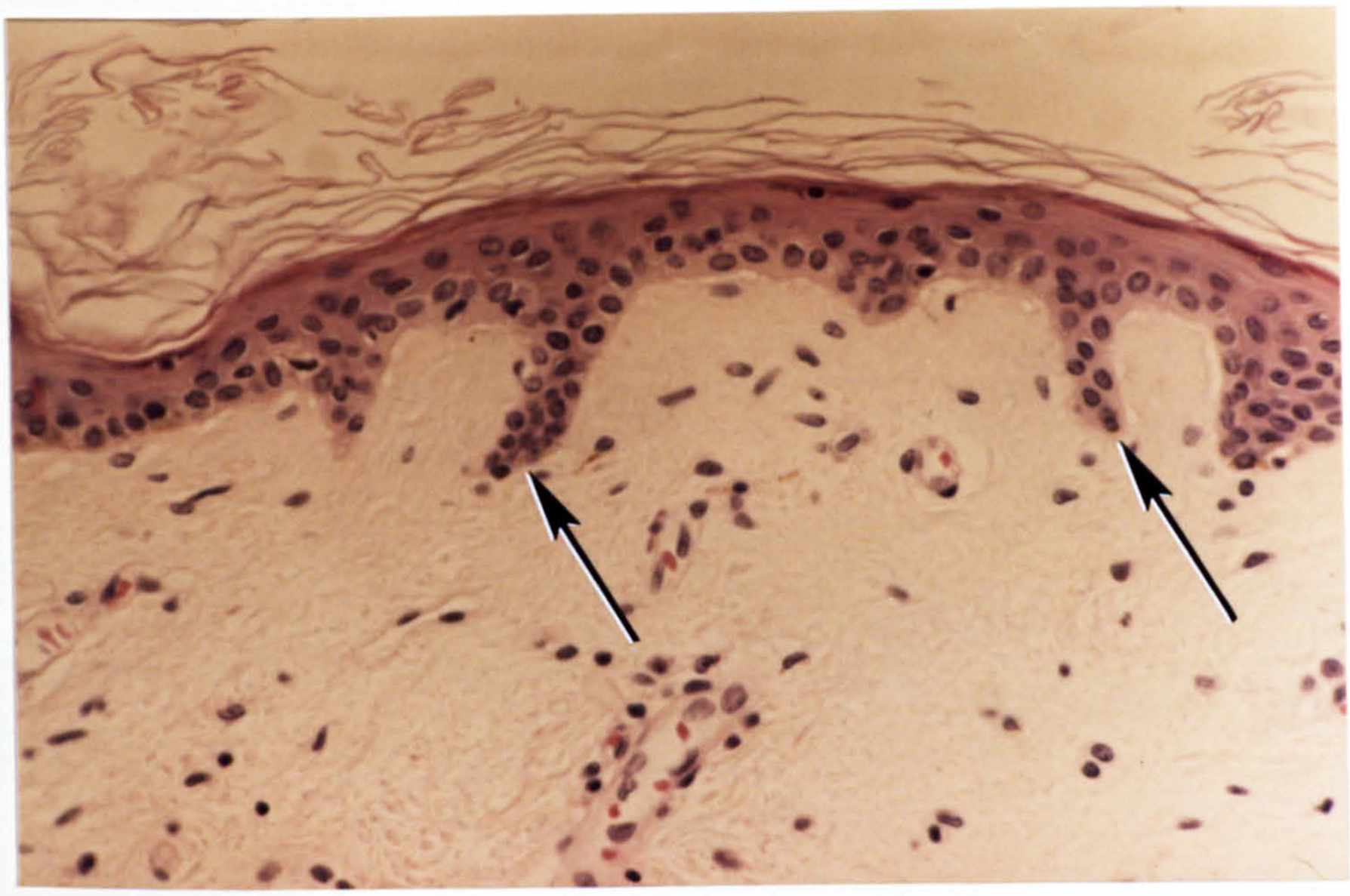


Figure 5 Section showing normal epidermis of a white Caucasian. The basal layer(↗) lacks the intense pigmentation seen in that of the negro.

(H & E X 250)

A horizontal pigmented network is formed by long cytoplasmic extensions of melanocytes interconnecting and weaving in among the other epidermal cells; within these melanocytes the amino acid tyrosine is enzymatically converted into melanin. BLUM (1959) describes the principal role of melanin in the human skin to be that of a light trap, an epidermal screen of pigment protection placed between ultra-violet light and the highly vascular dermis.

EDWARDS and DUNTLEY (1939) are credited with the identification of a new pigment. On examination of the stratum corneum they found a pigment resembling melanin in its general pattern of absorption but differing in that the new pigment had an absorption pattern in the violet of the visible spectrum. Because of its resemblance to melanin they designated the pigment "Melanoid". Since melanoid resembles melanin spectrophotometrically and since it is found in cells derived frm the melanin-bearing cells, it is thought logical to regard melanoid as a degradation product of melanin: the amount of melanoid found in any skin is related to the amount of melanin found there.

Skin colour difference between sexes

It is generally accepted that women are of a lighter skin colour than men. This is not as might be expected attributable to environmental exposure and work patterns. STRONG (1927) found that the female skin contains less blood and melanin. He identified the strong melanin areas in the female skin as the nape of the neck and

the axilla. Carotene being distinctly more evident in the female than the male, mostly in the breast and abdomen in contrast to the male who shows little carotene in these regions.

Skin colour differences in the races

The work of EDWARDS & DUNTLEY (1939) and FITZPATRICK (1961) confirms that the quantity of melanin is alone responsible for the colour difference in the dark skinned races. Edwards and Duntley further define the principle colour differences to extra melanin derivative melanoid. The research findings of skin colour indicate that coloured races owe their characteristic skin colour to variations in the amount of melanin. To this pigment must be added the derived pigment melanoid. No pigments other than those found in the white races are encountered in the dark skinned races and the general pattern of pigment distribution is identical in both groups.

DEVELOPMENT

Of the many difficulties encountered in facial reconstruction by prosthetic means, the material used is of particular importance. The colouring of the face and skin is not uniform and is subject to constant variations due to temperature, emotion and general health, all presenting individual problems. Few materials qualify for use as facial prostheses since the exacting specifications required for human tissue substitution are difficult and, in some respects, impossible to simulate in a synthetic material. Living tissue is constantly adapting and replenishing, being always in a dynamic state.

Although a prosthetic material can never simulate these dynamic facters, many materials have found application throught the years. It was not until the later part of the 19th Century that the "plastic" materials were used. BULBULIAN (1945) used vulcanite rubber and cellulose nitrates. These early prostheses were rigid and heavy, colour being imparted to the outer surface, and failed to provide the lifelike appearance required. TUCKFIELD & WORNER (1945) found Poly(methyl-methacrylate) to have many advantages with regard to translucence and colour. They recognised that the material had potential despite being a rigid polymer. It is of interest to note that until 1960 some 95% of facial prostheses constructed in the United Kingdom were of Poly(methyl-methacrylate) (ROBERTS, 1968). The first noted departure from the concept of rigid materials has been credited to ZINSSER (1913), BERCOWITSCH (1928) and BATSON (1935). These workers used a flexible gelatin glycerine compound. However,

the functional life of this compound was limited to only a few days before hardening and discolouration occurred. BULBULIAN (1939) and CLARKE (1941) made extensive use of prevulcanized latex in liquid form, but again the duration of effective use by the patient was limited because of severe shrinkage and discolouration. Liquid prevulcanized latex found favour until the introduction of plasticizers for vinyl resins in the 1940s. HUME (1943), TYLMAN (1943), FONDER(1955), FENN LIDDELOW and GIMSON (1961), ROBERTS (1966) used poly(vinyl chloride) for the construction of facial prosthetics. The physical properties following a period of wear were found to deteriorate together with loss of colour. This material was considered to have advantages over all others until the introduction of silicone elastomers to facial prosthetics. BARNHART (1960) introduced silicone elastomers. He used a room temperature vulcanizing (RTV) (Silastic) in combination with Poly(methyl methacrylate) dental stainer polymer. The dental polymer was used as a filler and intrinsic colour base. Some of the physical properties of the elastomer were unsatisfactory, in particular tensile strength and tear strength. The Poly(methyl methacrylate) polymer produced a granular effect on the elastomer resulting in low resistance to deformation (ROBERTS, 1971).

A number of contributors to facial prosthetics have used modified silicone elastomers. MATALON et al. (1968) used a clear RTV* elastomer pigmented by means of Du Pont oil soluble dyes. CHALIAN (1968) employed heat vulcanizing elastomer (Silastic MDX 44514). He introduced metallic oxide pigments in the material by means of a small roller mill. AL-QUDSI (1968) used a silicone elastomer (Silastic 382), coloured with metallic oxide pigments.

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* RTV.. Room Temperature Vulcanizing

KANTER (1970) reports the use of an RTV elastomer (Derma-Sil). He coloured the translucent elastomer base by means of mineral pigments. ROBERTS (1971) described the use of a clear prosthetic elastomer base (Silastic 399). The skin colour of the base was simulated by art powder pigments. Extrinsic tinting was achieved by use of the pigments in a paintable solution of elastomer. The immediate aesthetic effect was satisfactory, but again the material had a short functional life and a low tear strength. SCHAAF (1970) used heat vulcanizing elastomer (Silastic MDX 44515) and a RTV elastomer (Silastic 399). Metallic oxide pigments were used to obtain intrinsic colours. The final colour characterization of the prosthesis was achieved with water colour pigments introduced into the vulcanized elastomer by means of a tattoo needle. PRATT (1973) described the use of colour batched RTV elastomer (Silastic 399) blending the colour batches to form a skin colour base elastomer. WELLINGTON & PAGE (1974) used Rhodorsil coloured by art oil pigments. Because the elastomer used was an industrial grade they bonded a polyethylene sheet to form a fitting surface to the skin. LONTZ et al. (1974) have combined an RTV silicone elastomer (Silastic 372) and a high temprature heat vulcanizing elastomer (Silastic MDX 44515). They describe the combined elastomer compound as having a modulus of elasticity close to that of human tissue. The claim is based on data of 8 to 3.7 x 10^4 Nm-2 for the modulus of elasticity and a strength-to-modulus quotient of 17.5 as derived from stress-strain profiles of fresh canine artery. AINA et al. (1966) used an RTV elastomer to simulate negro skin colour. Pigmentation was by use of inorganic iron oxides. He concluded that silicones could be pigmented to reproduce negro skin colour and texture with good aesthetic properties.

Materials currently used

Acrylic Resin

Poly(methyl methacrylate), so common to dentistry as a denture base and tooth material, is readily available and inexpensive. A wide variance of skin tone colours can be achieved by means of high concentrate acrylic polymer stains. The simple technology involved of combining the monomer and polymer followed by conventional dental laboratory polymerization have kept the rigid material in use. ROBERTS (1966) describes the disadvantages of rigid polymers as:

1. Discomfort at the site and surrounding areas of the defect.
2. Lack of response to facial movement.
3. Surface shine following a short period of wear.
4. Limited use in undercut areas used for retention.
5. Unsuitable for cosmetics.
6. Psychologically less acceptable to the patient than flexible materials.

If able to conform to the physical characteristics required, flexible materials have distinct advantages over rigid materials. They are:-

1. Comfort in contact with the tissues.

2. More readily adaptable to the contour and periphery of the defect.

3. Some facial movement reciprocated by the material.

4. Undercut areas may be utilized for retention.

5. Surface texture more readily takes cosmetics.

6. More than one prosthesis can be constructed from the mould.

Vinyl Resins

A plastisol is a dispersion of the resin in a compatible plasticizer which, when heated to a prescribed temperature, can be converted from a viscous fluid to an elastomeric polymer. An organisol is an emulsion of the plastisol with volatile thinners. The thinners are usually aromatic and aliphatic hydrocarbons, or a blend of these. Numerous plasticizers have been used for compounding plastisols and organisols. These constitutents of the material often migrate from the cured material and as such have come under investigation with regard to toxicity (BOWERY & LEWIS, 1968; HOLLINGSWORTH, 1971; GILDING, 1977).

The final physical properties of the plastisols and organisols when cured depends on the molecular and particle size together with the formulation used in their production. The temperature of gelation is important. Some of this group of materials require a temperature

of 190°C to obtain the maximum physical properties, and need metal moulds to effect sufficient heat transfer. LAMMIE & STORER (1977) and CRAIG & GIBBONS (1963) describe the inherent characteristics in these materials as that of a plasticizer migration resulting in an initial loss of physical and mechanical properties. Facial prostheses constructed from plastisols and organosols discolour, harden, shrink and lose their flexibility. These physical and mechanical changes occur within 3 to 6 months representing an unacceptable wear period - for a prosthetic restoration. KING (1970) indicates that the material is unsuitable for use if the patient lives in a high temperature, bright sunlight environment.

Polyurethane Elastomers

Polyurethanes are among recent polymers introduced to facial prosthetics. GONZALEZ (1970) has used polyurethane with success. FRICH (1969) describes polyurethane polymers as being characterized by the linkage or presence of urethane groups, although other groups such as esters and ethers may be present in the molecule. These elastomers are synthetic formulations of long chain linear polyesters or polyethers reacted with disocyanates. They can be thermoplastic or thermosetting. Gonzales describes the material as being, when correctly processed, chemically inert, resistant to solvents and ozone, and having a high tear strength. The modulus of elasticity of the material resembles that of soft tissue. The disadvantage of the use of Polyurethanes is the degree of precision required in processing, and the complex equipment and instrumentation required. MARGETIS (1978) describes an experimental two component polymer facial prosthesis

material formulated from latex and Poly(methyl-methacrylate) cross-linked with formaldehyde. This material has organic pigments dispersed in the underside of the surface layer of the acrylate skin to achieve the illusion of depth. Final colouration is by use of an air brush to apply organic pigments in a vinyl solution.

Silicone Elastomers

Polysiloxane elastomers have found a prominent place in facial prosthetics. Medical grade polysiloxane elastomers now have a good history in surgery and medicine. The first attempts to find applications for silicones in the medical field were made by BARONDES & JUDGE (1950) and BROWN & FRYER (1953). This group of elastomers is relatively inert, flexible, biologically compatible, chemically resistant to ozone and indifferent to temperature changes. Their absorption of body fluids is low (LONTZ et al., 1974; ROBERTS, (1976).

Silicone elastomers are available in two main vulcanizing groups - heat vulcanizing and room temperature vulcanizing. The heat vulcanizing elastomer may be modified by fillers to achieve a wide range of International rubber hardness degrees (IRHD). However, the most common is that of IRHD 30-50-70, grade 30 having found most application (DRANE, 1970; FRISCH, 1978; GUIGNOT, 1978). The vulcanizing agent used in elastomers for prosthetic application is dichlorobenzoyl peroxide. The temperature required to complete vulcanization is around 150°C followed by a post-vulcanization cure. Colour can be introduced prior to vulcanization by means of a roller mill. WINTER (1983)

described the formulation of a room temperature curing elastomer for facial prosthetics (Cosmesil). The base elastomer is in transparent form, and by the addition of curing additives, a cross-linking agent and catalyst, a high tear strength soft tissue-like elastomer can be produced. Colouring agents suspended in silicone fluid provide a colour range to simulate basic skin shades. The final cured prosthesis can be tinted by extrinsic pigments.

The room temperature vulcanizing silicone elastomer can be seen to have been extensively used for facial prostheses. The elastomers are available in one and two component systems, and require mixing and colouration. The two component system is the most common RTV elastomer used in facial prosthetics. The components are catalyst and the base compound, silicone polymer containing filler. Because of the need to mix in a catalyst and colourants, the viscosity of the polymer used is low. The catalyst used is stannous octoate. In the one component system, the polymer base already contains the formulation for vulcanization which takes place in contact with water vapour in the atmosphere. Chemical condensation takes place resulting in continuous displacement of the equilibrium by the evaporation of the acetic acid formed. Vulcanization begins at the surface and proceeds towards the interior as water diffuses in and acetic acid diffuses out. This single component system has not found general acceptance for facial prostheses. HULTERSTROM (1976) found application for this elastomer in ear prostheses, colouring the elastomer with organic pigments. The mechanical properties of this elastomer are not sufficient to withstand the daily usage by facial prosthesis patients. Its main application is that of an adhesive and can be

used to complement and repair silicione elastomer restorations and as a sealer for extrinsic tinting. The problem of room temperature vulcanizing elastomers applied to facial prostheses has been the poor mechanical properties and difficulty of colour simulation. Most RTV prostheses can be described as fragile with poor tensile and tear strength. These limitations have received attention during this research.

The development of materials for prosthetic facial reconstitution has been equal to the advances made in materials science. Complimentary to this has been the understanding of the structure and physiological function of human skin. The most satisfactory materials which can be formulated to simulate skin and tissue are polysiloxanes. The research thrust at this centre has been to develop a silicone elastomer for use in prosthetic reconstruction in support of plastic and maxillo-facial surgery.

Retention of Silicone Elastomer Facial Prosthesis

The development of silicone elastomers for facial prostheses has extended the range of methods of retention to take advantage of the physical properties of the material.

The success of a prosthetic restoration depends on the means and method of retaining the prosthetic material in the required location on the face. Confidence of the patient in the prosthetic reconstruction is enhanced by good retention.

The knowledge that the prosthesis will remain securely in position throughout daily routine further increases patient acceptance of facial reconstruction by prosthetic means.

Perhaps the most significant advance in the retention of facial prostheses in this category is that afforded by the implantation of osseointegrated fixtures. This method of retention termed "osseo-integrated retention" was introduced to the dental profession in 1982 and has had a profound effect on the capacity of the oral surgeon to achieve a previously unobtainable level of oral rehabilitation.

This technique has been of particular benefit to patients who suffer from insufficient retention preventing them from wearing conventional dentures. Osseointegration techniques in the oral cavity range from the partial endentulous to the entire dental arch. BRÅNEMARK et al. (1977) first described his new dental implant system, the osseointegrated screw. ALBREKTSSON et al. (1986) reported a ten year clinical success rate of more than 90 per cent. The positive outcome of this osseointegrated screw technique is attributed to a firm implant bone anchorage without interposed soft tissue and a reaction-free mucosal penetration (BRÅNEMARK et al. 1985).

In 1985 Brånemark reasoned that it ought to be possible to use a skin-penetrating implant on the same principles as the osseo-integrated dental implant representing the device that permanently penetrates the soft tissue of the oral cavity.

From this concept the clinical program of percutaneous titanium implants commenced (TJELLSTRÖM et al. 1981). ALBREKTSSON et al. (1987) gives two indications for this surgery:

1. A stable anchorage of an external bone-anchored aid in certain cases of hearing disorders.

2. A stable anchorage of a facial prosthesis.

ALBREKTSSON reported the use of 389 skin-penetrating implants used in one of these indications in 174 patients.

The skin-penetrating abutment implant

The implant is in the form of a 3.75 mm wide 3- or 4 mm long screw of pure titanium (99.75 per cent pure with 0.05 per cent iron, 0.10 per cent oxygen, 0.03 per cent hydrogen) ALBREKTSSON et al. (1983). The implant has a flange to prevent accidental perforation of dural structures during surgery (Figs 6 & 7).

Brief outline of surgical procedures

A curved skin incision is made under local anaesthesia and a periosteal flap dissected and raised. The bone is drilled at a very low rpm with profuse saline cooling. Enlargement of the drilled hole is gradual by means of larger drill bits.

The hole is threaded with a tap of pure Titanium at speeds of some 20 rpm. A main point at this stage of the surgery is to

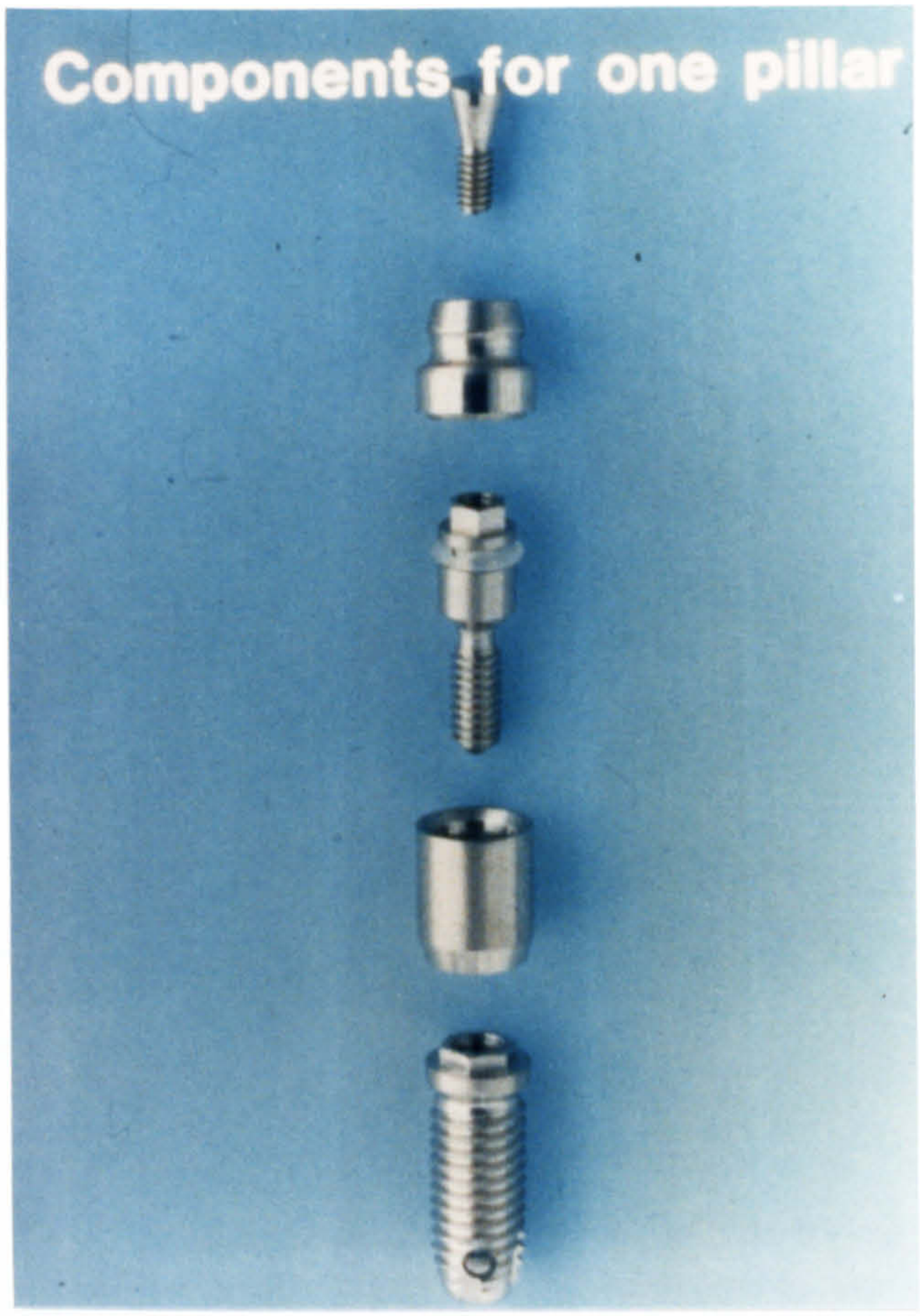


Figure 6 Skin-penetrating abutment

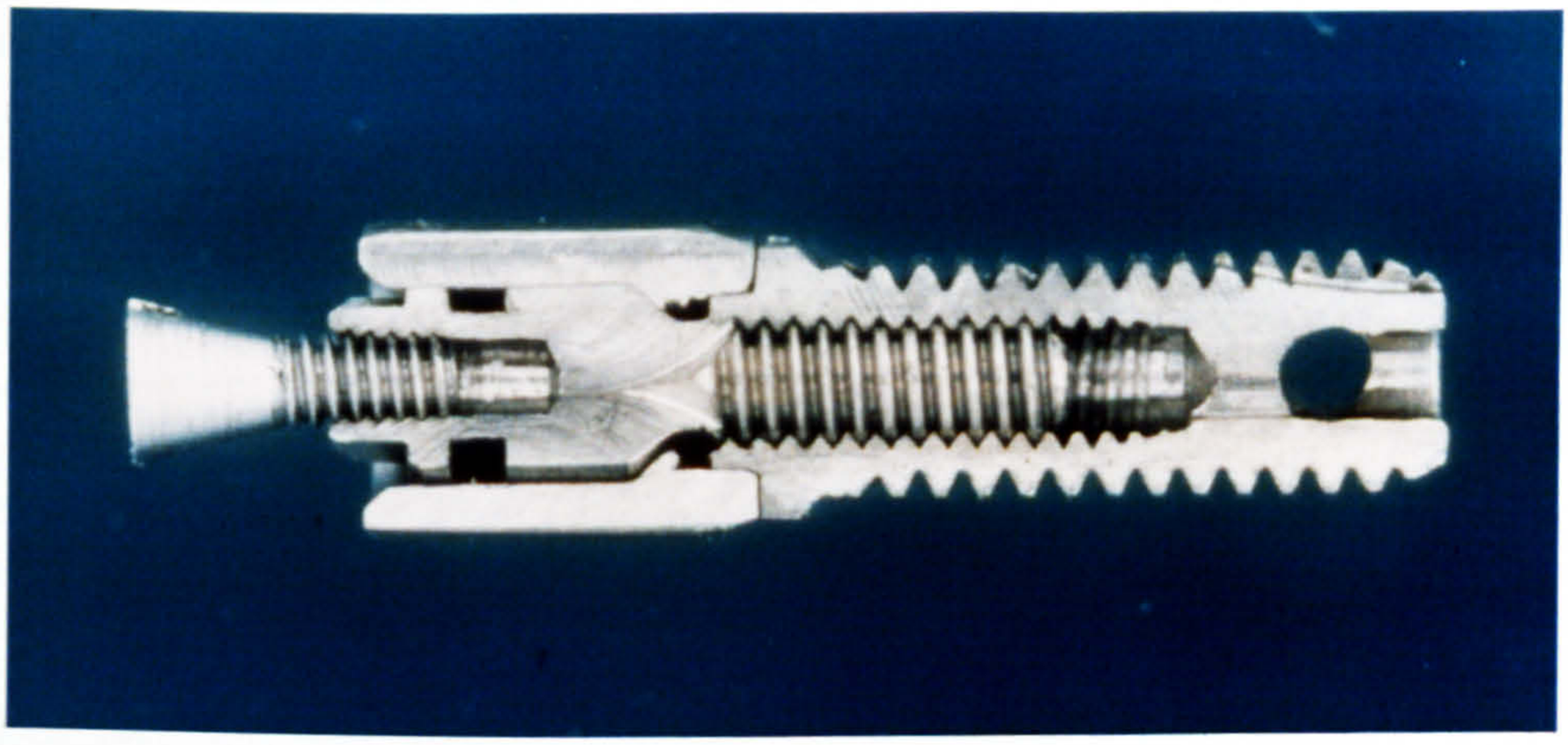


Figure 7 Sectioned abutment assembled

prevent trauma and damage to the bone.

Into the threaded hole a titanium fixture is placed using rotary instruments. To protect the top of the inserted implant and the internal thread a cover plate screw is placed. Finally the skin flap is replaced and closed. After a period of some three to four months the implant fixtures become fully integrated in the bone.

At the second stage of surgery a new skin incision is made around the implant site and subcutaneous tissue removed to achieve tight contact between skin and underlying bone. The cover screw of the integrated implant is replaced with the titanium abutment (Figs. 8 & 9) which penetrates the skin. Some four weeks later it is possible to start the construction of the superstructure - prosthesis. The bone anchored (osseointegrated) implants are connected by means of a lost wax cast 18 ct. gold superstructure (Figs. 10 & 11) and on this connecting superstructure the facial prosthesis is incorporated (Fig. 12). The facial prosthesis is then able to be clipped into position.

There are many potential indications for permanent skin-penetrating implants to retain prostheses and devices to the body. Facial prostheses constructed to percutaneous osseointegrated implants have advantages apart from firm fixation, these are, defined alignment and margin integrity.

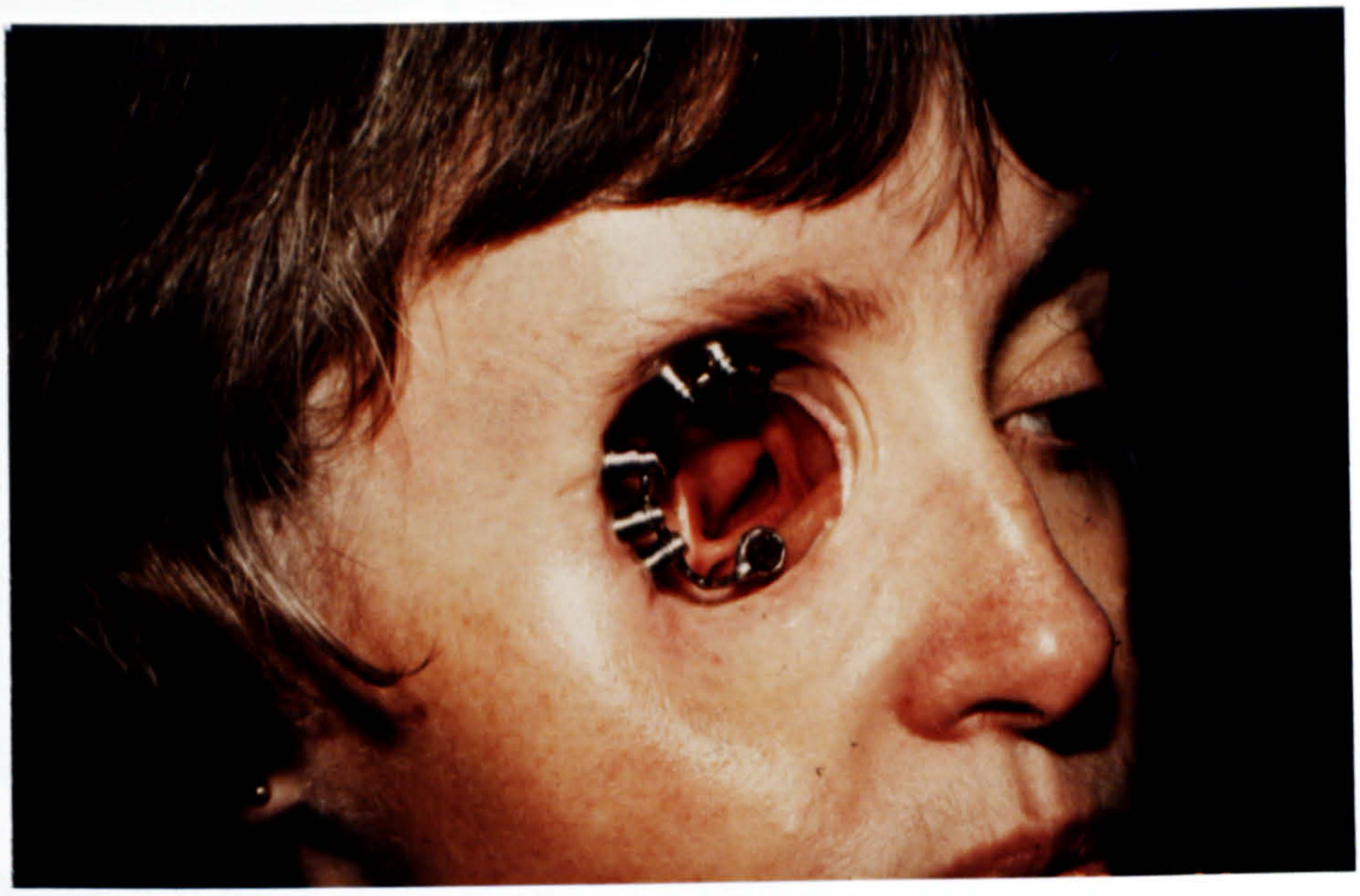


Figure 8 Titanium abutments connected to integrated implants in orbital margin for prosthesis location and retention

Figure 9 Prosthetic Silicone Elastomer orbital restoration with superstructure incorporated

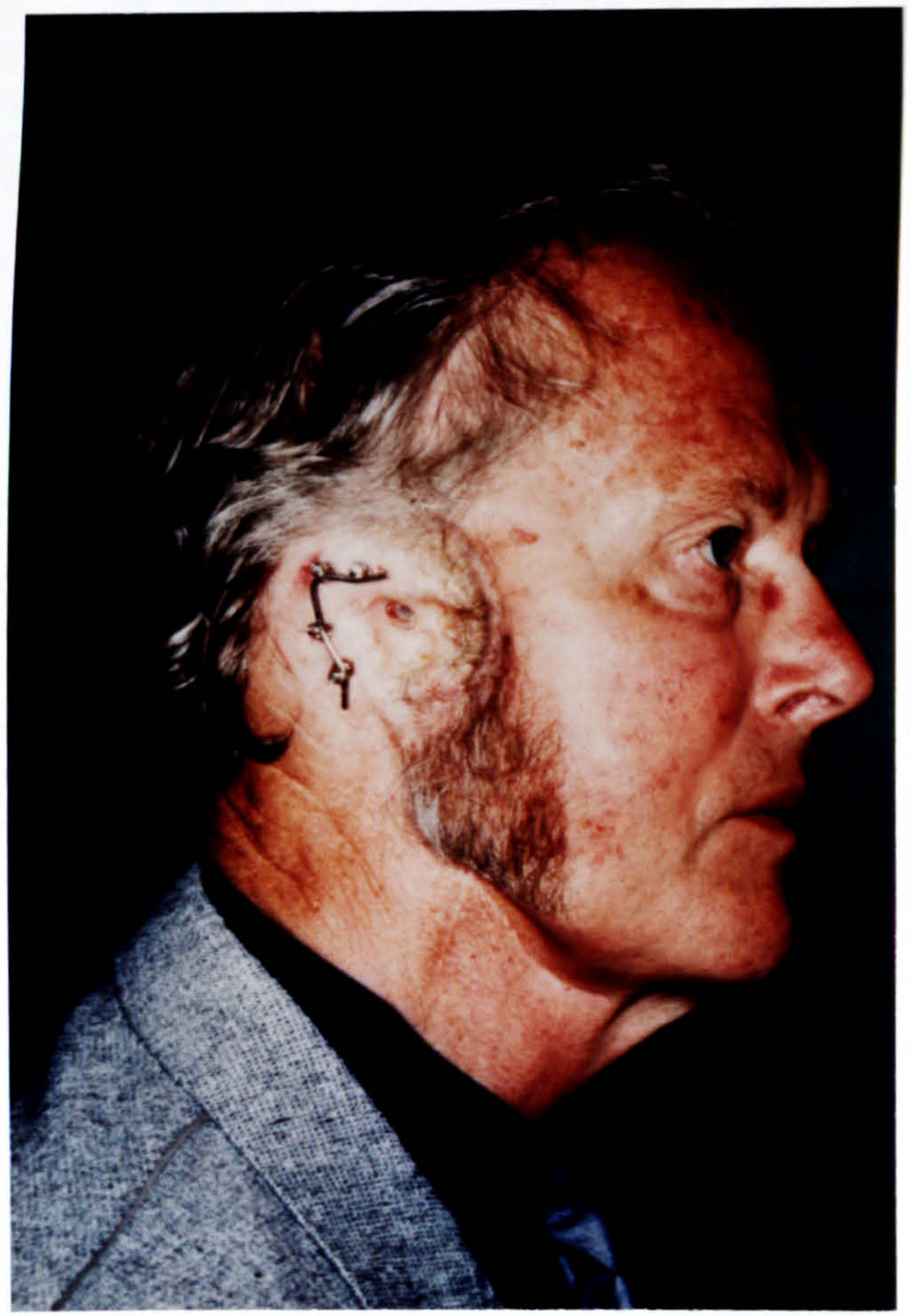


Figure 10 Osseointegrated implants with cast-gold superstructure used for ear location and retention

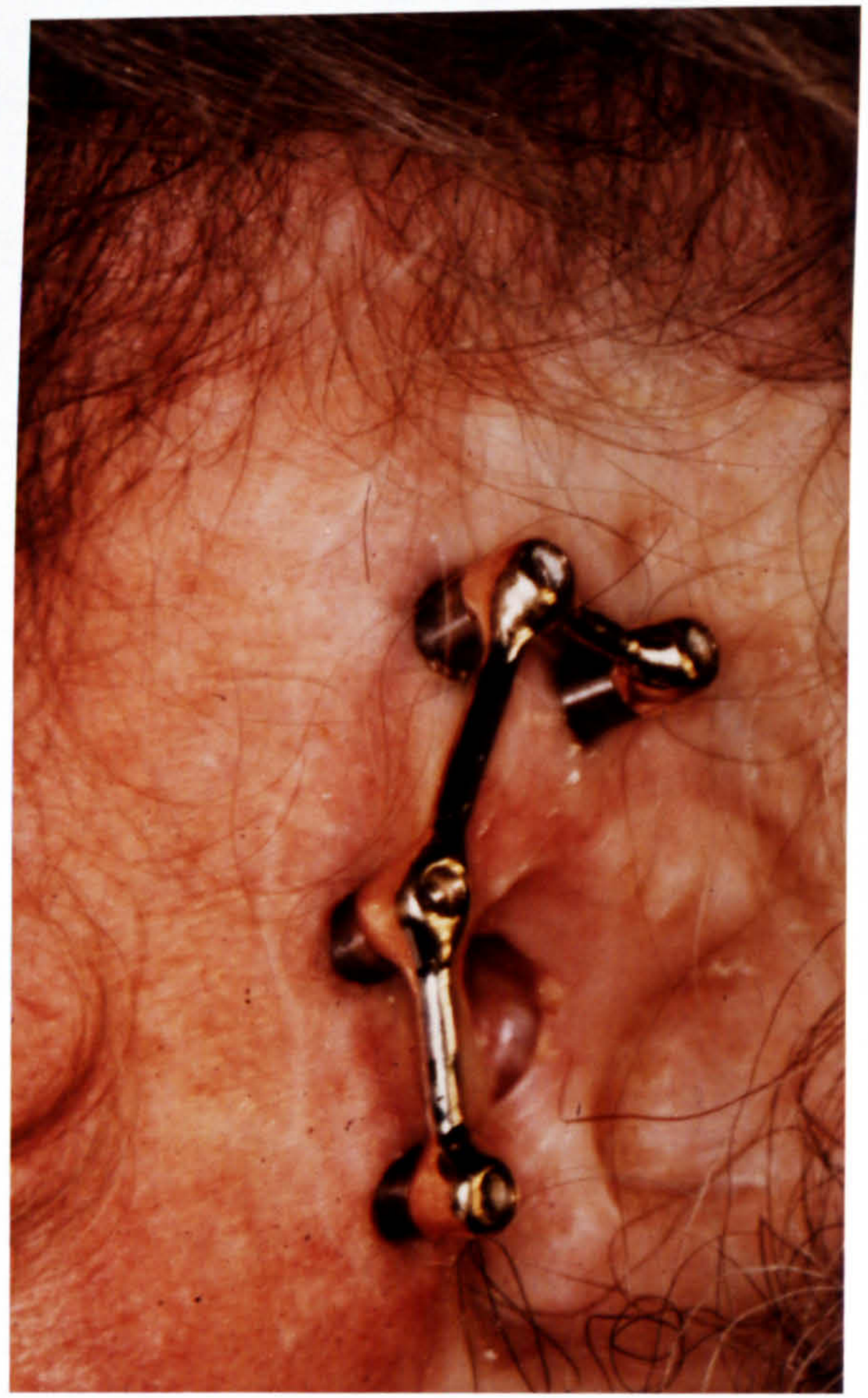


Figure 11 Cast gold cups on osseointegrated abutments connected to form superstructure

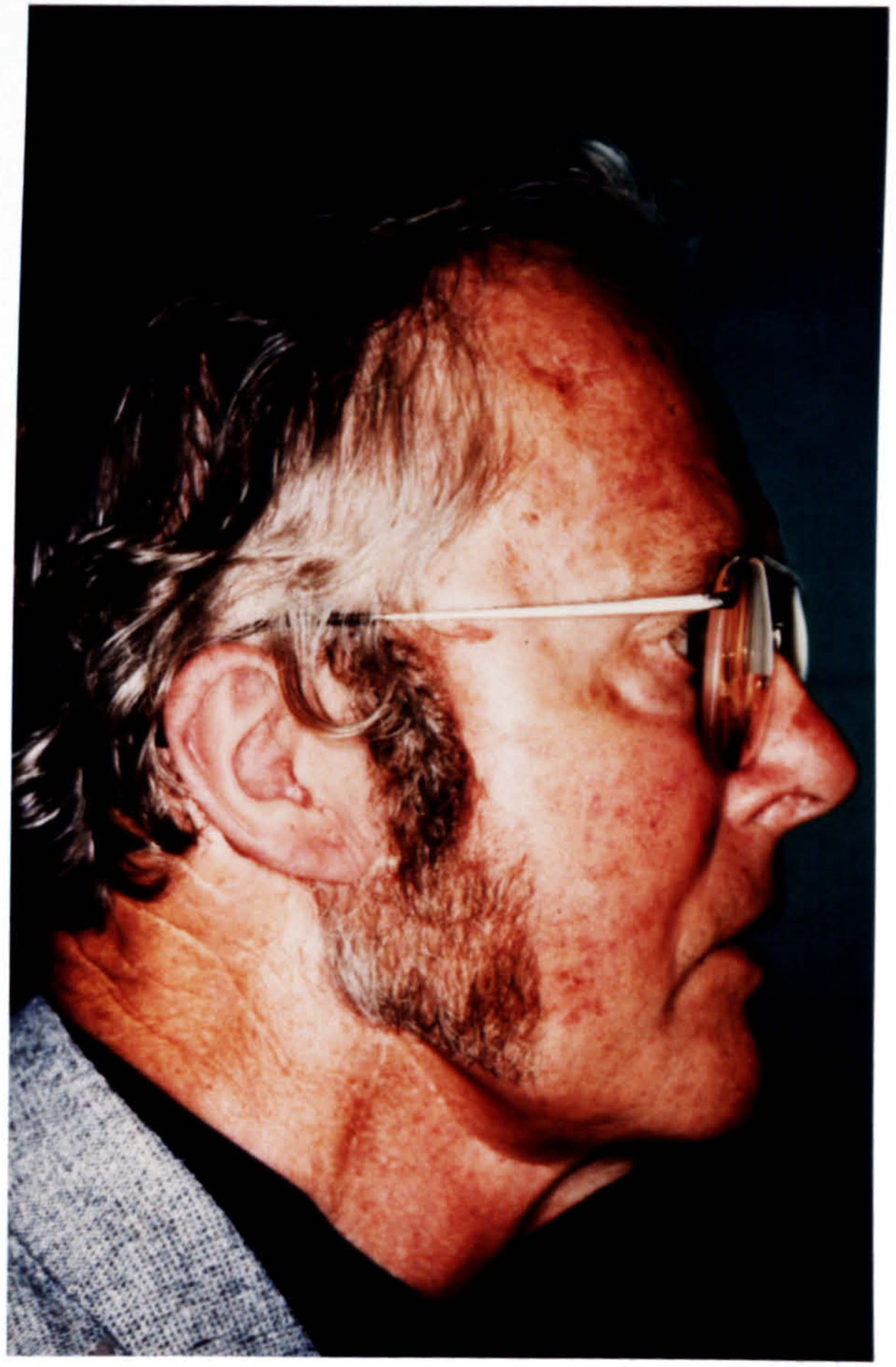


Figure 12 Prosthetic Silicone Elastmer ear restoration with superstructure incorporated

Magnets

A method of facial prostheses retention by magnets is described by SWARTZ et al. (1982) (Fig. 13). Samarium-Cobalt magnets were implanted into subcutaneous pockets in three patients. This technique was used to achieve instantaneous fixation and orientation of the facial prosthesis. Sm-Co magnets are produced by compression of the elements of samarium and cobalt, both of which are initially in powder form.

The two elements are fused under conditions of high temperature and pressure. High magnetic fields are maintained as the powders are compressed into solid metal blocks. TSUTSUI et al. (1979) used Sm-Co magnets as a dental material and established the high corrosion resistance and inertness of the Sm-Co magnets.

SWARTZ et al. encapsulated the magnets used in their study with methacrylate to increase the inertness of the implant.

The Sm-Co magnets exert a 50 per cent increase in magnetic strength over conventional chromiumsteel magnets. Following implantation of the magnets the facial prosthesis with mated Sm-Co magnets was constructed. Swartz et al. report good retention and orientation in the three patients described. The use of implanted magnets has been further extended for experimental fixation of devices to the body, and could be a method of retention for long term attachment in ileostomy patients (SANDEI et al. 1979; HOLLENDER et al. 1976). The disadvantage of percutaneous implant methods of retention

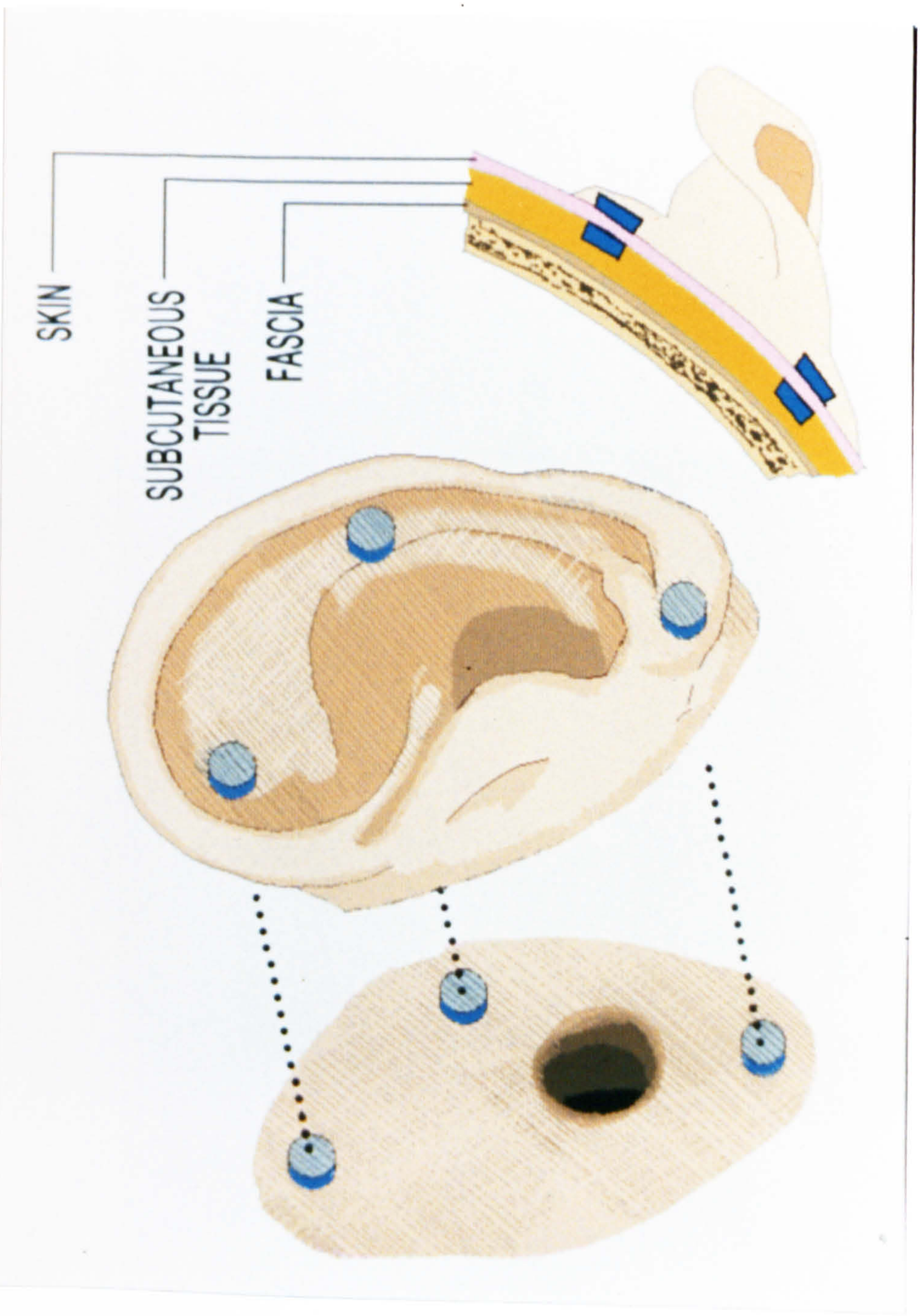


Fig. 13 Sm–Co Subcutaneous magnet implants used to locate and retain a prosthetic Ear restoration

is that surgical procedures are required. Post operative infection and discomfort are also considerations. The high cost of the implants and instrumentation involved are further restrictions to this form of retention. Patients who would benefit from retention by implants require careful selection and post operative management. The alternative and most frequently used method of retention is by contact adhesive. The use and development of adhesives to retain prosthetic devices is described in Part Three of this research.

Evaluating Facial Prosthetic Materials

The principal requirements for a successful facial prosthesis have been described by RAHN & BOUCHER (1970), and BULBULIAN (1967). A suitable material should be compatible with the supporting tissues and be non-irritant, have good elongation, tensile strength and have a similar modulus of elasticity to that of tissue. The material must not harden, and must retain its flexibility in a temperature range of $5^{o}C$ to $60^{o}C$. It should be capable of having its mechanical properties modified and controlled to the needs of specific prostheses. It must have a colour simulation of the skin on which it is placed and be reproducible. It must have a surface texture which is skin-like, be odourless, non-flammable and a poor conductor of heat. It must be dimensionally stable in its final form and thereafter be easily tinted and repaired. It must be easy to clean and resistant to abrasion, weathering body stainants and micro-organisms in the facial region. It must be relatively inexpensive, readily available commercially and be capable of laboratory manipulation.

The essentials of the ultimate criteria described may be at present beyond the current perimeters of our technology. At the first International Symposium on Facial Prosthetics, in the presidential address BEZROUKOV (1976) stressed the need for more evaluation of facial prosthetic materials, stating that there was little published evidence to indicate that clinical success could be correlated with measurable properties of facial prosthetic materials.

In a review of the limited literature available the paramount difficulty is seen to be objective measurement and formulation of the significant properties of facial prosthetic materials. Two principal areas have lacked investigation. These are colour matching (aesthetics) and mechanical properties specific to patient acceptance. Following the pioneer work of EDWARDS & DUNTLEY (1939), CANTER (1978) considered colour to be one of the most elusive qualities to reproduce. He posed the hypothesis that a facial prosthetic material could be structured to maximize a prosthetic material, in particular Silicone elastomer, to facial prosthetics. ROBERTS (1979) investigated the colour factor in Silicone elastomer used for facial prosthetics by means of reflectance spectrophotometry. In that study he measured the reflectance of selected Silicone elastomers together with that of human skin. Different ethnic groups with differing melanin concentrations were evaluated. Roberts, in his study, considered that since pigmented materials have colour because of a limited absorption of light at some point or points in the visible spectrum, examination of spectrophotometric curves would make it possible to identify the pigments required to match and colour simulate human skin in an ethnic group. He demonstrated that such a method could be used to achieve standard basic skin shades.

Table 2

Base Skin Shade

PIGMENT	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
WHITE	0.14	0.12	0.10	0.12	0.14	0.16	0.10	0.13	0.10	0.16	0.16	0.12	0.15	0.12	0.16	0.18	0.14	0.16	0.10	0.20	Blank Base
BROWN	0.06	0.03	0.12	0.16	0.08	0.01	0.16	0.08	0.04	0.01	0.05	0.05	0.08	0.05	0.04	0.04	0.08	0.0	0.02		
MAHOGANY BROWN							0.05									0.12	0.03	0.08			
RED	0.01	0.01	0.06	0.04	0.02	0.03	0.06	0.02	0.03					0.04		0.03	0.02	0.03	0.03		
YELLOW			0.03	0.02	0.02	0 02	0.03	0.03	0.04	0 02	0.02		0.03	0.02							
BLUE	0.01	0.01		0.01	0.01		0.01		0.01	0.03			0.02		0.02		0.01	0.02	0.02		
BLACK		0.01		0.01			0.01								0.01		0.03	0.01			
GREY																		0.02			
RED FLOCK	0.02	0.02		0.01		0.02		0.01		0.01		0.02	0.02		0.02						
BLUE FLOCK	0.01				0.03									0.02							
BROWN FLOCK				0.01		0.02											0.03				

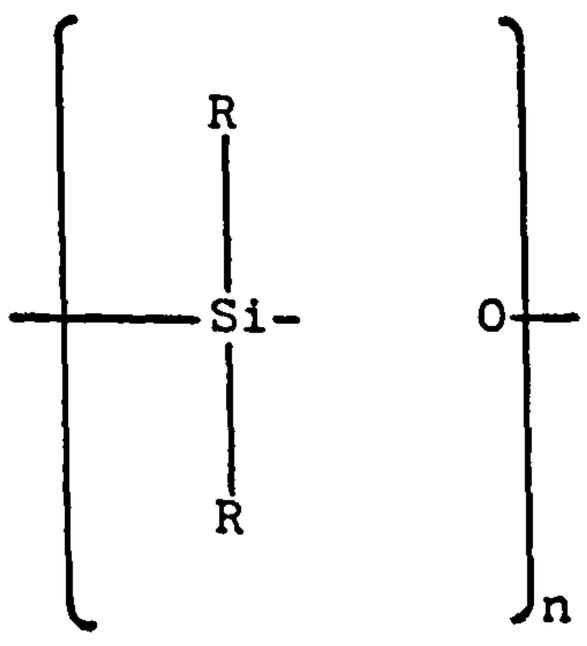
Base Shade Pigmentation Loading
(Weight in g.per/50g of base)

The shade formula used to pigment the prosthetic elastomer used in this research is the result of that study. The ROBERTS shade formula is based on a standard, observer system. The colour spectrum covers the maximum shade variation. Twenty-one shades are used (Table 2). This includes a blank base prosthetic elastomer.

The formulation uses a high concentration of organic pigment, which conforms to EEC directives regarding purity of cosmetic and food colouring. Only micro amounts of pigment are required to effect appreciable shade change.

A brief Introduction to Silicone Polymers

The synthetic silicone polymer can be defined as an alternating silicone-oxygen backbone chain with organic side groups, described by the following repeat unit:



where R is an organic radical

By the variation of both "R" and "n" the polyorganosiloxanes are not a single product, but a group of highly diverse materials which can vary from thin fluids, to resinous products, and finally solid and elastomeric materials.

Because of the inorganic backbone to the chain, the polymers have received much attention for both high and low thermal applications. In fact the first silicone materials manufactured commercially were silicone fluids in the form of grease-like materials used as insulation on spark plugs of military aircraft FORDHAM (1966). Today the use of silicones is diverse, and applied over a vast market range including: aerospace, aircraft, consumer, electrical, automotive and medical. Their use in medical applications has been a major success since medical grade silicone elastomers are:

1) Physiologically and chemicall inert.

2) Not physically modified by tissue fluids.

3) May be well pigmented towards skin tones with a similar texture and hardness approaching natural tissue.

4) Ease of cleaning.

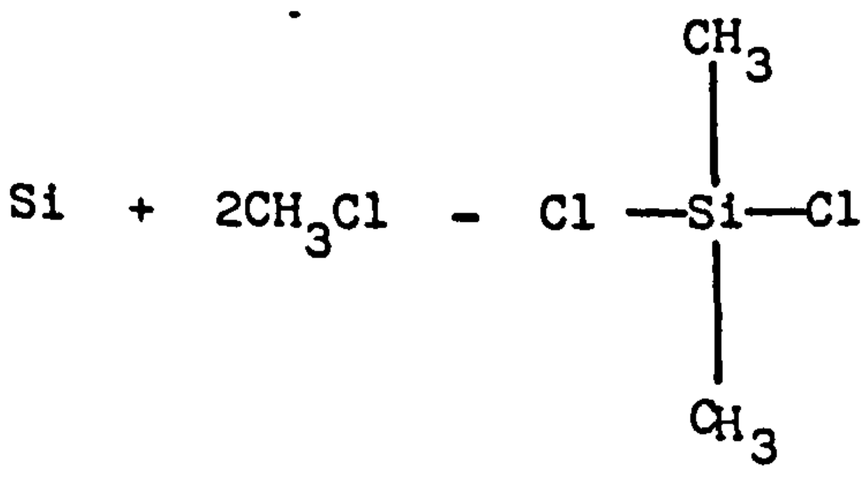
5) Hydrophobic in nature.

Chemistry of Formation of the Silicone Polymer

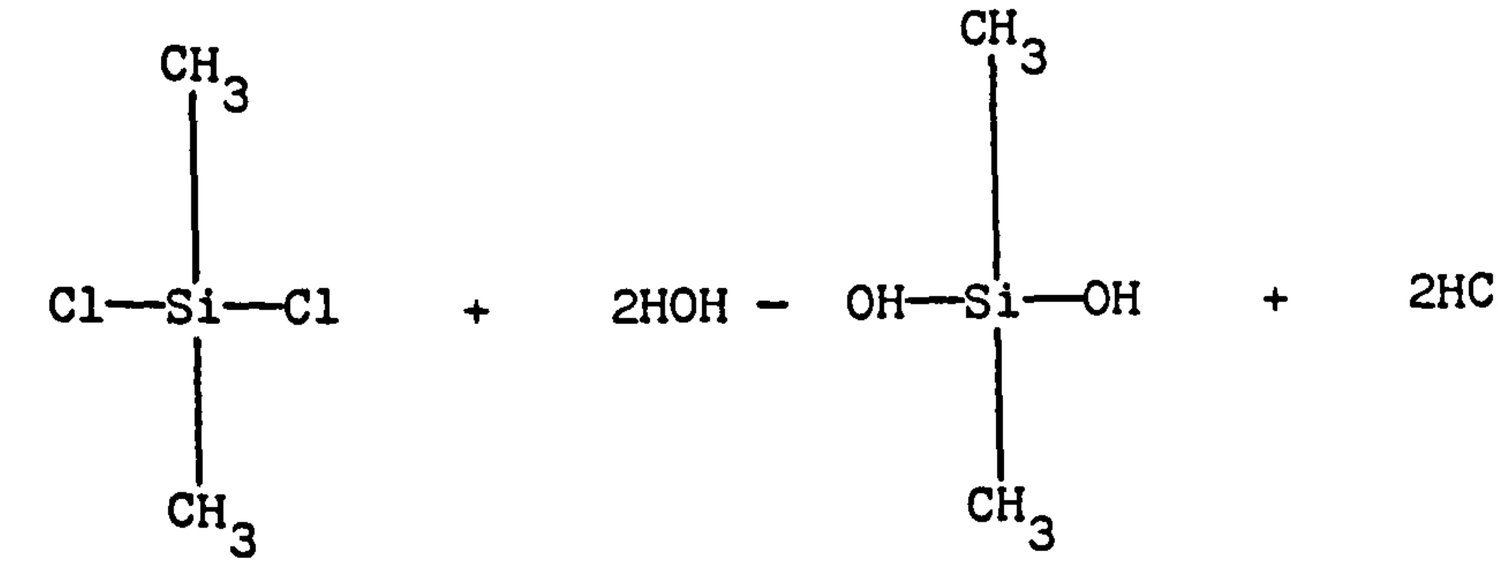
The initial stage of the formation of the polymer in its simplest form, i.e. the dimethylsiloxane repeat unit, involves the reduction of silica to elemental silicon:

$$SiO_2 + C - Si + CO_2$$

Under certain conditions, silicon undergoes a reaction with methyl chloride to produce dimethyl dichlorosilane as follows:

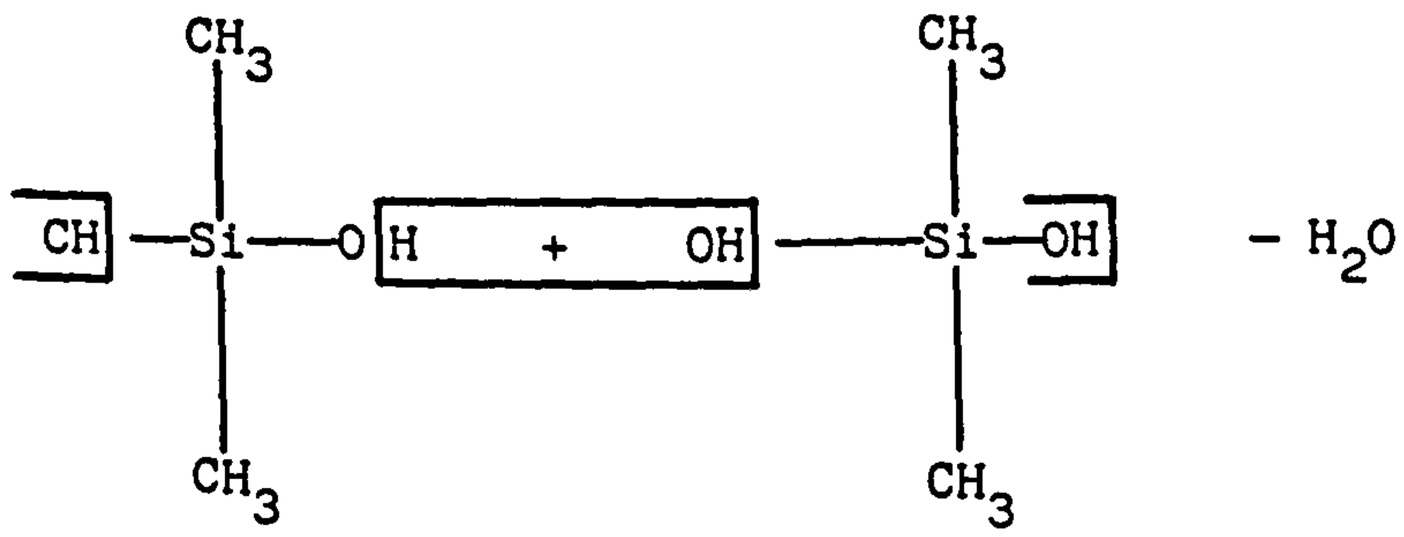


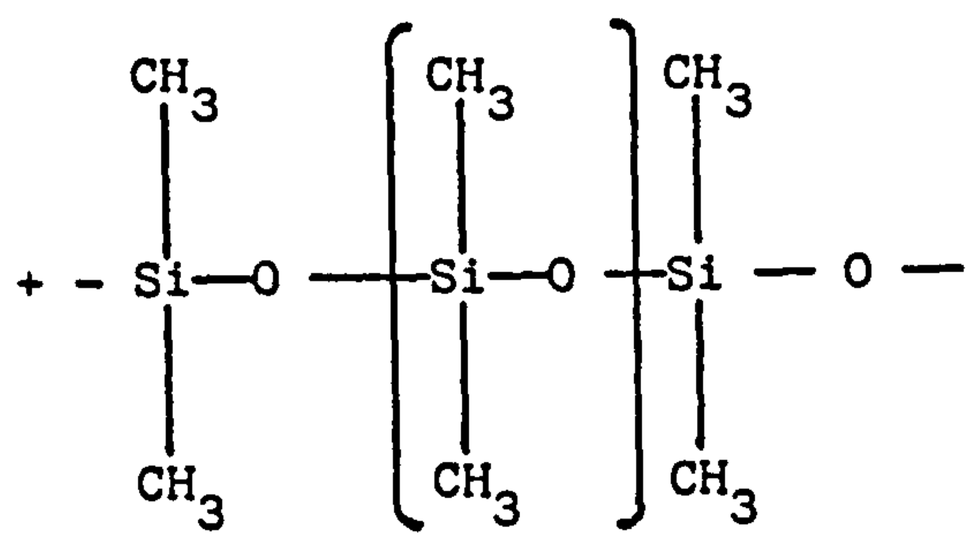
This product is vigorously distilled to remove the presence of any trifunctionality which would lead to undesirable branching in the polymer. The silane is now hydrolysed,



"diol"

The diol is very unstable and condenses with a neighbour to form the silicone polymer plus water.

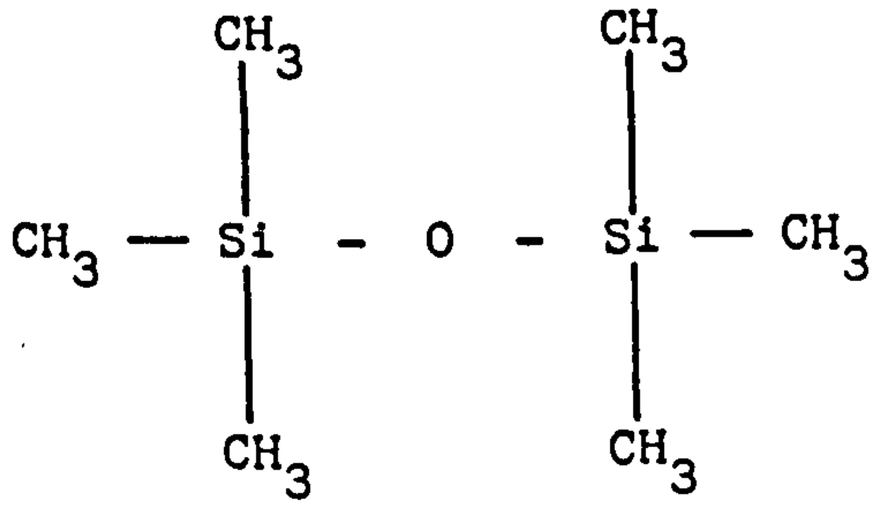




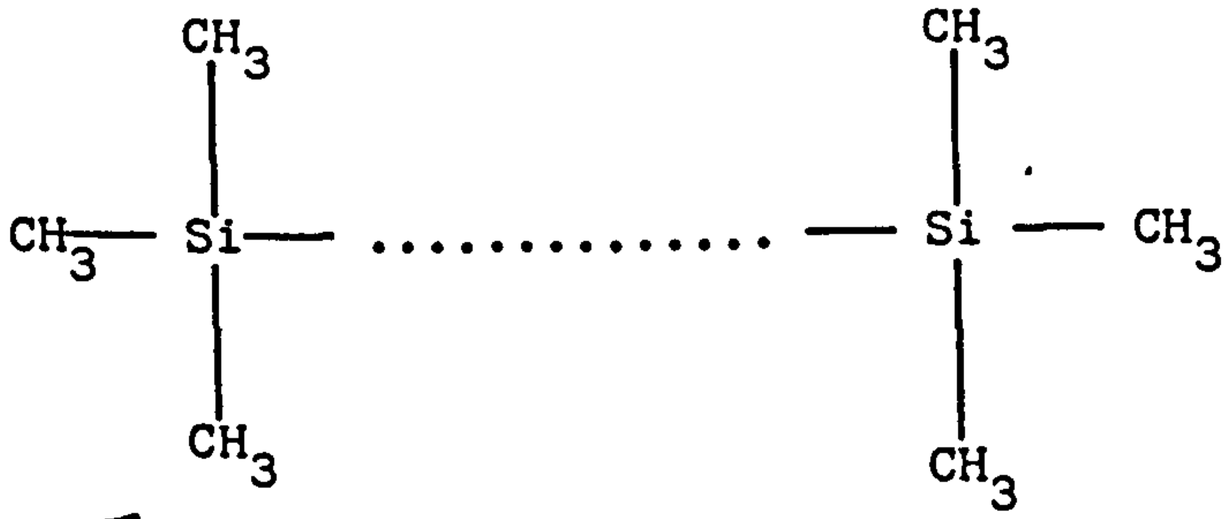
n

The mechanisms for this reaction are very much more complex than the overall stoichiometric equation, for example there are about ten individual reactions to produce only the dimer (MARK & GAYLORD,1977).

The polymer chains are believed to be terminated by OH groups. With the addition of hexamethyldisiloxane,



the polymers can be end-blocked by methyl groups and the mixture equilibrated.



End of Polymer Chain.

Predetermined average molecular weights may be obtained. The polymers are clear water-white fluids, with a viscosity depending on the mean average length of the polymer chain. The following table describes the molecular weight variance by both number average and weight average, with respect to viscosity measured in centistokes, thus an indication of the number of dimethylsiloxane units per chain length is given.

Viscosity of Polydimethyl Siloxane Compared to Average Length of the Polymer Chain

Viscosity (Centistokes)	Approximate Number of Dimethyl Siloxy Units	
	By Number Average Molecular Weight	By Weight Average Molecular Weight
0.65	2	2
1.00	3	3
2	5	5
10	16	17
50	46	60
100	70	100
350	130	200
1,000	200	350
10,000,000	3,000	5,400

Silicone Elastomer

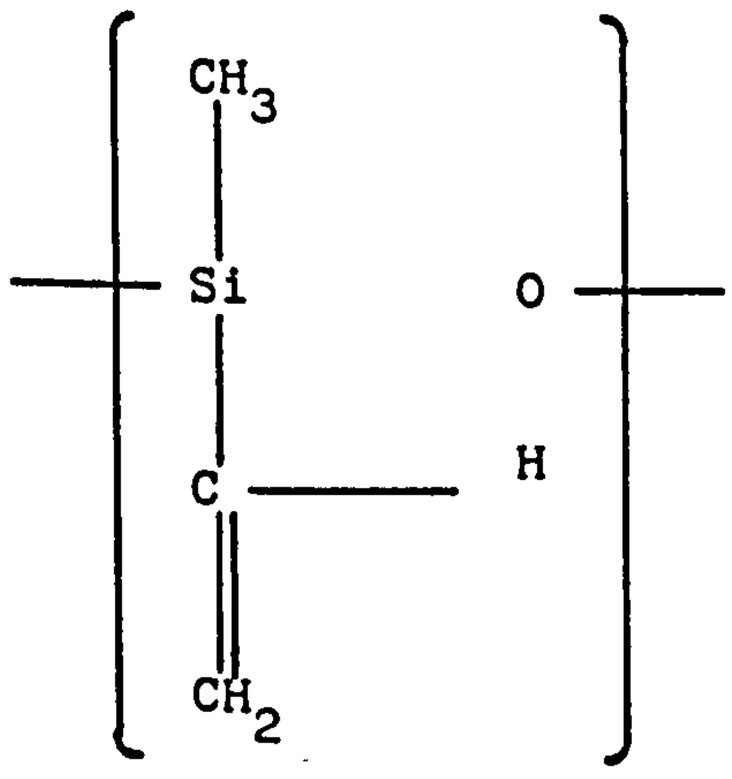
There are basically two types of silicone elastomer, those which cure under the influence of heat, i.e. Heat Vulcanizing Silicones (H.V.) and those which require no exotherm reaction to cure, i.e. Room-Temperature Vulcanizing Silicones (R.T.V.). both contain fillers to increase their mechanical strength, and vulcanizing agents for cross-linking. However, they do not contain the wide variety of additives found in the majority of organic rubber compounds. Medical grade silicones contain no further additives except those mentioned above.

Curing Mechanism of Heat-Vulcanizing Silicones

The most commonly used filler within these silicones is a very finely divided silica with a particle size of approximately 30 mμ. The percentage of filler is varied depending on the desired texture of the final silicone. Generally an increase in the percentage of filler to polymer increases the "hardness" of the final elastomer.

There are two types of polymer available in this category, depending on the desired texture of the final prosthesis.

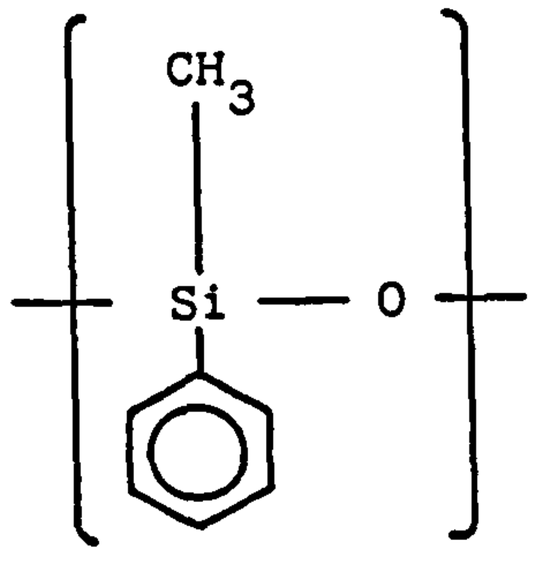
Medium to hard grades are composed mainly of dimethylsiloxane units but with very small amounts of methylvinyl siloxy units copolymerised with it.



Methylvinyl Siloxy Unit

The above unit directly assists in the vulcanization of the polymer.

A softer grade of elastomer can be obtained by incorporating along with the above two units, a small percentage of methylphenyl siloxy units.



Methylphenyl Siloxy Unit

The addition of this relatively bulky phenyl group in the polymer chain is to reduce intermolecular forces, thereby reducing chain stiffness. The polymer is described as phenylmethyl/vinylmethyl/ dimethyl silicone copolymer.

In order for vulcanization to occur the addition of bis-2,4-dichlorobenzoyl peroxide is essential. A small percentage (1%) of this vulcanizing agent is evenly dispersed into the silicone gum and with the application of heat the peroxide decomposes at relatively low temperature, such that cross-linking then occurs.

The mechanism for this vulcanization is as follows: firstly the decomposition of dichlorobenzoyl peroxide to yield free radicals, followed by the free radical attaching itself to the vinyl group of the methylvinyl siloxy unit.

A new radical has been formed which readily subtracts a hydrogen atom from the methyl group of a neighbouring chain, at the same time the dichlorobenzoyl group detaches itself from the vinyl group. There are now two free radicals which can react to form a propyl cross-link.

The dichlorophenyl radical is regenerated for further cross-linking. On completion of the network, the free radical decomposes and is not incorporated within the elastomer, unlike sulphur chains in organic rubbers.

The elastomer is basically a cross-linked silicone polymer with the addition of silica filler.

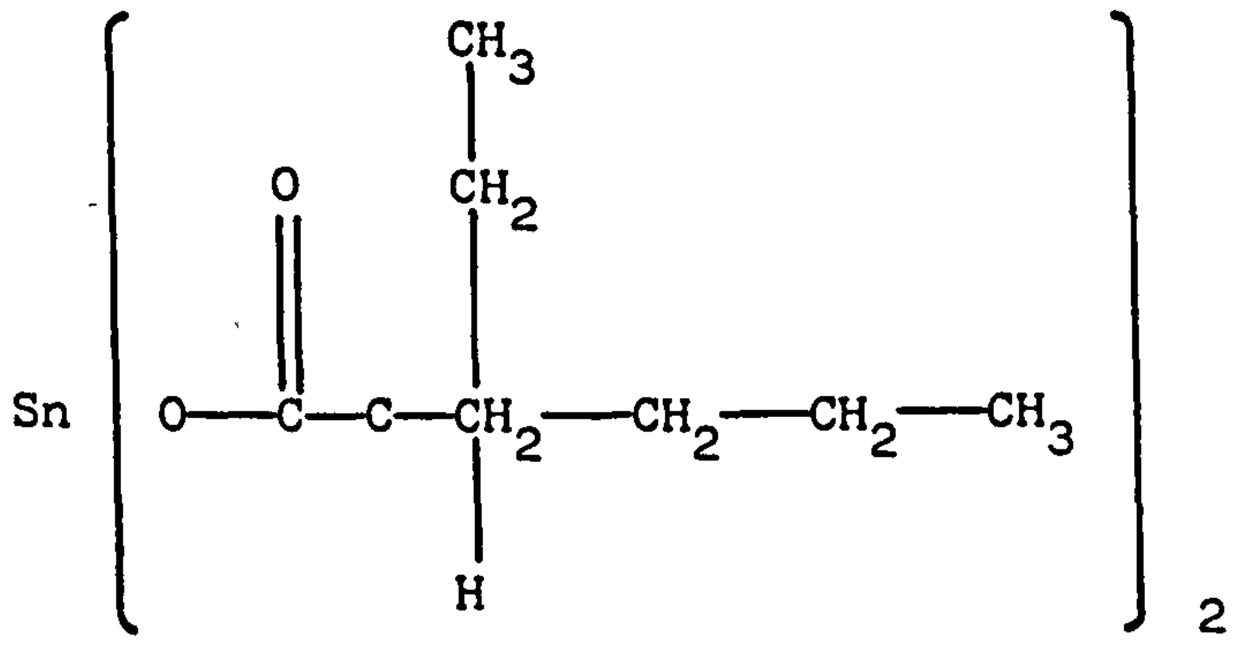
Curing Mechanism of Room-Temperature Vulcanizing Siliciones

There are two main categories of RTVs: two components and one component systems. The two component systems require a catalyst addition and polyfunctional cross-linking agents dispersed in the compound before vulcanization will occur, whilst the one component system requires only the presence of moisture.

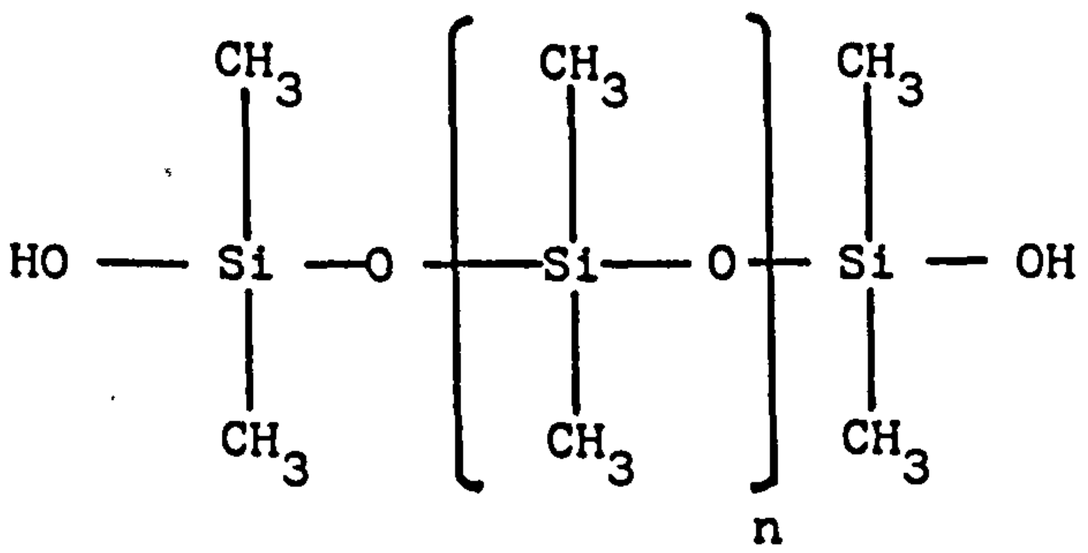
Two Component RTV

The viscosity of these polymers are appreciably lower than that of HV elastomers, since the addition of a catalyst is necessary prior to use, which requires an even dispersion throughout the base.

For this reason the filler content is considerably less, and consists usually of diatomaceous earths, also the polymer chain is approximately seven times smaller in magnitude (~1000 silicone units) than that of HV elastomers (7000 silicone units). Because of these factors the RTVs are generally mechanically weak in comparison to HVs.



The mechanism for cross-linking is quite different to that of HV elastomers. The polymer used contains a high degree of hydroxyl-terminated polydimethyl siloxanes.



However cross-linking can only be accomplished with the use of polyfunctional cross-linking agents, for example esters of orthosilicic or polysilicic acids; such as the ester propyl orthosilicate

$$Si(OCH_2—CH_2—CH_3)_4$$

The resultant condensation reaction between silonol and propyl-oxysilane groups leads to cross-linking, with the elimination of alcohol.

MATERIALS AND METHODS

A sample of currently available silicones used to construct facial protheses were considered in this research. These materials were mechanically tested in an attempt to relate the physical properties to their chemical composition, and to assess their suitability for use as soft facial prosthetics. Table 3 outlines the materials used and their respective supplier.

No technical data was available from suppliers on the nature and percentage of fillers, the catalyst used for cross-linking purposes or the mean chain length of the polymer within the investigated silicone elastomers due to formulation confidentiality.

Vulcanization of the HV Silicone

The first three of these silicones namely "Polyshield", Mollomed and "HV 25" required no additional catalyst (the catalyst was present within the formulation). Both AB132025 and "Silskin" pastes required the further addition of a cross-linking agent, consequently they were of a much reduced viscosity in order to obtain homogenous mixing of the catalyst prior to use. A ratio of 10:1, of polymer to catalyst was adopted for these two silicone elastomers.

In all cases a pre-determined amount(~10 gms) of the gum/ paste, containing polymer, filler, and cross-linking agent was evenly dispersed into a mould. The shape and dimensions of this mould are

Table 3 Materials and Suppliers

MATERIAL		SUPPLIER
Heat Vulcanizing Silicones (HVs)		
1. POLYSHIELD HV COMPOUND	(A gum, containing polymer, catalyst, and filler)	Leanshield Ltd., Cheshire, UK.
2. MOLLOMED	(" " " " " " ")	Molloplast Regneri & Co. KG, W. Germany
3. HV 25	(" " " " " " ")	" " " "
4. AB 13205	(A paste, containing polymer and filler, the catalyst is separate)	L.B. Chemicals, Stockport, UK.
5. SILSKIN	(" " " " " " ")	Bradford Experimental Elastomer
Room Temperature Vulcanizing Siliciones (RTVs)		
1. SILSKIN	(see above)	(see above)
2. SILASTIC 382	(A paste, containing polymer and filler, the catalyst is separate	Dow Corning Ltd., USA.

described in Fig. 14. Four "G" clamps were fastened to hand tight pressure at each corner of the plates to clamp the mould. Vulcanization of the silicone elastomer was completed either by:

(a) immersion of the mould into a water-bath at 100°C for one hour,

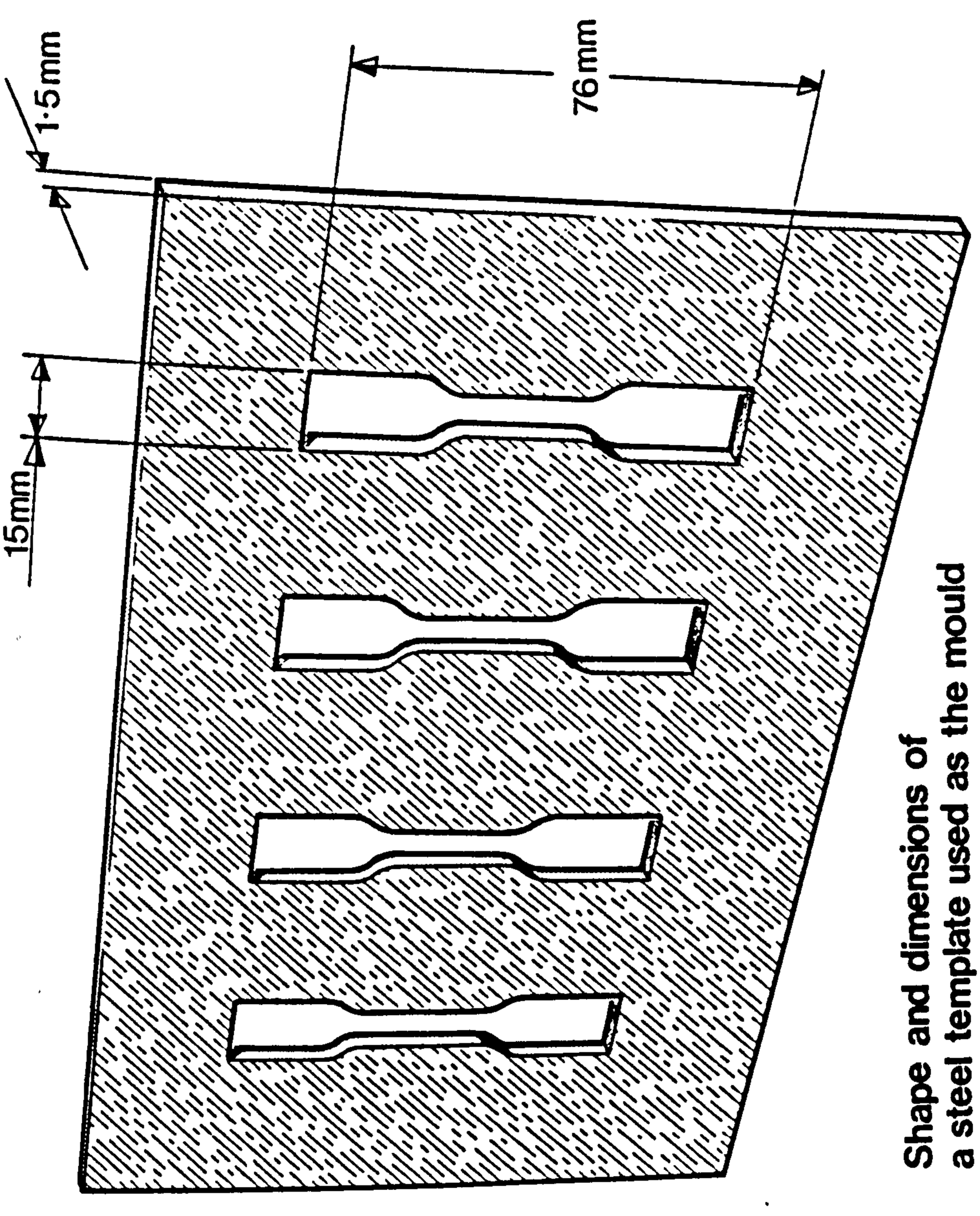
or

(b) Within a hot-air fan oven set at 150°C for one hour.

After the vulcanization time interval the mould was removed from the heat source and allowed to cool to room temperature. The specimens were then removed and excess flash trimmed from the cured samples, which were already of a required shape for load-extension testing.

Vulcanization of the RTV Silicone

The previously described procedures for the HV silicones were adopted for the RTV silicones. "Silskin" is a two way elastomer in that it can be vulcanized either at room-temprature or at elevated temperature. At room-temperature, twenty-four hours under pressure is required to fully vulcanize the silicone, a temperature of 150°C for 1 hour in an oven or water-bath completes the high temperature vulcanisation.



Shape and dimensions of
a steel template used as the mou

Figure 14

"Silastic 382" required considerably less catalyst and vulcanisation is rapid. The table below gives the catalyst concentration to working, and vulcanization times for this elastomer.

Catalyst Concentration Ratio to Working Time for Silastic 382

% by Weight of Catalyst	Working Time (approx.) Mins.	Vulcanization Time (Approx.) Mins.
1.0	4 mins	10 mins
0.5	10 mins	30 mins
0.25	30 mins	90 mins
0.125	100 mins	180 mins

Variation of the Ratio of Polymer to Catalyst

For the heat vulcanizing silicione "AB132025" a 12:1, 10:1, 8:1 and 6:1 ratio of polymer to catalyst was used, and the mechanical properties of the resultant vulcanized elastomers compared, to determine significant variations.

The addition and Dilution of a Silica Filler to Medical Grade Silastic 382 (RTV) Silicone

The main reason for incorporating fine particle fillers into these silicones is to drastically increase their mechanical performance.

For this reason an addition of silica filler known as "Aerosil"* (particle size = 16 mμ) has been added to "Silastic 382" silicone elastomer and the mechanical properties compared. The filler content was also reduced by several dilutions of Silastic 382 polymer with silicone fluid;** again mechanical testing data have been compared with the original silicione elastomer.

Mechanical Testing

The mechanical testing in this research was completed on an Instron 1026 table top model tensometer. The mean cross-sectional area of each specimen was initially monitored with the aid of a micrometer gauge, prior to installation of the specimen within the specimen grips of the tensometer.

The tensometer was initially calibrated using a 5 Kg. weight. A constant extension rate of 50 mm/min. was maintained on the cross-head drive, with the same speed setting on the automatic chart recorder, thus extension on the chart recorder was the true extension of the specimen. The initial gauge length was monitored and kept constant throughout the testing. Load-extension charts were automatically plotted with the use of an autographic pen recorder.

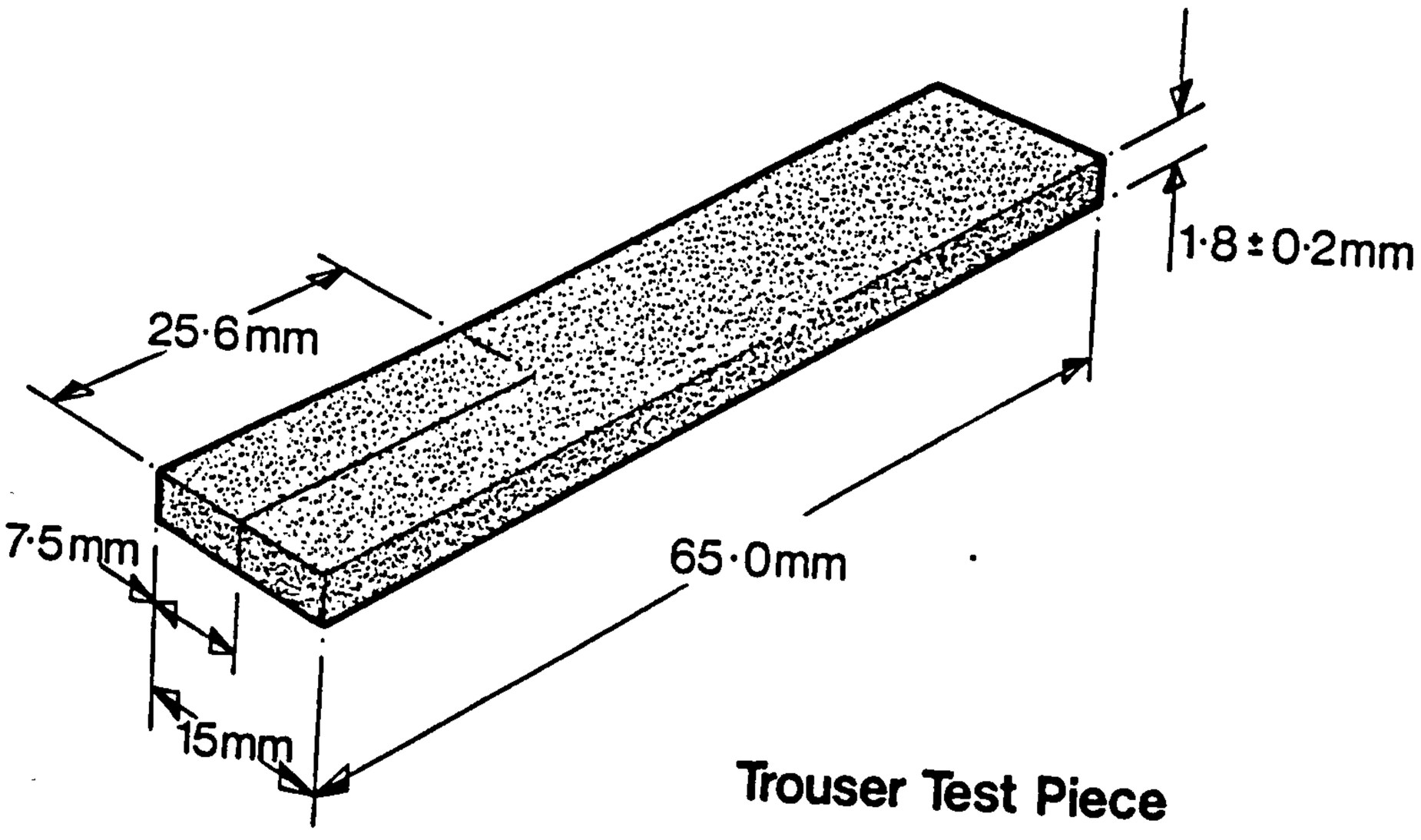
In order to determine the tear strength of these elastomers

*Degussa AG, Frankfurt, W. Germany.

**Medical fluid 360 20 cs viscosity, Dow Corning

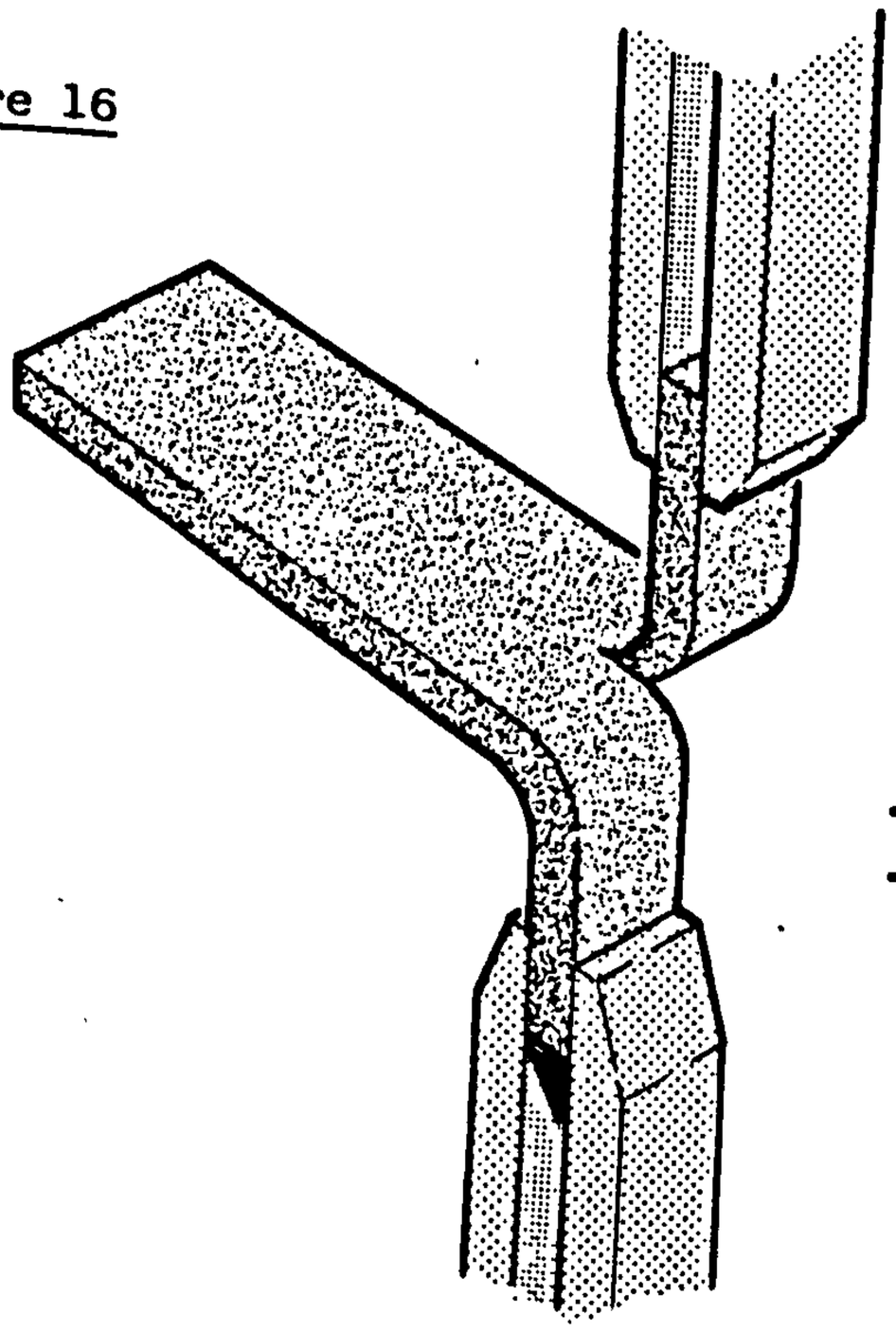
a modified method to that outlined by the British Standards Institution BSI: (1982) was considered. This method was based on the use of a trouser test piece, and is preferred to the other techniques, since it is not sensitive to the length of cut made. Figs. 15 and 16 show the dimensions of the trouser test piece and the positioning of it within the testing machine grips. This is a modified version because the specimens are of different dimensions to that outlined in the standard. The last 1 mm of the cut forming the trouser shape was made with a scalpel blade.

Figure 15



Trouser Test Piece

Figure 16



Positioning of Trouser Test Piece in Testing Machine

RESULTS AND DISCUSSION

Physical Appearance of the Elastomers after Vulcanization

On removal from the mould the vulcanized silicone elastomer had the general physical characteristics of organic rubbers well above their glass-transition temperature, since they possessed the ability to stretch and retract rapidly and were extremely flexible. No evidence of contraction in both HV and RTV specimens following cross-linking was observed.

Mechanical Testing Results

The stress-strain relationships for the elastomers were notably linear up to failure. This is of interest since the majority of organic elastomers are as illustrated in Fig. 17 in which there is a marked change in modulus (⅓ of original) after extension (usually 200-300%). Fig. 18 describes a typical result using the HV elastomer (HV 25) recorded by the pen recorder during testing. An explanation for this linearity may be due to the relatively high percentage of filler incorporated in the elastomer, since pure silica would give a perfectly linear relationship of stress-strain up to failure (perfectly elastic behaviour) whilst gum with no fillers should behave as shown in Fig. 17.

By combining the two graphs the marked change in modulus would become less significant for an increase in percentage of filler.

A typical stress-strain relationship for an organic elastomer (Natural Rubber), showing a change in modulus after some 200-300% extension

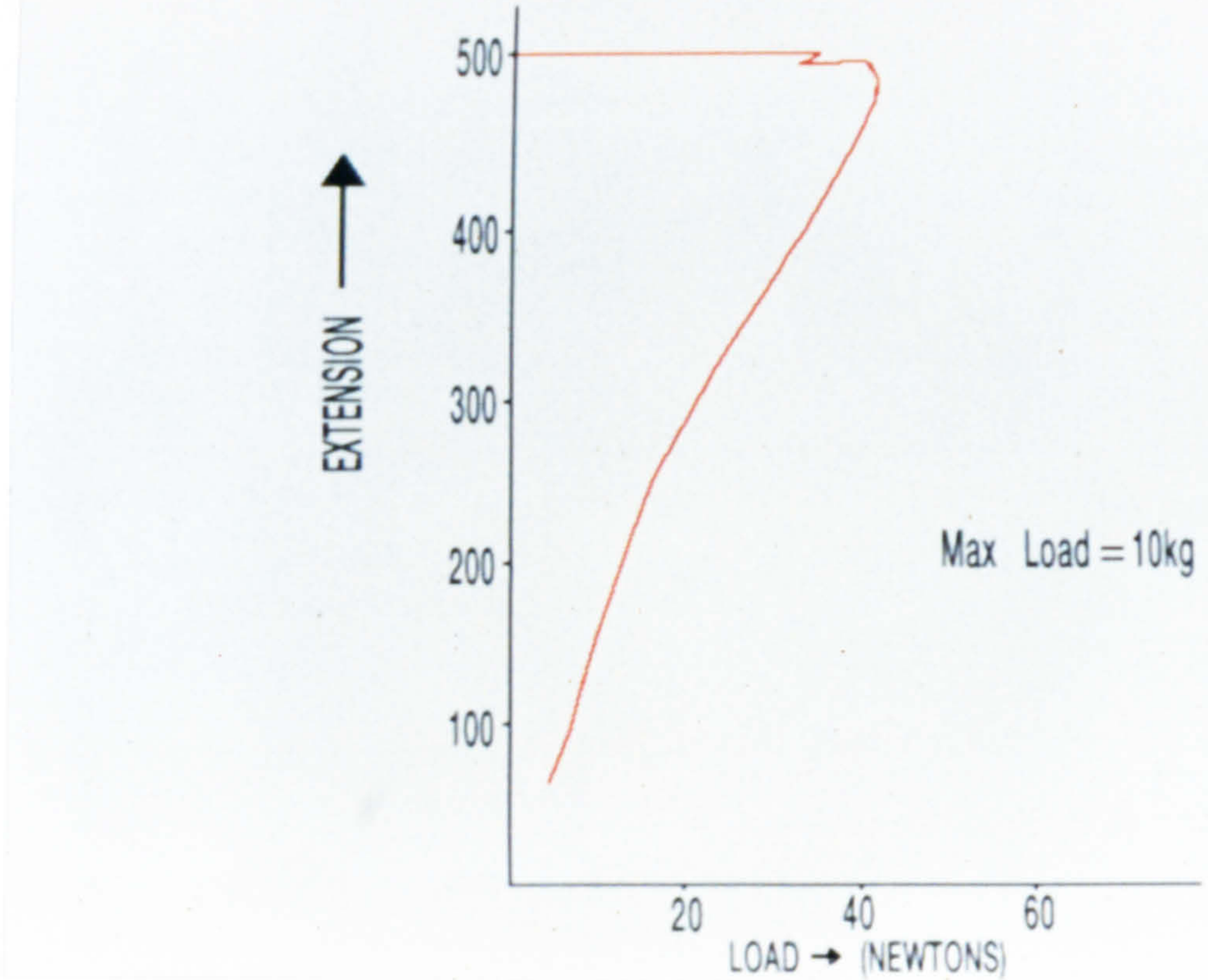


Figure 17

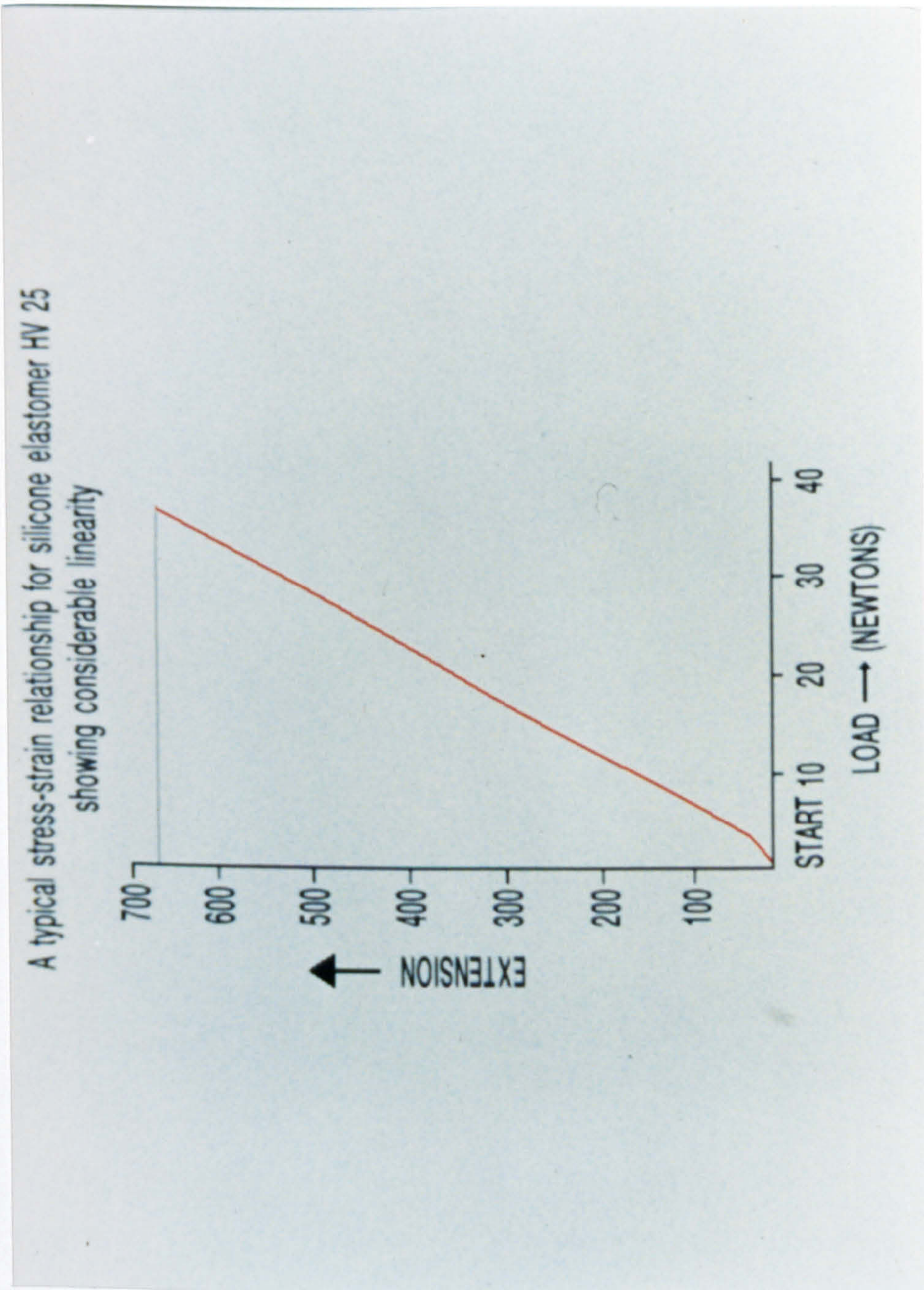

A typical stress-strain relationship for silicone elastomer HV 25
showing considerable linearity
EXTENSION
700
600
500
400
300
200
100
START 10
20
30
40
LOAD → (NEWTONS)

Figure 18

The following mechanical properties were determined from load-extension relationships.

$$\underline{\text{Maximum Tensile Strength}} = \frac{\text{Load at Point of Failure}}{\text{Original Cross Sectional Area}}$$

$$= \text{X Kg F mm}^{-2}$$

$$= \text{X} \times 9.807 \text{ N mm}^{-2}$$

$$= \underline{\underline{\text{Y}}} \text{ MPa}$$

where X and Y are integers.

$$1 \text{ Kg F/m}^2 \doteq 9.807 \text{ N/m}^2 \doteq 9.807 \times 10^6 \text{ N/mm}^2 \doteq 9.807 \text{ MPa}$$

$$\underline{\text{Maximum Percentage Elongation}} = \frac{\text{Extension}}{\text{Original Gauge Length}} \times 100$$

$$= \underline{\underline{\text{A\%}}}$$

Modulus (Rigidity) according to Hooke's Law

$$E = \frac{\text{Stress}}{\text{Strain}} = \frac{\dfrac{\text{Load}}{\text{Original Cross-Sectional Area}}}{\dfrac{\text{Extension of Gauge Length}}{\text{Original Gauge Length}}}$$

$$= \underline{\underline{B}} \text{ MPa}$$

$$\text{Tear Strength} = \frac{\text{Maximum Load Recorded Prior to Failure}}{\text{Mean Thickness of a Specimen}}$$

$$= \frac{F}{d}$$

$$= \underline{\underline{C}} \text{ KNm}^{-1}$$

where F = maximum force in Newtons

d = mean thickness in millimetres of the test piece

where A, B and C are integers.

Tables 4, 5 and 6 show the results of mechanical testing.

Results of the Variation of the Ratio of Polymer to Catalyst

Table 7 describes the effect of varying the ratio of catalyst to polymer. Both an increase and a decrease of catalyst led to a reduction in modulus, which has been well illustrated in Plot 1.

Table 4

MECHANICAL TEST DATA FOR THE SILICONE PROSTHETIC ELASTOMERS

Specimen No.	Silicone Compound Used	Vulcanizing Technique			Mean Value For Cross-Sectional Area (mm^2) ($\pm 0.05\ mm^2$)	Original Gauge Length (mm)	Final Gauge Length (mm) (± 3 mm)	Determination of Modulus (E)			Maximum Tensile Strength (MPa)	% Elongation at Failure
		Room Temp	Water Bath	Oven (150°C)				Stress (MPa)	Strain	$E = \frac{Stress}{Strain}$ (MPa)		
1	HV25		x		16.67 mm^2	33 mm	244 mm	1.912 MPa	6.06	0.316 MPa	2.47 MPa	740%
2	"		x		16.05 "	"	253 "	1.833 "	5.48	0.334 "	2.72 "	767%
3	"		x		14.54 "	"	252 "	1.821 "	5.61	0.325 "	2.66 "	764%
4	"		x		13.25 "	"	272 "	1.999 "	6.36	0.314 "	2.76 "	824%
5	"			x	15.29 "	"	309 "	2.469 "	7.27	0.340 "	3.11 "	936%
6	"			x	15.71 "	"	310 "	2.435 "	7.00	0.348 "	3.40 "	939%
7	"			x	16.88 "	"	242 "	2.033 "	5.76	0.353 "	2.56 "	733%
8	"			x	16.28 "	"	318 "	1.958 "	5.93	0.330 "	2.80 "	964%
9	POLYSHIELD (HV)		x		19.29 "	"	97 "	2.237 "	2.45	0.913 "	2.90 "	294%
10	"		x		24.17 "	"	88 "	2.110 "	2.15	0.981 "	2.84 "	267%
11	"		x		23.48 "	"	84 "	1.713 "	1.82	0.941 "	2.61 "	255%
12	"		x		22.45 "	"	95 "	1.987 "	2.03	0.979 "	2.99 "	288%
13	"			x	17.90 "	"	54 "	2.082 "	2.36	0.882 "	2.65	302%
14	"			x	17.06 "	"	85 "	1.840 "	2.06	0.893 "	2.53 "	258%
15	"			x	19.53 "	"	82 "	1.720 "	1.94	0.887 "	2.40 "	248%
16	"			x	20.30 "	"	92 "	1.739 "	1.82	0.955 "	2.90 "	279%
17	AB132025		x		13.12 "	"	44 "	0.734 "	1.40	0.524 "	0.74 "	133%
18	"		x		12.86 "	"	52 "	0.861 "	1.68	0.513 "	0.85 "	158%
19	"		x		13.04 "	"	76 "	0.952 "	1.74	0.546 "	1.23 "	229%
20	"		x		12.93 "	"	58 "	0.618 "	1.17	0.528 "	0.98 "	175%
21	"			x	13.03 "	"	73 "	0.828 "	1.55	0.534 "	1.21 "	221%
22				x	13.08 "	"	57 "	0.645 "	1.17	0.551 "	0.95 "	173%
23	"			x	13.43 "	"	56 "	0.599 "	1.15	0.521 "	0.80 "	170%
24	"			x	12.76 "	"	74 "	0.961 "	1.63	0.590 "	1.19 "	224%

Table 5

MECHANICAL TEST DATA FOR THE SILICONE PROSTHETIC ELASTOMERS

Specimen No.	Silicone Compound Used	Vulcanizing Technique			Mean Value For Cross-Sectional Area (mm^2) ($\pm 0.05\ mm^2$)	Original Gauge Length (mm)	Final Gauge Length (mm) (±33 mm)	Determination of Modulus (E)			Maximum Tensile Strength (MPa)	% Elongation at Failure
		Room Temp	Water Bath	Oven (150°C)				Stress (MPa)	Strain	$E = \frac{Stress}{Strain}$ (MPa)		
25	MOLLOPLAST-B		x		18.41 mm^3	33 mm	47 mm	0.732 MPa	0.86	0.851 MPa	1.35 MPa	142%
26	"		x		20.14 "	"	61 "	1.120 "	1.40	0.800 "	1.65 "	186%
27	"		x		19.36 "	"	54 "	0.636 "	0.73	0.871 "	1.59 "	163%
28	"		x		19.23 "	"	52 "	0.582 "	0.69	0.842 "	1.44 "	157%
29	"			x	14.07 "	"	54 "	0.697 "	0.62	1.124 "	1.74 "	164%
30	"			x	14.27 "	"	39 "	0.928 "	0.91	1.020 "	1.22 "	118%
31	"			x	14.32 "	"	40 "	0.651 "	0.58	1.122 "	1.23 "	121%
32	"			x	14.15 "	"	45 "	0.821 "	0.72	1.140 "	1.38 "	136%
33	SILSKIN		x		13.91 "	"	114 "	1.118 "	1.92	0.582 "	1.51 "	345%
34	"		x		15.51 "	"	107 "	0.996 "	1.80	0.563 "	1.49 "	324%
35	"		x		12.84 "	"	116 "	1.107 "	1.85	0.598 "	1.45 "	352%
36	"		x		13.58 "	"	115 "	0.847 "	1.45	0.584 "	1.49 "	348%
37	"	x			13.61 "	"	105 "	0.972 "	2.52	0.386 "	1.32 "	318%
38	"	x			13.56 "	"	83 "	0.629 "	1.79	0.351 "	0.90 "	252%
39	"	x			13.45 "	"	104 "	0.962 "	2.27	0.424 "	1.39 "	315%
40	"	x			13.67 "	"	110 "	0.984 "	2.29	0.430 "	1.51 "	333%
41	"			x	15.35 "	"	122 "	1.148 "	1.88	0.611 "	1.59 "	270%
42	"			x	14.72 "	"	118 "	1.015 "	1.84	0.552 "	1.53 "	358%
43	"			x	14.87 "	"	126 "	1.218 "	2.03	0.600 "	1.71 "	392%
44	"			x	15.21 "	"	110 "	0.735 "	1.27	0.579 "	1.54 "	333%
45	SILASTIC 382	x			13.73 "	"	33 "	1.029 "	0.80	1.290 "	1.16 "	100%
46	"	x			12.69 "	"	27 "	0.770 "	0.60	1.283 "	1.11 "	82%
47	"	x			13.07 "	"	31 "	0.563 "	0.45	1.251 "	1.16 "	116%
48	"	x			13.02	"	39 "	1.130 "	0.86	1.314 "	1.45 "	118%

Table 6

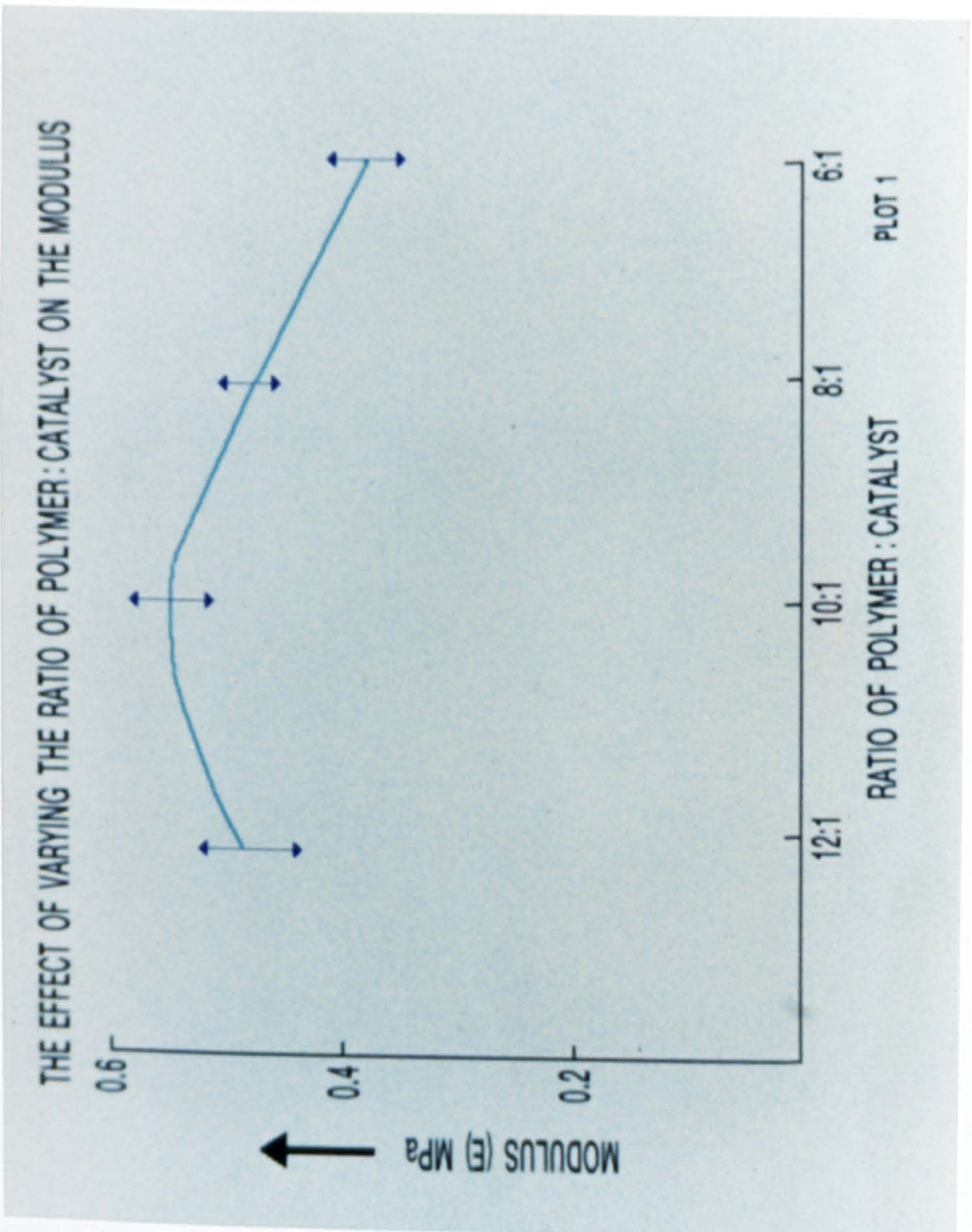
TEAR STRENGTH DATA FOR THE SILICONE PROSTHETIC ELASTOMERS USING TROUSER TEST PIECES

Specimen No.	Silicone Compound Used	Vulcanizing Technique			Mean Specimen Thickness d (mm)	Maximum Force (F) Recorded (N)	Trouser Tear Strength $T_s=\frac{F}{d}$ (kNm^{-1})	Mean Tear Strength kNm^{-1}	Standard Deviation from the mean
		Room Temp	Water Bath	Oven (150°C)					
1	HV 25		x		1.63 mm	4.51 N	2.77 kNm^{-1}		
2	"		x		1.60 "	4.36 "	2.73 "	2.68 kN^{-1}	(±0.08)
3	"		x		1.51 "	3.87 "	2.56 "		
4	"		x		1.72 "	4.54 "	2.64 "		
5	"			x	1.62 "	4.49 "	2.77 "		
6	"			x	1.69 "	4.71 "	2.79 "	2.97 "	(±0.19)
7	"			x	1.81 "	5.72 "	3.16 "		
8	"			x	1.96 "	6.22 "	3.17 "		
9	POLYSHIELD		x		2.05 "	7.94 "	3.87 "		
10	"		x		1.76 "	6.34 "	3.60 "		
11	"		x		1.83 "	6.51 "	3.56 "	3.61 "	(±0.16)
12	"		x		1.80 "	6.13 "	3.41 "		
13	"			x	1.83 "	6.77 "	3.70 "		
14	"			x	2.05 "	8.19 "	4.00 "		
15	"			x	1.83 "	6.91 "	3.78 "	3.92 "	(±0.19)
16	"			x	1.96 "	8.22 "	4.19 "		
17	MOLLPOLAST-B		x		1.70 "	0.96 "	0.56 "		
18	"		x		1.68 "	0.98 "	0.58 "	0.57 "	(±0.01)
19	"			x	1.66 "	0.98 "	0.59 "		
20	"			x	1.63 "	0.97 "	0.60 "	0.60 "	(±0.005)
21	AB132025		x		1.35 "	1.81 "	1.34 "		
22	"		x		1.26 "	1.96 "	1.56 "	1.45 "	(±0.11)
23	"			x	1,56 "	2.54 "	1.63 "		
24	"			x	1.42 "	1.73 "	1.22 "	1.43 "	(±0.21)
25	SILSKIN		x		1.18 "	3.82 "	3.24 "		
26	"		x		1.41 "	5.30 "	3.76 "	3.50 "	(±0.26)
27	"			x	1.37 "	5.68 "	4.15 "		
28	"			x	1.15 "	4.21 "	3.67 "	3.91 "	(±0.24)
29	SILASTIC 382	x			1.38 "	0.72 "	0.53 "		
30	"	x			1.52 "	0.98 "	0.65 "	0.55 "	(±0.07)
31	"	x			1.57 "	0.88 "	0.56 "		
32	"	x			1.49 "	0.69 "	0.46 "		

Table 7

THE EFFECT OF VARYING THE RATIO OF CATALYST TO POLYMER ON THE MECHANICAL PROPERTIES USING THE PROSTHETIC SILICONE AB132025

Specimen No.	Ratio of Polymer Catalyst	Vulcanizing Technique			Mean Value For Cross Sectional Area (mm^2) ($\pm 0.05\ mm^2$)	Original Gauge Length (mm)	Final Gauge Length (mm)	Determination of Modulus (E)			Maximum Tensile Strength (MPa)	% Elongation at Failure
		Room Temp	Water Bath	Oven (150^oC)				Stress (MPa)	Strain	E = Stress / Strain (MPa)		
1	10:1			x	13.03 mm^2	33 mm	73 mm	0.828 MPa	1.55	0.534 MPa	1.21 MPa	221%
2				x	13.08 "	"	57 "	0.645 "	1.17	0.551 "	0.95 "	173%
3				x	13.43 "	"	56 "	0.599 "	1.15	0.521 "	0.80 "	170%
4				x	12.76 "	"	74 "	0.961 "	1.63	0.590 "	1.19 "	224%
5	8:1			x	12.54 "	"	66 "	0.821 "	1.76	0.466 "	1.17 "	200%
6				x	11.82 "	"	84 "	0.956 "	1.97	0.490 "	1.05 "	255%
7				x	12.43 "	"	86 "	0.828 "	1.82	0.450 "	1.08 "	261%
8				x	11.89 "	"	70 "	0.660 "	1.45	0.450 "	1.05 "	212%
9	6:1			x	11.77 "	"	70 "	0.541 "	1.64	0.330 "	0.83 "	212%
10				x	11.14 "	"	92 "	0.792 "	2.06	0.380 "	1.15 "	279%
11				x	11.57 "	"	82 "	0.805 "	2.06	0.390 "	1.07 "	248%
12				x	11.89 "	"	80 "	0.866 "	2.18	0.397 "	1.03 "	270%
13	12:1			x	11.66 "	"	68 "	0.840 "	1.76	0.477 "	1.02 "	209%
14				x	11.51 "	"	88 "	1.150 "	2.21	0.520 "	1.35 "	267%
15				x	12.56 "	"	79 "	1.090 "	2.06	0.529 "	1.25 "	239%
16				x	12.44 "	"	69 "	0.906 "	2.06	0.440 "	1.06 "	206%


THE EFFECT OF VARYING THE RATIO OF POLYMER : CATALYST ON THE MODULUS
MODULUS (E) MPa
0.6
0.4
0.2
10:1
8:1
6:1
12:1
RATIO OF POLYMER : CATALYST
PLOT 1

Plot 1

Results of the Addition and Dilution of a Silica Filler to Medical Grade Silastic 382 (RTV)

The incorporation of only a small percentage (4%) by weight of "Aerosil" silica filler was difficult to achieve a homogenous mixture due to the tremendous increase in viscosity. There was, however, a significant increase in both modulus and tensile strength (Table 8). Similarly a reduction of mechanical properties was observed by an apparent dilution of the filler.

The results were found to be in agreement with mechanical performance data, since the elastomers with improved mechanical properties contained higher percentages of filler than compared to those with lower percentages.

This investigation has critically assessed several available silicone elastomers used for facial prosthetics, and the following conclusions have been made.

There was some variation in the mechanical properties for the elastomer "HV 25" between water-bath and oven vulcanization processes. The discrepancy is more obvious for the rest of the elastomers and is illustrated by the histograms in Figs. 19a, 19b and Fig. 20 which show mean mechanical property data and standard deviations from the mean versus vulcanization techniques.

Table 8

A COMPARISON AS TO THE EFFECT OF ADDITION AND DILUTION OF SILICA FILLER (AEROSIL 16mu) TO SILASTIC 382 (RTV)

Percentage by weight of Addition/ Diltion of Filler	Percentage by weight of Catalyst Addition	Vulcanizing Time (mins)	Mean Cross-Sectional Area (mm^2)	Original Gauge Length (mm)	Final Gauge Length (mm)	Determination of Modulus (E)			Maximum Tensile Strength (MPa)	% Elongation at Failure
						Stress (MPa)	Strain	$E = \frac{Stress}{Strain}$ (MPa)		
Addition to 26.8%	1%	10 mins.	16.24 (mm^2)	33 mm	22 mm	1.510 MPa	0.55	2.745 MPa	1.74 MPa	67%
" " "	"	"	15.21 "	"	39 "	2.480 "	0.91	2.725 "	2.82 "	118%
" " "	"	"	16.81 "	"	37 "	1.750 "	0.64	2.734 "	2.87 "	112%
" " "	"	"	15.83 "	"	34 "	1.547 "	0.57	2.714 "	2.78 "	103%
Normal (23%)	"	"	13.73 "	"	33 "	1.029 "	0.80	1.290 "	1.16 "	100%
" "	"	"	12.69 "	"	27 "	0.770 "	0.60	1.283 "	1.11 "	82%
" "	"	"	13.07 "	"	31 "	0.563 "	0.45	1.251 "	1.16 "	118%
" "	"	"	13.02 "	"	39 "	1.130 "	0.86	1.314 "	1.45 "	118%
Dilution to 20.1%	"	"	15.60 "	"	39 "	0.629 "	0.73	0.865 "	0.89 "	118%
" " "	"	"	14.22 "	"	55 "	1.103 "	1.21	0.910 "	1.44"	166%
" " "	"	"	14.14 "	"	33 "	0.402 "	0.57	0.705"	0.62 "	100%
" " "	"	"	14.55 "	"	43 "	0.714 "	0.80	0.891 "	1.25 "	130%
Dilution to 17.9%	"	"	13.09 "	"	26 "	0.225 "	0.47	0.479 "	0.28 "	79%
" " "	"	"	13.71 "	"	27 "	0.501 "	1.00	0.501 "	0.68 "	82%
" " "	"	"	15.40 "	"	46 "	0.318 "	0.48	0.663 "	0.41 "	139%
" " "	"	"	15.17	"	36 "	0.213 "	0.49	0.435 "	0.30 "	109%

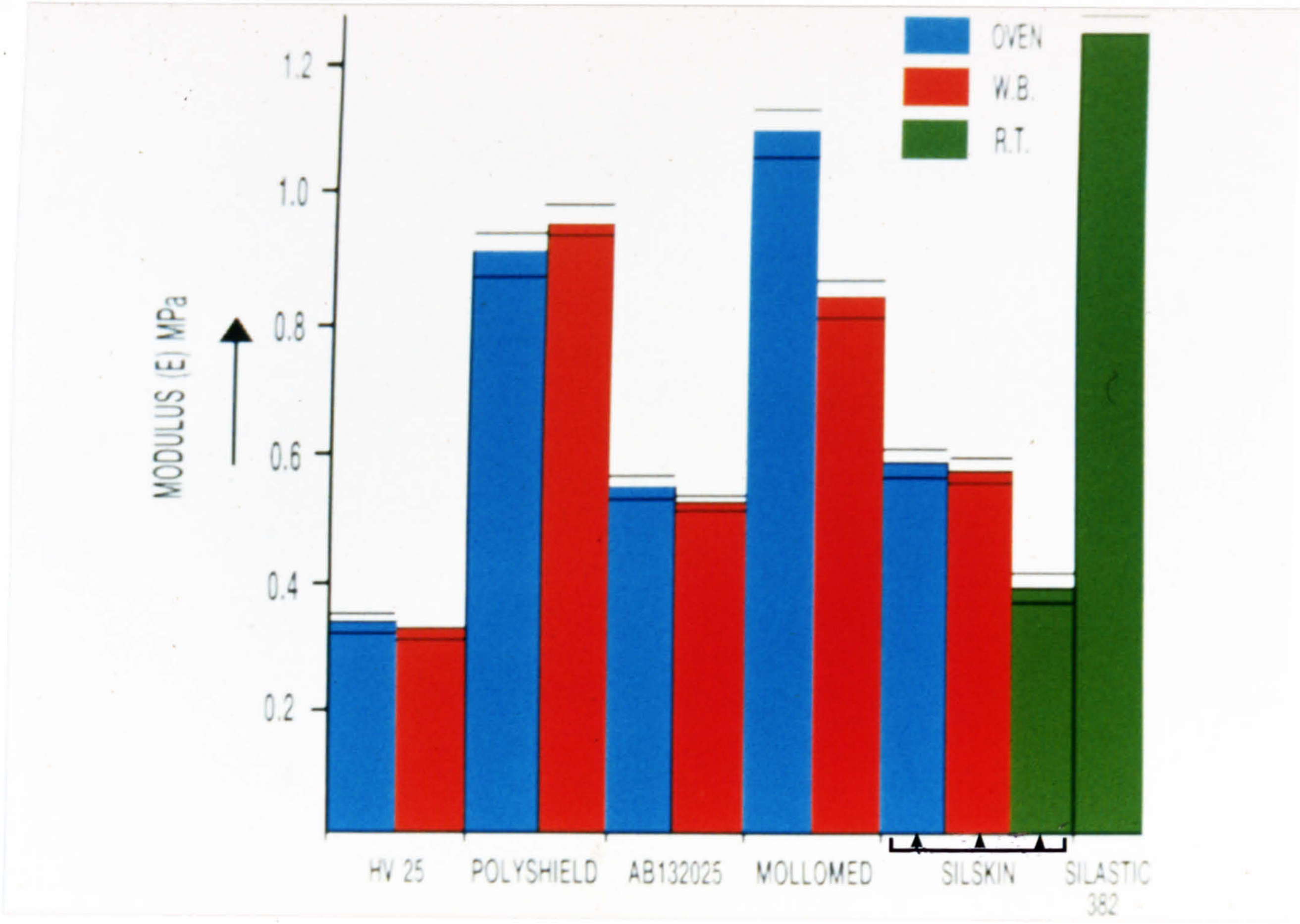

OVEN
W.B.
R.T.
MODULUS (E) MPa
1.2
1.0
0.8
0.6
0.4
0.2
HV 25
POLYSHIELD
AB132025
MOLLOMED
SILSKIN
SILASTIC 382

Figure 19a

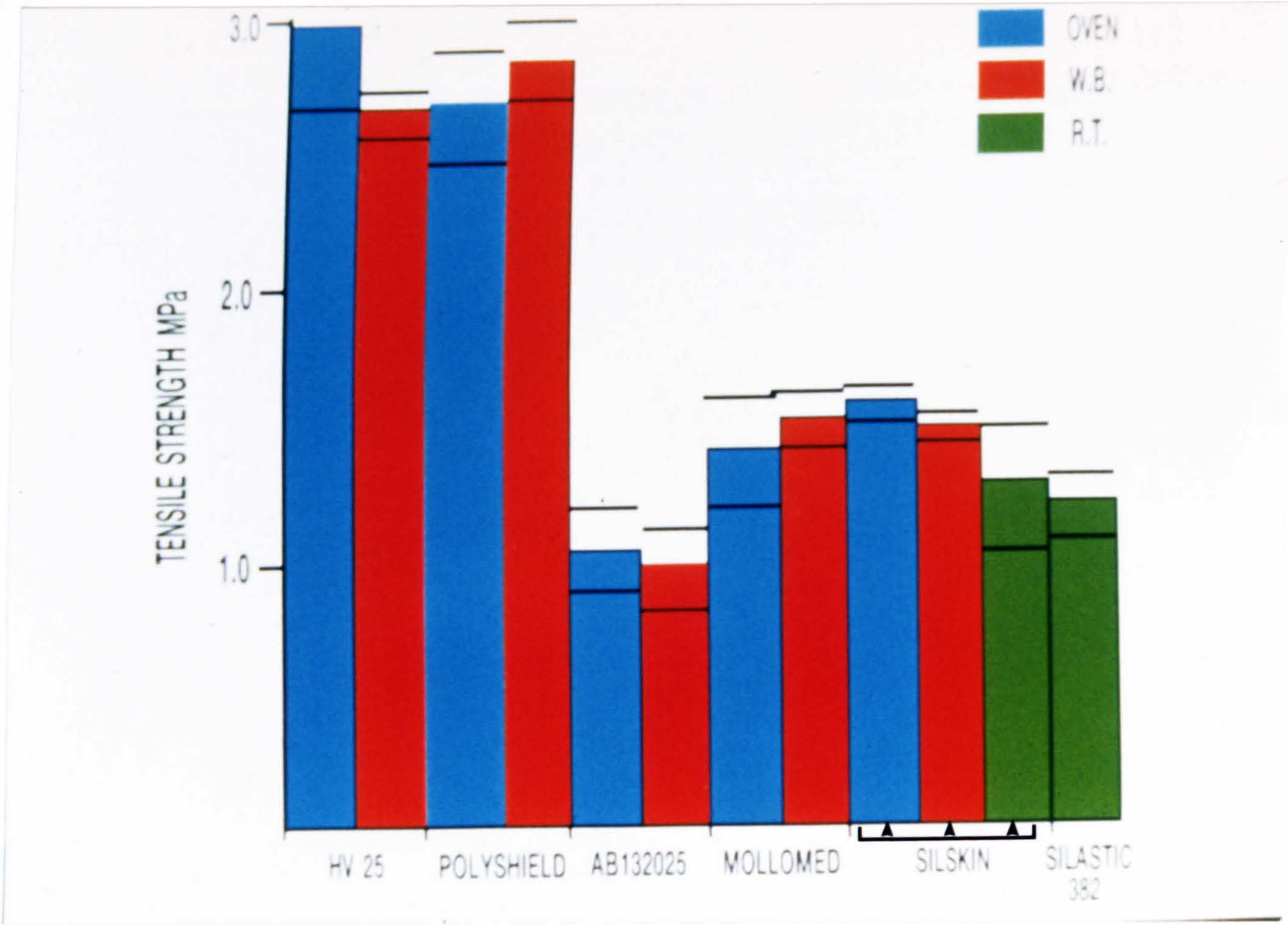

3.0
2.0
1.0
TENSILE STRENGTH MPa
OVEN
W.B.
R.T.
HV 25
POLYSHIELD
AB132025
MOLLOMED
SILSKIN
SILASTIC
382

Figure 19b

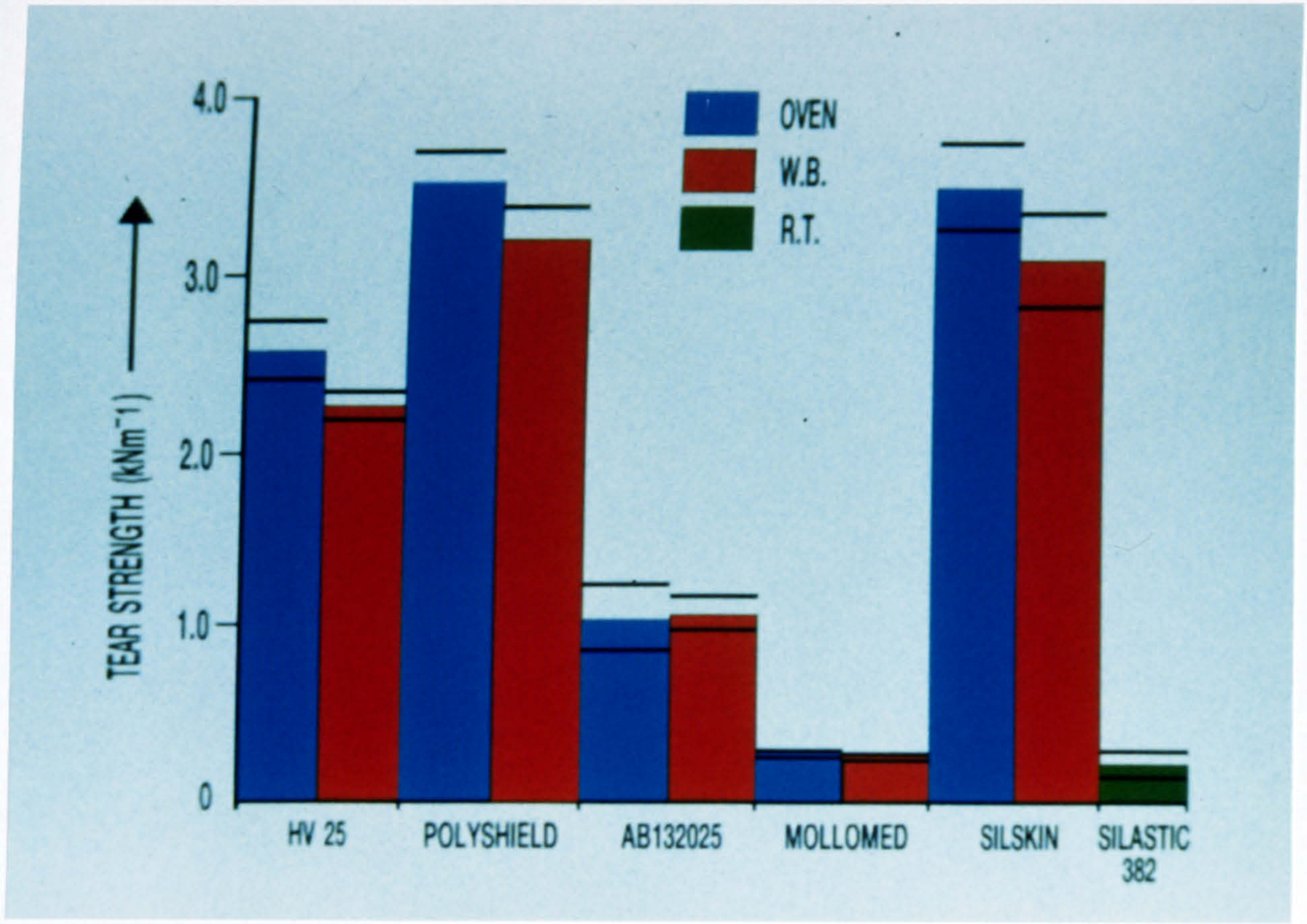

4.0
3.0
2.0
1.0
0
TEAR STRENGTH (kNm⁻¹)
OVEN
W.B.
R.T.
HV 25
POLYSHIELD
AB132025
MOLLOMED
SILSKIN
SILASTIC 382

Figure 20

In the majority of cases, oven vulcanization produced higher values for the mechanical properties. However, the variation was quite minimal and may be even less significant for larger numbers of test pieces. This slight difference may be due to incomplete vulcanization using a water-bath (100°C). McGREGOR (1954) indicated that "peroxide" vulcanizing agents decompose at temperatures above 115°C and preferentially at 150°C, and at lower temperatures the reaction may be too slow for practical purposes.

There were slight differences between the mechanical properties of the HV elastomers compared to the RTV elastomers. This has been attributed to two major influences: the molecular chain length of the polymer chains of HV elastomers is some seven times greater than that of RTV elastomers which leads to increased viscous effects, thereby improving mechanical performance. It is the contribution of the volumetric concentration (particle size) of silica particles as the filler and not the concentration by weight which governs elastomers' mechanical performance and their viscosity. These factors have been well demonstrated by incorporating some 4% by weight of "Aerosil", silica filler of particle size 16 mμ, to "Silastic 382", which not only increased the viscosity of this polymer prior to vulcanization, but also led to improved mechanical performance, approximately doubling the modulus and tensile strength. As expected there was a reduction in the mechanical properties as the apparent percentage of filler within "Silastic 382" was diluted with the use of silicone oil.*

The effect of increasing or decreasing the percentage by weight of vulcanizing agent used within "AB 132025" HV elastomer

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* Medical fluid 360 20cs viscosity Dow Corning

proved that the optimum requirement to completely vulcanize all the sites eligible for cross-linking purposes throughout the polymer was a 10:1 ratio, of polymer to catalyst. Both an increase or decrease of the catalyst led to reduced mechanical performance. Increasing the percentage of catalyst possibly led to a fully cross-linked elastomer, but with retained catalyst acting something similar to a plasticizer by reducing the modulus; whilst insufficient catalyst probably led to incomplete vulcanization of all these eligible sites.

Table 9

Silicone Elastomer	Tensile Strength	Tear Strength	Total Points
Polyshield	4	5	9
HV 25	5	3	8
AB 132025	0	2	2
Mollomed	2	1	3
Silskin	3	4	7
Silastic 382	1	0	1

The highest number of points were given to the facial prosthetic elastomer which gave the best mechanical performance data for the corresponding physical property, with a progressive decrease of points allocated to the elastomer as the properties decreased. (Table 9).

Polyshield has been found to be a useful Elastomer for the prosthesis that requires less flexibility. In some prosthetic restorations the bridge of the nose requires a firm base, if the patient wears spectacles. Also, the backing of a large prosthesis may be required to provide support for the more resilient mass of the restoration, and provide support over a wide area of skin contact.

The HV 25, with its high tensile and tear strengths, has been found an advantage in undercut tissue areas. The elastomer alows fine margin production and easy removal from the mould chamber during laboratory procedures.

AB 132025 has low physical characteristics and as such limited application to facial prosthetics. A role has been found for this elastomer as a temporary prosthesis and short-term applications.

Mollomed has a satisfactory tensile strength but a low tear strength. Particular care is required during laboratory procedures to avoid damage to a prosthesis. The design of mould is of importance with the low tear strength elastomer to avoid damage to margins of the prosthesis. The life of the prosthesis in clinical use will also be limited due to user damage by the patient.

Silskin has proved to be a most satisfactory Elastomer which is accepted well by the patient in terms of clinical application. Although from this investigation it has been found to have a lower tensile strength than Polyshield and HV 25 Elastomers it is well within the parameters of clinical requirements. Tear strength is

good in relation to Polyshield and greater than that of HV 25. This physical characteristic allows for good margin integrity and handling properties both in the laboratory and patient use. A particular advantage of Silskin is its versatility of vulcanization (i.e. oven, water bath and room temperature). This three-way vulcanization is of great importance in a busy National Health Service Prosthetics Centre. A prosthesis can be constructed within the day, resulting in cost savings to the treatment programme.

Colour simulation is very good and pigments mix well in the Elastomer base (Table 2). Patient acceptance is difficult to define in measurable terms: however all the patients who have prosthetic restorations constructed from Silskin speak well of it with particular reference to comfort, feel and general usage. Silskin now forms the main prosthetic silicone Elastomer used in this plastic surgery unit. The Elastomer Silastic 382 is confined to room temperature applications. The low tensile and tear strength of the vulcanized elastomer limits its use to temporary prostheses, although the elastomer has the advantage of rapid vulcanization (10 - 180 minutes). Silastic 382 can be effectively used as a resilient core filler in large self-retained facial restorations, in particular the orbital area. In such applications the low tensile and tear strengthsare of no importance in the final form. Silastic 382 has found an application in small area prosthetic reconstruction in particular during stages of surgery.

PART II CLINICAL APPLICATIONS

CLINICAL APPLICATIONS

The laboratory of the department of Plastic and Maxillo-Facial Surgery was formed in 1960 at St. Luke's Hospital, Bradford. The Facial Prosthetics Clinic was also established in that year.

The number of patients referred for prosthetic reconstruction has increased each year to a figure of over 300 patients. The prosthetic treatment of the patients is further enhanced by the continued review and maintenance of patients on the clinic list. The main areas of referral derive from plastic surgeons (70%), ear, nose and throat surgeons (12%), ophthalmic surgeons (10%), and other surgical specialities (8%). The cases referred cover a wide range of facial and body defects each with its own individual problems and history.

To produce a satisfactory prosthetic restoration each patient must be regarded as a different problem with distinct peculiarities, advantages and disadvantages. The individual characteristics of these patients require careful selection of the materials used. Plastic and reconstructive surgeons of today are well aware of the values and limitations of prosthetic materials. They are also aware of the limitations of surgical reconstruction.

The decision to use prosthetic reconstruction shows commitment and confidence in this form of treatment both as a permanent or temporary measure. RANK (1953) describes the attitude towards facial

prosthetics, "Plastic surgeons so frequently regarded as agents of the supernatural need a strong sense of perspective and responsibility in managing the number and variety of patients nowadays referred to them. The patient who has endured much is not properly rewarded by some ugly daub for a nose, some hopeless excrecence for an ear, or an eye region he prefers to cover by a patch or unattractive glasses ... One refers rather to the use of prosthetics by choice for certain defects simply because it has more to offer the patient than has plastic surgery which we well appreciate but the lay public does not. Critical consideration of surgical probabilities rather than wishful thinking of possibilities should in due humility and without any sense of shame lead us to advise a prosthetic restoration for many cases' ...

The materials examined and developed in this research have found wide clinical application in this centre. The volume of cases has enabled the prosthetic elastomer bases used to be subject to stringent patient evaluation.

Often on review of a particular patient the prosthesis in use would indicate a change of material. Problems have developed because a patient now lives in a different environment, or has a change of employment. A very hot climate makes the method of retention a consideration since certain adhesives are less effective due to perspiration. The prosthetic elastomer may need to be changed to function effectively with a different adhesive. A change of prosthetic material may be required due to dusty manual work conditions. These, together with the trauma of patient handling, indicate a possible alternative prosthetic elastomer, the selection being based on the physical

characteristics ~~of the materials~~ described in this research. Women have been found to accept a prosthetic restoration more readily than men, and complain less regarding general prosthetic limitations.

In this respect women are less vain, accepting explainable problems of prosthetic reconstruction. Because of the care a woman gives to the use of a prosthesis, a material can be selected with less physical characteristics with more emphasis on aesthetics. The advantage of cosmetics available favours the female patient. A limited range of non-perfumed cosmetics for male use are now being used to cover skin blemishes (Cosmetic Camouflage).

The prosthetic elastomers described in this research have been used extensively on other parts of the body. The elastomer Silskin with its characteristics and versatility of application is ideal for body prosthetic reconstruction. A particular area of success is that of nipple-areola complex following breast reconstruction. This prosthetic application is now becoming widely used in plastic surgery. Indications for this technique as an alternative to surgical reconstruction are low cost, no hospitalisation and consistent aesthetic results.

The following selected case reports are described to indicate the application of the prosthetic elastomers. The principal objective in each case has been to restore the defect, improve aesthetics and re-establish the self-confidence of the patient.

CASE REPORTS

Case 1 (Fig. 21)

A 68 year old male retired mill worker. Defect: total loss of left ear following excision of epithelioma. The tragus has been retained as a location point for a prosthesis. The patient was not suitable for surgical reconstruction due to age and general health. He is an active man who enjoys gardening and plays bowls.

His skin complexion indicates his outdoor interests. Silskin prosthetic elastomer was selected for the prosthesis and pigmented to simulate the patient's basic skin shade. Particular attention was given to colour match the areas of vascular concentration.

No external tinting was required. The tragus was a useful aid to the patient in positioning the prosthesis. He did not wear spectacles and had no wish to do so. Retention of the prosthesis was by polydimethyl siloxane contact adhesive applied to the fitting surface of the prosthesis. The patient reports no problems with the prosthetic restoration and is very pleased with the result.

Review every twelve months.

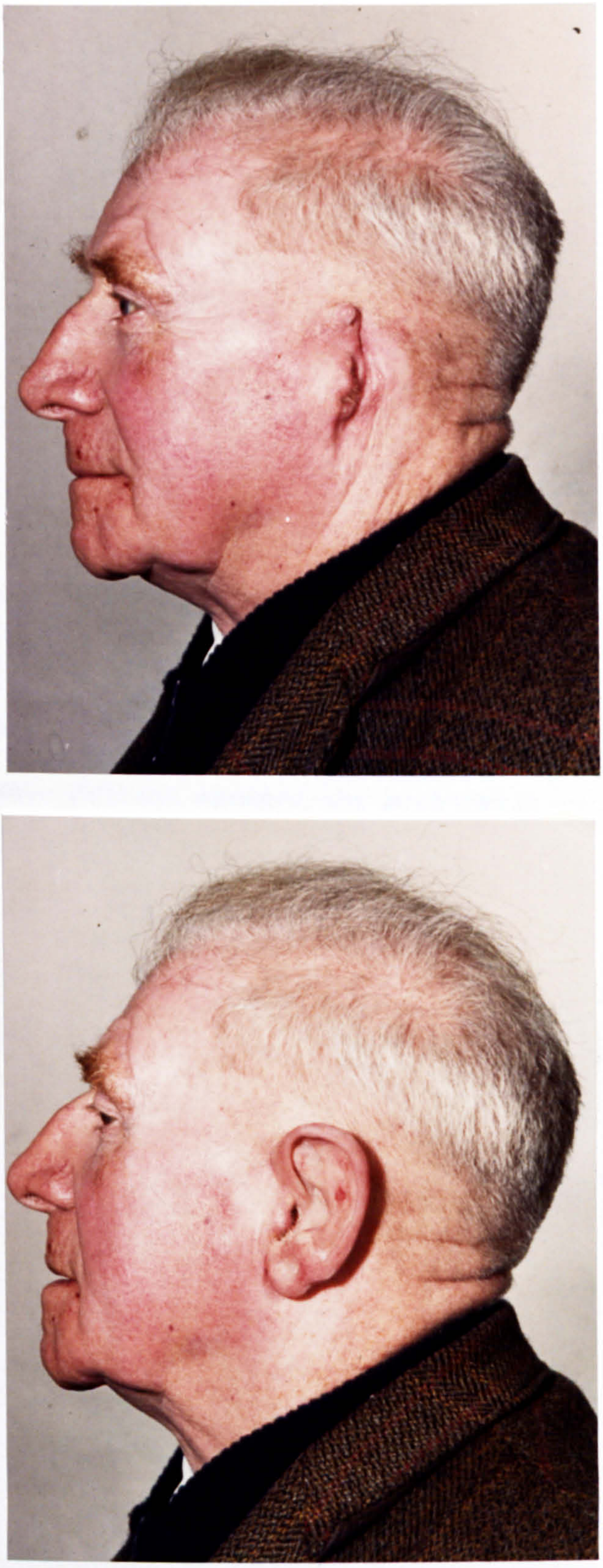
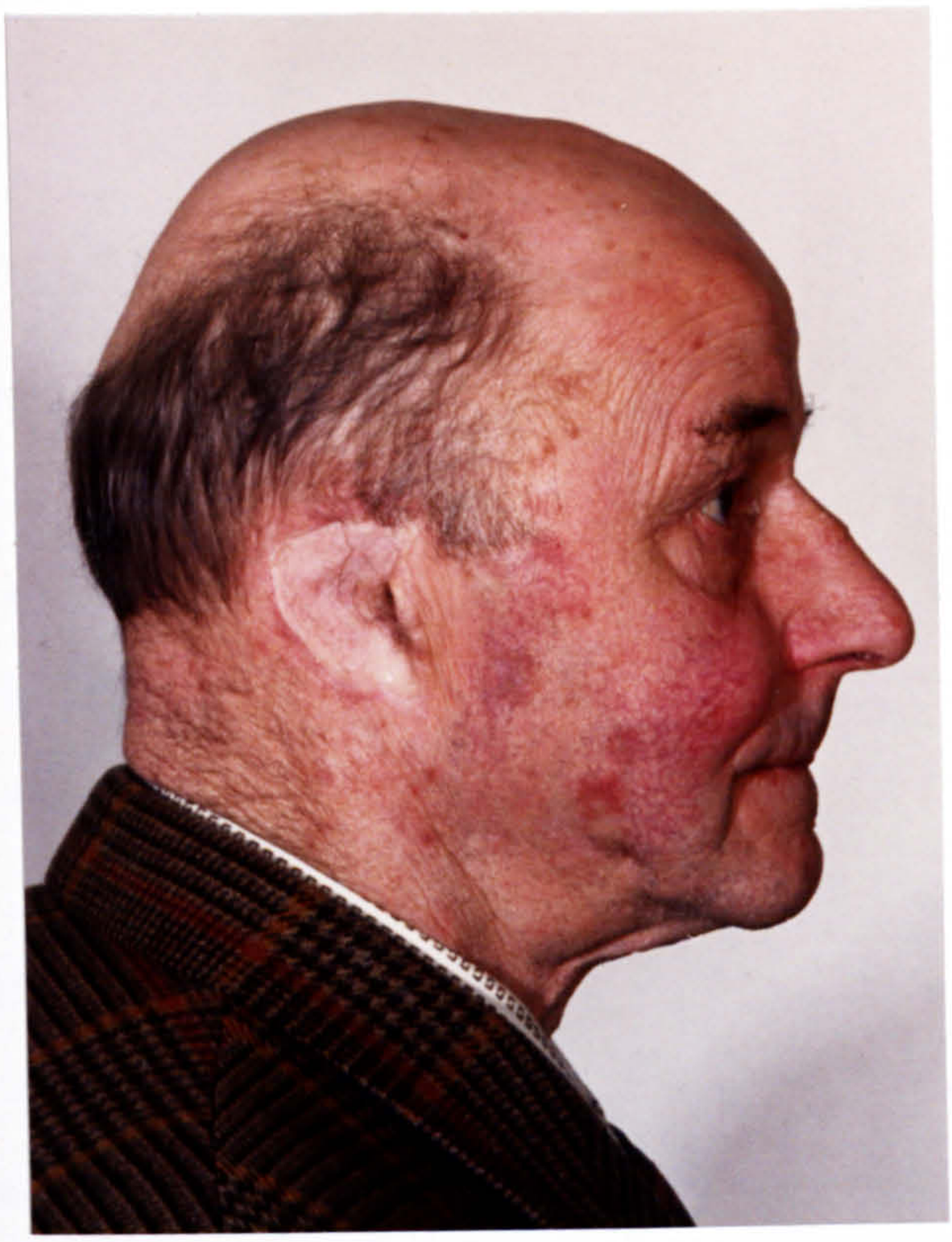


Figure 21

Case 1

Case 2 (Fig. 22)

A 69 year old farmer. Defect; total right ear removed following excision of basal cell carcinoma. Prosthetic reconstruction considered the more satisfactory treatment programme in relation to health and age of patient. Immediate prosthesis required due to social commitment (getting married). Silicone Elastomer AB.132025 used first for temporary restoration. Information obtained from this temporary prosthesis regarding skin shade, and patient attitude to the restoration. The prosthetic Silicone ElastomerAB.132025 was pigmented to basic skin shade. Heavy pigmentation characteristics could be simulated. Retention was by means of polydimethyl siloxane contact adhesive. Patient managed the prosthesis well. On review at five weeks a small linear tear in the anterior margin of the prosthesis was noted. Patient reported this had occurred during cleaning the prosthesis. The temporary prosthesis (AB.13205) was worn for four months. New and final prosthesis was constructed in Silskin prosthetic elastomer to prerecorded shade data. Some external tinting applied to emphasize fine pigment characteristics. Patient and bride pleased with result. Review every twelve months.



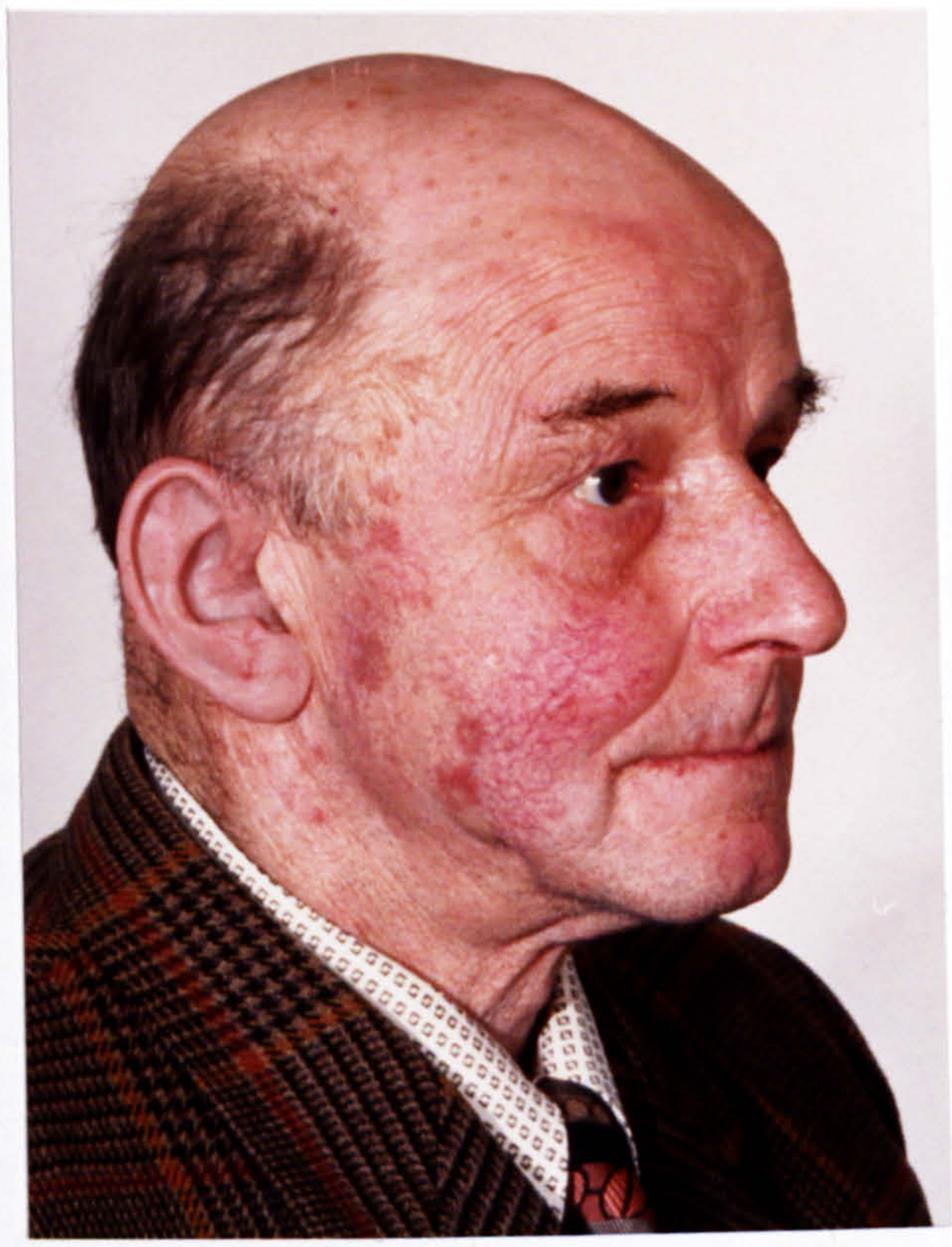
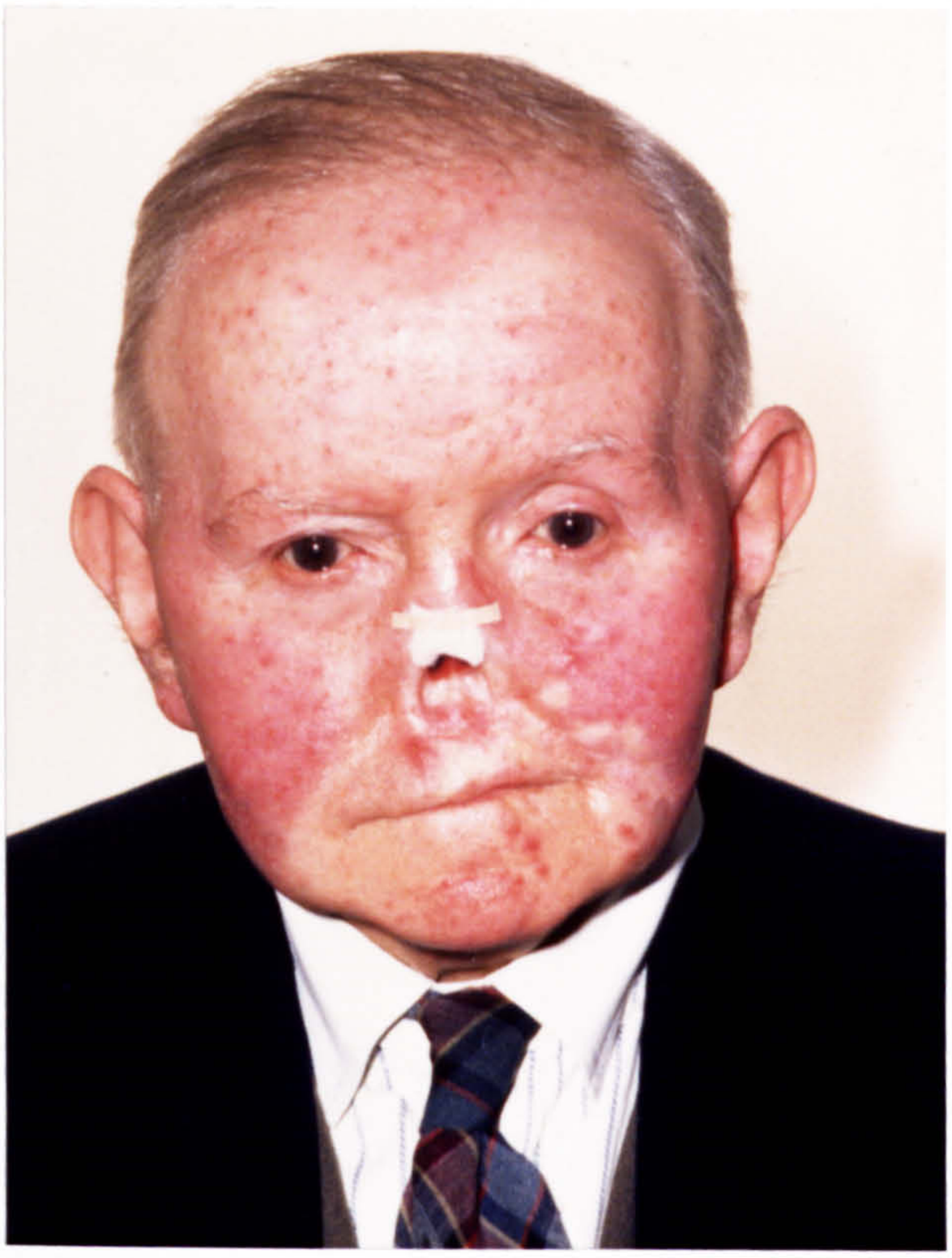


Figure 22 Case 2

Case 3 (Fig. 23)

A 70 year old retired textile worker. Defect; new nose required following excision of basal cell carcinoma. Patient referred by general practitioner following consultation regarding a skin rash caused by the patient wearing a nose prosthesis constructed in aluminium and coloured by oil paint. The prosthesis was made by an ophthalmic company and the patient had worn this for nine years. Skin patch tests confirmed the patient's skin reaction to the metallic base. No reaction was noted to silicone elastomer. The patient was advised to discard the aluminium prosthesis and no prosthesis was worn for two months. The skin condition improved and prosthetic treatment commenced. To enable the patient to adapt to a resilient prosthesis the prosthetic elastomer Molomed was used pigmented to base skin shade as a temporary restoration. Patient managed the prosthesis well. Prosthesis retained by Polydimethyl Siloxane contact adhesive. Provision for spectacles in the prosthesis allowed for removal and gave support. Patient progressed well. Molomed temporary prosthesis warm for three months. Final prosthetic restoration constructed in Silskin. After some revision of shade characteristics the patient was pleased with result, and his skin condition has improved. Review every twelve months.



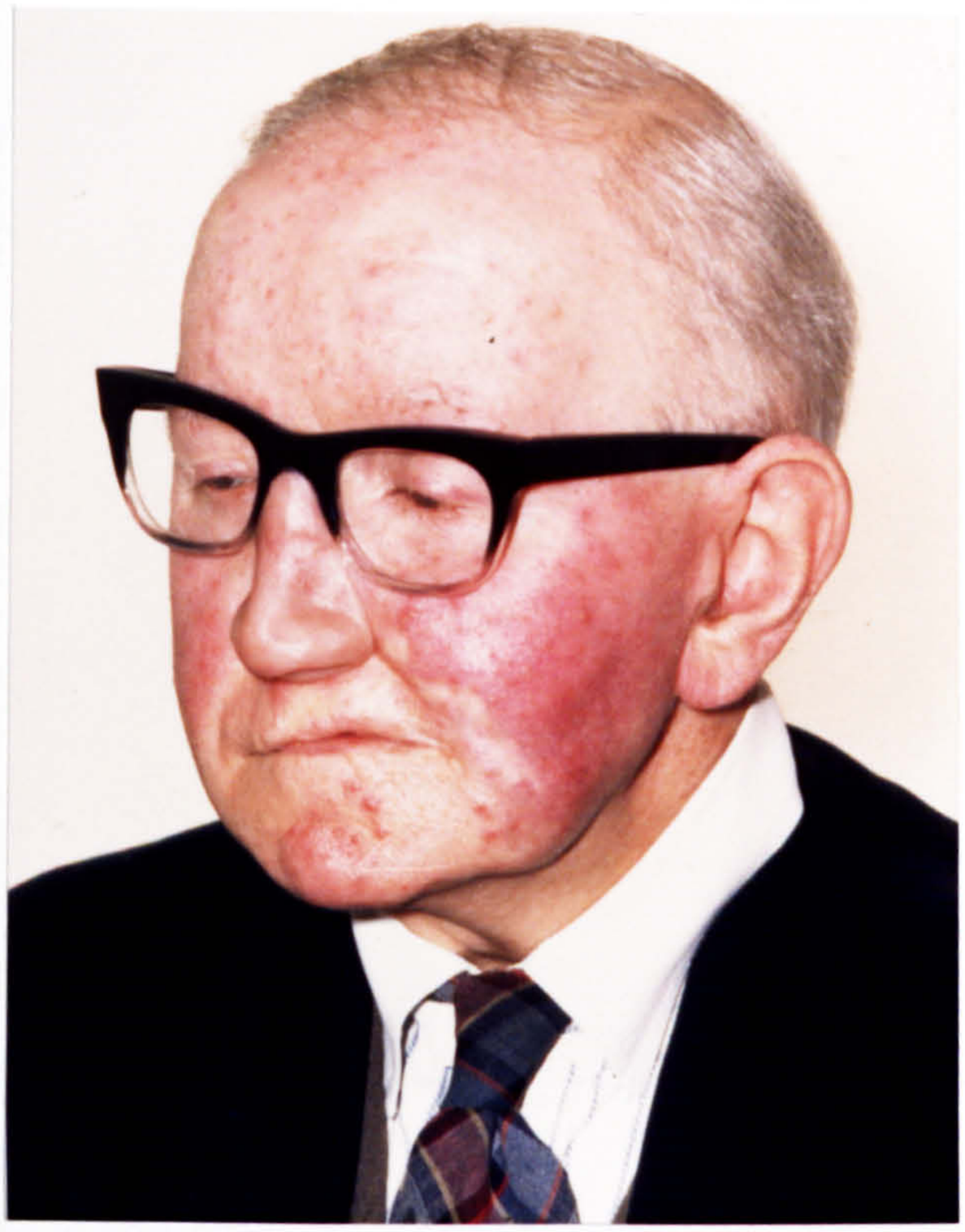


Figure 23

Case 3

Case 4 (Fig. 24)

Male 61 years old construction worker. Defect; nose removed following excision of basal cell carcinoma. Patient wishes to return to his work on a building site. Referred for prosthetic reconstruction as a patient unsuitable for surgical reconstruction. HV25 prosthetic elastomer selected to maximize the undercut areas of the defect and provide stability. HV25 pigmented to basic skin shade with particular reference to vascular concentrations. Patient wears spectacles, and hence provision made in prosthesis to locate spectacle bridge. Retained by means of Polydimethyl Siloxane contact adhesive. Patient reviewed at four weeks, he reports good progress and is pleased with results. Minor points of ulceration corrected by reduction of HV25 elastomer. Patient manages the prosthesis well, and can carry out his employment without difficulty. HV25 considered a satisfactory material for the patient with regard to his work environment. Review again in twelve months.

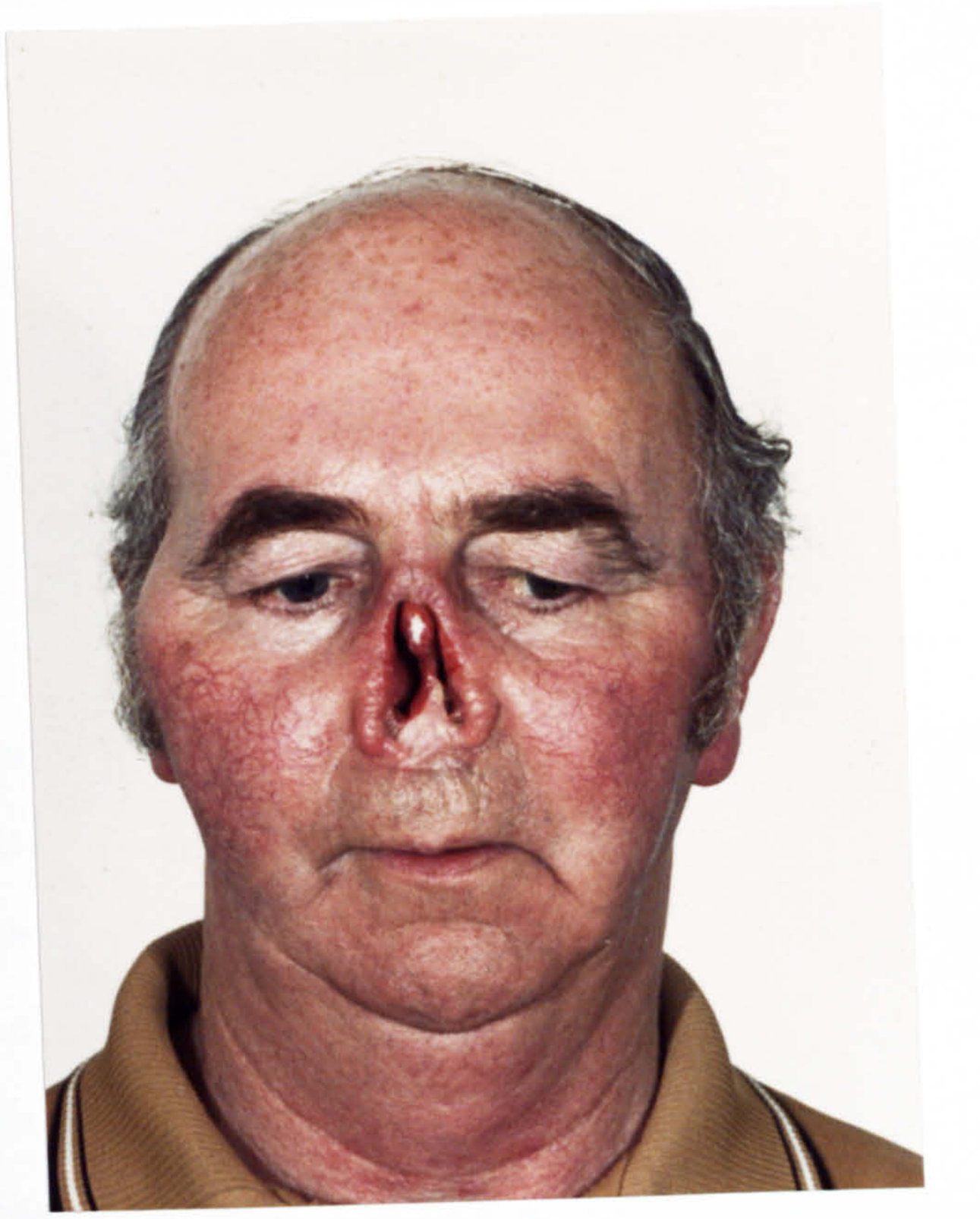


Figure 24 Case 4

Case 5 (Fig. 25)

Male 58 years old, electronics engineer. Defect; total removal of nose and upper lip area following excision of basal cell carcinoma. Lip and nasal margin repaired by means of forehead flap. No further surgical reconstruction considered. Referred for prosthetic restoration. Silskin prosthetic elastomer, pigmented to simulate patient's basic skin shade, was selected for the prosthesis and the treatment plan was to include simulation of the patient's moustache. Hair was taken to produce the moustache on Dacron mesh base. Patient wears spectacles at various times during his work. Provision made in prosthesis to support bridge of spectacle frame. Retention by means of Polydimethyl Siloxane contact adhesive. Moustache bonded to Silskin prosthesis with Cyanoacrylate 413. The moustache masks the defect of the upper lip and margin of the prosthesis. Particular use has been made of the naso-labial folds to blend the margins of the Silskin prosthetic restoration. On review at four weeks patient has no problem in management of the prosthesis. He is very pleased with the result and has been complimented by his friends. With this confidence he has returned to his employment. Review again in twelve months.

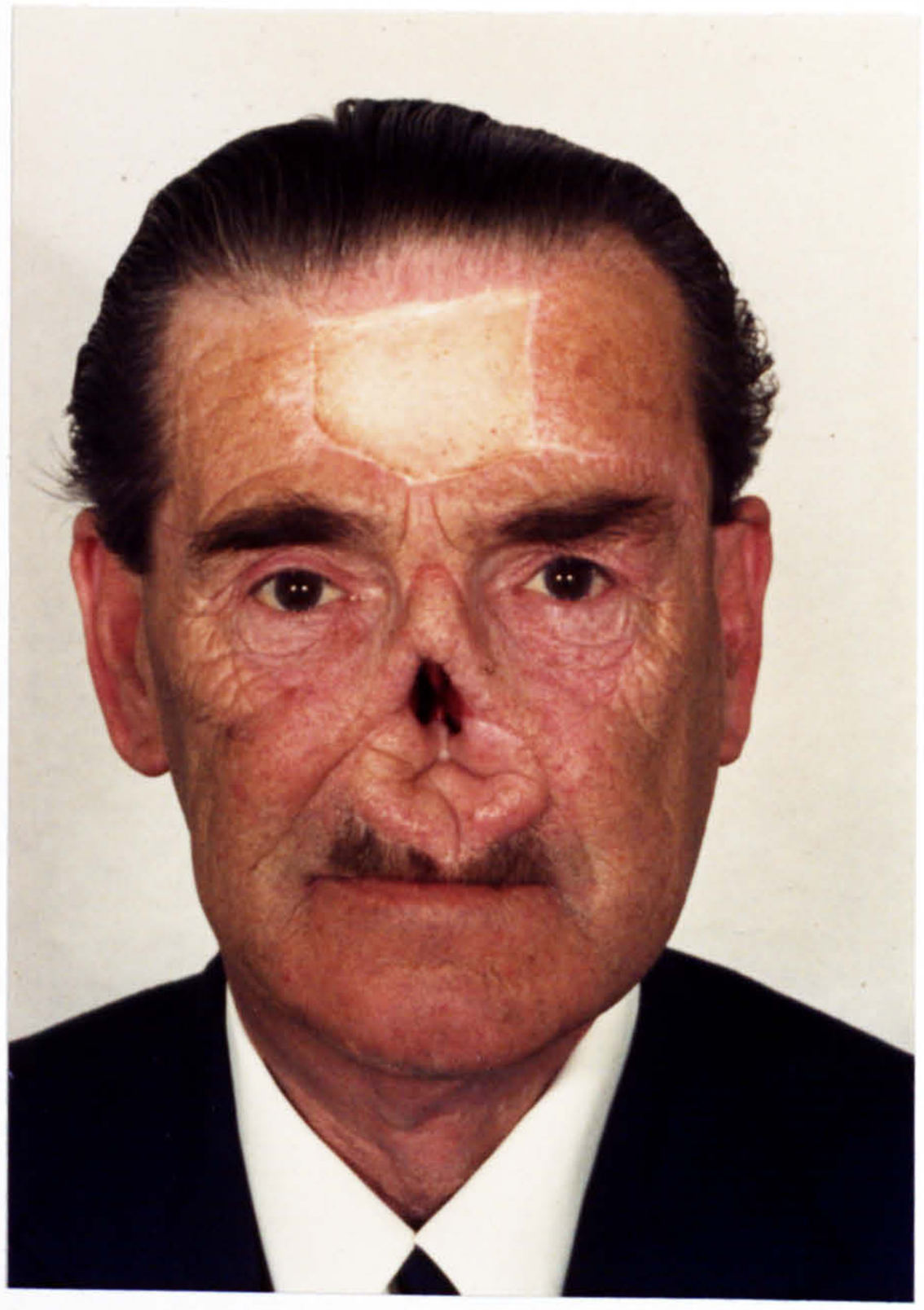


Figure 25

Case 5

Case 6 (Fig. 26)

Male, 60 years old butcher. Extenteration of right orbital area for malignant neurilemoma. The extensive defect involved the associated maxillary cavity. Referred for prosthetic reconstruction. Some collapse of facial tissue in molar region due to resection of maxilla. Treatment planned to first restore contour and dental function. Obturator constructed with hollow bulb extension to restore facial contour and provide support for eye and orbital prosthetic restoration. Dental obturator worn for four weeks to establish comfort and function. Some sore points corrected during that period. A Silskin prosthetic elastomer prosthesis was constructed of pigmented material to simulate patient's basic skin shade. Facial prosthesis designed to fill orbital cavity and interface the dental obturator maxillary bulb. The cavity area of the Silskin prosthesis was filled with Silskin 382 to provide a resilient lightweight restoration. The prosthetic eye unit is removable for cleaning and for transfer of duplicate prostheses. The upper orbital margin incorporates an eyebrow produced from the patient's own hair and constructed on Dacron mesh base. Eyebrow bonded to Silskin by Cyanoacrylate 413. Silskin Prosthetic Elastomer prosthesis retained by polydimethyl siloxane contact adhesive on peripheral margins of prosthesis. Patient wears spectacles and on review at four weeks is managing both obturator and facial prosthesis well. He is very pleased with result and now works part-time. Review again in twelve months.

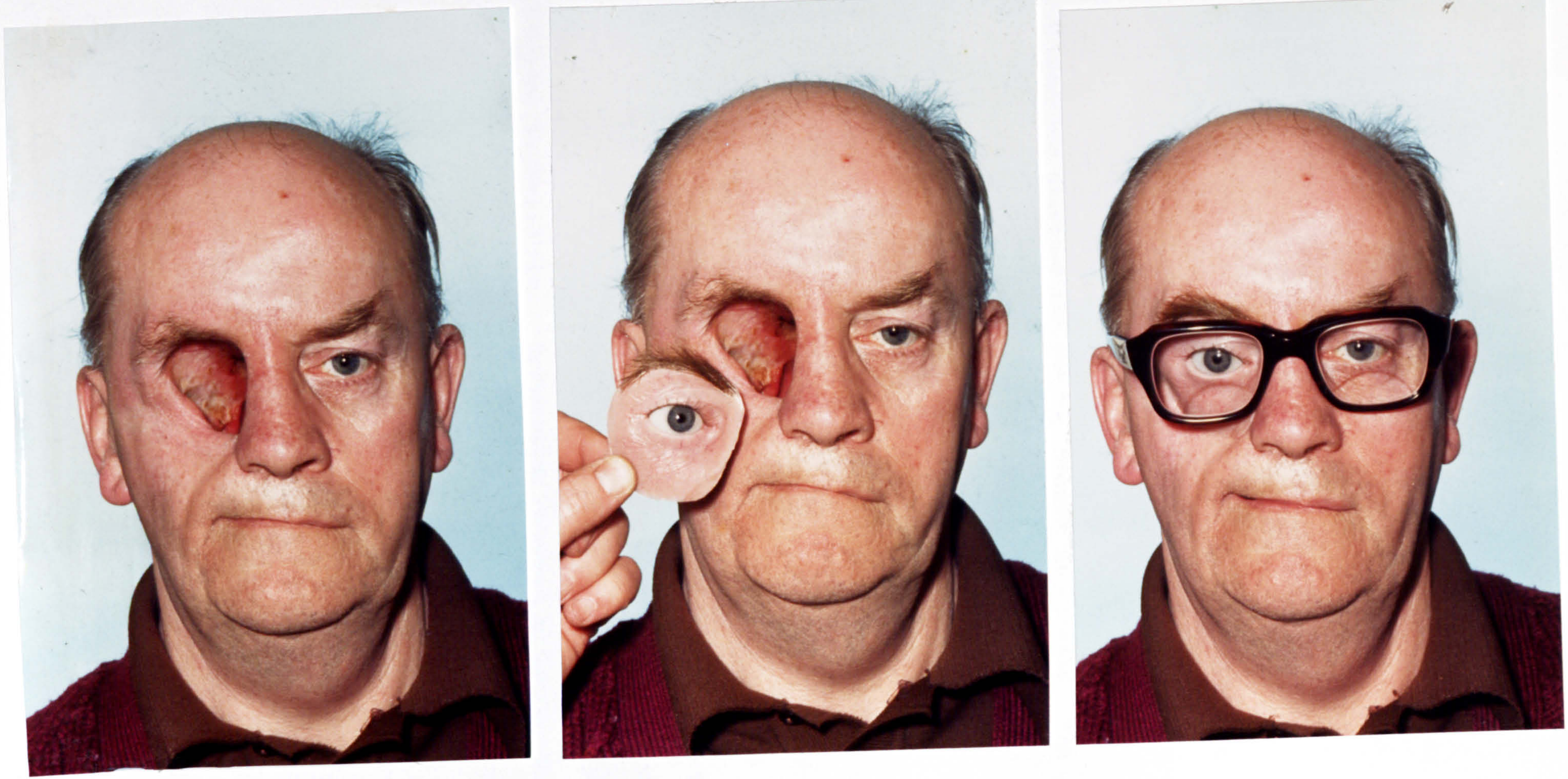


Figure 26

Case 6

Case 7 (Fig. 27)

Female 60 years of age. Extenteration of right eye and orbit for ophthalmic tumour. Cavity skin lined. Patient referrred for prosthetic reconstruction to renew her current prosthesis. She had worn a hard acrylic (Polymethyl Methacrylate) prosthesis for five years. The prosthesis was attached to her spectacle frame for retention. The acrylic prosthesis had deteriorated and required replacement. As part of the treatment plan Polyshield HV prosthetic elastomer was selected for the replacement prosthesis. The patient requested a material which was less flexible than the other prosthetic elastomers available. She had become used to the rigid properties of the first prosthesis. Polyshield HV was considered a compromise in material characteristics. The patient has obtained new spectacles. The defect margins are contained in the front view by the frame of the lens. This advantage was used to enhance the aesthetics of the new prosthesis. Polyshield HV prosthetic elastomer was pigmented to simulate the patient's basic skin shade. The eye unit is removeable for cleaning and future transfer to duplicate prosthesis. Eyelash provided to eyelid rim. Restoration retained by Polydimethyl Siloxane contact adhesive on periphery of prosthesis. On review at four weeks patient reported problems in using the adhesive. Further tuition given. Patient very pleased with result and commends the feature of being able to remove the spectacles and leave the prosthesis in position. On review at twelve months patient very happy and confident with prosthesis.

Figure 27

Case 7

Case 8 (Fig. 28)

Female 57 years old. Extenteration of eye and orbit for malignant melanoma. Patient referred for prosthetic reconstruction with the request for a temporary covering for the defect. This was to observe the defect site in consideration of future surgery. Temporary cover plate constructed of AB 132025 prosthetic elastomer. Following a satisfactory report at nine weeks a permanent prosthesis was indicated. The prosthetic elastomer Silskin was selected and pigmented to simulate the patient's basic skin shade. To complement retention and location an undercut area in the supra orbital crest was used. The eye unit is removeable for cleaning and future transfer of duplicate prostheses. An eyelash was bonded to the rim of the eyelid. Prosthesis retained by the topography of the orbital cavity supplemented by Polydimethyl Siloxane contact adhesive on periphery of prosthesis. Patient wears and interchanges spectacles. On review at four weeks patient reports some pressure in area of extension into undercut area. The extension reduced to avoid this problem. Patient very pleased with result and has been complimented by family and friends. She has renewed her social life with confidence. Review every twelve months.

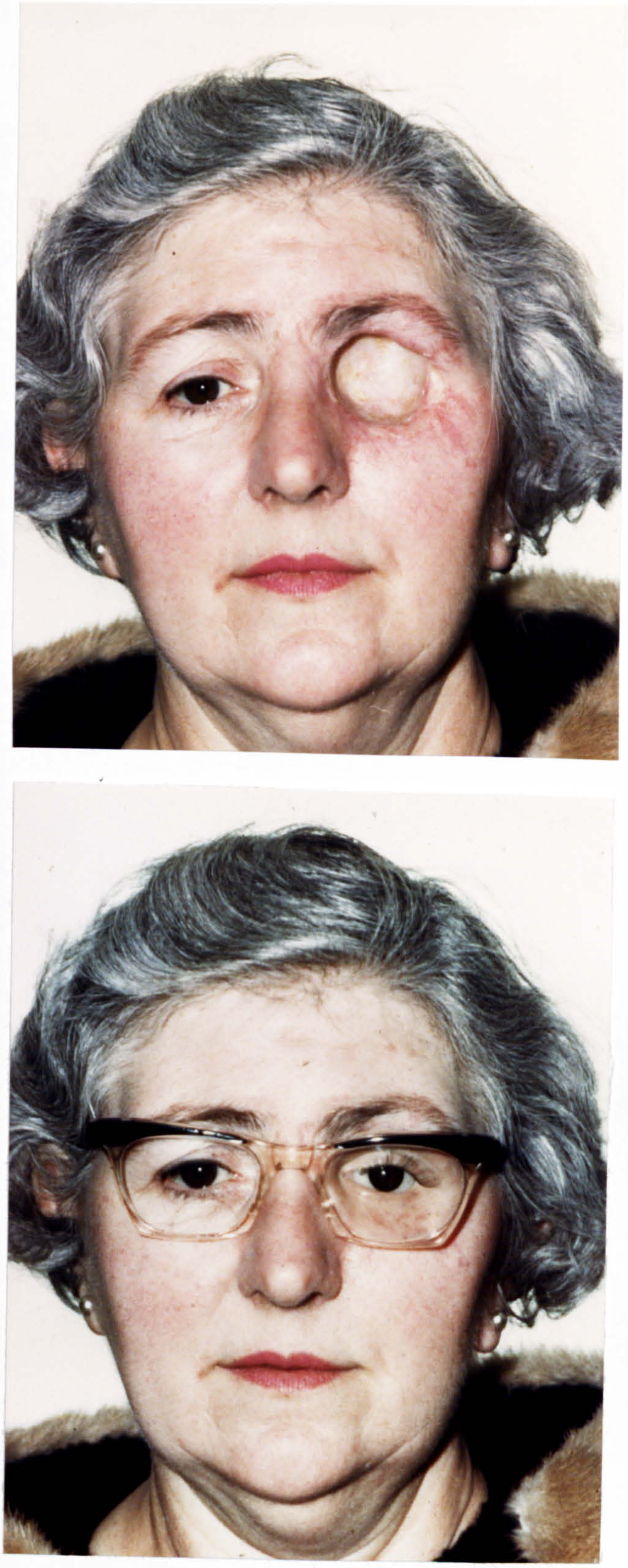
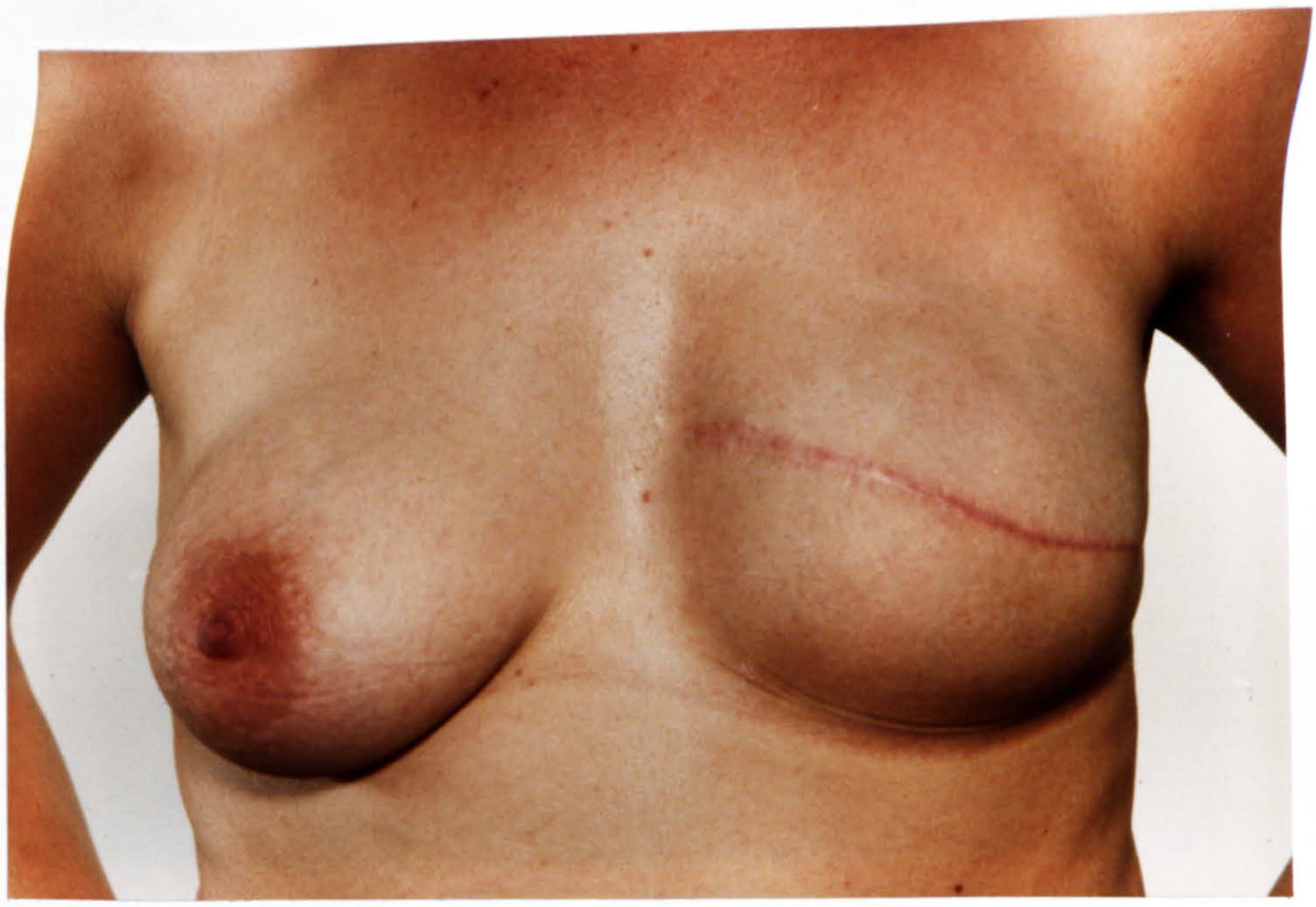


Figure 28 Case 8

Case 9 (Fig. 29)

Radical mastectomy,patient 33 year old nurse. Left breast reconstructed by use of Silicone elastomer tissue expander, 850 cc size. Following a programme of Saline injections required expansion achieved to 510 cc. Tissue expander replaced with 440 cc Silicone gel filler breast implant. Post-operative contour satisfactory. Patient referred for prosthetic reconstruction of the left nipple-areola complex. An impression was recorded of the companion right side nipple-areola complex. Sodium Alginate impression material used. Shade data and pigmentation characteristics of areola were recorded for laboratory procedures. Silskin prosthetic elastomer was used to construct an individual anatomical replica nipple-areola complex. The prosthesis is retained on the breast by means of Polydimethyl Siloxane contact adhesive. Patient instructed in management of prosthesis. Very happy with result. Review at six months.



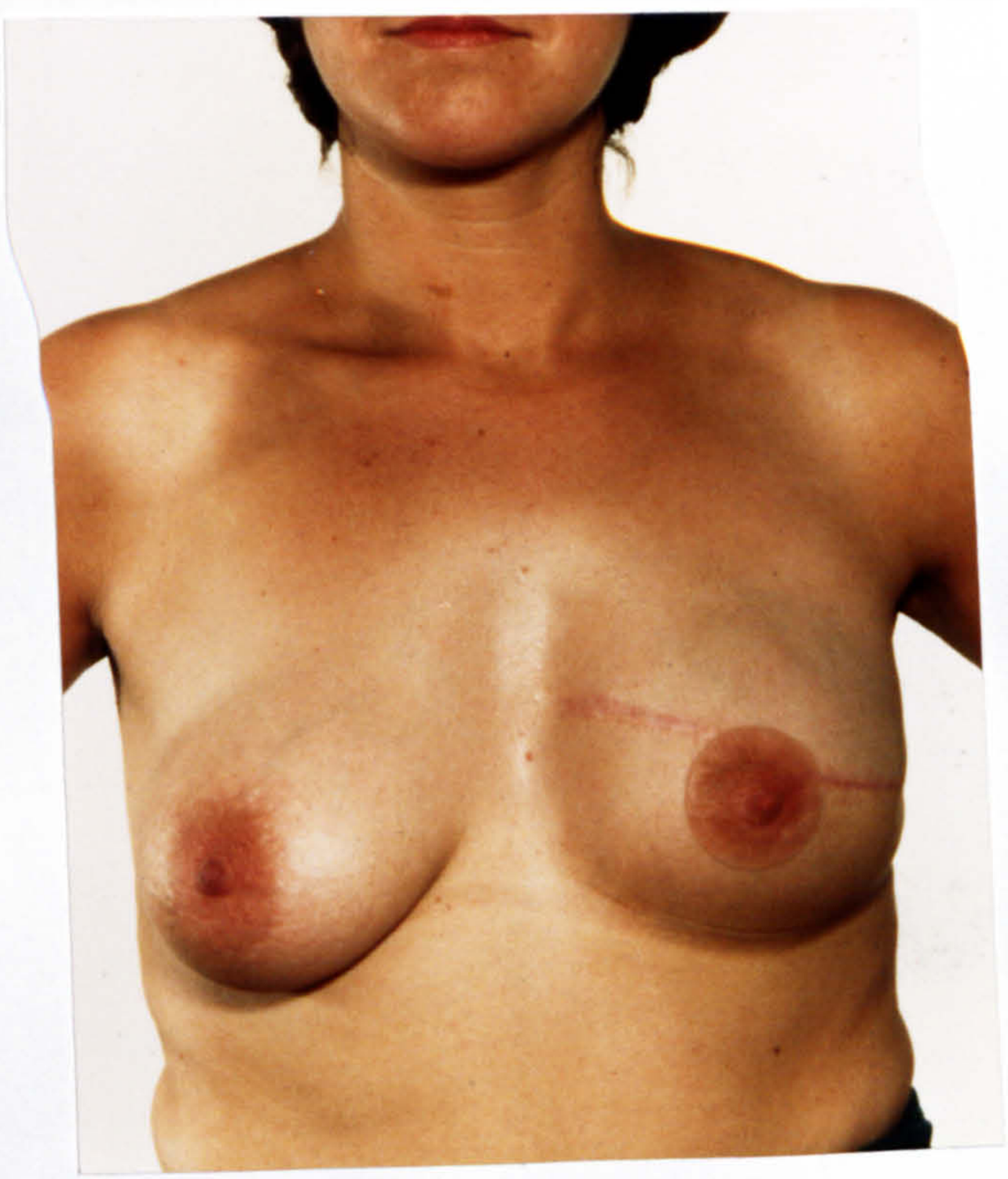


Figure 29

Case 9

Case 10 (Fig. 30)

Radical mastectomy, patient 46 years old. Right breast reconstructed by use of Silicone elastomer tissue expander 850 cc size. Saline injection programme completed to required expansion of 1090 cc. Tissue expander replaced with 700 cc Silicone gel filled breast implant. Post-operative contour satisfactory. Patient provided with a standard commercial nipple prosthesis (Fig. 31). Not happy with appearance, following a brief period of wear declined to use this prosthesis. Referrred for individual prosthetic reconstruction. Impression recorded of left companion nipple-areola complex using Polysulphide rubber impression base. Shade data and individual pigmentation of the areola were recorded for laboratory procedures. Silskin prosthetic elastomer used to reconstruct the nipple-areola complex. Prosthesis retained in position by means of Polydimethyl Siloxane contact adhesive. Patient instructed in management of prosthesis. She is very pleased with the result and reports sea bathing on holiday with the prosthesis securely in place. Review at six months.

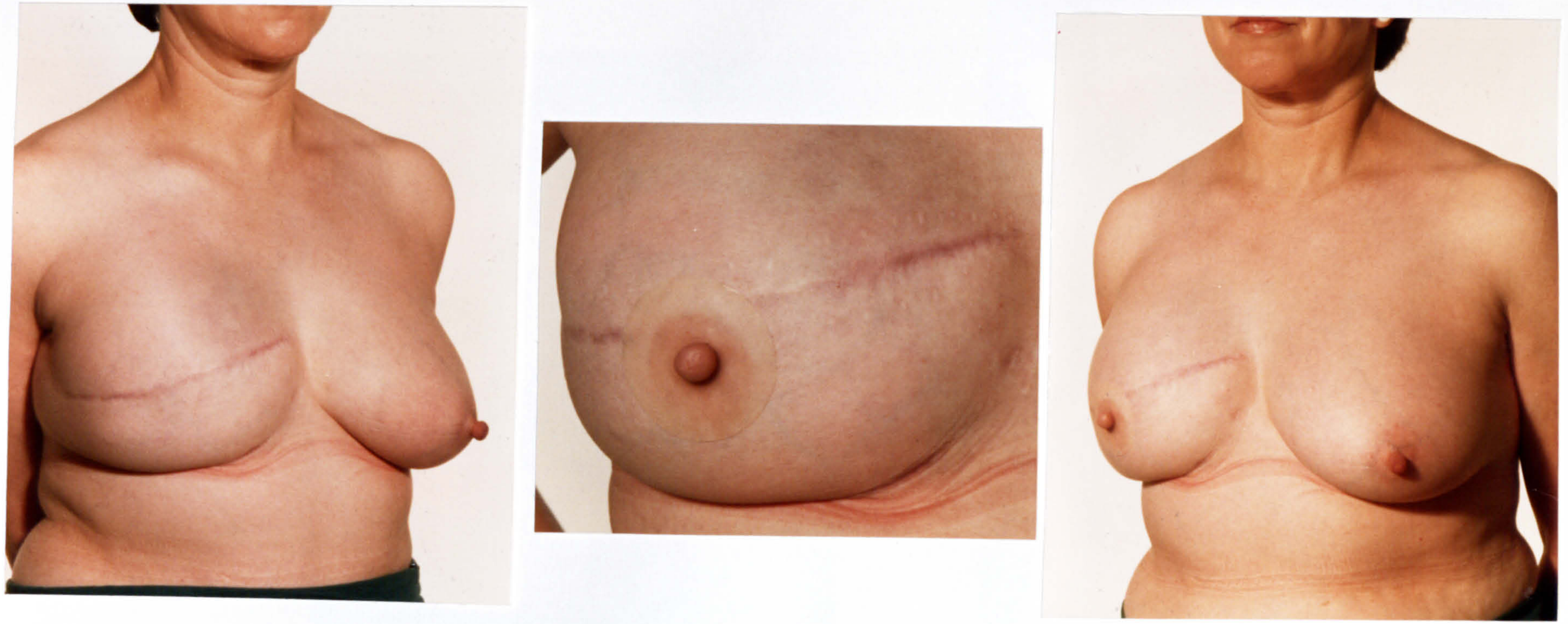
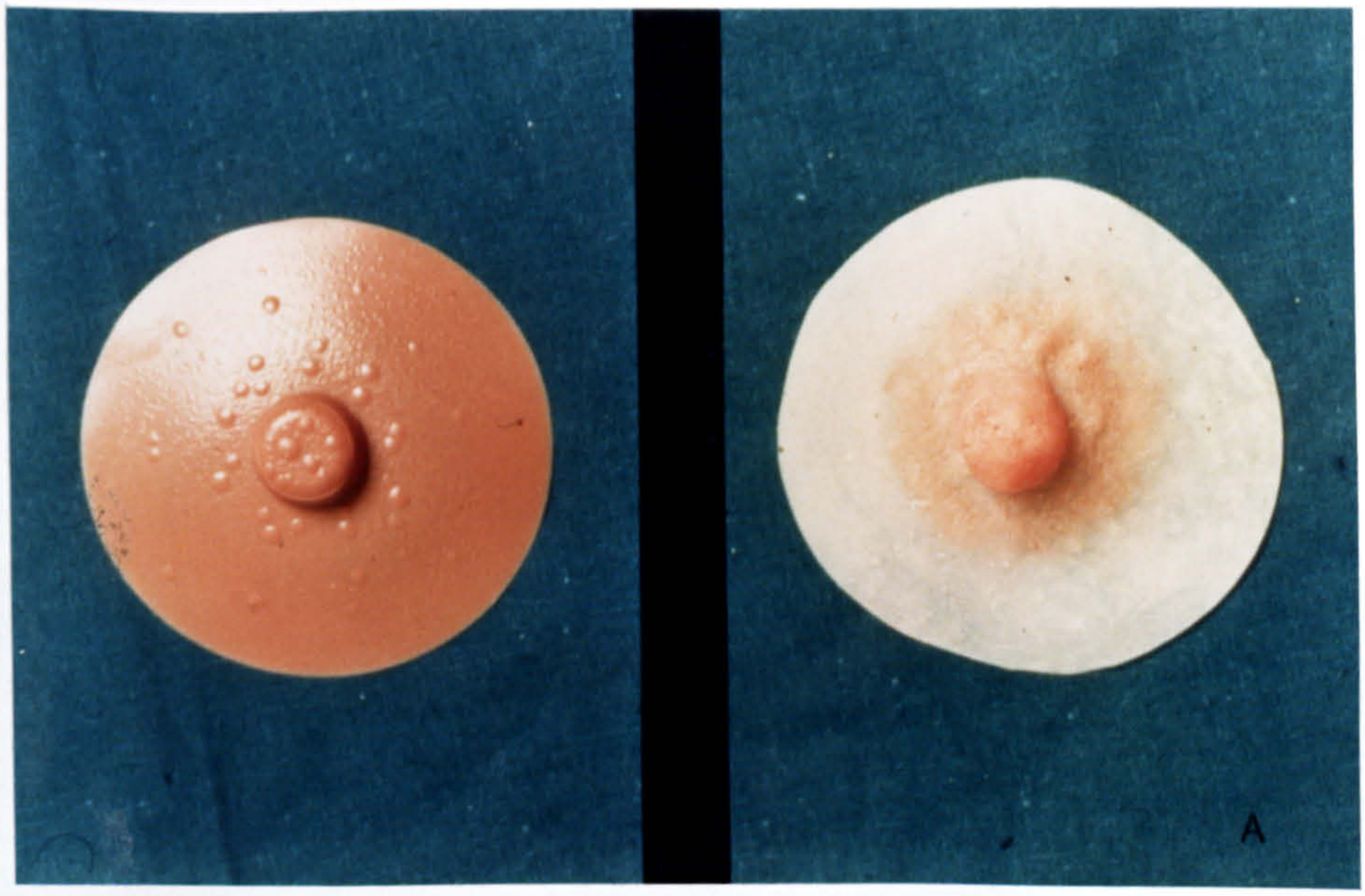
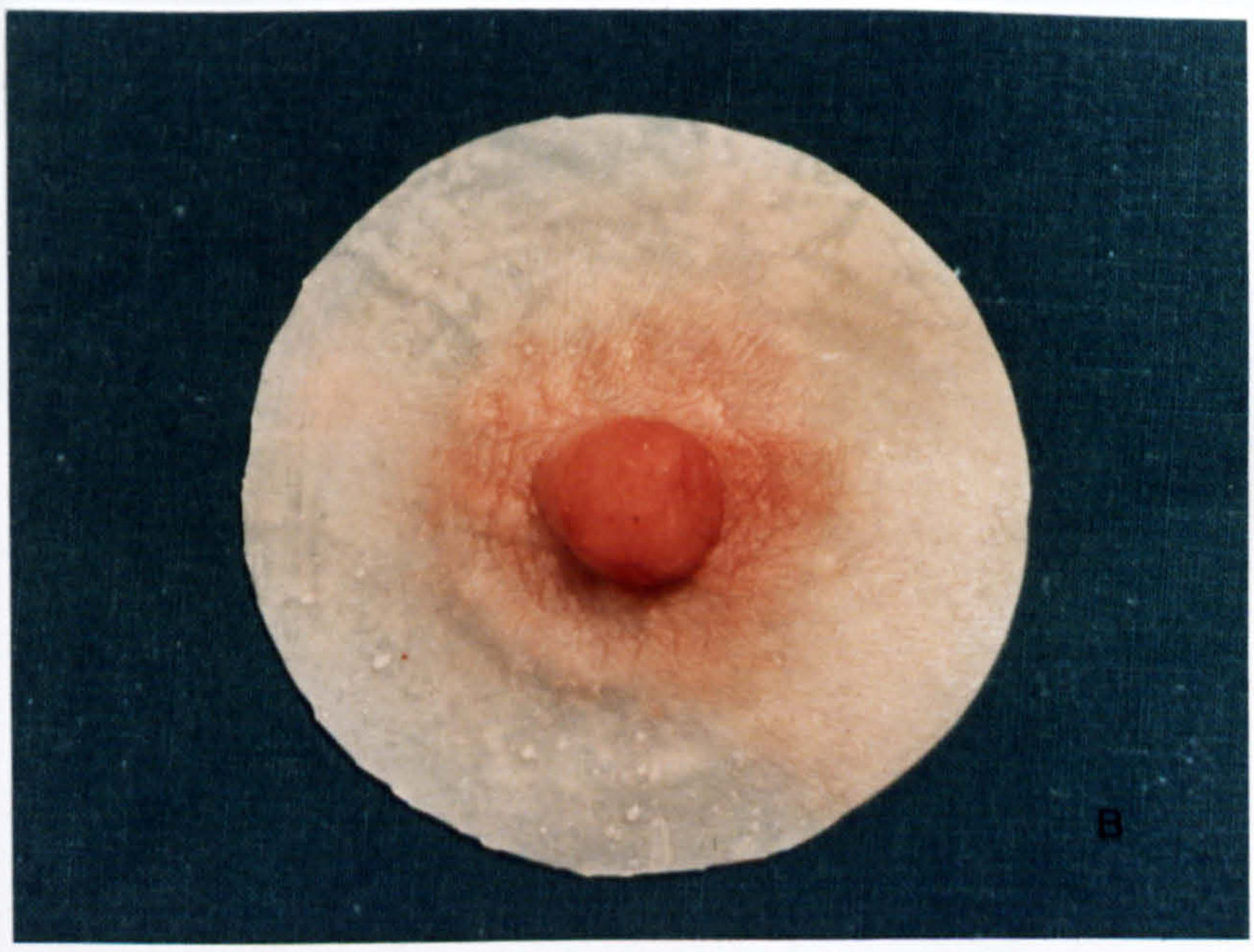


Figure 30

Case 10



A



B

Figure 31 Prosthetic Nipple-Areola complex prostheses. Prosthetic Elastomer:- (SILSKIN) (a) contrast with standard commercial prosthesis, (b) anatomical and aesthetic characteristics of SILSKIN elastomer.

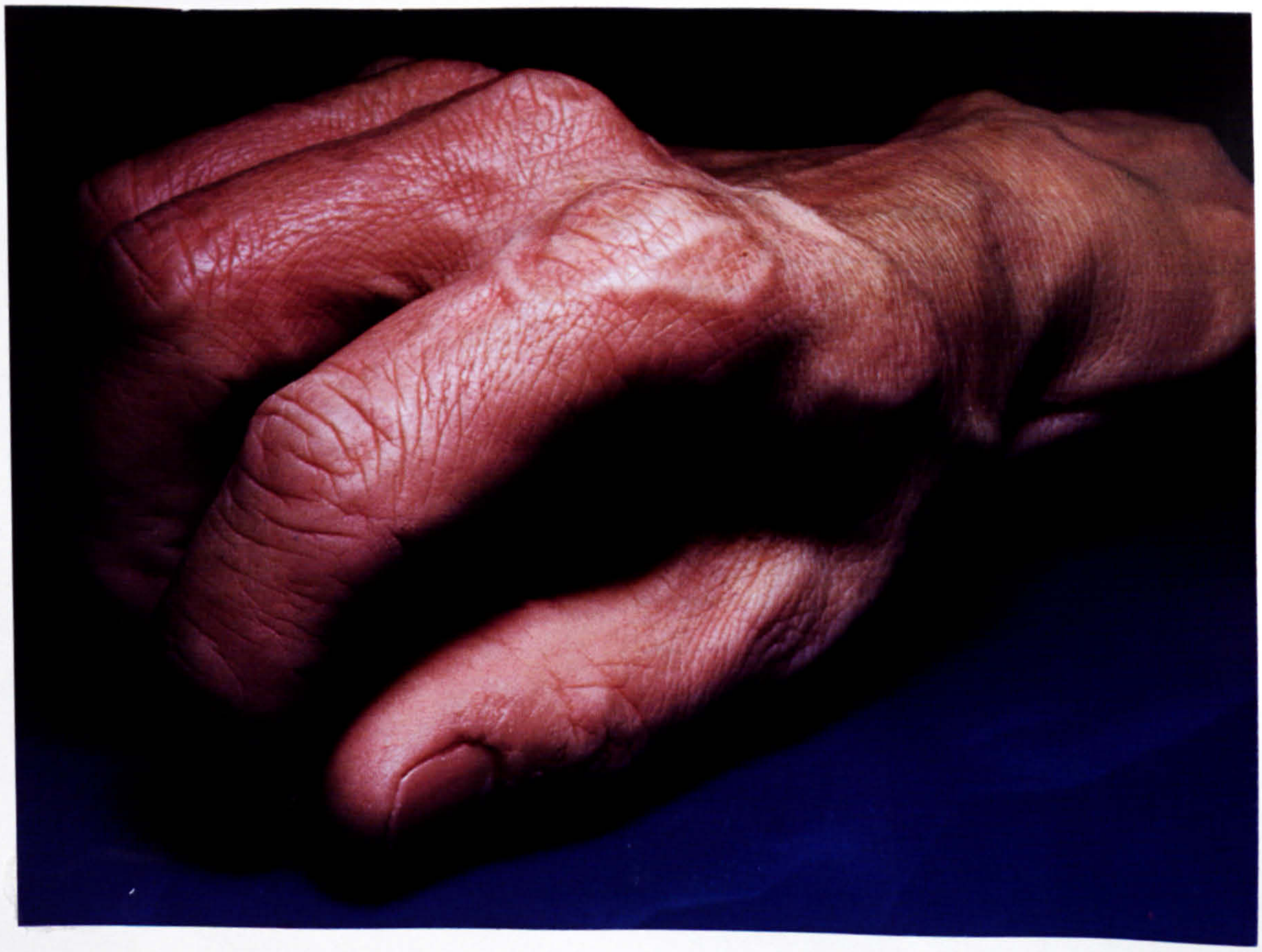


Figure 32 SILSKIN prosthetic elastomer used as a cosmetic covering for a myoelectric hand prosthesis

PART III ADHESIVES

There are agents in nature able to make bodies stick together by very strong attraction and it is the business of experimental philosophy to find them out.

Sir Isaac Newton
1718

INTRODUCTION

Prosthetic Adhesive

An important requirement in facial reconstruction by prosthetic means is the selection of adhesives which must provide functional retention, be hygienic, non-inflammatory and non-allergenic. The adhesive must be simple to apply and easily removed, be inexpensive and readily available in stable form. Over the years many adhesives have been developed in the form of proprietary formulations. This practice continues with products that do not indicate the composition of the adhesive, a feature particularly evident in the many forms of adhesive dressing materials for the skin. The dressing type adhesive needs only to serve a short-term, one-time application to human skin and as a thin layer to provide protection against external bacterial infection during primary wound healing.

In respect of facial prosthetics a speical need exists for developing an adhesive formulation with well characterized components. In contrast to that of the one-time use dressing adhesive is the repeated priming and removal from the prosthesis and skin surface. This involves a complexity demanding interactions at the (a) prosthesis-adhesive and (b) adhesive-dermal interfaces with the exudates from the skin that interfere with the adherence. In Part III the factors involved in the selection, formulation and application of adhesive compounds for wound closure and adhesives specific to facial prosthetics termed surgical adhesive for wound closure and external adhesive, are examined. The fundamental, physical and chemical concepts of adhesion are investigated from which the compounds and their functional criteria can be determined.

The human skin is the interface for which the applied adhesive must be formulated to provide the necessary adherence of reasonable duration from several days to several weeks. In the chemical sense, the principal substrate is the insoluble protein keratin along with the continuous extruding perspiration comprising chemical metabolites (Table 10). In the deepest layer of the epidermis new cells are formed by mitosis and these constantly push outward and take the place of the keratinous cells that are sloughed off. This layer can be readily penetrated by aqueous media and by low molecular weight solvent, and esters: it is the first line of sensitivity to such components contained in the external adhesive that results in inflammatory responses. This provides the early indication that the fomrulated adhesive should avoid these additives in particular when using thinning or diluting agents.

Sweat glands and their ducts push outward from the dermis and through the epidermis to the surface of the skin discharging the metabolites (Table 10) which, in varying degrees, affect the durability of the adhesion. The most active exudates in this respect are water, lactic acid and lactates, lipids, and urea which are strong hydrogen-bonding substrates that work against the keratinous epidermal surface and thereby cause breakdown of bonding at the adhesion interface

LONTZ (1960) (unpublished paper).

METABOLITE COMPONENTS OF HUMAN SWEAT		
Electrolytes		mg/100 ml
pH	4.5 - 7.5	-
Sodium		24 - 312
Potassium		21 - 126
Calcium		5 - 32
Chloride		36 - 468
Bicarbonate		0 - 23
Nitrogen metabolites		
Amino acids (10) as NPN		24 - 64
Urea		12 - 57
Nictotinamide		trace
Other		
Lactic acid (lactates)		1 - 30
Glucose		1 - 3
Lipids (varied oils, etc.)		0 - 30
Sweat exudation 300 - 700 ml/day		

LONTZ (1960)

Table 10

Chemical types of external adhesive

Adhesives in a wide variety of form and application have been used for almost every conceivable application from structural engineering to medical and surgical adhesion. Adhesives formulated for expected or specific durability such as medical applications must be cleared for toxicity and allergic reactions. A classification of adhesives based on the chemical characteristics of polarity is summarised in (Table 11.)

Classification in terms of degree of polarity is one of practical convenience in the identification of hydroxyl and carboxyl groups; their absence or presence in high or low proportions is a means of distinguishing the extreme range. Exudates from skin vary in extremes of polarity, formulations comprise mixtures of these extremes to accommodate the principal physical forms that provide adhesion. The principal forces are dependent upon the forces of hydrogen-bonding which is displacing the classification of polarity, especially since hydrogen-bonding can be used as the criteria of adhesion forces and strength LASSETTRE (1940).

Adhesion mechanisms and factors

The generally accepted concepts of mechanism and factors contributing to adhesion between two substances are based on inter-molecular forces SCHMIDT (1948). Foremost is the concept of what forces or energy are available at the surface and can this energy be concentrated at the two interfaces relevant to facial prosthetic

CHEMICAL CLASSIFICATION OF ADHESIVES IN MEDICAL USE

Polarity		Chemical Type	Selected Examples
Low	(a)	Hydrocarbons	Hydrocarbon gums
			Hydrocarbon elastomers
	(b)	Halogen hydrocarbons	Chloro-elastomers
			Chloro vinyl polymers
Medium	(a)	Nitrogen, sulfur, silicone-containing	Nitrile elastomers
			Thipolasts
	(b)	Oxygen-containing	Rosin, shellac, acrylics, phenolic, acetals
High	(a)	Oxygen-containing	Starches, dextrin, plant gums
			Cellulose ethers and esters
			Polyvinyl alcohol
	(b)	Amide and amine	Protein
			Casein
			Polyamides, urea and melamine resins

Table 11

retention in the model (Fig. 33), namely the surface interface prosthesis - adhesive and concurrently adhesive - skin. Phase 1 and 5 are the solids joined, 2 and 4 are their surface layers and 3 is the adhesive film between them. If a pull in the direction of the arrows is applied to the joint the rupture starts at a point where the local stress exceeds the local strength. If a stress, at a first approximation is considered to act along the axis of the joint it gives way along its weakest cross section. BICKERMAN (1958) describes the adherence in terms of surface energy.

A molecule in the interior of a stable solid is surrounded on all sides by other similar molecules so that the intermolecular attraction is, on the average, balanced and the same in all directions. On the surface, the attractive force is unbalanced because of the boundary phase, that is, a smaller number of molecules. The surface molecules are subject to an inward, hence adherent attractive, i.e. with available surface energy. From this one can summarise that like molecular configurations between the surfaces at the interface should provide the needed mutual adhesion, namely, the facial prosthesis-adhesive interface as one formulation and the adhesive-skin the other, but with a common attribute or third component identifiable with tackiness.

Tackiness

When applied to an adhesive, it means the resistance which must be overcome to separate two solid adherents between which there is an adhesive still in the fluid, mobile, liquid state.

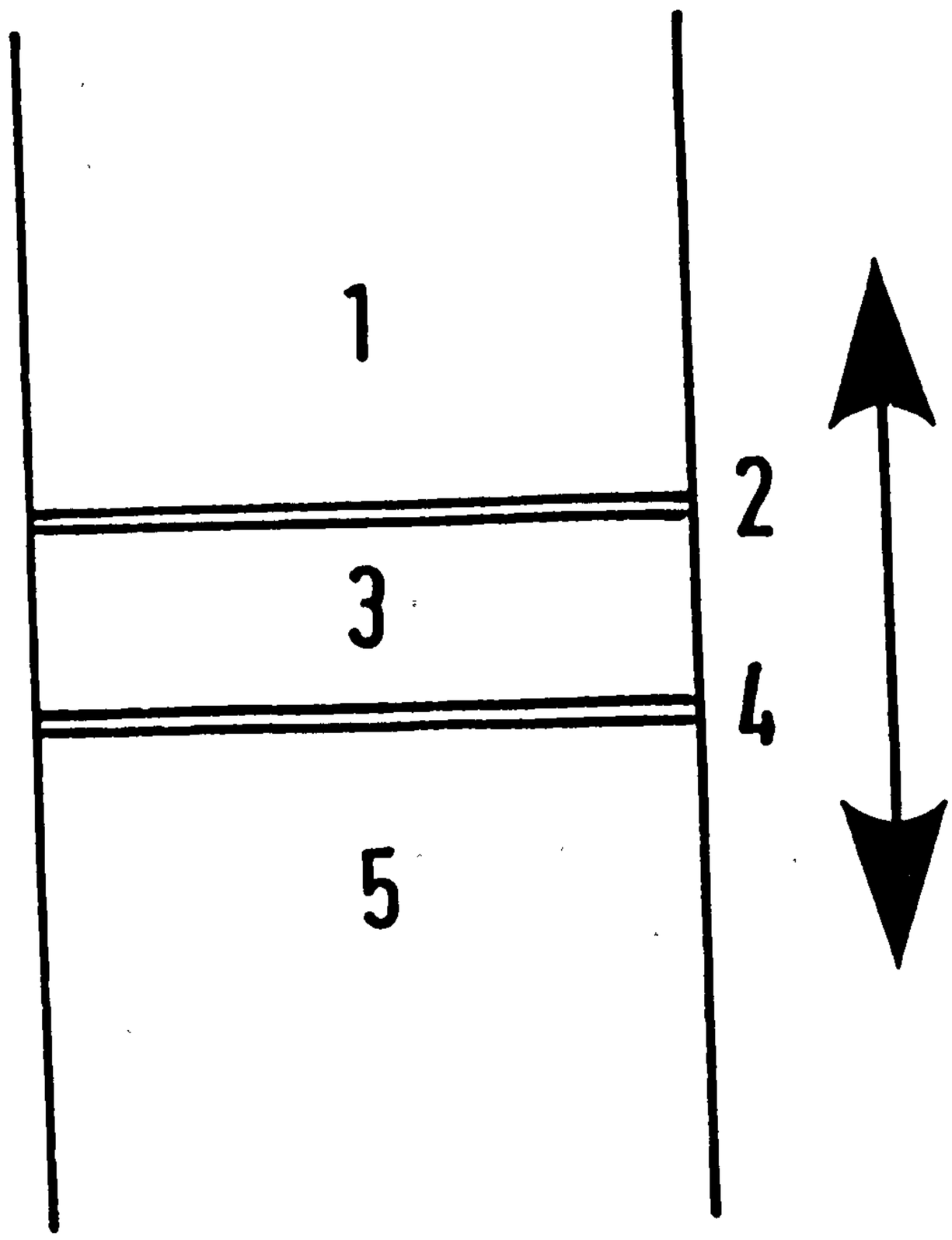


Figure 33 Schematic view of an adhesive joint, 1 and 5 the adherends, 2 and 4 - interfacial layers, 3 - the adhesive film. In a tensile test force is applied in the direction of the arrows.

After BIKERMAN (1958)

The concept follows by consideration as shown in Schematic Fig. 34 of two circular models, A (prosthesis) and B (the skin) between which there is a layer of liquid or deformable adhesive (C) bulging out of the periphery with an initial thickness. The force (F) necessary to separate the two interfaces in an interval of time has been proposed by STEFAN (1874). This is that the force required to separate two solids between which a liquid layer is present is inversely proportional to the duration of its action. The force is necessary not to overcome an attraction between solids or between a solid and a liquid but to impart to the liquid layer the speed determined by speed of separation. Therefore it is proportional to the viscosity of the liquid. If A is lifted from the support B by force F and if t is the time spent in raising the distance between A and B from h_1 to h_2 then:

$$Ft = \frac{3\pi\eta\alpha^4}{4}\left(\frac{1}{h_1^2} - \frac{1}{h_2^2}\right)$$

If the adhesive layer originally (that is, before separation) was very thin and the experiment continued until complete separation of A and B occurred, then $1/h_2^2$ can be neglected in comparison with $1/h_1^2$. From the experimental value of Ft the original clearance h_1 can be computed, and this magnitude used for estimating the solid surfaces in contact.

An adhesive for facial prosthesis must have adhesion on contact: however this can deteriorate or lose adhesion in hours or even minutes out of the province of the Stefan equation. For facial prosthetic application, the patient would require to have the adherence for several days and possibly several weeks, presuming

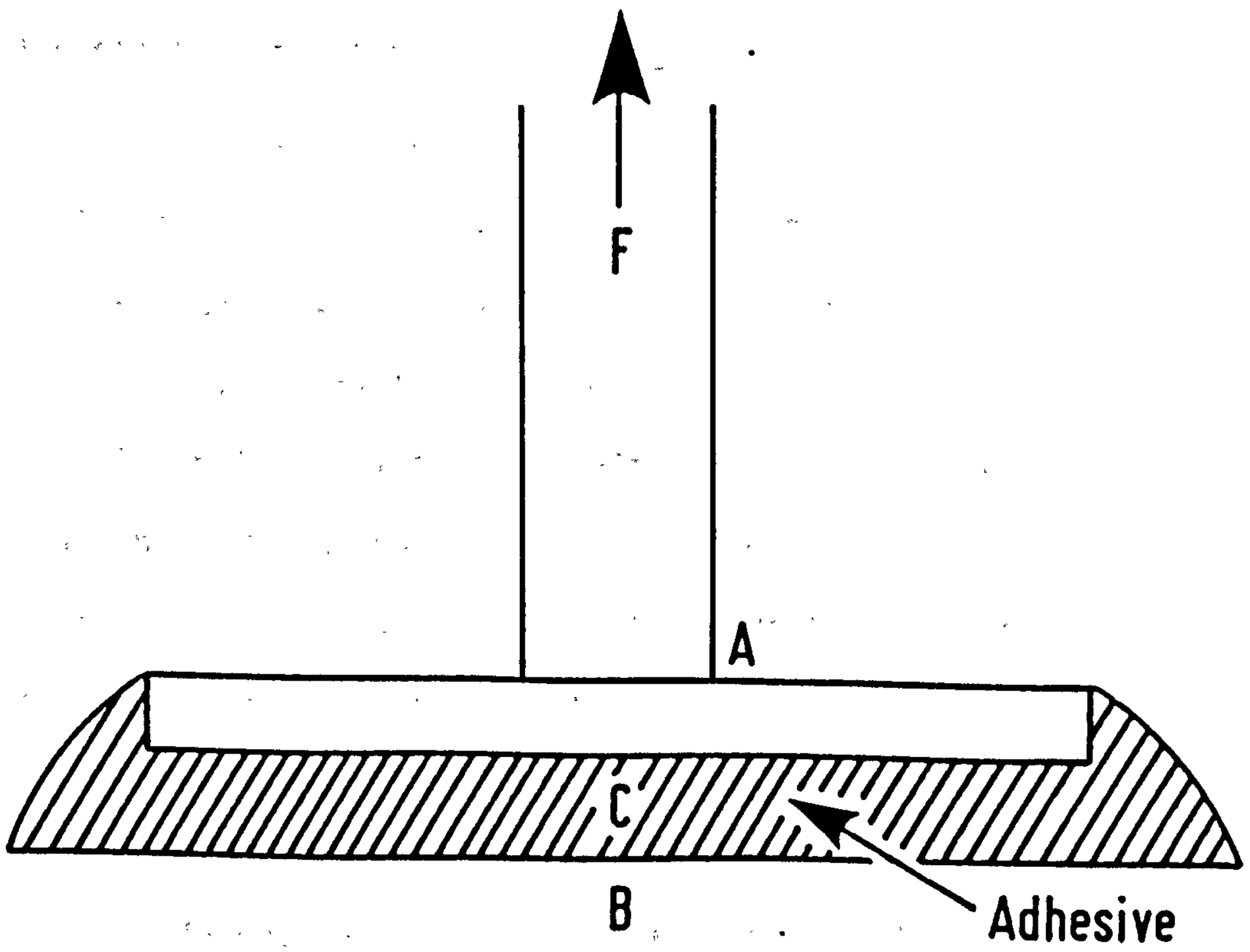


Figure 34 Schematic: Stefans experiment, resistance to overcome two adherent surfaces. (A) prosthesis lifted by (F) (B) skin (C) adhesive.

that personal hygiene is maintained. The hypothesis is that standard force-time (Ft) values be used for both the prosthesis-adhesive interface and the adhesive-skin interface, the two of which may be different. It is evident that the viscosity component (n) in the above equation is highly important to ensure anatomical confirmation and needs to be optimized to make sure that failure at the respective interface is not due to stress rupture but rather to flow.

General concepts for facial prostheses adhesion

In the case of prosthetic fixation to living tissue, adhesion is a complex involvement of two surface conditions namely, a highly polar skin substrate with an abundance of oxygen-containing entities, notably hydroxyl, carboxyl and amide groups on the one hand and relatively low polarity with an insufficiency of hydrogen-oxygen containing groups. The exceptions are the interchain non-polar oxy linkages such as are included in plasticizers for polyvinyl chloride and the chain structure of polysiloxane. The adhesion from a chemical sense has to provide for an interlayer for the adhesive, selected and formulated (Table 12) to accommodate each one of the two dissimilar surfaces, namely living tissue and the facial prosthetic material. These two dissimilarities are described as hydrophilic or water-wetting for the living tissue, and hydrophobic water non-wetting for the prosthesis, a distinction that originates with the fundamental physical characteristics namely surface tension and ultimately the tendency for hydrogen binding. In the latter feature the extent of the active hydrogen bonding can be readily ascertained by

ADHESIVE FORMULATION FOR FACIAL PROSTHESES

Component	Function	Chemical Type	Proportion Range %
Viscous agent	Provide tackiness	Non-polar Low mol. wt. (Polyisobutylene)	40 - 60
Hydrophyllic	Absorption of aqueous exudates	High polarity (Cellulose esters, ethers)	20 - 30
Hydrophobic	Absorption of lipid exudates	Moderate or high polarity (Polyvinyl acetate)	5 - 10
Modifiers			
Emolient	Softening (decreasing viscoelasticity)	Non-polar (Naural glycerides)	2 - 5
Antiseptic	Reduce bacterial invasion	Bactericide or antibiotic	1
Pigments	Cosmetic	Red or pink dye	1
Thinner	Ease of spread	Ester solvent	5 -10
Propellant	Dispensing	Freon*	Var.)

(*Other chemicals may be substituted)

Table 12

infra-red spectrometry. These features along with a quality described as tackiness provide sufficient information for formulating adhesives that should serve adequately for topical skin adherence of reasonable time duration. Formulation of an adhesive serving the dual function of adherence to the facial prosthesis and adherence to the living tissue is the matter of compounding all three types of the polar groupings indicated in Table 11 in their correct proportions for the various facial prosthetic materials used and individual patients concerned.

Forces working against adhesion

From the time an adhesive is applied to the respective surfaces there are forces initiated and increased which work against the adherence and ultimately cause detachment of the prosthesis from the skin. These can be considered in terms of (a) adverse chemical effects due to exudates or sweat from the skin (Table 10) and (b) mechanical or tensile difference of the facial prosthesis and adhesive with relatively extensible skin whose biochemical properties must approximate, in the initial stress-strain profile, that of living tissue.

Adverse Chemical Effect

The principal adverse effect can be credited to the accumulation, at the interface of the polar compoents, of sweat, thereby moving the force potential of the adhesive from the skin to a built up layer of the sweat and exudate metabolites. The relatively high hydrogen bonding

affinity of the components of sweat, especially the water which may vary from 0.2 to 2.0 grams per day along with the lactic and amino acids. This coupled with the increasing accumulation at the interface, can only result in progressive weakening of the adhesion and eventually complete detachment of the facial prosthesis. An important requirement for an adhesive formulation is to include sufficient amount of water-imbibing or hygroscopic ingredient to absorb the expected level of the exuding water and internal moisture to predicted levels BULBULIAN (1973). Such compounds can be the soluble high polarity group such as cellulose carboxymethyl cellulose, and polyvinyl alcohols, which are commercially available and in specified grades, approved for medical applications.

Viscoelastic Requirement

The adhesive formulation must be as indicated by the Stefan equation (see above, page 110), or visco-elastic component and one compatible with the low polarity prosthetic material substrate. This formulation will provide adherence, and also retain the viscous or visco-elastic characteristic. These requirements for the facial prostheses single out viscous hydrocarbons, one example of which is the commercial polyisobutylenes LONTZ (1969). The gum compounds have a high degree of tackiness and remain unchanged by the metabolic exudates and provide the criterion of flow movement according to the Stefan equation with the important factor of viscosity, which for successful, functional retention should be in the range of 3,000 to 10,000 cP. Since gum compounds are usually much higher in viscosity, an addition should include low voscosity hydrocarbons to reduce the viscosity of the hydro-carbon gum for functional use.

The resulting formulation of the low-polarity compound now provides a stable interface having in addition to the thickness, now more appropriately described as pressure-sensitive adhesion, the feature of low viscosity and high-low modulus. The latter enables the intervening adhesive layer to conform to the initial, tactile modulus or viscosity of the skin and with the facial prosthesis. The prosthesis material must have a low modulus, in the range of 3 to 8 kilograms per square centimeter, in order to provide its conformity with the elasticity of the adhesive and of the skin.

The adhesive formulation should not change in consistency on aging which often occurs with certain medium polarity adhesives notably shellac, rosin, and certain acrylics which have a strong tendency to harden by oxidation or auto-polymerization.

Formulation

The compound formulation (Table 12) often found in adhesive surgical dressings and tapes, can be used to increase the adhesion for a specific prosthetic material and for the differences in the skin exudates of different patients. For example polyvinyl chloride plasticized facial prosthesis can be expected to require a different balance of the low and high polarity additives compared to poly-siloxanes (silicones) and polyurethanes. Also, the type of plasticizer usd in polyvinyl chlorides will dictate adjustment in these two principal components. In addition, modifiers and thinning ester solvents, innocuous to human skin may be included along with pleasant odorants. In some cases, topical anaesthetics especially for easily

sensitive skins may also be included. The final requirement is that of the ease of removing expended and oxidised adhesive along with any sebaceous debris. A cleaner formulated of non-irritating solvents, such as ~~Trichloroethane~~ TRICHLOROETHANE ~~or~~ ~~Isopropanol~~ ISOPROPANOL formulation, is the most effective for most external adhesives.

Tissue adhesive

For some 2,000 years the union and closure of human tissue has been achieved by means of needle and thread. Many types of ligating materials have been employed with varying success. These have been primarily natural products such as cotton, wood-fibre, linen and animal sinews.

In modern surgical science synthetic materials such as Nylon and Dacron have gained importance. During the past twenty-five years surgeons have become increasingly interested in replacing and augmenting conventional sutures by means of adhesive bonds.

There are several reasons for this clinical interest. COOPER & FALB (1968) indicate the advantages as: (1) The potential rapidity with which tissue union can be achieved; (2) the ability of a bonding substrate to effect complete tissue closure, thus preventing seepage of body fluids; (3) the advantage of forming bonds without deformation of the tissue; (4) the possibility for improvement in the repair of tissue effected by age and disease where suture methods are difficult; (5) the ability to effect tissue closure in inaccessible areas of the body.

BAKER (1984) describes the conventional suture of facial skin as the 'Zipper effect' (due to the needle puncture pattern on either side of the wound) with the consequential poor aesthetic results. This effect is absent when adhesive closure is used and is of obvious value in cosmetic surgery.

The first instant-bonding adhesive, an acrylate polymer, was formulated unintentionally in 1941 by Eastman Kodak Co. USA, when experimenting with clear acrylic monomers as possible materials for gunsight lenses.

Cyanoacrylate was found to have the right optical properties but also found to adhere to everything in contact with it. In the presence of humidity the liquid turned into a strong adhesive. Cyano-acrylate remained a laboratory curiosity in research and development. After the war the unique bonding qualities of the polymer were recog-nised and the adhesive became available for industrial use (ARDIS 1949) and has since been documented extensively in chemistry literature. COOVER et al. (1959), LEONARD et al. (1966), GRODE et al. (1970).

Since the early encouraging reports on the use of tissue adhesives in surgery by NATHAN et al. (1960), STRAATSMA et al. (1963), ELLIS & LEVINE (1963), an extensive range of clinical applications has been reported in the medical literature (1960-1987) = 441 papers. Most of the major surgical specialities report the use of cyanoacrylate as a tissue adhesive. Selected examples are described below.

Otolaryngology

KOIDE (1965) reported the use of biological adhesive for reconstructive surgery in the middle ear. WATSON & MAGUDA (1965) used a trilene-di isocyanate of acrylic acid in tympanoplastics for constructing columellae and interpositions. FUJIWARA et al. (1966) reported good results in eight cases of reconstruction of the auditory ossicle chain using a formulation of methyl cyanoacrylate and nitrile rubber. VYSLONZIL (1969) reported the successful reconstruction of the incudo-

stapedial joint using butyl-2-cyanoacrylate in tympanoplasty, also in cases of decompression of the facial nerve with temporal removal of the incus. DECHER (1971) reported 57 cases of conglutination by means of butyl-2-cyanoacrylate, which showed good average results. SCHNIEDER (1972) reports 123 cases of middle ear reconstruction using butyl cyanoacrylate. He indicates that to obtain satisfactory results the application of the adhesive must be kept to small amounts delivered by means of an applicator. Results of healing and restoration of the hearing function were equal or better than those achieved by standard methods of tympanoplasty.

Plastic Surgery

OUSTERHOUT et al. (1971) used butyl cyanoacrylate and heptyl cyanoacrylate on 40 patients in the treatment of split thickness skin graft donor sites. Each site was divided and one area treated by fine mesh gauze (control), the other with cyanoacrylate applied by means of a small spray gun. In 36 of the 40 patients butyl cyanacrylate was used. Good results are reported with this use of cyanoacrylate. This method of local treatment of split thickness skin graft donor sites in comparison to the fine mesh gauze offered a saving in time for both surgeon and nursing care. There was a decreased loss of blood at the time of surgery, especially in patients with prolonged bleeding times. A decrease in post operative pain was noted.

LEONARD et al. (1966) indicates that the initial reduction of pain at the surgical site may be due to macro-quantities of the cyano-

acrylate being absorbed causing a mild local anaesthesia at the distal nerve endings. In both the control and cyanoacrylate sites the healing time was approximately the same. Eighty-two per cent of the patients treated preferred the cyanoacrylate method of local treatment of split skin donor sites.

There was no evidence in this study to suggest antigenic properties of cyanoacrylate and none of the patients in this series demonstrated any form of allergic reaction.

BROMBERG et al. (1964) and STONE (1966) each reported the use of methyl-2-cyanoacrylate to fix skin grafts, and each reported satisfactory results. ROBERTS (1976) reports the use of butyl cyanoacrylate in the treatment of 18 patients following acute burns and for reconstruction of burn contractures.

ROBERTS conducted a series of in vitro experiments of both sutured joints and cyanoacrylate joints. The adhesive bonded joint was found to be stronger in thin skin grafts. The adhesive-joined skin was approximately equal for all the skin thicknesses used and equal to sewn joints of grafts 0.12 mm thick. The adhesion between the underside of the graft and surrounding skin was found to be stronger than that between the edge of the graft and skin. ROBERTS lists the advantages of cyano-acrylate as:- (1)rapid time to effect fixation, e.g. some 10 per cent of time taken to make an equivalent sutured joint; (2) no risk of subgraft bleeding as may occur during fixation with sutures; (3) can be used to join pieces of graft together both when bare and when backed with tulle gras. This is a particular benefit in tangential excision and grafting procedures; (4) graft fixation is made easier if application has to be carried out on the ward without anaesthetic; (5) no sutures to be

removed, as adhesive detaches itself in 2-4 weeks. When used for children's hands, this may save a general anaesthetic; and possible chance of infection.

SHARPE (1985) used butyl cyanoacrylate for the fixation of skin grafts in burns patients. The adhesive was found to be of particular use in 20 burns patients following the Bradford Fire. The patients who received skin graft fixation by means of cyanoacrylate are reviewed later in the text (3 year review: see page 173).

SHARPE et al. (1988) also used butyl cyanoacrylate for skin graft fixation following the Aberdeen oil rig disaster as an addition to other methods of fixation.

Maxillo-facial and Oral Surgery

BHASKAR et al. (1966) They used butyl cyanoacrylate under a wide range of oral conditions. They report the response of surgically treated gingiva to butyl cyanoacrylate to be consistently excellent. When butyl cyanoacrylate was used on the oral mucosa epithelization occured faster than conventional dressings. As the underlying tissues healed the adhesive was exfoliated or could be lifted from the area. Cyanoacrylate can be used in gingivectomy where it is difficult to retain usual dressings. BHASKAR et al. (1968) They report ed fixation of free mucosal grafts in the oral cavity and protective covering of oral ulcerations. BHASKAR concluded that the use of cyanoacrylate in oral surgery is highly promising.

AVERY et al. (1982) used butyl cyanoacrylate in 8 cases in maxillo-facial surgery. The cases described involved fixation of bone to bone, soft tissue and silicone implants. The adhesive was used to locate and bond small bone fragments in cranio-facial surgery. Methods of fixing orbital floor implants constructed of silicone elastomer involve stainless steel wires or surgical impaction. AVERY et al. used the cyanoacrylate to secure the implant to the floor of the orbit. ROBERTS & EASTWOOD (1983) used butyl cyanoacrylate to secure orbital floor implants in blow-out fractures of the orbit

Neurosurgery

Neurosurgeons have found extensive use for cyanoacrylate adhesive for arteriotomies, arterial anastomoses and the encasement of aneurisms. CARTON et al. (1962) reported their experimental repair with Eastman 910 (methyl-2-cyanoacrylate). They also report the successful patch repair of an internal carotid artery. The use of methyl-2-cyanoacrylate was discouraged by HOPPENSTEIN et al. (1965) who reported thrombosis of arteries when this ester was used. Since that report neurosurgeons have made more use of butyl cyanoacrylate. VANDER ARK et al. (1970) relates their experience in the repair of cerebrospinal fluid fistulae with isobutyl-2-cyanoacrylate. He states that the ideal adhesive for neurosurgery would have the following properties: (1) no toxicity to neural and vascular tissues; (2) strong and rapid bonding to bone, dura, facia, muscle and synthetic materials; (3) ability to bond in the presence of blood and cerebrospinal fluid; (4) be simple to apply. VANDER ARK found cyanoacrylate useful in neurosurgery where it is difficult to maintain a dry field. MAXWELL & GOLDWARE (1973) also reported

successful use of isobutyl-2-cyanoacrylate in a wide range of neuro-surgical procedures. TINDALL (1983) describes extensive experience in sealing cerebrospinal fluid leaks using isobutyl-2-cyanoacrylate. ZANETTI & SHERMAN (1973) indicate the feasibility of occluding aneurisms by direct injection of isobutyl-2-cyanoacrylate. This technique was further developed by SHEPTACK et al. (1977) in 20 cases used a direct injection of isobutyl-2-cyanoacrylate ~~was used~~ for occluding aneurisms. Follow-up 6 years after operation showed 80% success rate.

Ophthalmology

Ophthalmic surgery has found frequent use for cyanoacrylate adhesive. NAKAGAWA & NONAKA (1964) used butyl-2-cyanoacrylate for the reattachment of extraocular muscles. ELLIS & LEVINE (1963) have covered thin areas of the sclera with tissue and polymer plates, fixation was achieved by means of butyl-2-cyanoacrylate. CALABRIA et al. (1970) and HUNG & HILTON (1982) describe satisfactory and encouraging results from the use of butyl-2-cyanoacrylate in anchoring an encircling episcleral band in retinal detachment surgery. TSE et al. (1984) successfully used butyl-2-cyanoacrylate to seal cerebrospinal fluid (CSF) fistulas. Intraoperative CSF leakage is an infrequent complication of orbital surgery. The risk of meningitis warrants immediate attention intra-operatively. TSE et al. describe three cases of sealing CSF leakage and report good and effective results. On the application of small droplets of butyl-2-cyanoacrylate the CSF leak ceased immediately. SPITZNAS et al. (1973) They reported an extensive series of the use of butyl-2-cyanoacrylate in 100 cases of retinal surgery. They had no serious

complications attributed to the application of the cyanoacrylate. In one patient in the series the adhesive penetrated through the perforation into the vitreous body but did not cause any complication. SPITZNAS et al. concluded from their extensive experience that butyl-2-cyanoacrylate can be recommended unconditionally as a routine measure for certain situations in retinal surgery. Fixation of implants in the orbital area are described by TSE (1986). He used butyl-2-cyanoacrylate in 12 cases with excellent results in each patient. The rapid polymerization of the adhesive proved complimentary to the surgical procedure. The implant material used in this series was compression moulded methyl-methacrylate.

Obstetrics and Gynaecology

STEVENSON & TAYLOR (1972) used methyl-2-cyanoacrylate in the Fallopian tubes in 12 patients. The adhesive was injected into the uterus in a trial series before hysterectomy by means of a modified Foley catheter. The patients were women suffering from persistent dysfunctional uterine bleeding. The technique was free from side-effects. STEVENSON and TAYLOR selected methyl-2-cyanoacrylate for its fluidity and ability to readily enter the Fallopian tubes. They suggest their technique can be developed to control persistent menorrhagia and offer a method of permanent sterilization in women. NEUWIRTH et al. (1980) also reports the use of 0.6 ml methyl-2-cyanoacrylate delivered to the Fallopian tubes by means of the FEMCEPT* device. The women treated were prior to hysterectomy and on an ambulatory basis. No significant complications or side effects were noted and 78% Bilateral tubal closure was achieved in this study.

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*Dispensing instrument for placing drug material into canals of the Fallopian Tubes of a female primate. FDA Reg. No. 1187503

NEUWIRTH et al. (1983) in a further study of female sterilization used a radiopaque methy-cyanoacrylate. The adhesive with its radiopaque loading (Barium Sulfate) made it possible to determine tubal entry of the methyl-cyanoacrylate, again the FEMCEPT device was used for application, satisfactory results are reported.

The present study

The leading manufacturer of cyanoacrylate adhesives in the Western world today is the Loctite Corporation. This international company was approached in 1983 to consider supporting the research possibilities regarding the use of cyanoacrylate in plastic and reconstructive surgery. The proposal was initiated by the Professor and Head of the School of Biomedical Sciences, University of Bradford.

Loctite UK have supported this study with particular regard to adhesive selection and identity for plastic surgery and prostheses. The research has also involved the development of a precision delivery method of the adhesive to the surgical site. The cyanoacrylate adhesives used in this study are Loctite formulations.

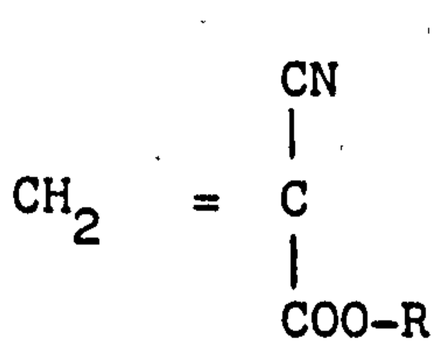
On the 11th May 1985 the Bradford fire disaster occured at the Valley Parade football ground. The surgical skill of the plastic surgeons operating in the aftermath of this disaster resulted in many original techniques and devices being devised.

Among these was the use of cyanoacrylate adhesive for skin graft fixation. This adhesive enabled surgeons to deal with the volume of patients with severe burns in a short time.

The experience gained from this period and the subsequent rehabilitation of these patients has provided added stimulus for this study.

Cyanoacrylates

Cyanoacrylates are a homologous series of liquid monomers which polymerize when applied to a moist tissue surface and have the ability to bond human tissues together. The alkyl 2-cyanoacrylates were first recognised to have adhesive properties by COOVER et al. (1959). The cyanoacrylates have the general formula LEONARD et al. (1966):



R = side chain

The number of alkyl groups in the side chain may be increased from one (methyl cyanoacrylate) up to any number but usually no further than eight (octyl cyanoacrylate) providing a series of adhesive compounds.

Cyanoacrylate adhesives differ physically to meet the defined application. The main distinguishing feature between the esters is the size of the molecule.

Methyl, the original cyanoacrylate ester, is the smallest. A large number of molecules from adhesives with this ester can be applied over a given area. Consequently a larger number of polymer

chains can be formed resulting in bonds with high tensile strength. methyl cyanoacrylate adhesives are by formulation recommended for rigid structures.

The ethyl ester is slightly larger than the methyl, although adhesive properties are very similar. However, because of their larger size the number of molecules per given area is less than that for methyl adhesives. This results in a less rigid adhesive.

The butyl ester is considerably larger than the methyl or ethyl esters. Because of this butyl cyanoacrylate adhesives when compared with methyl and ethyl based adhesives are slower curing, relatively weaker and less volatile. Whilst a slower cure speed has obvious advantages to some surgical applications such as alignment of bone and soft tissue, it is its low volatility which gives a butyl cyanoacrylate adhesive its main advantage.

The larger molecule is less volatile than the other two esters, hence odour from chemical reaction is reduced. A particular feature of this ester is that 'blooming' is eliminated. Blooming is the term describing a white stain on the bond line caused by the rapid condensation of cyanoacrylate vapours. This is of importance in surgical procedures.

No particular adhesive has been yet formulated that will bond everything. Different materials in differing environments require considered selection of adhesives.

To select the most suitable cyanoacrylate for both medical or industrial use requires an understanding of cure and adhesion mechanisms.

Factors which affect cure speed and bond strength can be identified and possible bond-failure eliminated. In general terms an adhesive must first flow and spread so that it thoroughly wets the surfaces to be bonded, penetrating into and filling all surface irregularities. It must then change from its liquid state into a solid which links the surfaces together. Cyanoacrylate adhesives solidify due to their reaction with moisture on the surface of the tissue to be bonded.

Cure Mechanism

Cyanoacrylate adhesives are maintained in a liquid state by an acidic stabilizer (Hydroquinone) which inhibits the molecules from cross linking (Fig. 35 & Fig. 36).

Partly ionised molecules of water which are normally found on all surfaces exposed to the atmosphere have the ability to overcome the stabilizer (Fig. 37).

When the cyanoacrylate adhesive is applied to the tissue surface the stabilizer is removed, the molecules join and a cure begins and is completed in seconds (Fig. 38 & Fig. 39).

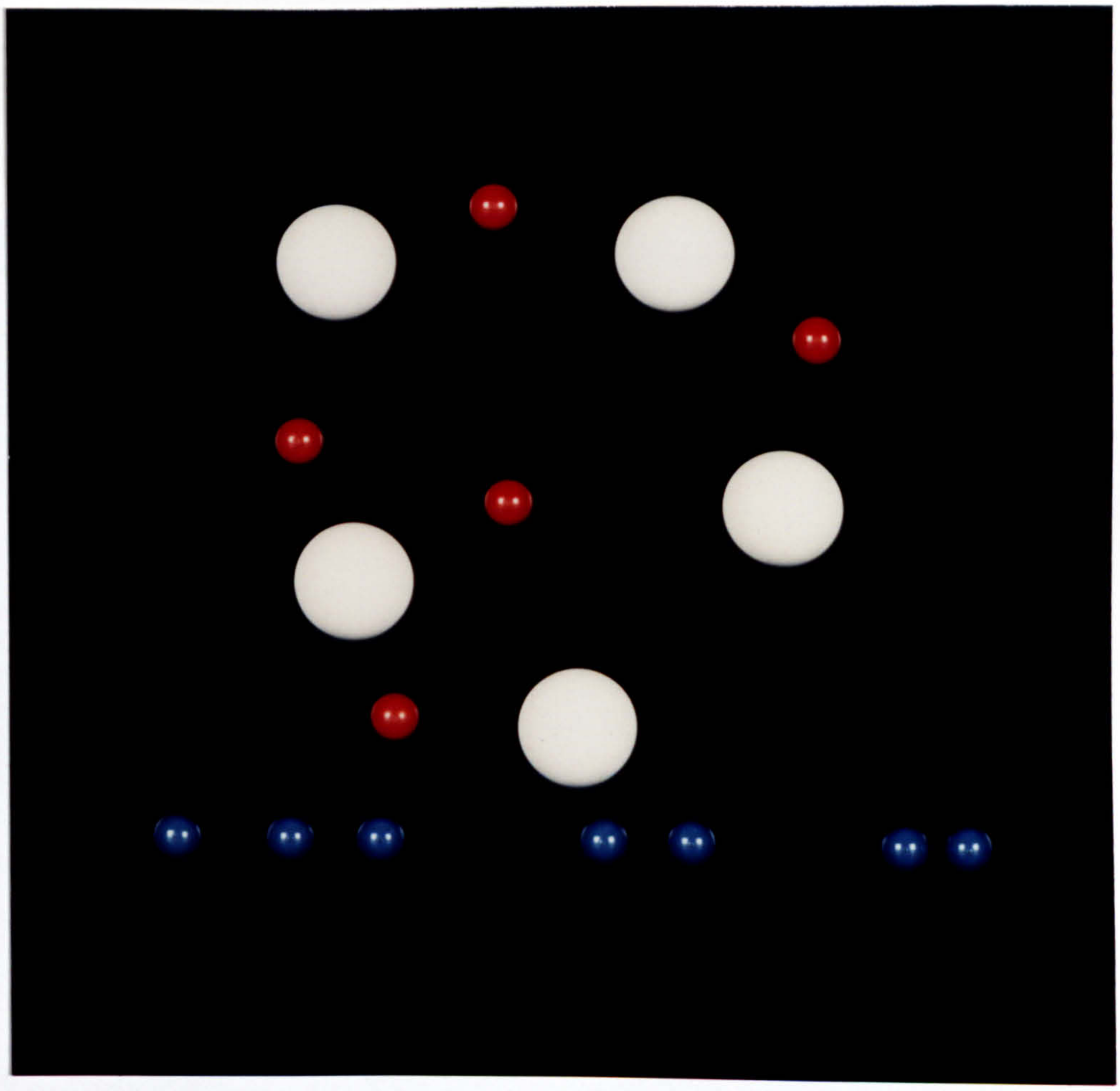


Figure 35

Acidic stabilizer (red) inhibits Adhesive molecules (white) from linking. Partly ionised molecules of water (blue) on surface.

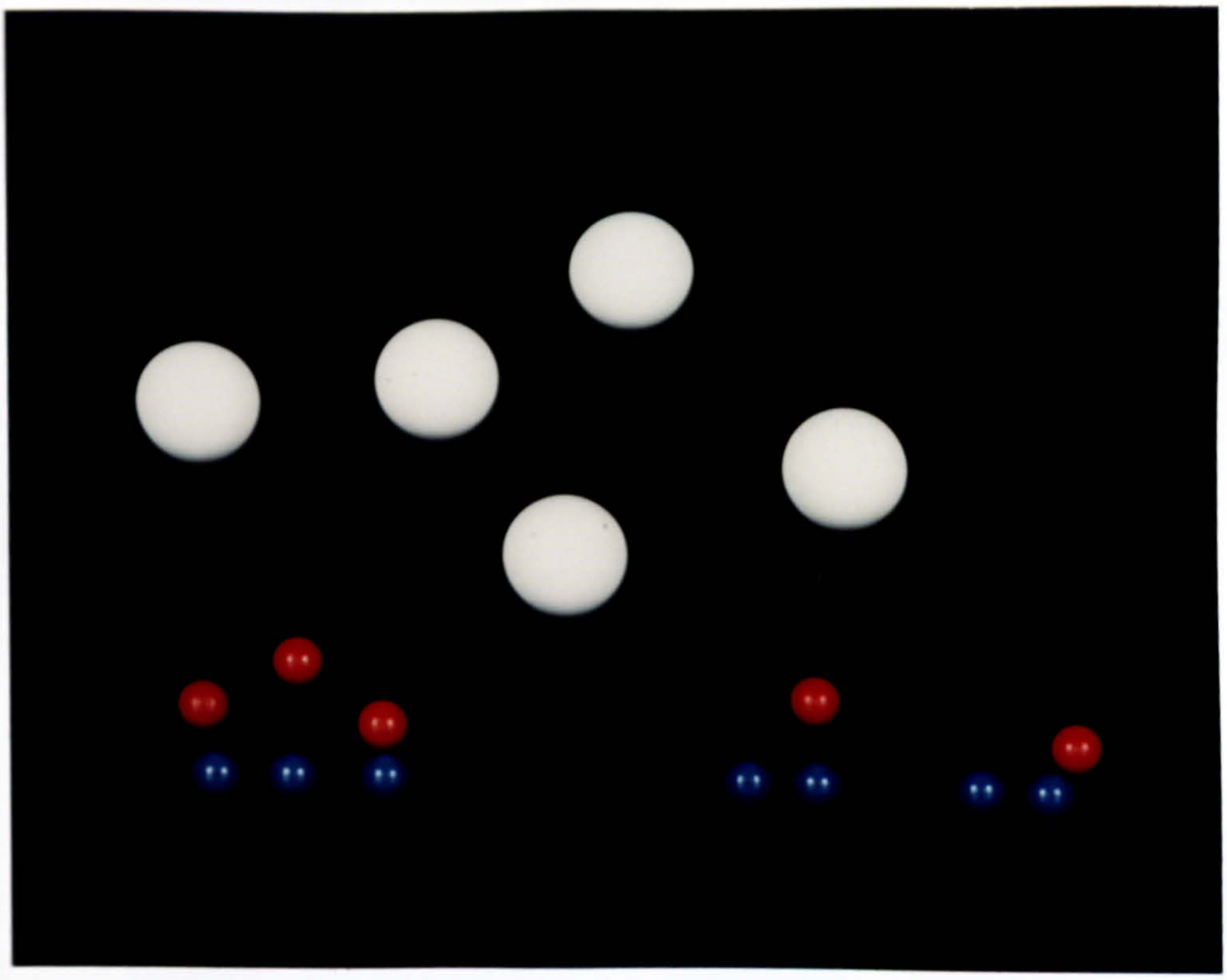


Figure 36

Water molecules (blue) on surface neutralise the stablizer (red).

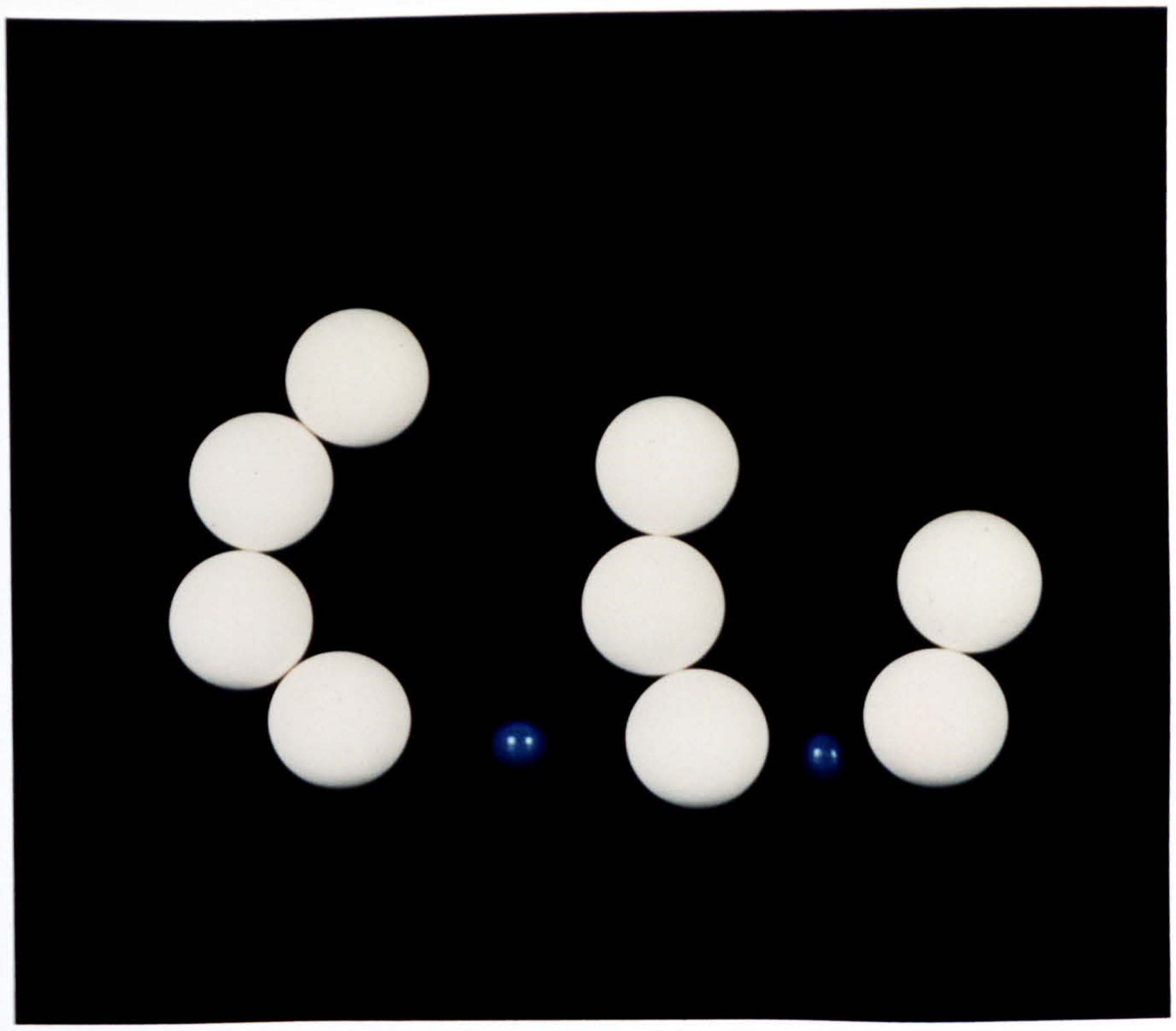


Figure 37

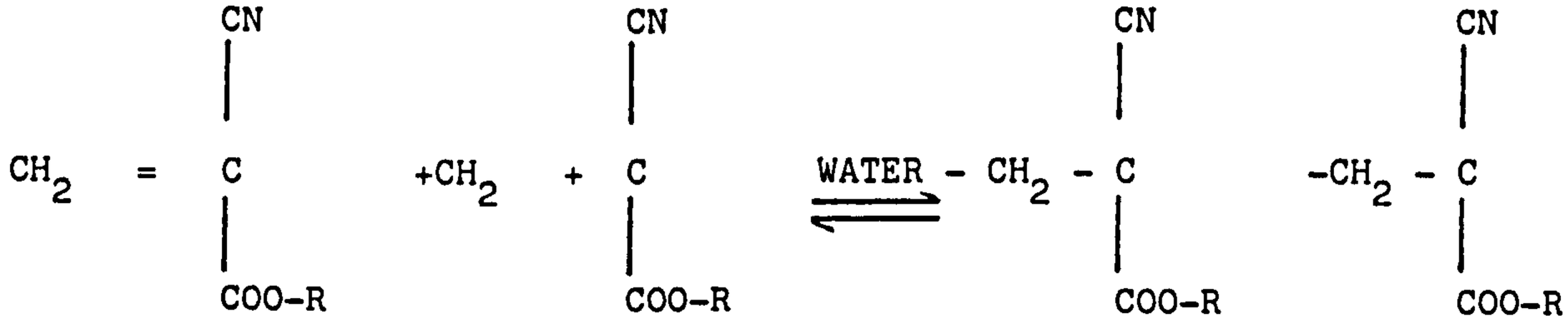
Water molecules (blue) have removed the stabilizer and cure begins.

Figure 38

Polymerisation chains interlock to bind surfaces of molecules together.

Figure 39

Polymerisation chains continue to form, increase and interlock to produce bonds with structural strength.



The cure mechanism of cyanoacrylate adhesive is affected by a number of factors:

(1) if the ambient moisture content (humidity) is too low (below 40-60%).

(2) if the bond space is too wide for surface moisture to affect the cure mechanism. This may relate to bone and tissue approximation.

(3) if too much adhesive is applied to the tissue surface in relation to size of area to be bonded. The cure time in such cases is extended, due to polymer mass and moisture penetration.

(4) excessive deposits of debris on the tissue surface such as cream or oil films. The presence of coagulated blood will also reduce the effect of the cure mechanism and reduce the bond.

A cure speed of 10 seconds is ideal for skin tack down in respect to skin graft fixation. In cases where tissue approximation is needed 20 seconds is a satisfactory working time. Precision dispensing allows fast cure times to be exploited.

Adhesion mechanism

Adhesion is achieved by attraction between molecules of cyanoacrylate adhesive and molecules of the surface to be bonded.

The strength of the adhesion relies mainly upon the approximation of the molecules attracted to each other, the nature of the molecule, the physical or mechanical locking and keying action of the adhesive into the irregularities of tissue surface. The cyanoacrylate penetrates into the interstices of the tissue and becomes immobilised by polymerization.

Bond strength depends on the morphology of the tissue site and the preparation of the interface.

Viscosity

A wide range of viscosities are available: (3 cP to 10,000 cP). Viscosity has been found to be an important consideration in clinical application.

Viscosities below 5 cp give problems of control at the surgical site. A cyanoacrylate in the very low viscosity range tracks away from the point of application. If the viscosity is too high it is difficult to dispense in the precision equipment (described later in text).

High viscosity cyanoacrylate also acts as an interface spacer, which is a disadvantage in surgical procedures, e.g. skin graft fixation.

A viscosity of 120 cp has been found to be ideal in our clinical applications. This viscosity enables flow characteristics to be maximized with regard to the precision dispensing technique developed in this study.

Haemostatic properties

Cyanoacrylate adhesives have been found to act as a fast and effective haemostatic agent.

Low-flow bleeding over large surface areas make it difficult to use conventional surgical methods of haemostasis. In such cases the use of topical haemostatic materials are an advantage and indicated ROBERTS (1985).

The management of surgical bleeding by the use of cyanoacrylate is extensively reported by MATSUMOTO (1970). He describes the role of cyanoacrylate in a range of applications as a haemostatic agent.

Cyanoacrylate was extensively used during the Vietnam war. Used as a fine spray the adhesive is credited as a life-saving agent in the first line treatment of critically wounded servicemen with uncontrollable haemmorhage MATHISEN (1980).

The mechanism by which cyanoacrylates achieve haemostasis is a matter of conjecture at this present time. It is a hypothesis that the cyanoacrylate film causes mechanical blockage to slow the blood flow. The adhesive may serve as a surface agent to activate the clotting cascade.

There is preliminary evidence that cyanoacrylate may form a porous film which becomes invaded with blood. Subsequent clotting occurs within the pores of this film.

Toxicity

During this study it was not possible to determine the toxicity of cyanoacrylate in general surgical use.

The key literature shows that toxicity investigations have been exhaustively carried out on cyanoacrylates for medical use. Histotoxicity effects of a wide range of cyanoacrylates on rats, guinea pigs, rabbits, cats, dogs, pigs, chimpanzees and human patients, as well as cultured fibroblasts have been assessed VINTERS et al.(1985).

Studies with B-^{14}C tagged methy-cyanoacrylate show that polymers formed in vivo are biodegradable CAMERON et al.(1965). Rats and guinea pigs were used as experimental animals by REYNOLDS et al. (1966). The data produced indicates that the metabolites produced from the degradation were eliminated through the normal excretory routes, none of the radioactive degradation products were ultimately retained in the tissues. In implantation experiments in guinea pigs the tagged polymer disappeared after 107 days. In rats the radioactive polymer had substantially disappeared within 154 days.

Further comparison experiments with several cyanoacrylates were made to determine the rates of disappearance. The data indicates

that the methyl homologue degrades at a faster rate, the n-butyl at the slowest. The polymers with branched alkoxy groups degrade at an intermediate rate (Fig. 40).

The mechanism of polymer degradation has been demonstrated by LEONARD et al. (1966). They showed that cyanoacrylate polymer degrades in the presence of distilled water with the formation of formaldehyde. The process of degradation reaches an equilibrium state at which the amount of formaldehyde produced remains constant. This equilibrium value is reached slowly at pH7 at 25°C. In neutral boiling water the equilibrium can be reached at a faster rate (Fig. 41).

The data of LEONARD indicates that the rate of aqueous degradation is considerably slower for the polymers of the higher alkyl esters. Methyl cyanoacrylate degrades much faster than others and the rate lessens for higher groups of the series. LEONARD's experiments show that the rates of degradation in vitro are analogous to the in vivo results. An important indication from this work is that as the homologous series is ascended the inflammatory responses in tissue are decreased. The butyl and higher homologues appear to be well tolerated by the tissues.

The conclusion from the data available (WOODWARD et al. 1965; MATSUMOTO et al. 1967; LEHMAN et al. 1966; MATSUMOTO et al. 1967) is that the length of the alkyl chain determines the toxicity in the tissues with methyl being the most toxic and butyl being the most acceptable.

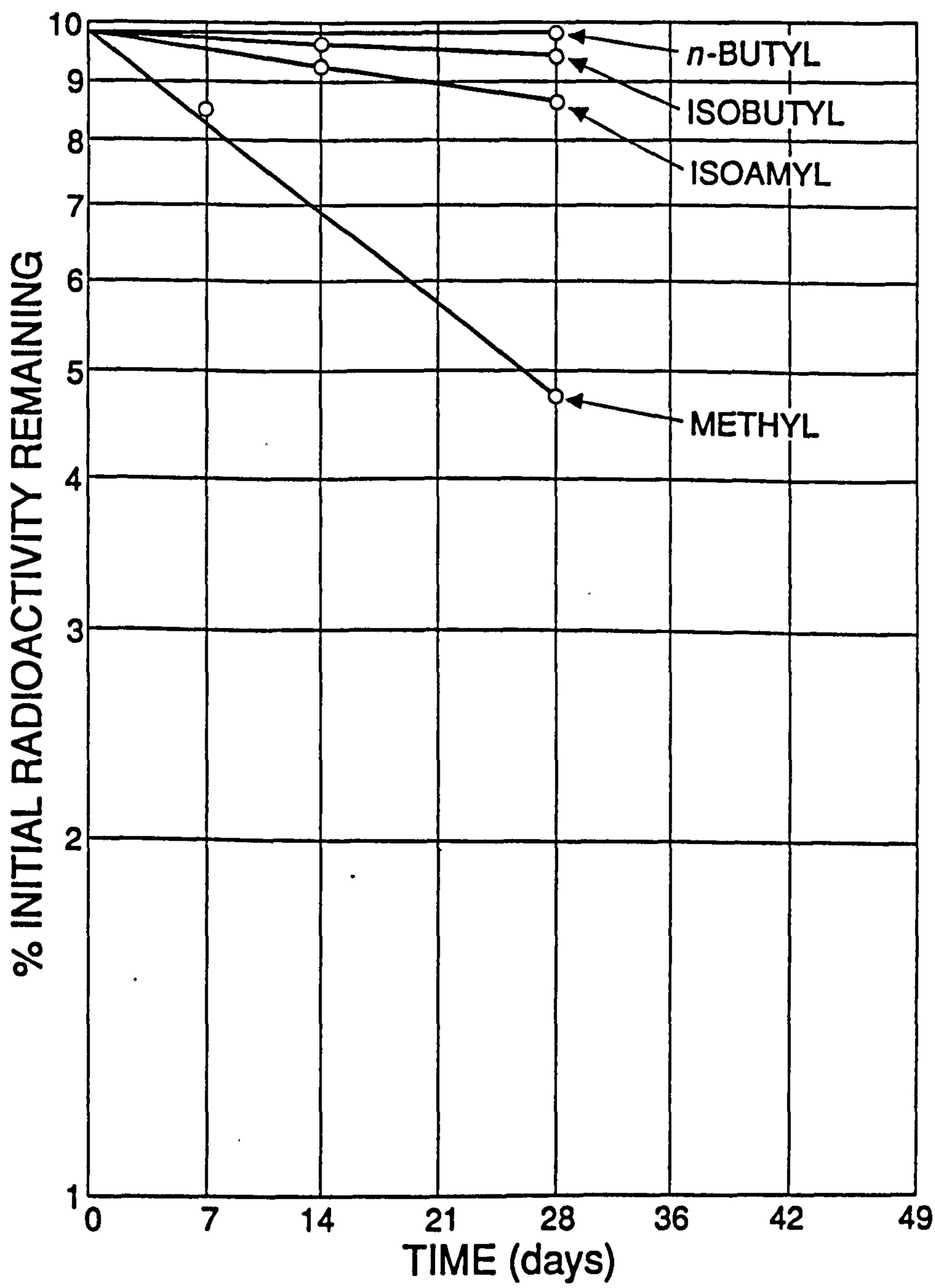


Figure 40

After Leonard: Adhesion in Biological Systems (1970)

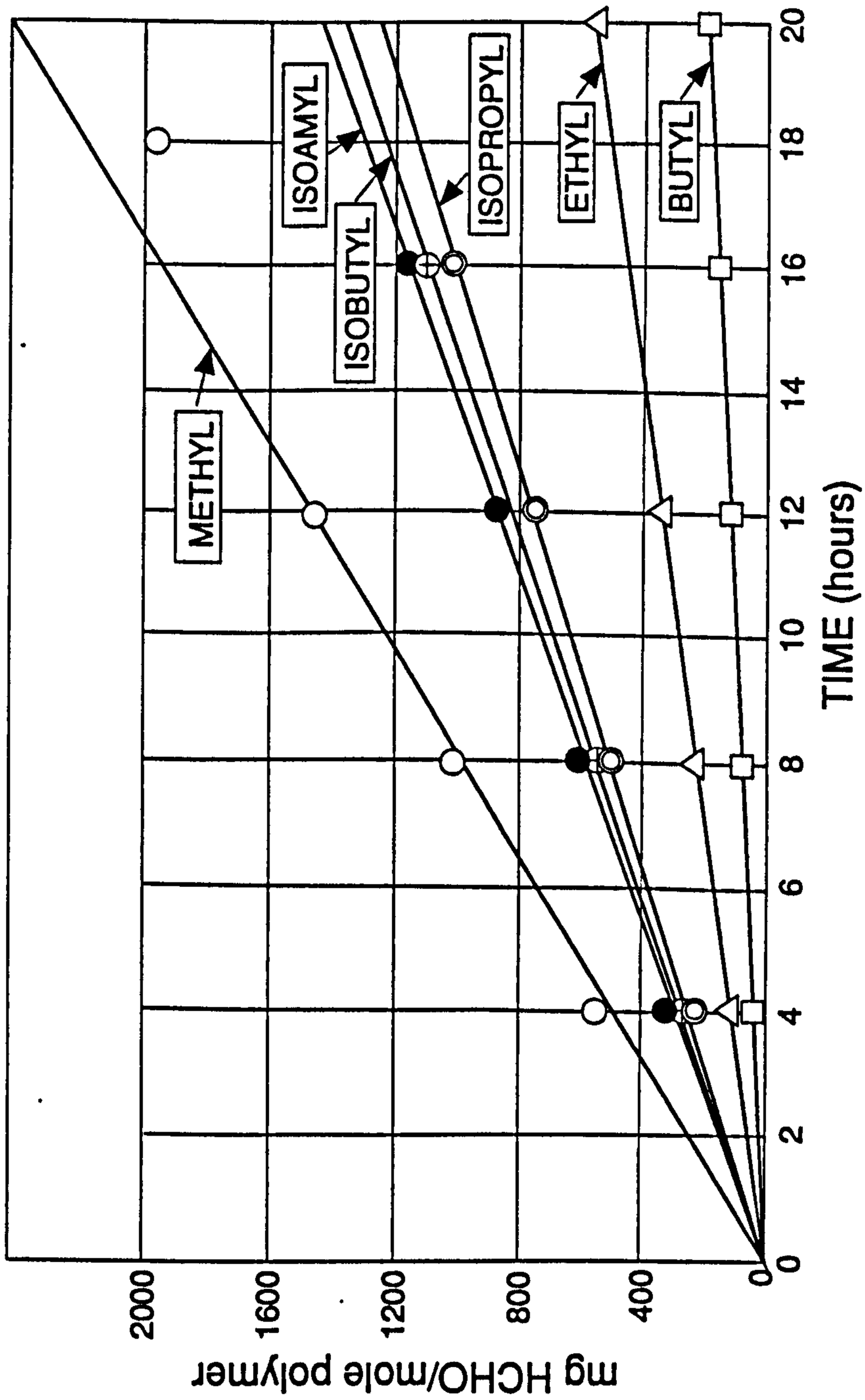


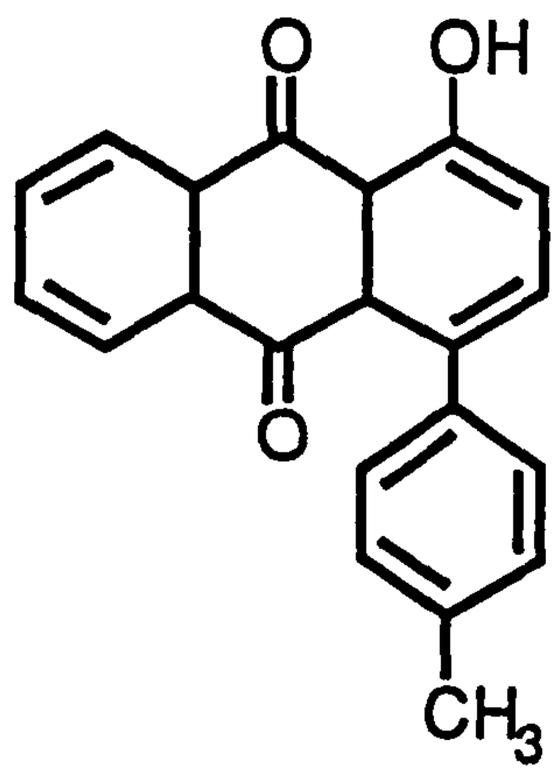
Figure 41

After Leonard: Adhesion in Biological Systems (1970)

Colour Indicators

The philosophy that colouring elements in biomaterials introduce a further toxicity factor has influenced colour additions to cyanoacrylate tissue adhesives. The advantage of including a pigment is to provide a means of identifying the adhesive when placed on the tissue surface in contrast to blood and body fluids.

Standard cyanoacrylate bases are colourless and visually difficult to identify at the surgical site. A colour contrast would overcome this problem. Histoacryl (butyl 2 cyanoacrylate) has the individual feature of containing a contrast of intense blue dye. This colour is produced by 0.1% of 1-hydroxy-4 (-p-toluidino)-antranchinon:-



No reports of problems relating to this pigment addition have been reported in the literature. ROBERTS (1985) noted temporary pigment staining of the tissues five weeks after surgery.

Novelty fluorescent agents as additions to cyanoacrylate tissue adhesives have been investigated in this study. The use of these indicators requires instrumentation to irradiate the cyanoacrylate.

Sterility

Considerable controversy exists concerning the sterility and sterilization of cyanoacrylates for medical use. FASSETT (1961) in toxicity studies of Methyl 2-cyanoacrylate concluded that his in vitro investigation proved the ester to be self-sterilizing. He placed drops of Methyl 2-cyanoacrylate containing Escherichia coli and Staphylococcus aureus onto dishes containing nutrient agar and incubated at 37°C for 24 hours. No bacterial growth was seen on the plates. AWE et al. (1963) investigated Methyl 2-cyanoacrylate. From this bacteriological study they indicate cyanoacrylate to be both bacteriostatic and bacteriocidal in vitro. Mild inflammatory reaction, but no tissue necrosis was seen on histological section of dog heart and aorta. The mild degree of inflammatory reaction seen in the histological sections compared favourably with the cellular response evoked by accepted surgical suture. Again they conclude from sterility testing that cyano-acrylate is self-sterilizing and that only the containers need to be sterilized.

LEHMAN et al. (1966) reported the effects of straight chain alkyl 2-cyanoacrylates upon the growth of Escherichia coli and Staphyococus aureus in vitro. No growth resulted; it was considered from this that cyanoacrylates were bacteriotoxic and therefore self-sterilizing. JANDINSKI & SONIS (1971) demonstrated the destruction of growing colonies of bacteria in vitro. They used a method of zoned bulls eye pattern cultured

nutrient agar to measure the degree of inhibition on four bacteria.

Isobutyl cyanoacrylate was used in this study. It was observed that from the four bacteria (S. aureus, ~~Gaffkya,~~ Streptococcus, N. catarrhalis) Staphylococcus Micrococcus Tetragenus viridans, Neisseria S. aureus was the only one destroyed completely by the application of the cyanoacrylate. The other bacteria showed zones of inhibition on a decreasing scale from the centre to the outer zone.

The opinion that cyanoacrylates are self-sterilizing by their chemical formulation is supported by CHARNLEY (1970), HULLINGER (1962), ROBERTS (1966), ROBERTS (1967) from experience with monimers of methyl-methacrylate in bone cement used in orthopaedic surgery.

KAPLAN & BORCHARDT (1966) investigating the antibacterial properties of Methyl 2-cyanoacrylate in a series of surgical experiments on guinea pigs found bacteria present from cultured fluid from wound sites bonded with cyanoacrylate. MATSUMOTO (1971) also found in bacteriological studies of wound sites bonded with cyanoacrylate ~~the~~ bacteria ~~was~~ present, in drained fluid. He indicates that these esters may not be bacteriostatic and bacteriocidal as others conclude conclude. Sterilization is recommended for container materials and methods of application.

Sterilization

The problem of sterilizing cyanoacrylates is that the cure mechanism is activated and the material polymerised by the use of non-standard sterilization protocols. Autoclave systems are not used since the water vapour present rapidly promotes polymerisation.

Ethylene oxide reacts with cyanoacrylate, destabilising the adhesive. A further problem is that of gas absorption and degassing procedures.

Gamma irradiation by Cobalt 60 is a method claimed by manufacturers of cyanoacrylate tissue adhesive. The standard irradiation dose and time cycle is 2.5 Mrad (25kGY*) for 6-7 hours. Exposure time is dependent on the mass of the product irradiated and the density of the container used. Difficulties arise with the irradiation of cyanoacrylates. Viscosity levels of 120 cP and above polymerise at the standard dose rate of 25 kGY. Stepped down dose rates of 15.0 kGY and 12.5 kGY produce changes in viscosity. The cyanoacrylate is sterile but too thick to apply in droplet form. To overcome this problem manufacturers have used 7.5 kGY on 3 cl low viscosity cyanoacrylate. DIXON (1988) indicates that this level of irradiation may not be sufficient to destroy certain bacteria.

---

*1rad = 0.01 kGY (Gray units now replace Rads)

Dry heat is a well-established means of sterilization in medicine. Cyanoacrylates can be sterilized under correct conditions by dry heat. A temperature of 160°C for 1 hour is required and is the standard protocol in UK sterile supply units. The cyano-acrylate must be placed in a glass container free from air and moisture and the neck of the container sealed before being subjected to the dry heat cycle. This form of sterilization for commercial production requires specialised equipment to load and seal the sterile cyanoacrylate tissue adhesive in containers for storage and use. Limited amounts of cyanoacrylate tissue adhesive for immediate clinical use can be sterilized with a hospital facility.

A new experimental method of sterilizing cyanoacrylates is being developed. Photosensitised cyanoacrylate subjected to a laser light beam has been found in initial experiments to destroy bacteria in the material, with little alteration to the cure mechanisms. Protoporphyrin IX dimethylester mixed with cyanoacrylate is exposed for fixed periods of time to a laser light source.

The photodynamic action of the Protoporphyrin on the biological system is mainly due to the transfer of energy from the Protoporphyrin molecule to the oxygen present in bacterial cells. This transfer of energy upsets the electron structure of the oxygen atom transforming them momentarily into highly reactive singlet oxygen that attacks everything surrounding it. The generation of singlet oxygen ($^1O2$) is believed to be the cytotoxic agent which destroys the bacteria present. Work with this method of sterilization is continuing.

An important consideration in sterilization methods for cyanoacrylates is the selection of container and materials used in their construction. High density polyethylene is the most satisfactory material. A wall thickness of 0.8 mm is required for stabilization purposes during sterilization. Wall thickness of less than 0.8 mm has been found to split during irradiation. Glass is a satisfactory material for containers, in particular when dry heat methods are used. Before cyanoacrylate tissue adhesive is dispensed into a container the container itself must be clean and pre-sterilized.

MATERIALS AND METHODS

The cyanoacrylate tissue adhesive used in this study was n-butyl 413* 20cP supplied unsterile in 20 gram size non pigmented high density polyethylene containers with a wall thickness of 0.8 mm. The polymerising time is within 10 seconds and an operating temperature -60°C to +80°C.

Fluorescent agents

Various fluorescent agents were recommended as possible indicators for addition to n-butyl 413 cyanoacrylate. Thirteen agents were examined for (a) solubility, (b) fluorescence, (c) stability. The fluorescent agents examined were:

1. Anthracene
2. Acenaphthene
3. Salicylaldehyde oxime
4. Phenanthrene
5. Guaiacyl crabonate
6. Benzylidene acetophenone
7. Benzoin -oxime
8. Dibromofluorescein
9. 8-Hydroxyquinoline
10. Methyl p-hydroxybenzoate
11. Sodium fluorescein
12. Pylam LI-990**
13. Natmer LI 1158***

The agents were added to n-butyl 413 20 cP cyanoacrylate in 2% concentration. The cyanoacrylate-fluorescent formulation in 0.01 gram drop size were placed on glass dishes. Each drop was examined under ultraviolet (uv) light at 254 nm and 365 nm. All the fluorescent agents were examined separately in 2 gram amounts placed on glass dishes. The same uv light concentrations were used.

Sterilization procedures

Sterilization of n-butyl 413 cyanoacrylate used for all clinical tissue bonding in this study has been the dry heat method. A 50 ml pyrex glass conical beaker was used to contain the cyanoacrylate during sterilization. The 50 ml glass beakers used were first

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*n-butyl 413 Loctite **Proprietary names Loctite (Ireland) R&D

steam cleaned, hot air dried and packed in standard sterilizer bags. Sterilization of the beaker is carried out by the hospital central sterile supply department at the standard dry heat cycle of 160°C for 1 hour. The polyethylene containers, 20 ml size used to fit the Medical Bondmatic II applicator, were steam cleaned, hot air dried and packed in standard sterilizer bags. Gamma irradiation sterilization was used at the standard irradiation dose of 25 kGY for 7 hours. This procedure was carried out by Isotron plc, Bradford.

To prepare the n-butyl 413 cyanoacrylate tissue adhesive for use the 50 ml pyrex glass beaker is removed from the sterile pack under clean room conditions and 20 ml of n-butyl 413 20 cP cyanoacrylate dispensed into the glass beaker. The beaker is sealed bya film of medical grade silicone adhesive* A placed on the rim of the beaker, then covered with tin foil .007 inch thickness. The tin foil is adapted round the neck of the beaker to form a seal, with the silicone adhesive. The glass beaker is placed in a Gallenkamp OVH-400 oven/sterilizer at a constant temperature of 160°C for 1 hour. In predicted operations all sterilization procedures are completed in the morning ready for an afternoon operating theatre list. If time factors allow the oven may be switched off following the 1 hour cycle and the beaker and contents cooled to room temperature.

The sterilized cyanoacrylate is transported to the operating theatre and under sterile conditions the beaker opened and the cyanoacrylate dispensed into the pre-sterilized polyethylene container. The tubing and setting up of the Medical Bondmatic II is completed ready for use.

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*Dow Corning medical grade adhesive for implant use

Application Methods

The near instant setting time of cyanoacrylate adhesive on contact with tissues requires that its method of application be precise and confined to the location intended by the surgeon.

A number of methods of application have been used with varying success. The difficulty of application in clinical use has been a deterrent to more general use in surgery. MATSUMOTO et al. (1967), MATSUMOTO et al. (1972) used a small spray bottle to apply the adhesive over a surgical site. The adjacent area was protected by polyethylene sheet. This method has the disadvantage of lack of control, and confinement of of the adhesive to the surgical site. Spray application has clinical indications in acute hemorrhage control in large internal organs (MATSUMOTO 1967 and KIRKEGUARD et al. 1977).

A teflon roller constructed of 12-16 spike like projections per square centimetre was devised by GOTTLOB et al. (1980). The roller is passed through the cyanoacrylate so that each projection is charged with a drop of adhesive. Passed across the tissue or graft, the charged projections provide a grid pattern on the surface.

The roller can be modified to have grooves in place of projections. This design provides a strip pattern on the tissue or graft. GOTTLOB et al. describe the advantage of this technique as tissue ingrowth and union achieved by the pattern effect in constrast to a continuous layer.

Cyanoacrylate (HISTOACRYL) has been applied extensively in surgery by means of a polythene vial. The nozzle of the vial is designed to fit an extension tube of varied length and bore size. The tip of the vial nozzle is cut and the adhesive expressed by squeezing the vial.

Differing patterns of application are achieved by means of the extension tube selected.

This application method is an advantage in emergency situations such as military surgery. Storage and immediate availability are further considerations.

The disadvantages are lack of application control and handling problems. When squeezing the vial, adhesive often comes in contact with the surgeon's gloves. Even with the extension tube attached access to certain surgical sites is difficult.

Precision Applicator: Medical Bondmatic I

The deficiency in current clinical methods of cyanoacrylate application emphasizes the need to design and develop a precision system for use in the operating theatre BAKER(1983); SHARPE(1985). Loctite UK had an established industrial dispenser.* This was at first modified and following clinical trials redesigned to specific medical requirements and designated Medical Bondmatic I.**

---

*Applicator Model S.A.U.

**Medical Bondmatic pressure-time unit Mk. I constructed by Loctite UK.

The Medical Bondmatic I pressure time unit was constructed in 4 mm thick stainless steel. The size of the unit is 19 cm x 25 cm x 25 cm and weighs 4 kg.

The unit has been designed to dispense metered amounts of cyanoacrylate in a viscosity range of 10 cP to 10,000 cP. It will maintain a consistent precision repeatability of drop size from 0.01 gram through to a continuous flow.

The Medical Bondmatic I is an electro-pneumatic unit (Fig. 42). The unit requires a mains 240V 50Hz mains supply and an air supply of 60 p.s.i. from an air bottle or alternatively a "Sparklets" CO_2 bulb can be used. The cyanoacrylate tissue adhesive is forced under pressure from a reservoir to a normally closed pinch valve located on the side panel.

The pinch valve is opened by an actuation switch foot pedal and closed when the timer has complted its cycle. The precise amount of adhesive dispensed is dependent upon the air pressure applied and the length of time the pinch valve remains open. These two adjustments are made via the front panel instrumentation (Fig. 43). The unit fits on a standard operating theatre trolley.

Controls

The unit functions in two modes to allow the surgeon options of use. The dispense mode switch will activate the functions of continuous flow when the unit will run for the duration of the input signal supplied. In the time mode the unit will run for the duration of internal timer only.

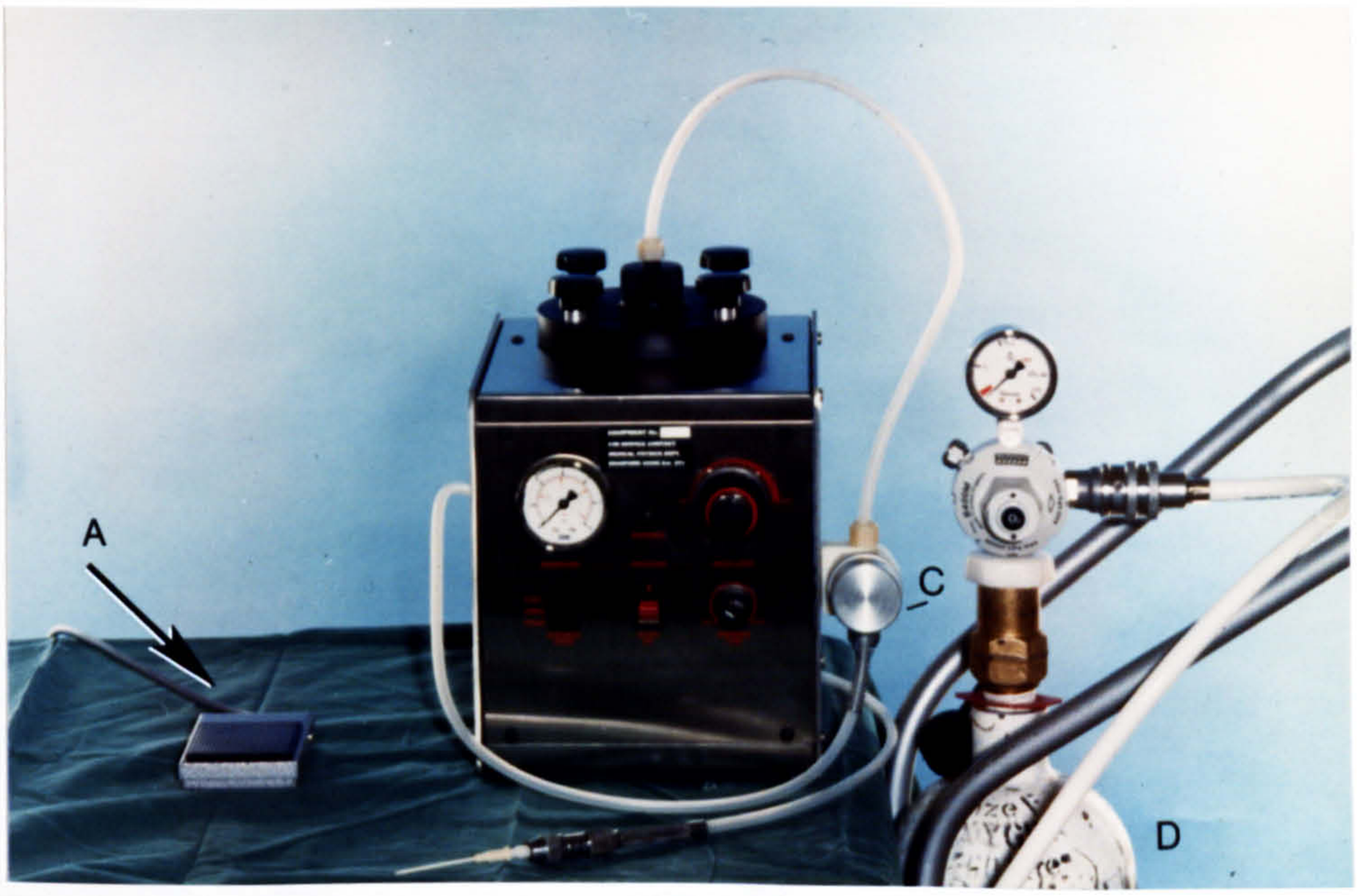


Figure 42 Assembled Medical Bondmatic I pressure-time unit ready for use.

(a) Switch foot pedal

(c) pinch valve

(d) air supply

MEDICAL BONDMATIC I
PRESSURE-TIME UNIT

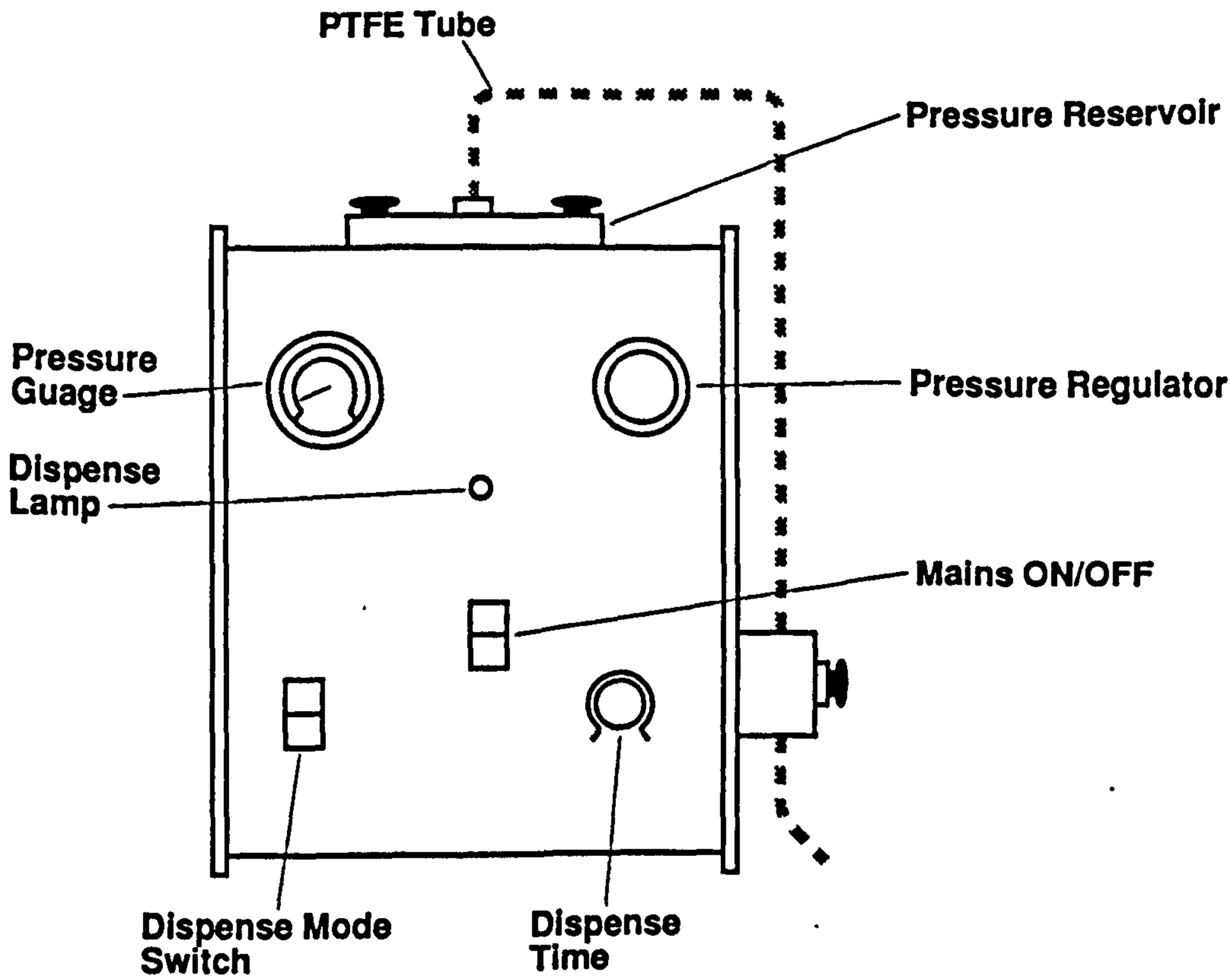


Figure 43

To generate flow in the system the unit is primed via thedispense mode switch held in the "prime" position. The switch will return to time control automatically when released. The time control unit is set at 0-2 seconds and operative when in the timed position mode.

Reservoir pressure is adjusted by means of the regulator. Pressure of the reservoir is indicated by the front gauge.

Tubing system

The tubing system for the Medical Bondmatic I, together with the lurelock connectors, are constructed of Polytetrafluorethane (PTFE). This material is non-reactive and does not form bonds with the cyanoacrylate and allows free flow in the tube (Fig. 44). A practical operating length of tube taken from the unit has been established as 1 metre. Extension or reduction of this length is possible by means of lurelock connectors. The PTFE tube system, together with pinch valve section and applicator nozzle (Teflon) are packed sterile ready for assembly in the operating theatre (Fig. 45). A hand-piece constructed of stainless steel is also packed sterile to mate with the tube assembly system.

Operation

In the operating theatre a 20 gram container of n-butyl 413 is placed in the pressure reservoir of the Medical Bondmatic I. The sterile tubing system is assembled with one end of the tube placed in the bottle. The assembly is completed through the pinch valve and located via the lurelock connectors to the 1 metre operating tube,

MEDICAL BONDMATIC I
PRESSURE-TIME UNIT
Schematic Of Tubing System

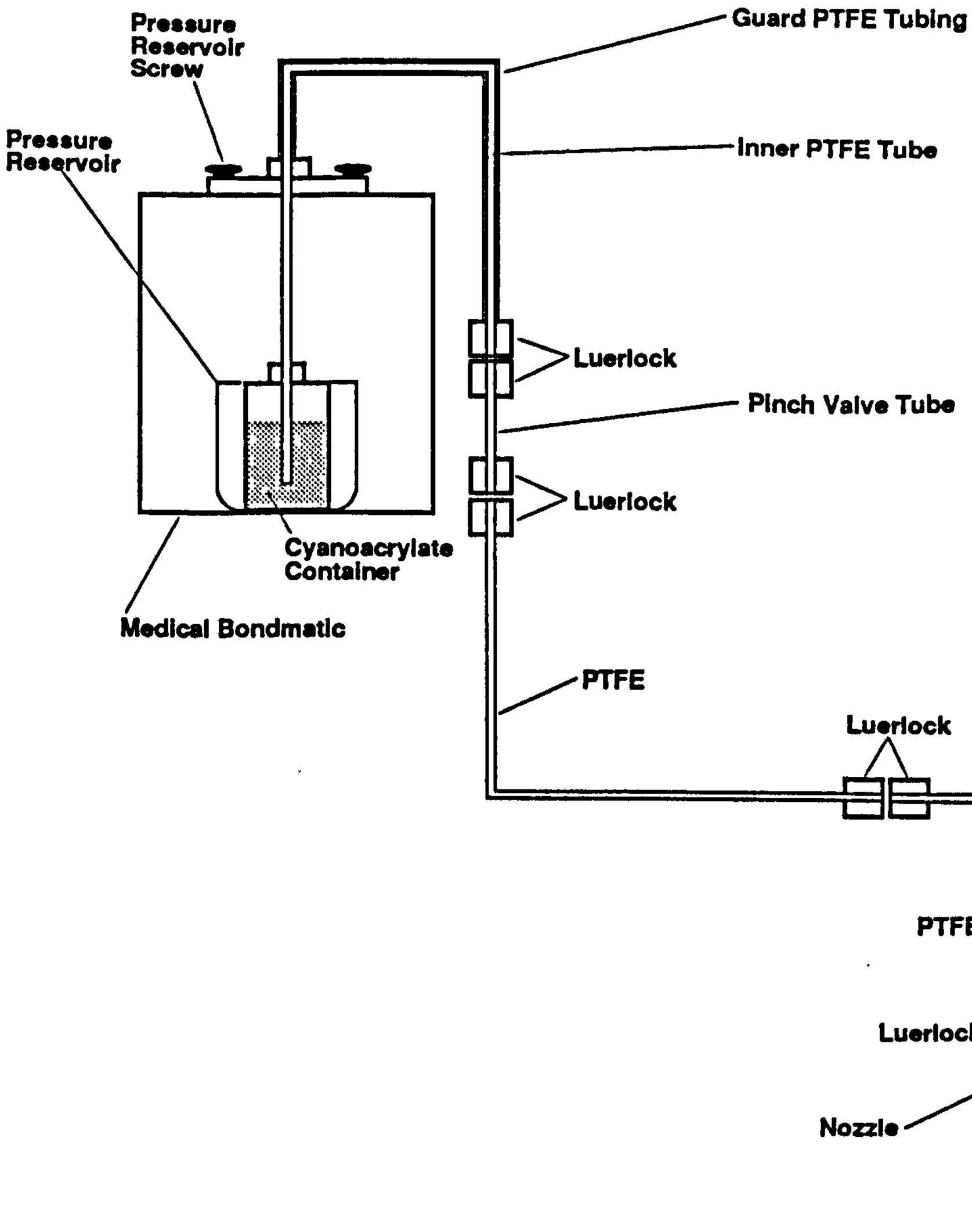


Figure 44

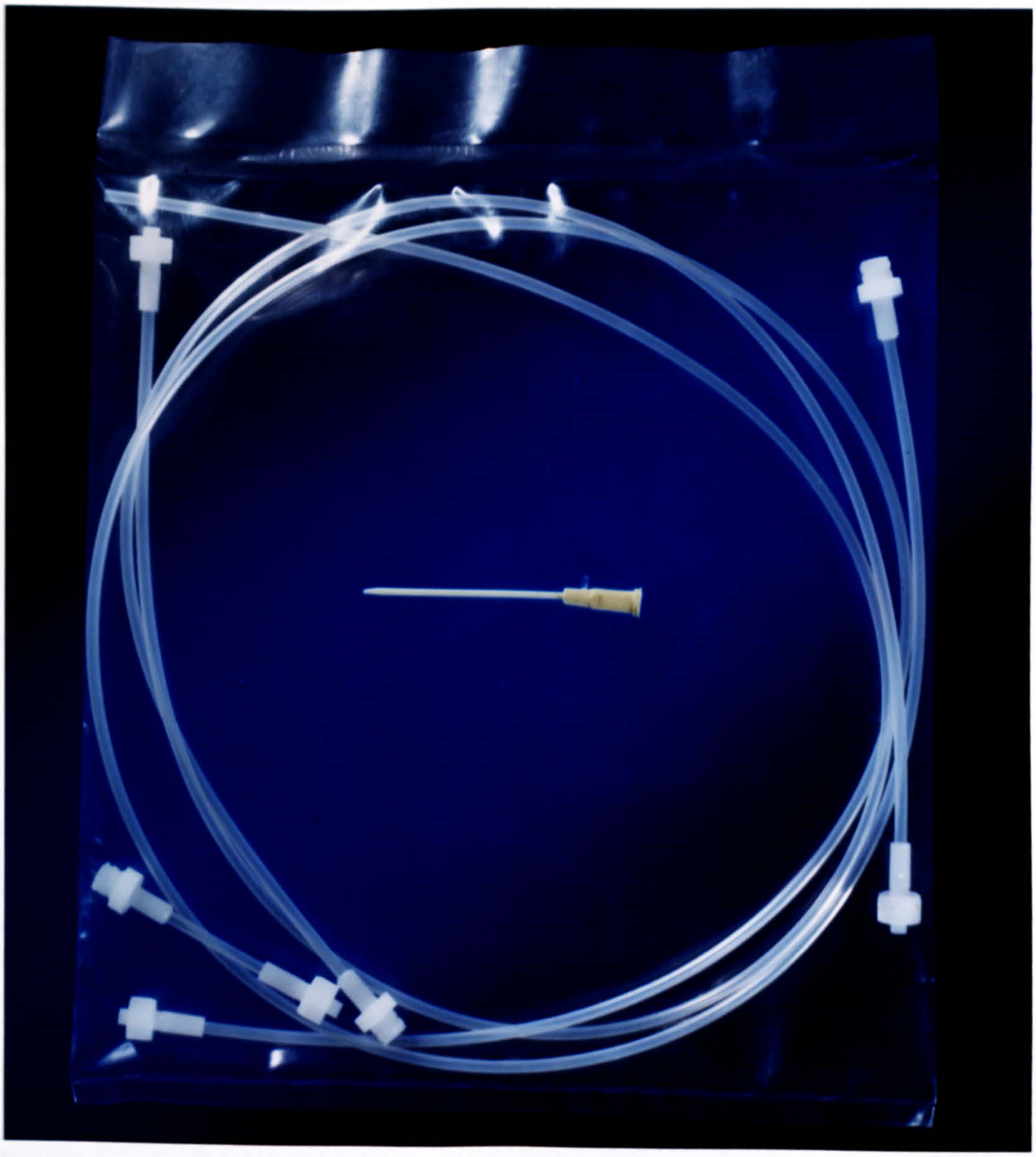


Figure 45

Sterile pack: containing tube system and nozzle ready for use in operating theatre.

which in turn is connected by a slide fit through the hand piece (Figs. 46 & 47).

A selection of nozzle sizes (Fig. 48) are available. For the majority of plastic surgery operations 22 SWG (b) has been used. In ENT surgery 17 SWG (a) with the extra length for access has found favour. Other nozzle sizes are used as the surgeon requires. The nozzle selected fits over the lurelock connector completing the assembly.

The Medical Bondmatic I is connected to the mains electricity supply, pressure reservoir filled by the air supply and adhesive flow established by priming. When positioned alongside the operating table ready for use (Figs. 49 & 50) the surgeon selects the function mode (time or flow) by means of the footswitch. A special stainless steel trolley has been designed to provide a working top and air bottle stand for the Medical Bondmatic Unit.

Medical Bondmatic II

Clinical experience over a four year period with the Medical Bondmatic I has served to identify points for improvement, resulting in the design of the Medical Bondmatic II (Figs. 51 & 52).

The improved unit 19 cm x 25 cm x 43 cm weight 8 kg, has handles on the side panels of the stainless steel case for ease of transportation.

Improved features incorporated are:-

Figure 46 Handpiece-nozzle lure lock assembly

Figure 47 Assembled handpiece-nozzle ready for use

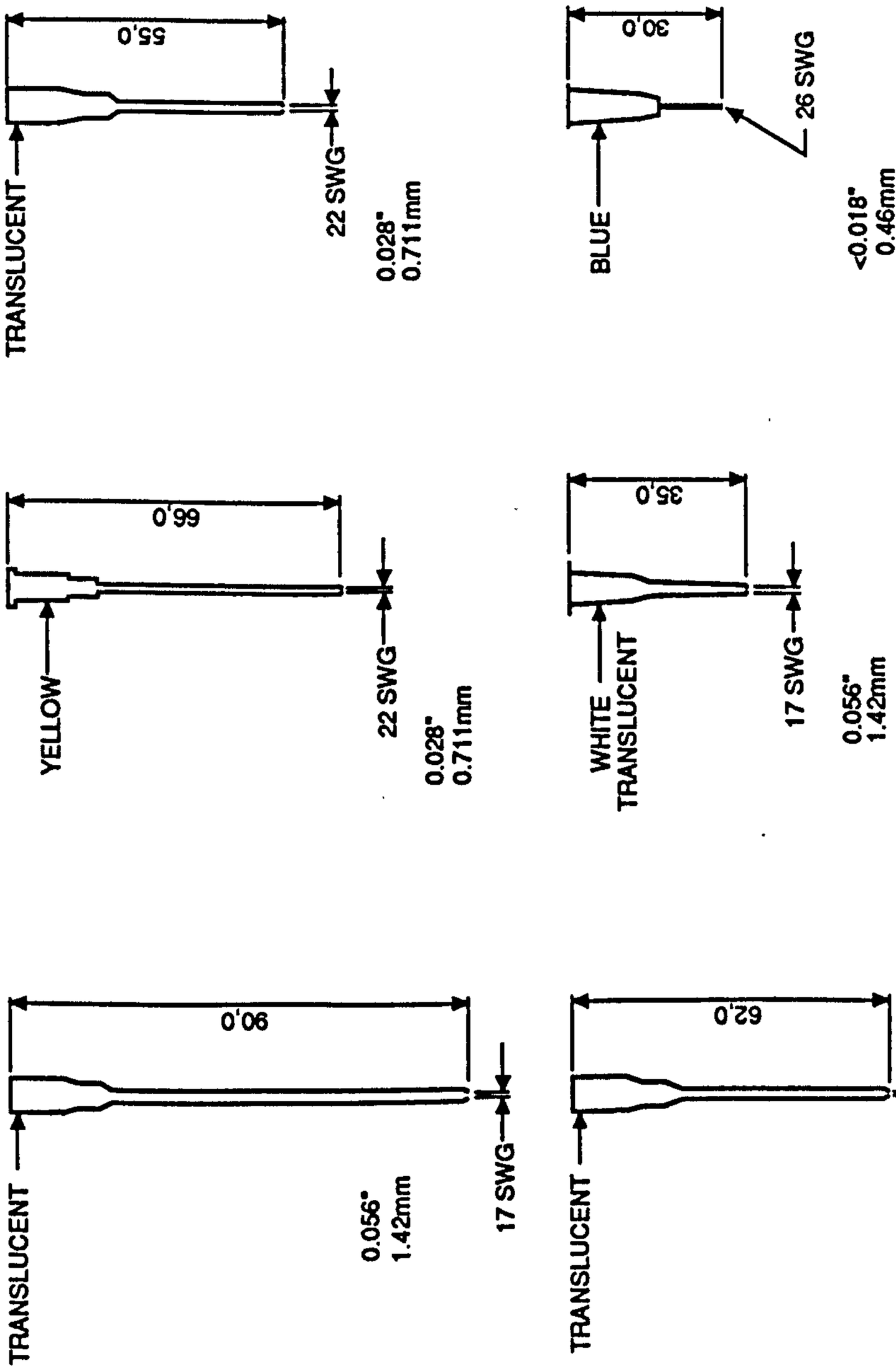

NOZZLE SIZES
TRANSLUCENT
55.0
22 SWG
0.028"
0.711mm
BLUE
30.0
26 SWG
<0.018"
0.46mm
YELLOW
66.0
22 SWG
0.028"
0.711mm
WHITE
TRANSLUCENT
35.0
17 SWG
0.056"
1.42mm
TRANSLUCENT
90.0
17 SWG
0.056"
1.42mm
TRANSLUCENT
62.0
19 SWG
0.040"
1.02mm

Figure 48

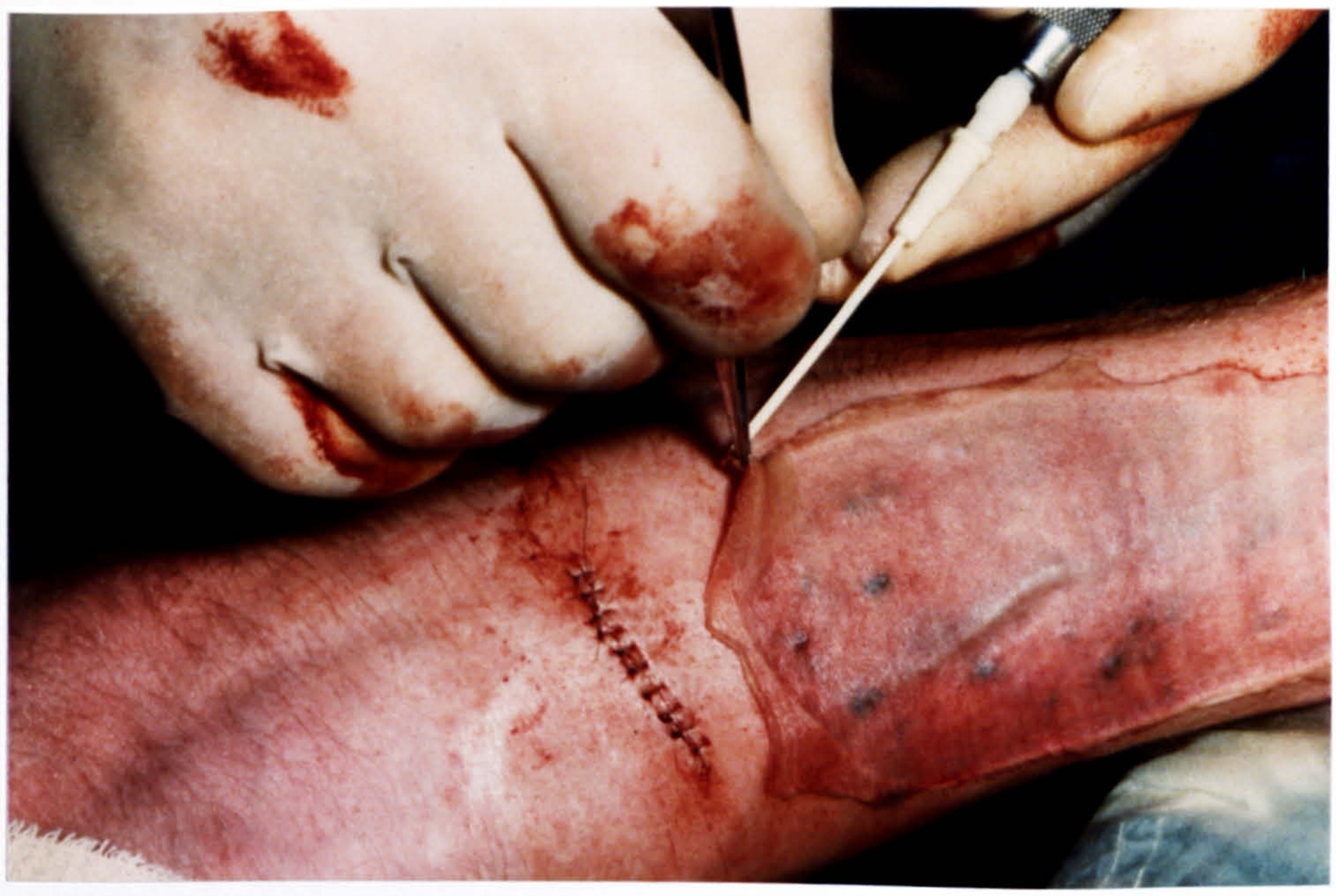


Figure 49 Medical Bondmatic I pressure line unit precision application of Cyanoacrylate: note contrast of conventional ligation.

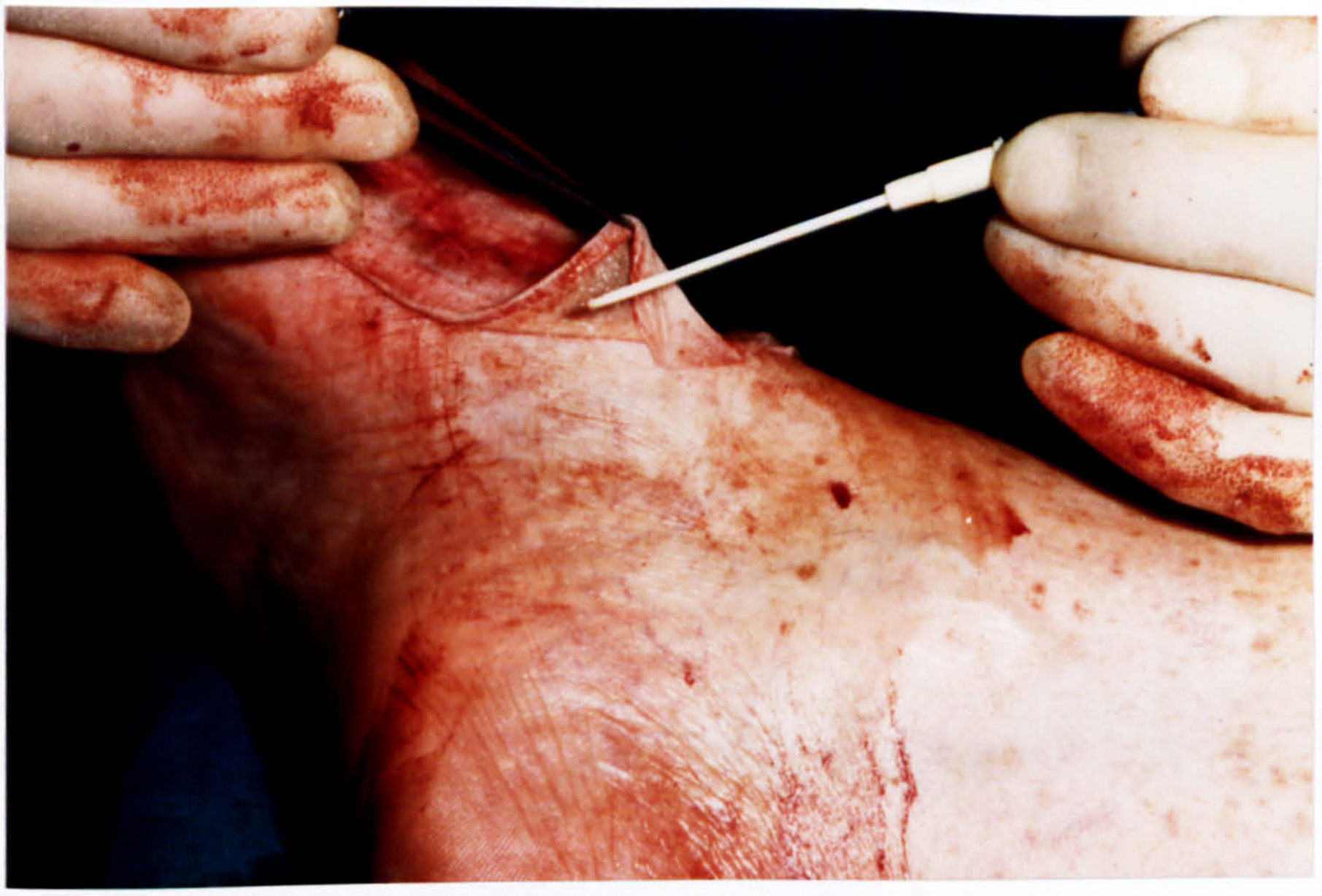


Figure 50 Cyanoacrylate tissue adhesive applied to margins of skin graft with 25 SWG nozzle

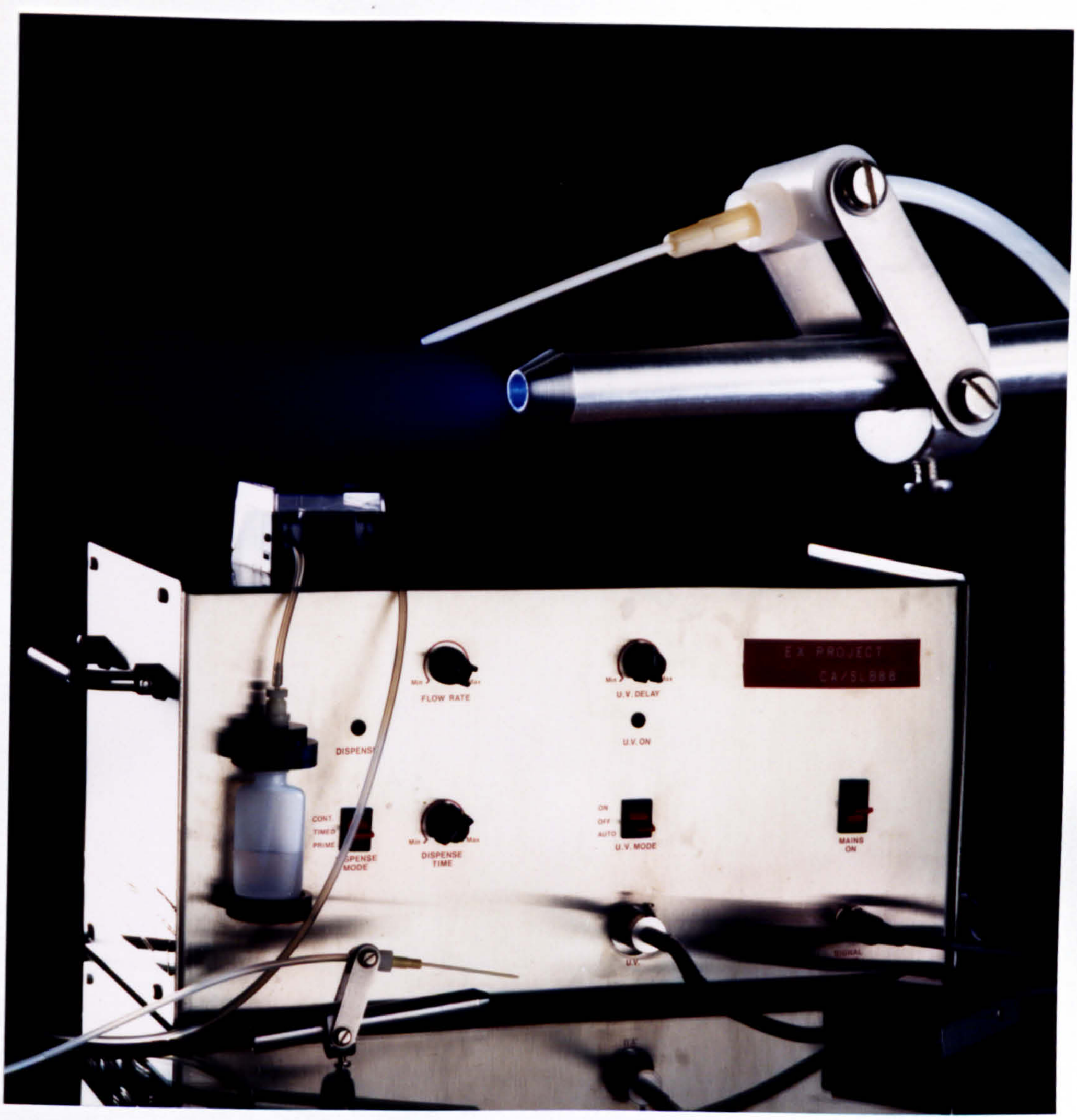


Figure 51

Medical Bondmatic II with peristaltic pump and fibre optic light option.

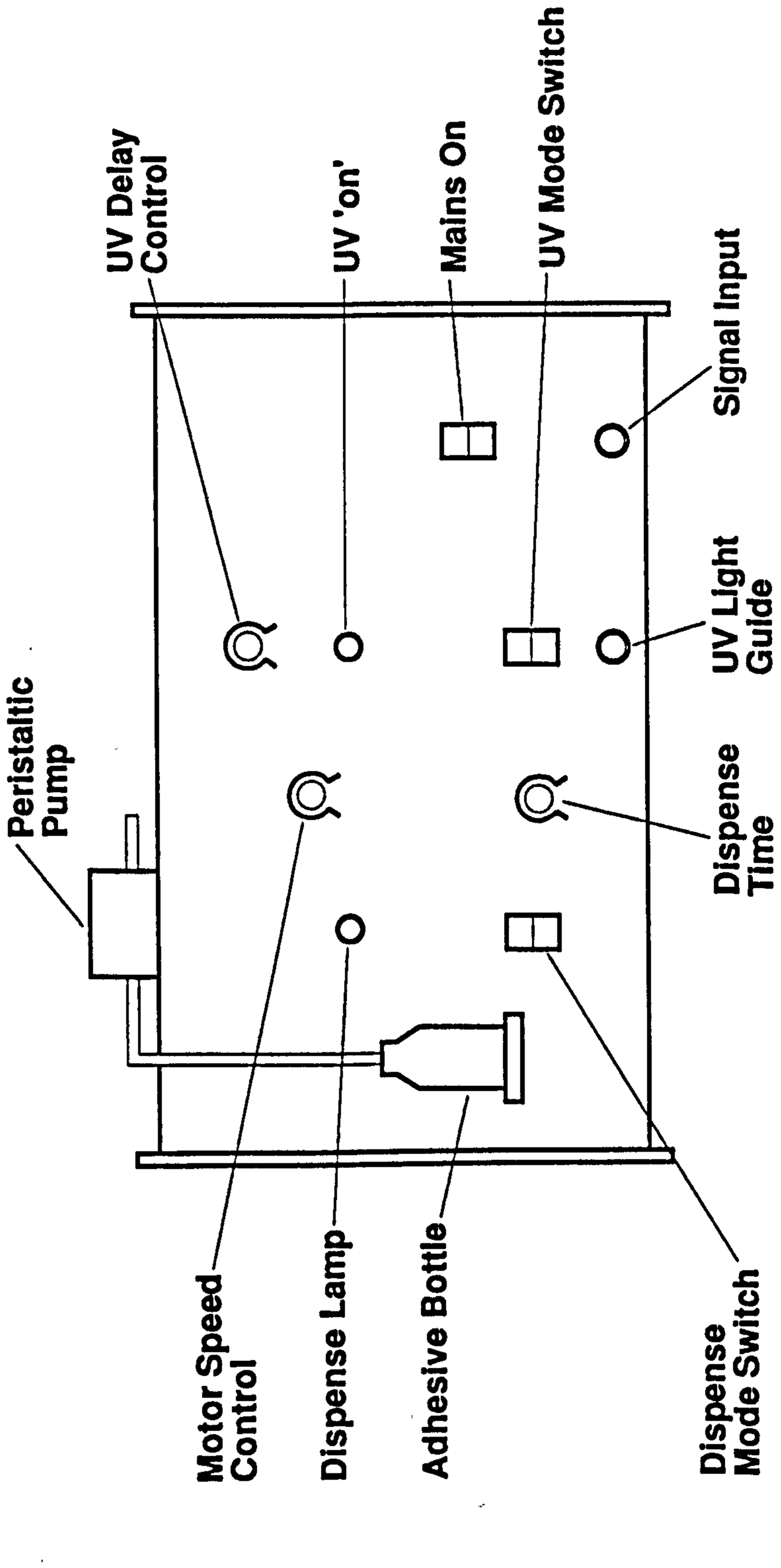

Medical Electronics Bondmatic II
UV Delay Control
UV 'on'
Mains On
UV Mode Switch
Signal Input
UV Light Guide
Peristaltic Pump
Dispense Time
Motor Speed Control
Dispense Lamp
Adhesive Bottle
Dispense Mode Switch

Figure 52

1. A peristaltic pump to replace the pressure reservoir. This provides trouble-free pumping of the tissue adhesive from the container direct to the handpiece applicator.

2. A simplified system for tubing the unit which reduces the time of assembly in the operating theatre.

3. A UV light unit (365 nm) is built in as an option for using fluorescent cyanoacrylate as it is dispensed. The UV light is trnsmitted down a flexible fibre optic light cable to colocate with the handpiece applicator (Fig. 53).

Controls

The Medical Bondmatic II has the two function modes as in the Mark I. The speed of the peristaltic pump relates to the amount of cyanoacrylate dispensed and is controlled from the front panel dial. The time switch on the unit is set at 0-2 seconds, the circuit operates when the mode switch is in the timed position.

To use the UV light option, the mode switch at 'ON' provides for continued UV light through the fibre optic cable. If this mode is not required the switch in the 'OFF' position allows only the cyano-acrylate adhesive to be dispensed.

In the automatic mode the UV light comes on just before the cyanoacrylate adhesive starts to dispense and remains on following the dispense cycle for a few seconds. This delay can be further adjusted by the UV delay control.

Figure 53

Fibre optic light colocated with the handpiece applicator

The cyanoacrylate tissue adhesive container is positioned externally on the Medical Bondmatic II. A location clamp allows the 20 gram container to be seated easily below the peristaltic pump which is positioned on top of the unit.

Tubing system

The tubing system for the Medical Bondmatic II is packed sterile as for the Mark I model. The system comprises a PTFE connector and tube extension to fit into the cyanoacrylate container. Medical grade silicone tube 1 metre long with lurelock connector. A PTFE tube sleeve for the handpiece with lurelock fitting and applicator nozzle (Fig. 54).

Operation

In the operating theatre a 20 gram container of n-butyl 413 is placed into the location clip. The silicone tube is connected via the lurelock fitting and inserted into the cyanoacrylate container.

The silicone tube is threaded through the peristaltic pump head. The free end of the silicone tube is connected to the PTFE tube which is sleeved through the pre-sterilized anodized aluminium handpiece. Finally the nozzle is fitted.

The UV light probe is connected if required by a push-fit into the handpiece assembly and the angle adjusted.

The fibre optic cable is connected into the unit front panel. When connected to the mains electricity supply the Medical

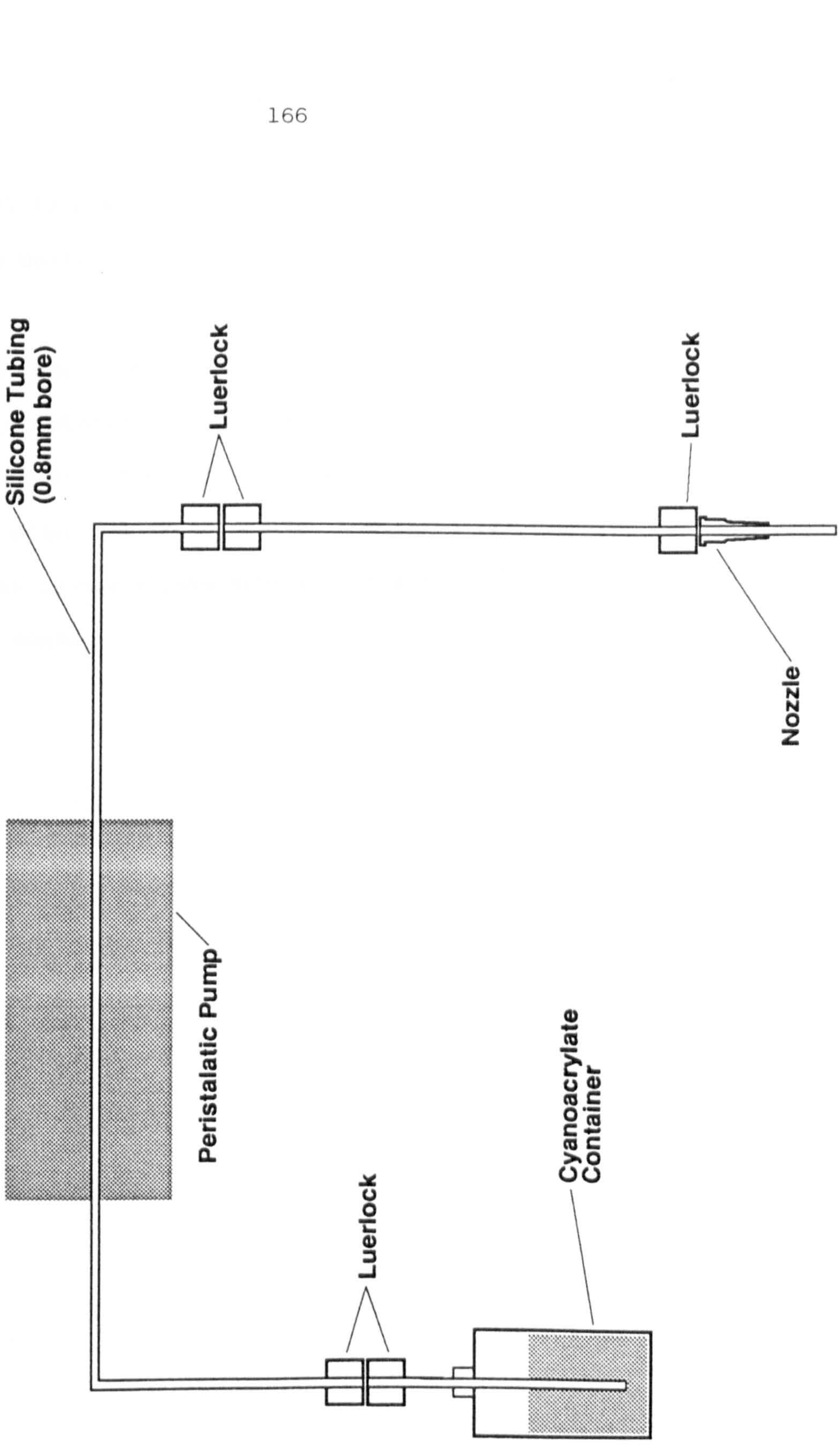

MEDICAL BONDMATIC II
SCHEMATIC OF TUBING SYSTEM
Silicone Tubing
(0.8mm bore)
Luerlock
Luerlock
Nozzle
Peristalatic Pump
Luerlock
Cyanoacrylate
Container

Figure 54

Bondmatic II is ready for use. The surgeon uses the footswitch to operate the unit.

It has been found that the tubed unit allows a theatre list to be completed without dismantling the system beyond the hand-piece and nozzle. The tube connectors and nozzle are graded as disposable while the handpiece is sterilized for each case. One container of cyanoacrylate adhesive is sufficient for an average skin graft case.

Survey

A national survey was completed on the use of cyanoacrylate adhesive in surgery. Two groups of surgeons, Plastic Surgeons and Oral and Maxillo-facial Surgeons, were chosen for the survey. These two surgical disciplines were known to use cyanoacrylate as tissue adhesives. Both groups are concerned with reconstructive surgery and collaborate in the treatment of patients.

Permission was obtained from the President of the British Association of Plastic Surgeons and the President of the British Association of Oral and Maxillo-facial Surgeons to conduct the survey. The Secretaries of both Associations at the Royal College of Surgeons of England provided current lists of their members. To ensure a good return from the survey and minimise the cost of postage, only United Kingdom members were circulated.

Each surgeon's name in the survey list was allocated a reference number for future individual contact if required. The mail-out envelope contained a letter to each Surgeon (Figs. 55 & 56). a questionnaire (Fig. 57) - this was the same for both groups of surgeons - and a pre-paid return envelope to the School of Biomedical Sciences at the University of Bradford.

The questionnaire contained eight questions to be answered by box-marking together with any relevant comments regarding the use of cyanoacrylate adhesives.

Plastic Surgery and Burns Research Unit

University of BRADFORD

Postgraduate and Undergraduate Schools of Biomedical Sciences

Professor
TERRY G BAKER DSc MRC Path FRSE

Plastic Surgery and Burns Research Unit
Director
DAVID T SHARPE OBE MA FRCS

Bradford West Yorkshire BD7 1DP
telex 51309 UNIBFD G
☎ 0274 733466 ext 215/6106/6162

Dear Sir

I am indebted to the British Association of Plastic Surgeons for permissionto send out this questionnaire. I am completing a doctoral research programme into the use of adhesives in surgery with particular reference to a specifically formulated cyanoacrylate base as a tissue adhesive. My research has also been concerned with the design and development of a precision method of delivery and application system for use in the operating theatre or clinic.

I currently hold an appointment as a Clinical Scientist in the Department of Plastic and Maxillo-facial Surgery at St Luke's Hospital, Bradford, where most of the clinical trials are being completed. The results so far are most encouraging.

I would greatly appreciate a few moments of your valuable time in providing me with the information I require to establish the present pattern and future possible use of adhesives in plastic and reconstructive surgery and if you feel able to comment further, your remarks would be of particular help to me. I enclose a pre-paid envelope for return of the questionnaire.

If you would like to know the final details of the formulated adhesive and delivery system, I would be pleased to send this to you at the completion of the research programme.

I do hope that you will be able to help me with my enquiries and I thank you in anticipation.

Yours faithfully

ALAN C ROBERTS
MBE, TD, DL, MPhil, CBiol, FIBiol

Figure 55

Plastic Surgery and Burns Research Unit

University of BRADFORD

Postgraduate and Undergraduate Schools of Biomedical Sciences

Professor
TERRY G BAKER DSc MRC Path FRSE

Plastic Surgery and Burns Research Unit
Director
DAVID T SHARPE OBE MA FRCS

Bradford West Yorkshire BD7 1DP
telex 51309 UNIBFD G
☎ 0274 733466 ext 215/6106/6162

Dear Sir

I am indebted to the British Association of Oral and Maxillo-facial Surgeons for permission to send out this questionnaire. I am completing a doctoral research programme into the use of adhesives in surgery with particular reference to a specially formulated cyanoacrylate base as a tissue adhesive. My research has also been concerned with the design and development of a precision method of delivery and application system for use in the operating theatre or clinic.

I currently hold an appointment as a Clinical Scientist in the Department of Plastic and Maxillo-facial Surgery at St Luke's Hospital, Bradford, where most of the clinical trials are being completed. The results so far are most encouraging.

I would greatly appreciate a few moments of your valuable time in providing me with the information I require to establish the present pattern and future possible use of adhesives in oral and maxillo-facial surgery and if you feel able to comment further, your remarks would be of particular help to me. I enclose a pre-paid envelope for return of the questionnaire.

If you would like to know the final details of the formulated adhesive and delivery system, I would be pleased to send this to you at the completion of the research programme.

I do hope that you will be able to help me with my enquiries and I thank you in anticipation.

Yours faithfully

ALAN C ROBERTS
MBE, TD, DL, MPhil, CBiol, FIBiol

Figure 56

Form No

UNIVERSITY OF BRADFORD
PLASTIC SURGERY AND BURNS RESEARCH UNIT
SURGICAL USE OF CYANOACRYLATE ADHESIVE-
-QUESTIONNAIRE

Please tick the boxes to indicate your answer, you may tick more than one choice for questions 3 and 4 if necessary

1 Do you use cyanoacrylate adhesive ? (If 'no', please proceed to question 7)	Yes	☐ A
	No	☐ B
2 How often do you use such adhesives ?	Less than once a year	☐ C
	1-12 times a year	☐ D
	13-52 times a year	☐ E
	53 or more times a year	☐ F
3 Which adhesives have you used ?	Histoacryl	☐ G
	Henkel	☐ H
	Name unknown	☐ I
	Others (please specify)	☐ J
4 What have you used it for ?	Skin graft fixation	☐ K
	Wound closure	☐ L
	Fixation of dressings or devices	☐ M
	Others (please specify)	☐ N
5 Have you had problems applying the adhessive ?	Yes	☐ O
	No	☐ P
6 Would a precision applicator help ?	Yes	☐ Q
	No	☐ R
7 If a superior adhesive were available would you consider its use ?	Yes	☐ S
	No	☐ T
8 Would you be interested in hearing the results of this survey ?	Yes	☐ U
	No	☐ V

9 Have you any other comments to make on the surgical use of cyanoacrylate adhesives ?

Thank you for taking the time to fill in this questionnaire could you please return it in the reply-paid envelope.

Figure 57

The questions asked were constructed to obtain information for the future development of cyanoacrylates as tissue adhesives, together with precision methods of application.

The number of questionnaires sent out totalled 1,034, comprising Plastic Surgeons 289, Oral and Maxillo-facial Surgeons 745. No time-limit was set for the return of the questionnaires.

Review of tissue adhesive patients

Among the patients who sustained severe burns in the Bradford football stadium fire twenty in all had grafts attached with n-butyl cyanoacrylate tissue adhesive.

A review of this group of patients was held three years following initial surgery. The twenty patients were asked to attend. Each patient was informed that the review concerned the use of tissue adhesive at the time of their surgery.

Of the twenty patients sent for 15 attended. 2 did not wish to attend, reporting that they were well and active. 1 failed to attend and 2 patients had recently died from unrelated causes.

The fifteen patients were examined in Mr. David Sharpe's plastic surgery out-patients clinic at St. Luke's Hospital, Bradford. The observations were recorded on purpose-designed forms (Figs. 58 & 59). Review observations were: GRAFT SURFACE TEXTURE - satisfactory = 80%; fair = 15%; poor = 5% GRAFT COLOUR - red = 13; hyper-pigmented = 80%; normal = 7% GRAFT CENTRE - flat = 0% GRAFT EDGE - flat = 95%; raised = 5% GRAFT ELASTICITY - normal = 87%; less = 13% INSTABILITY - none = 0% CYST FORMATION - none = 0% CONTRACTURE - none = 87%; moderate = 13%.

All the patients examined were cheerful and reported no significant clinical problems. All were pleased to be seen, and to meet their surgeon again. All expressed an interest in the fact that a non-conventional method had been used in support of their surgery.

PLASTIC SURGERY AND BURNS RESEARCH UNIT

TISSUE ADHESIVE REVIEW CLINIC

PATIENT'S NAME _____ **OBSERVER** _____

LOCATION _____ **DATE** _____

Graft Surface Texture	1. Normal	2. Satisfactory	3. Fair	4. Poor
Graft Colour	1. Normal	2. Red	3. Hyper-Pigmented	4. Hypo-Pigmented
Graft Centre	1. Flat	2. Raised	3. Depressed	
Graft Edge	1. Flat	2. Raised	3. Depressed	
Graft Elasticity	1. Normal	2. Less	3. More	
Graft Instability	1. None	2.Some	3. Severe	
Cyst Formation	1. None	2. Few	3. Many	
Contracture	1. None	2. Moderate	3. Severe	

COMMENTS :

Figure 58

PLASTIC SURGERY AND BURNS RESEARCH UNIT

TISSUE ADHESIVE REVIEW CLINIC

PATIENTS NAME _____

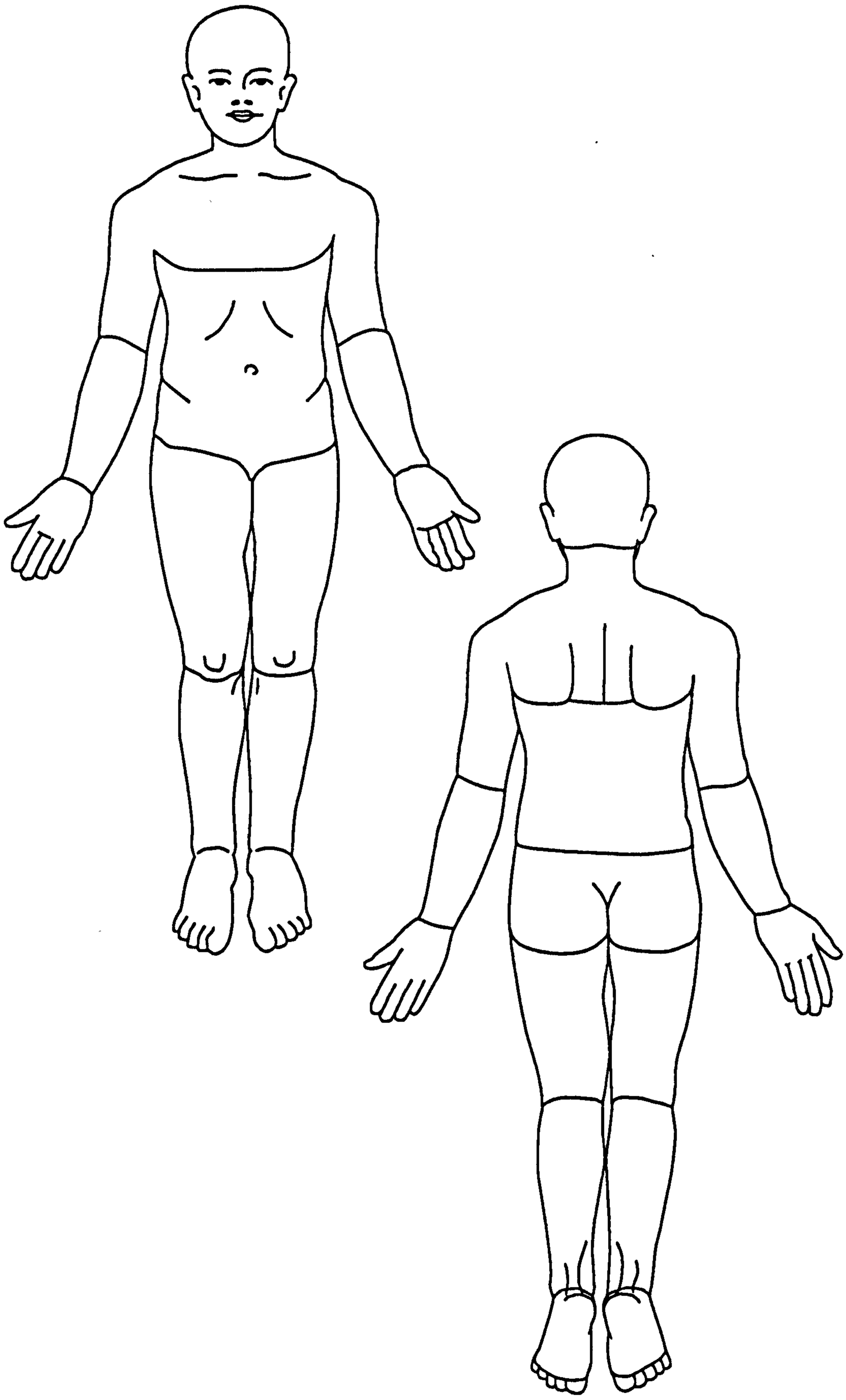
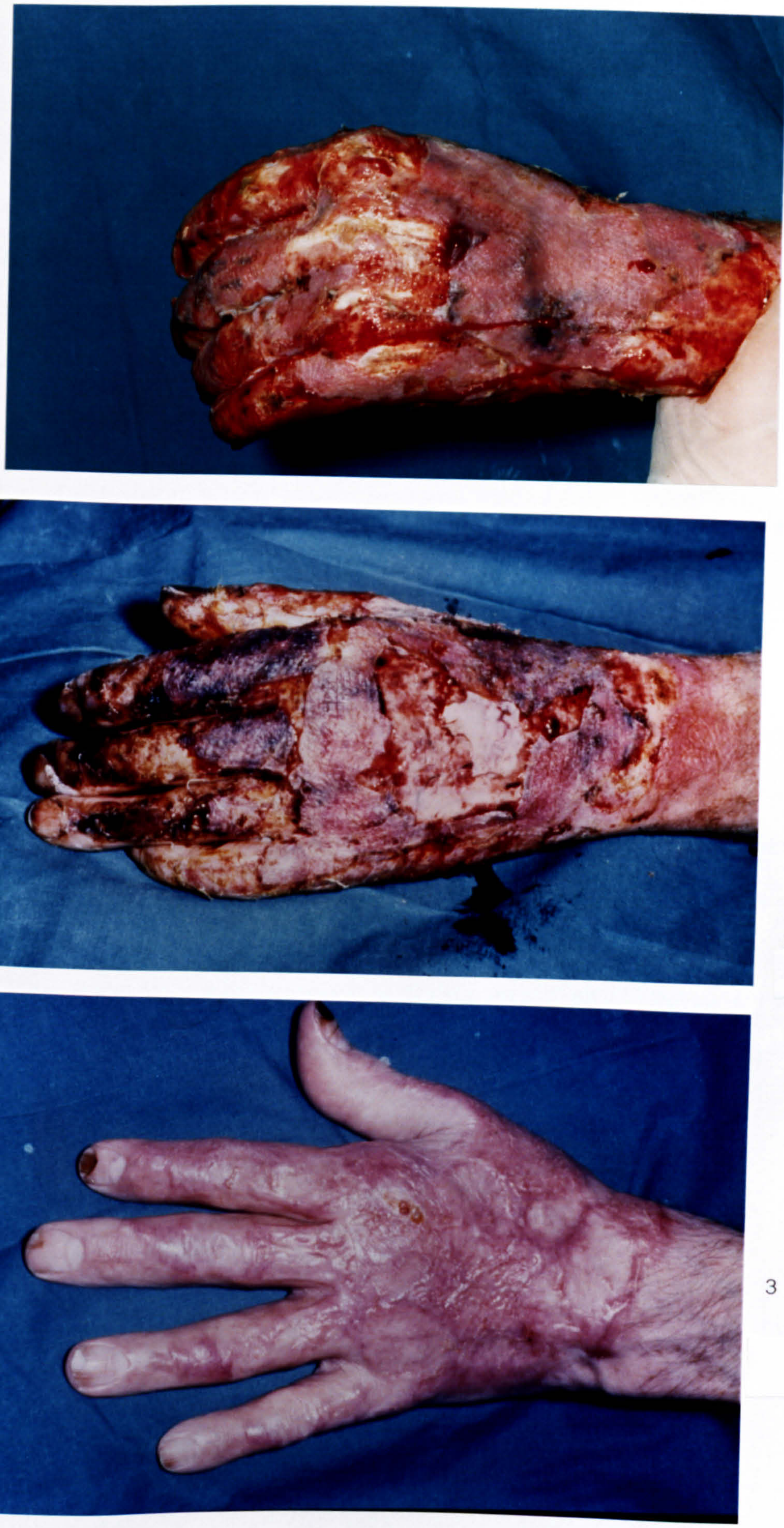


Figure 59

Case Reports

Case 1 (Fig. 60).

(12.5.85) Patient: male aged 65 years. Involved in Bradford football stadium fire. Sustained burns to hands, buttocks and back of legs. Total area of burns 19½%. Operation (14.5.85). Excision and partial shaving of forehead. Graft left exposed, tangential excision, left hand up to MEP joint. Tourniquet excision, right hand dorsum of hand and proximal and middle phalange down to paratenon. Tangential excision portion of wrist. Grafts attached with n-butyl cyanoacrylate. At first dressing (21.5.85) left hand 30% take of graft. Further stored skin applied. Right hand 60% take of graft. Forehead 90% take of graft. At second dressing (25.5.85) scalp mostly taken, left hand, second graft not taken - removed. Both calves redressed, donor site, right hand redressed. Home (27.7.85). Burns review clinic (31.10.85). Left hand functioning extremely well. Graft settled, no problem of function. Right hand has considerable disability and extension deformity. Unlikely to improve in view of underlying pathology of the tendon. Continued physiotherapy. Burns review clinic (23.1.86). Continues to make good progress with both hands, continue to review. Special review clinic (14.7.88). Good progress continues. Patient cheerful, areas of graft where tissue adhesive used observed and recorded, no problems.



1

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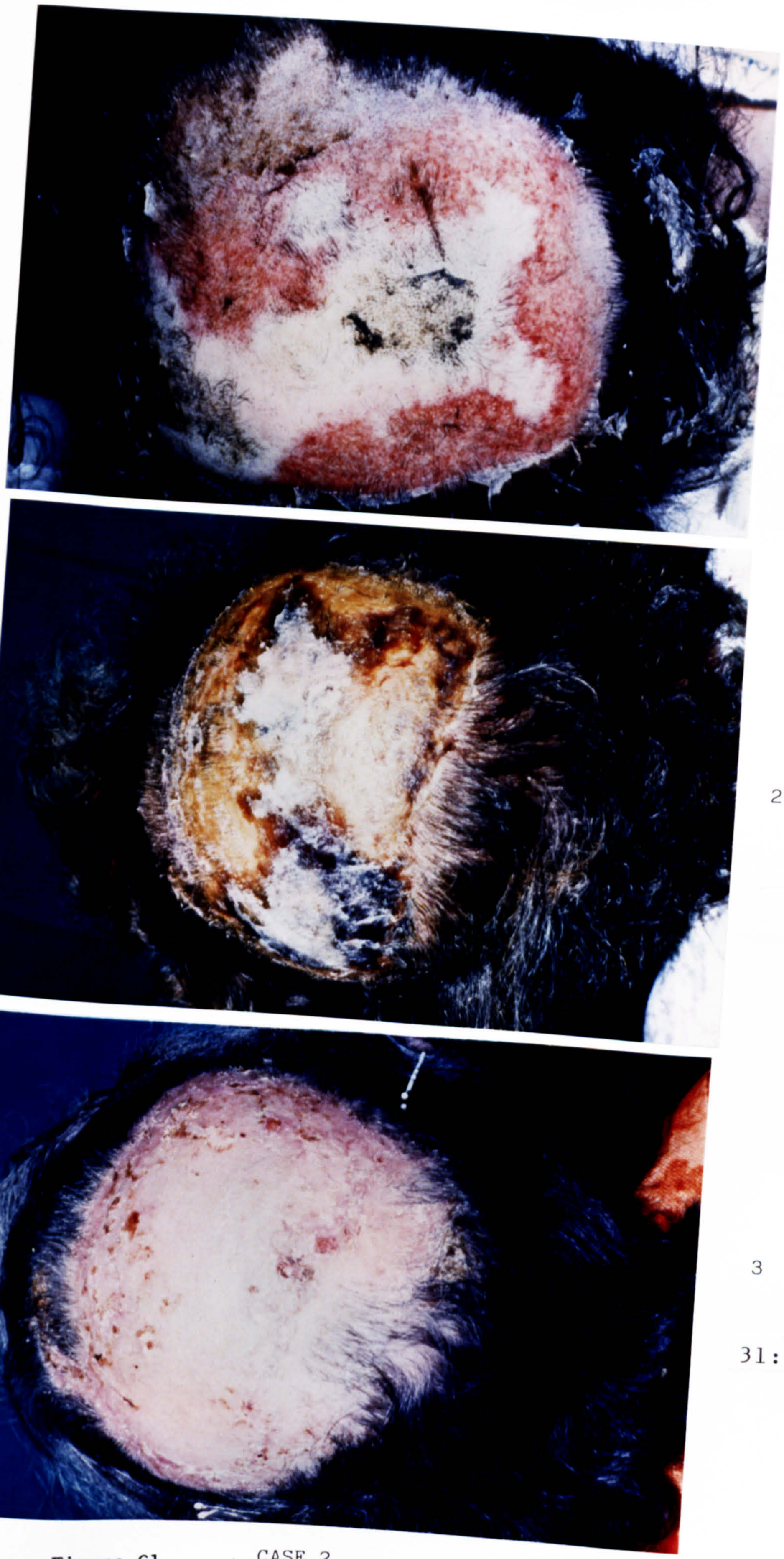
CASE 1

Figure 60

Case 2 (Fig. 61)

(11.5.85) Female aged 82 years involved in Bradford football stadium fire, sustained burns to top of head, dorsum of right hand, cheek and both calves. Total area of burn 3%. Operation (14.5.85). Joint division of scalp and burn of left leg to allow mobility. Arm tourniquet, shaving of dorsum of right hand plus proximal compartments. Meshed skin graft applied from forearm. Operation (10.6.88). Split skin graft from right upper arm applied to granulating area, dorsum of right hand. Operation (20.6.85). Defect 7" x 4" on scalp grafted with skin from left arm. Graft attached with n-butyl cyanoacrylate tissue adhesive. Home (28.6.88). Burns Clinic (2.7.85). Right hand healed. Scalp crusted plus a few raw areas posteriorly. Leg, small area to heal 2" x 1". Donor sites (R) and (L) not yet healed. Left leg nearly healed, left arm donor site virtually healed. Right arm donor site overgranulated. Burns Clinic (23.7.85). Leg healed, both arms healed. Dressing continued. Wig prescribed. Burns Clinic (30.7.88). Donor sites healed. Burns Clinic (31.10.85). Patient looks very well. Scalp healed well, reports no problems, no psychological upsets. Continue to review. Special Review Clinic (14.7.88). Patient very well, cheerful, continues to make progress. Graft area of scalp where tissue adhesive used observed and recorded, no problems.



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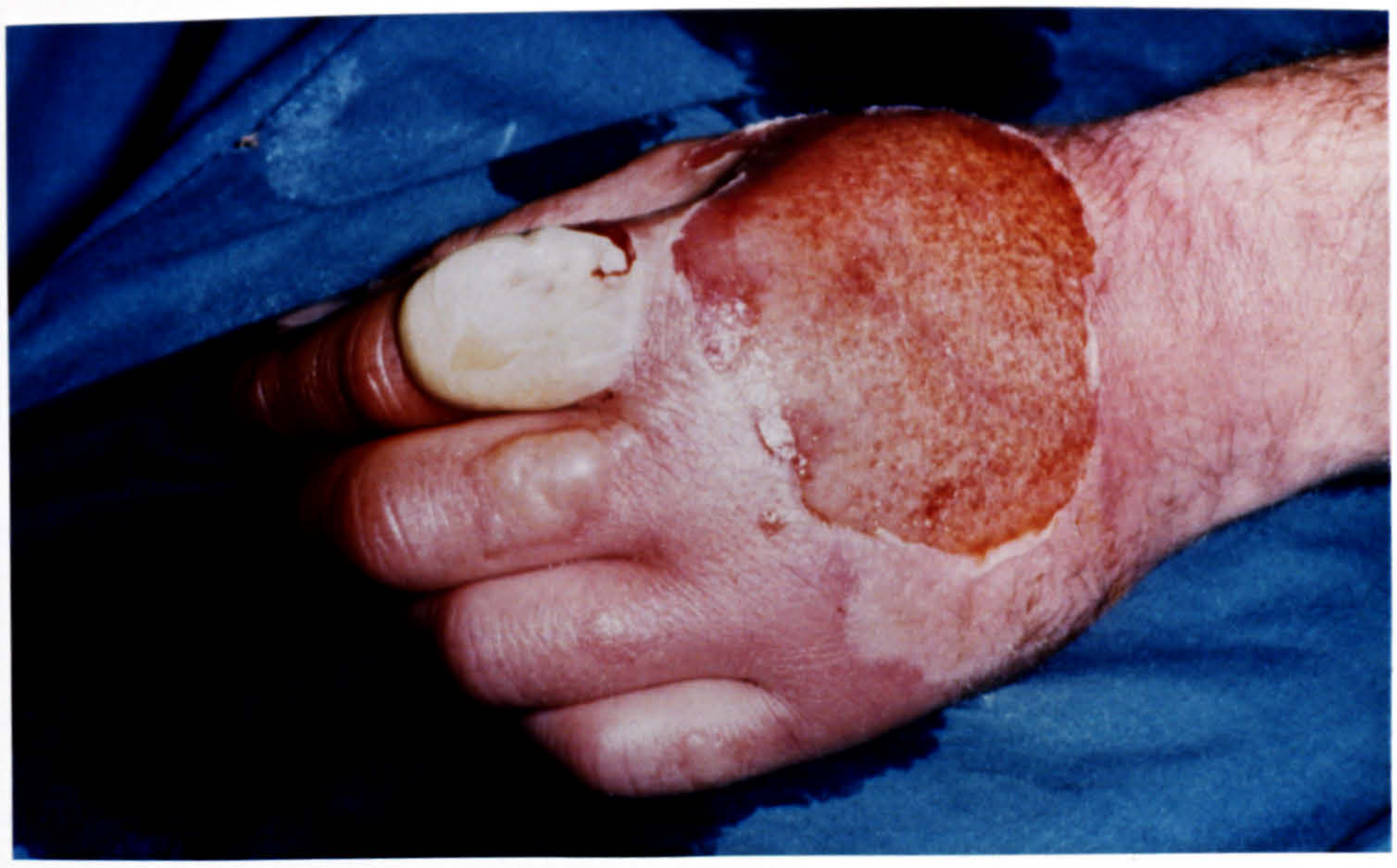
31:5:85

Figure 61 CASE 2

Case 3 (Fig. 62)

(12.5.85) Patient male aged 66 years. Admitted with burns of backs of both hands, both legs and backs of ears. Total area of burn 4%. Involved in fire at Bradford City football ground. Operation: left hand, test shave dorsum of index finger, split skin graft to web space. Shave and graft radial side of dorsum, graft attached with n-butyl cyanoacrylate tissue adhesive. Donor, left forearm, volar surface (19.5.85). Dressing (1.6.85). Swelling right ankle has settled. Flamazine bag right hand (10.6.85). Needs graft to right hand and right leg. Operation (14.6.85). Rub and split skin graft to both calves, areas 5 x 4 cm (left, 7 x 5 cm (right) grafts attached with n-butyl cyanoacrylate tissue adhesive. Split skin graft from left thigh, surplus skin stored (10.6.85). Right leg, graft good, left leg, graft still alittle mobile. (25.6.85) Grafts have taken, mobilise. Home (27.6.85). Burns Clinic (2.7.85). All healed, double tubigrip, continued review. Burns Clinic (10.10.85). Good improvement. Well healed, continue review. Special Review Clinic (14.7.88). Has made continued progress. Graft areas where tissue adhesive used observed and recorded, no problems.



1

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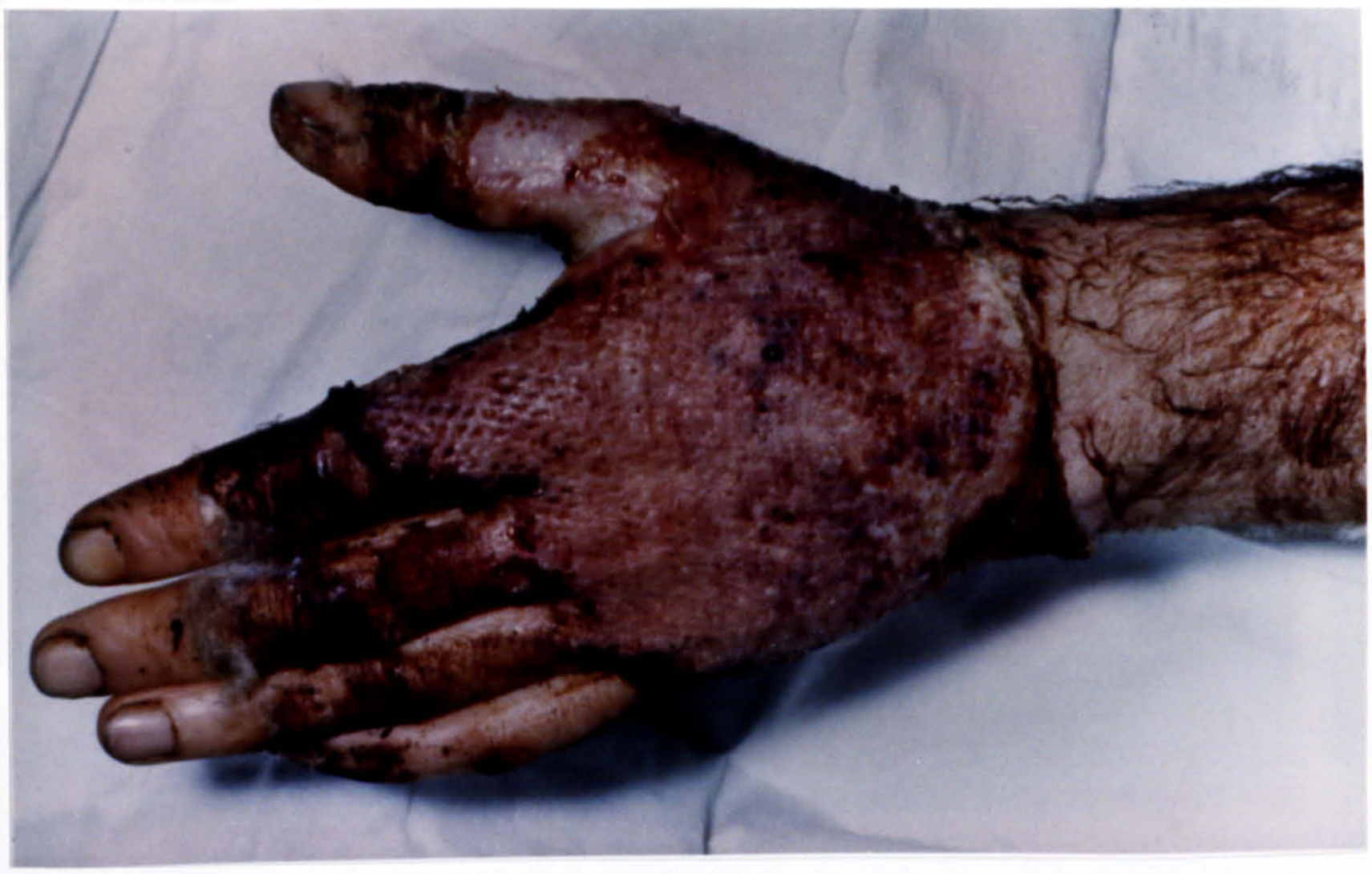

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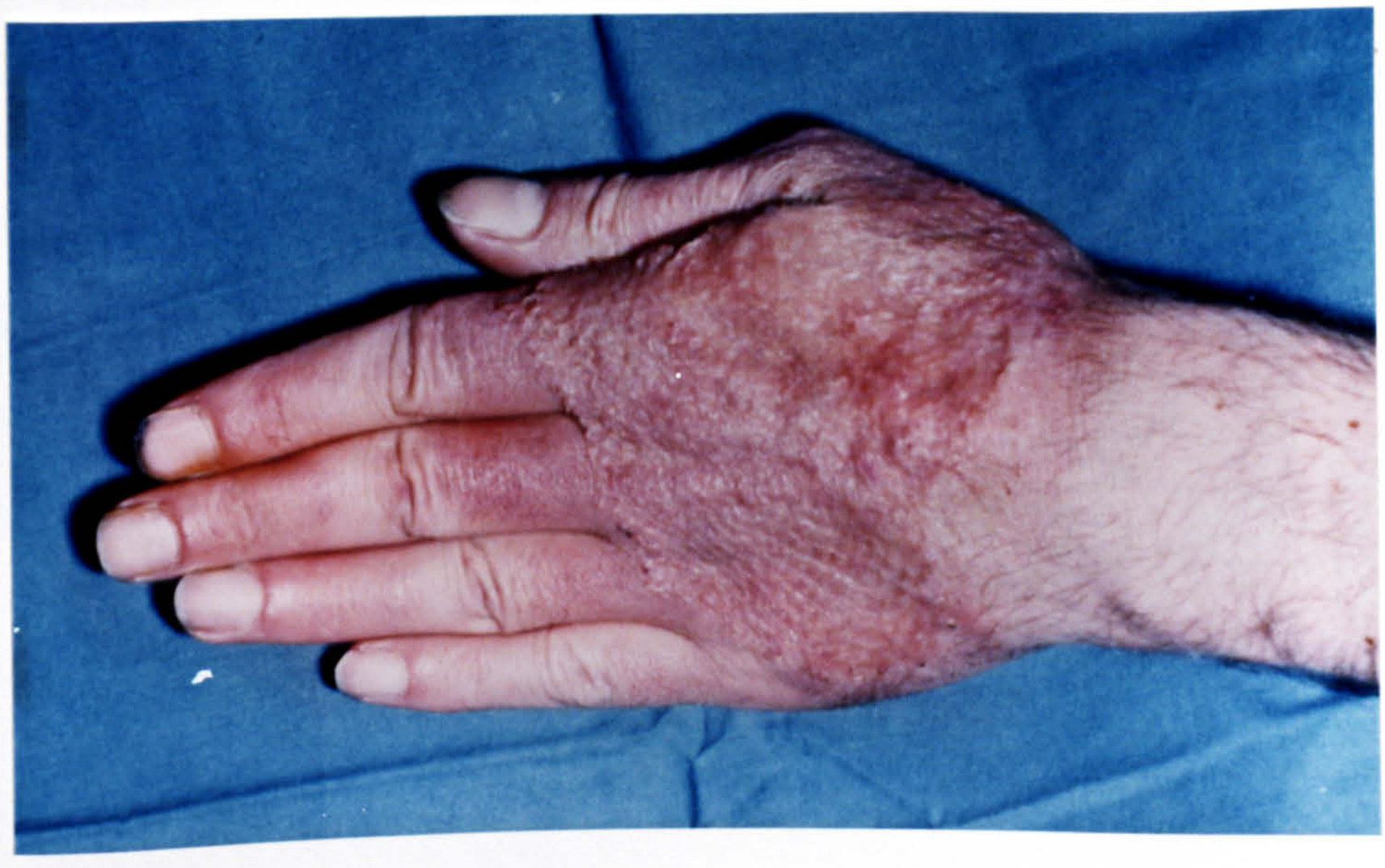


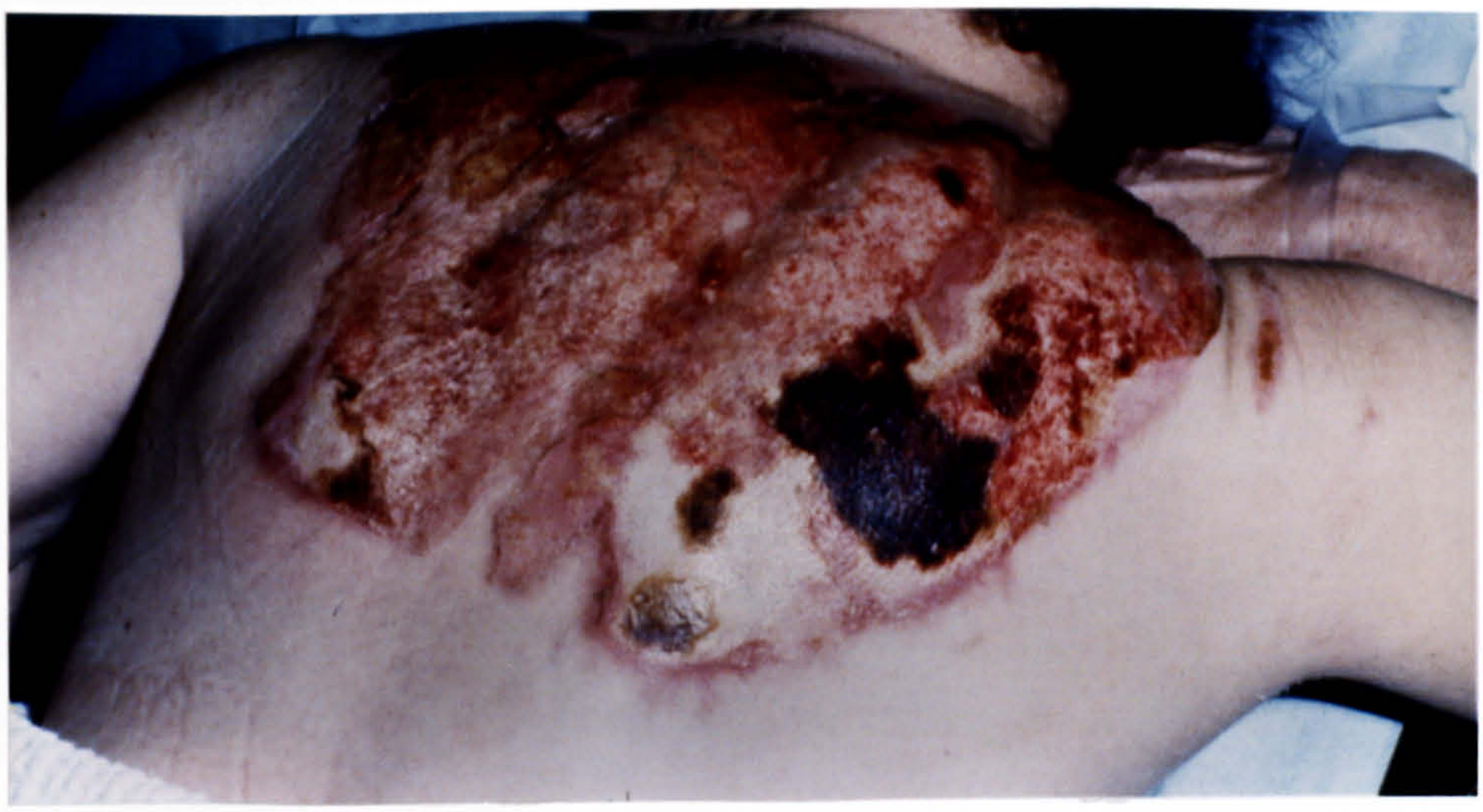
3

10:10:85

Figure 62 CASE 3

Case 4 (Fig. 63)

(11.5.85) Patient, female aged 67 years. Involved in Bradford football stadium fire. Sustained burns to face, both hands, back, shoulders and legs. Total area of burns 18%. Operation: Tourniquet, excision, full thickness burn dorsum left hand and finger; tourniquet removed and haemastasis achieved. Sheet graft applied. Right hand, excision full thickness burn dorsum right hand and fingers under tourniquet. Meshed. Split skin graft attached with n-butyl cyanoacrylate tissue adhesive (21.5.85). First dressing left hand 5% take of graft. Right hand 10% take of graft, both infected. Scalp 10% of graft taken (25.5.85). Right hand 10% take of graft, exposure of tendons but not necrotic. Left hand exposure of tendons but not necrotic. (7.8.85) Operation: grafting of granulating burns of both hands, left arms, forehead and back and both thighs. Head 3½% crusted burns desloughed and grafted. Right hand patchy granulations of dorsum of hand and fingers. Left hand, most of the hand and all fingers granulated. (28.6.85) Operation: granulation on back grafted, graft attached with n-butyl cyanoacrylate tissue adhesive. Home (27.5.85). Burns Clinic (31.10.85) hands improving, physiotherapy continued. Although short of skin on both extensor surfaces of hand, surgery is not indicated at present time. Scalp and back dressing continued. Burns Clinic (30.1.86) area of bone on skull has separated, epithelization has taken place. Both hands functioning well. Back area good progress, continue to rview. Special review clinic (14.7.88). Good progress. Patient very cheerful, pleased with results, no problems.



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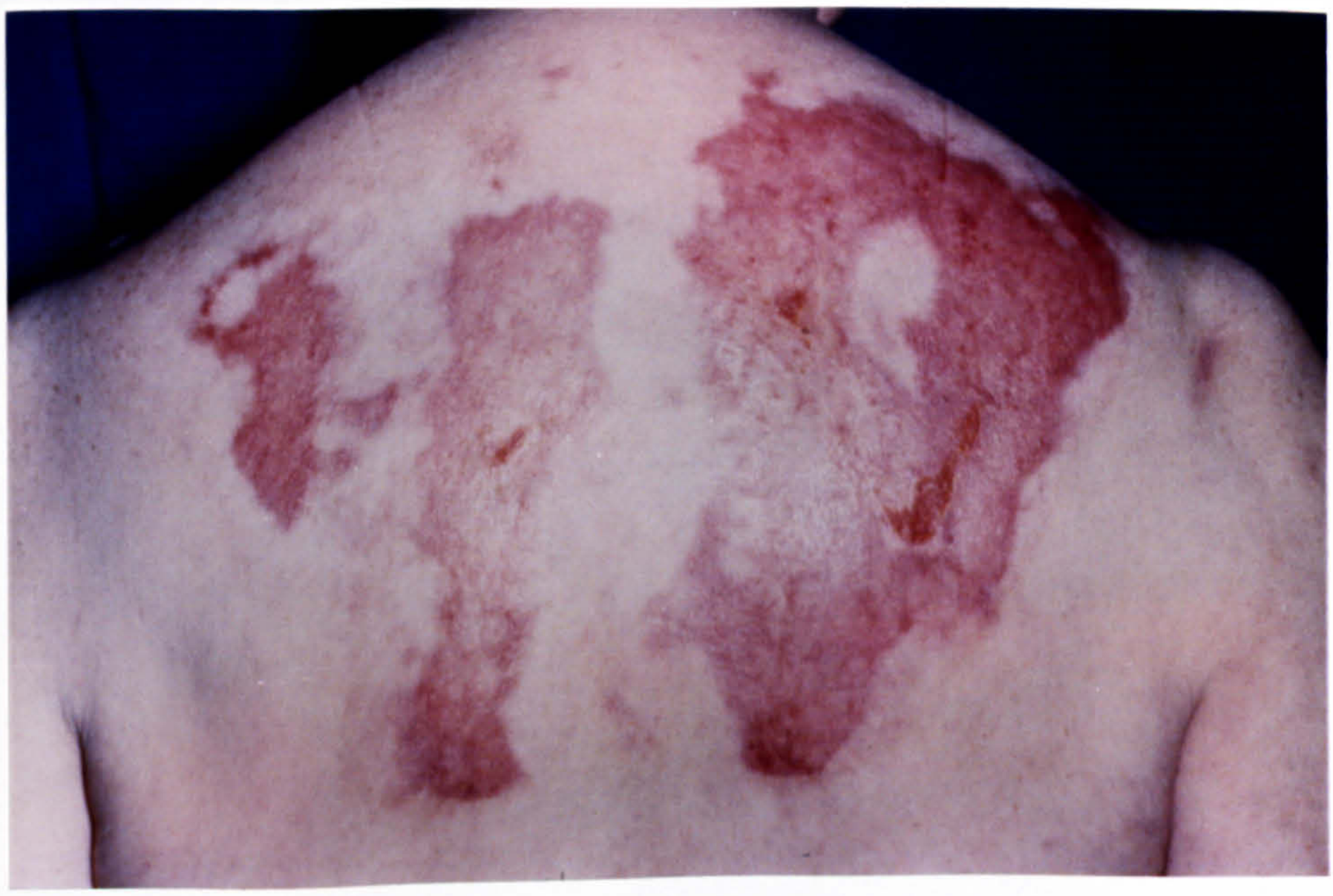


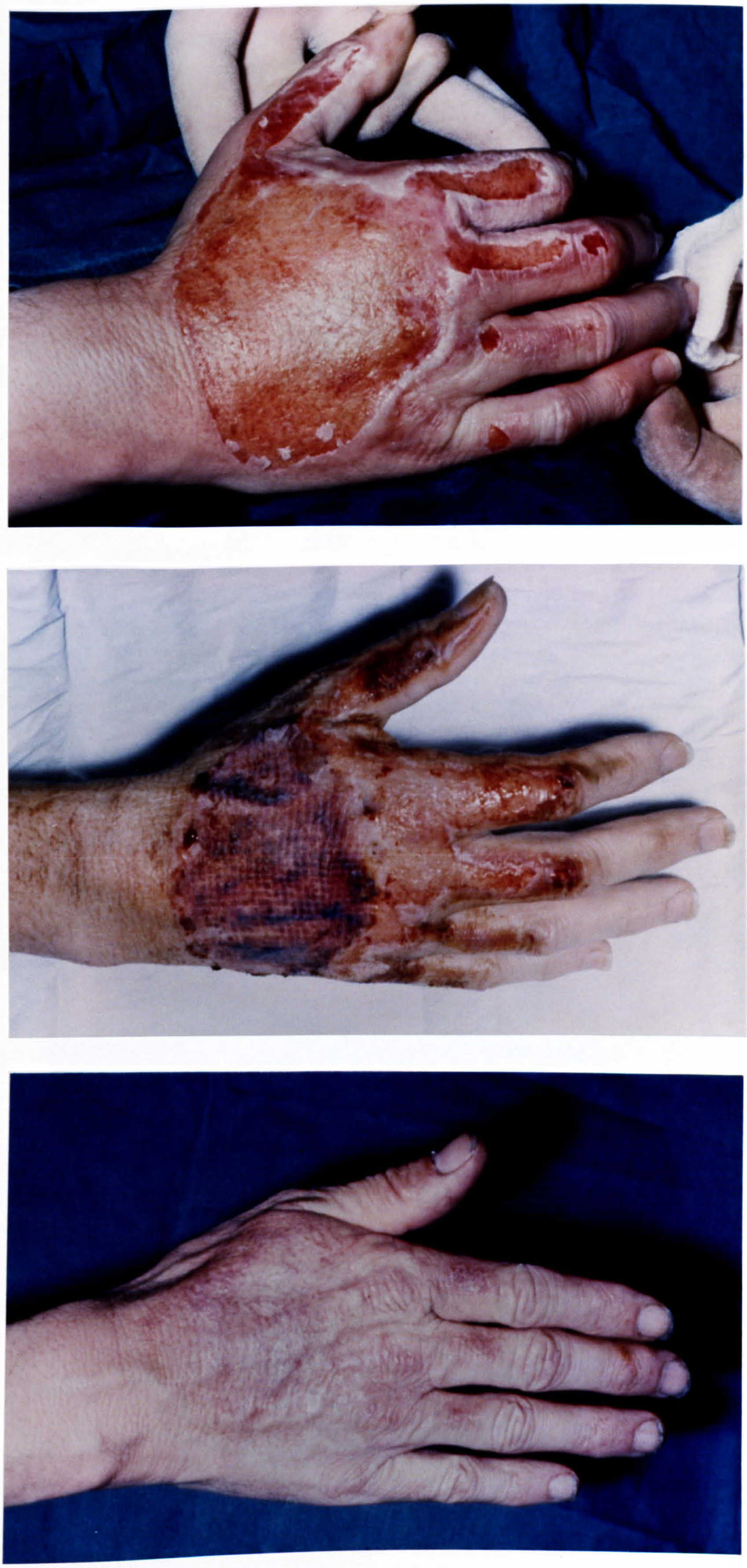
2

30:1:86

Figure 63 CASE 4

Case 5 (Fig. 64)

(12.5.88) Patient male aged 27 years. Admitted via Bradford Royal Infirmary casualty department. Involved in the Bradford football stadium fire. Sustained burns to both hands and back of head. Total area of burn 2%. Operation: (13.5.85). Tangential excision and graft to right hand. Graft attached with n-butyl cyanoacrylate tissue adhesive. Dressing (18.5.88). Home (27.5.85). Burns Clinic (4.6.85). Well healed full movement. Donor area, thigh healed, review three months. (12.9.85) Excellent result for right hand, further review in twelve months. Special review clinic (14.7.88). Excellent result on hand. Patient very pleased with this, reports an awkward scar of left leg which has been causing problems, keen sportsman, the skin keeps breaking down. Suitable for tisue expansion on both sides to stretch this out (2 x 500 cc rectangular or crescentic expanders) name on waiting list, no other problems.



1

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2

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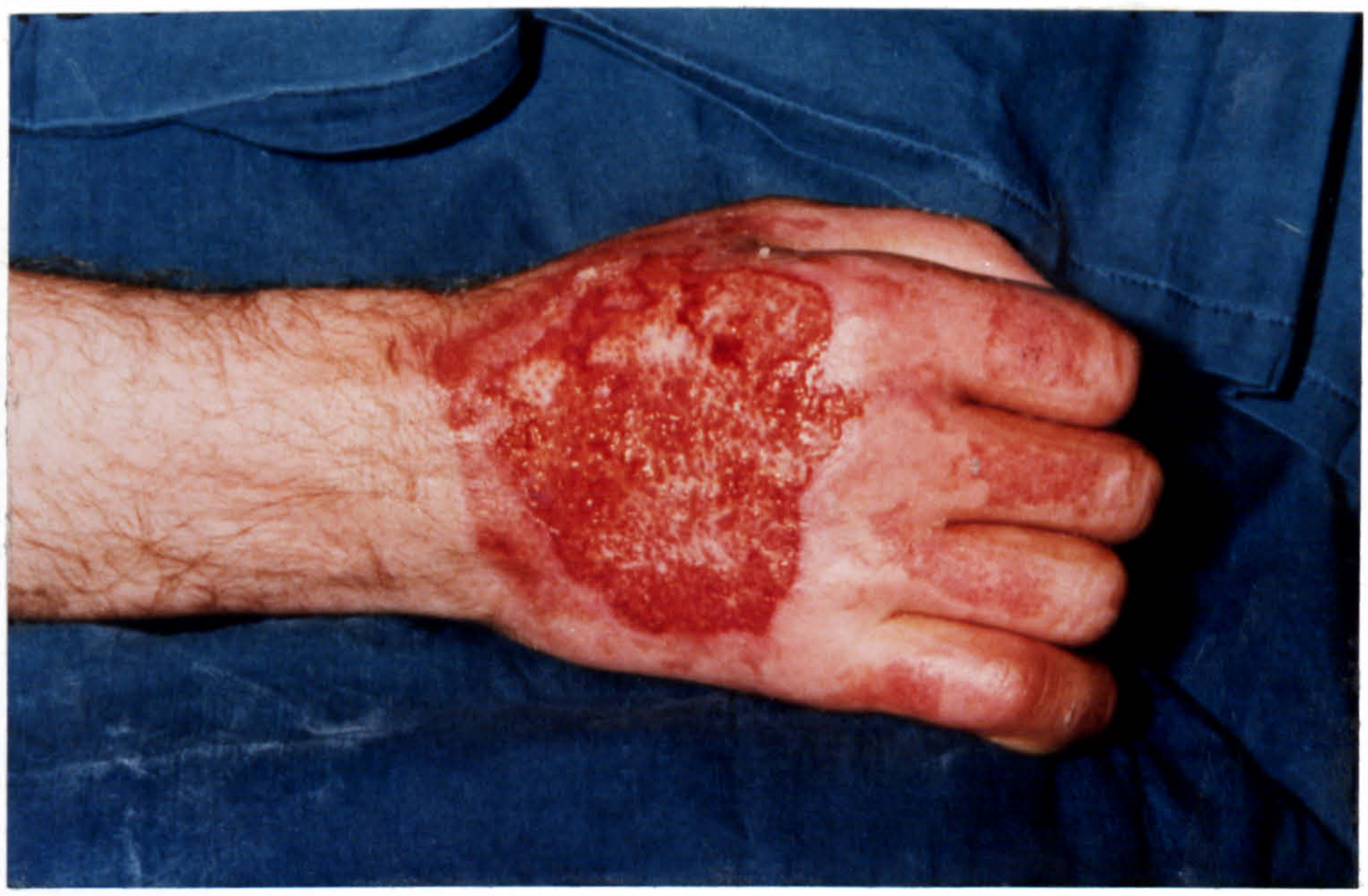
3

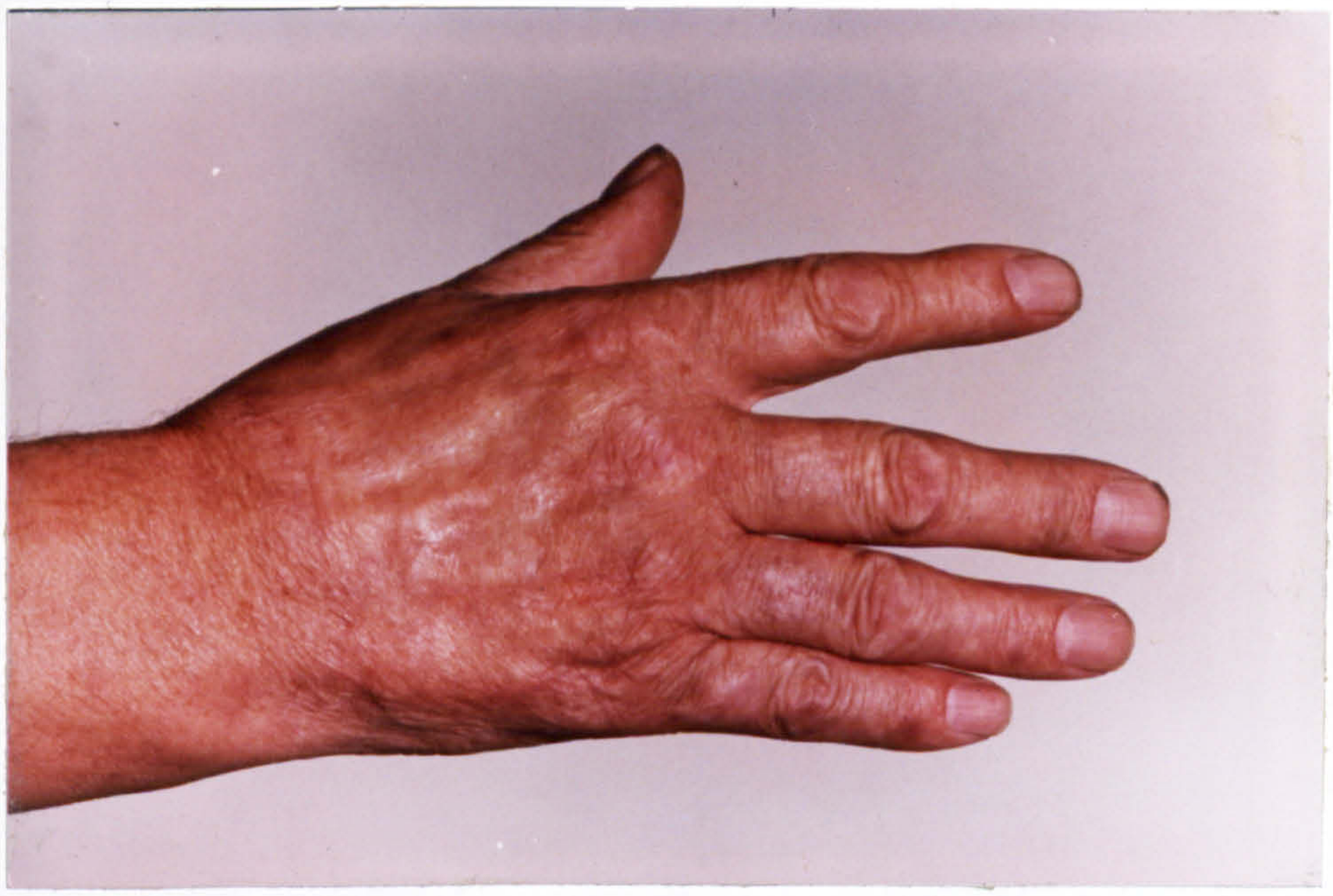
14:7:88

Figure 64 CASE 5



– A

10th June 1985



– B

14th July 1988

Figure 65

(A) One month after burn injury, initially treated conservatively with dressings. This failed to heal. Now has granulating wound. Skin graft applied and attached with n-butyl cyanoacrylate tissue adhesive.

(B) Result 3 years later.

RESULTS AND DISCUSSION

Prosthetic Adhesive

The classification of prosthetic adhesive based on the chemical characteristics of polarity set out in Table 11 provide the basis for grouping the type of prosthetic adhesive formulation most suitable for the prosthetic material selected.

In clinical practice the problem often occurs of patients not being able to attach a facial or body prosthesis due to non-adherence of the adhesive used. Patients are referred to this Centre for an opinion concerning non-adhesion of a device vital to the treatment programme. The solution to most of these problems is that of adhesive selection in relation to the material requiring attachment to the skin. By understanding the polarity groupings more effective adhesives can be selected to provide adherence and function.

The work of SCHMIDT and MARLIÉS (1948) concerning the mechanism and factors of adhesion is of particular relevance to the attachment and retention of facial prostheses and devices. The need is to concentrate energy at the limited surface area interfaces of prosthesis and adhesive together with that of the skin and adhesive.

The formulation of prosthetic adhesives compatible with the low polarity prosthetic materials set out in Table 12 provide adherence and retain the viscoelastic characteristic for this group of materials which are being increasingly used in the clinical area.

An essential property of a prosthetic adhesive has been found to be adhesion on contact with the skin. STEFAN (1874) determined the importance of the tackiness factor in adhesion and the effect of time of maximum adherence. The STEFAN tackiness factor is achieved with the viscous hydrocarbon group of adhesives. The high degree of adhesion in this group has been found most satisfactory in the attachment of Silicone Elastomer prostheses to the skin. Tackiness and adhesion even in the prescence of increased metabolic exudates make this group of adhesives the most acceptable to our patients.

The Plastic Surgery Department of St. Luke's Hospital, Bradford has developed the use of nipple-aerola prostheses following breast reconstruction. The technique places particular reliance on the adhesive used. The selection and use of a low polarity viscous hydrocarbon contact adhesive has provided effective adhesion. Patients report complete confidence in the prosthetic restoration based on ease of application and adhesion even during prolonged exposure to sun and sea water in tropical conditions.

The medium polarity group of adhesives was used in the early development of prosthetic materials. This group has been found to oxidise rapidly with subsequent loss of adherence. The medium polarity group is not effective in the adhesion of silicone elastomer and has not been used in this study.

High polarity group adhesives find limited use in facial prosthetics, being least effective for long-term adhesion and attachment.

All groups find application for temporary dressings and tapes. Commercial manufacturers use balanced formulations to the specialized application of their products.

Tissue Adhesives

Three cyanoacrylates have been examined as tissue adhesives in this study; methyl, ethyl and n-butyl. The larger size molecule ester n-butyl cyanoacrylate 413 120 cP with a cure speed of 10 seconds has been satisfactory for our clinical requirements. The n-butyl 413 cyanoacrylate is more tolerated by the tissues than the other lower homolo gs. The n-butyl degrades at a slower rate than both methyl and ethyl cyanoacrylate. Both are not well tolerated by the tissues. The tissues more easily metabolize the lower concentration of degradation of the n-butyl 413.

The difficulty of selecting a method of sterilization for cyanoacrylate has been examined. Dry heat has been the method used in clinical applications. The experimental use of Protoporphyrin IX dimethylester as a sterilization agent has been used. This method combines both sterilization and fluorescence.

The precision applicator designed and developed for application of the cyanoacrylate in the operating theatre enables fast cure times to be exploited and defined amonunts dispensed. A peristaltic pump provides the pressure required to dispense the cyanoacrylate. The system combines a UV light option for location of cyanoacrylate tissue adhesive formulated with a fluorescent agent. The fluorescent agents investigated in this study have no history of medical use with tissue adhesive. When mixed with n-butyl cyanoacrylate in concentrations of 2% agents (page 147) numbers 2, 3, 4, 5, 8, 10 were soluble with the cyanoacrylate and no destabilization occured. Agents number 6, 7,9 were not soluble and caused polymerization.

All the fluorescent agents numbers 1 to 10 mixed with the cyanoacrylate. When examined under UV light at 254 nm and 365 nm showed an effective level of fluorescence. The soluble fluorescent agents examined appear to lose their fluorescence due to chemical attenuation in combination with the cyanoacrylate. They are therefore considered unsuitable as indicators for tissue adhesive.

Concentrations of agentsl to 10 in amounts over 2% destabilized the cyanoacrylate causing polymerization. Of the fluorescent agents 1 to 10 examined separately on glass using the same UV light only Anthracene, Acenaphthene and Phenanthrene gave any significant fluorescence. Again, the level of fluorescence was considered insufficient to provide the contrast indication required for surgical application.

Fluorescent agent number 11, Sodium fluorescein, an established fluorescent in ophthalmic surgery, did not mix with cyanoacrylate. Agent Pylam LI-900 is a bright yellow compound. When mixed with cyanoacrylate in 2% concentration this agent was soluble and conferred its distinct yellow colour to the cyanoacrylate, no destabilization occurred.

When irradiated by UV light at 254 nm and 365 nm an intense fluorescence resulted. Examined separately on glass under UV light agent LI-990 produced the same level of bright fluorescence. The agent is currently used for industrial fluorescent applications. In vitro studies of this agent are continuing. Fluorescent agent Natmer LI-1158, again an industrial fluorescent, was not completely soluble with the cyanoacrylate in a 2% concentration. This agent gave an acceptable fluorescence both in its powder form and when mixed with the cyanoacrylate.

Of the fluorescent agents examined in this study only LI-990 is considered satisfactory regarding solubility, fluorescence and stability. Further toxicity studies of this agent are indicated to establish its future in medical application.

During the investigation of sterilization methods, photo-sensitisation of cyanoacrylate by protoporphyrin IX dimethylester was used experimentally. Protoporphyrin IX dimethylester was soluble with n-butyl 413 cyanoacrylate mixed as a concentration of .001%. When irradiated by UV light at 365 nm the cyanoacrylate fluoresced strongly orange-red.

Survey

From the total number of questionnaires sent out (1,034) Plastic Surgeons (289), Oral and Maxillo-Facial Surgeons (745), the response was Plastic Surgeons 60.2% and Oral and Maxillo-Facial Surgeons 46.0%. The results are presented in Table 13 a & b.

It is of interest to note that more plastic surgeons (44.7%) used cyano-acrylate tissue adhesive. ~~more overall — 44.7%~~ than the oral surgeons - 18.8% (Fig. 66). In view of the complexity of oral and maxillo-facial surgery and the ~~predominant~~ frequent use of biomaterials in dentistry it might ~~could~~ be assumed that the oral surgeons would ~~predominate in the use~~ have been the major users of tissue adhesive.

SURGICAL USE OF ADHESIVE SURVEY

	Plastic Surgeons		Oral and Maxillo-Facial Surgeons	
	Number	Percentage	Number	Percentage
Questionnaires sent out	289		745	
Returned completed	159	60.2	325	46.0
Returned unanswered	15		18	
Ref. Q.1. Based on completed questionnaires				
Do not use adhesive	88	55.3	264	81.2
use adhesive	71	44.7	61	18.8
Ref. Q.2. Based on those using adhesive				
Used less than once a year	11	15.5	13	21.3
Used 1-12 times a year	37	52.1	44	72.1
Used 13-52 times a year	19	26.8	2	3.3
Used 53 or more times a year	4	5.6	1	1.6
No reply	0	0	1	1.6
Ref. Q.3. (Includes those who use more than one adhesive)				
Use Histoacryl	64	90.1	44	72.1
Use Henkel	1	1.4	0	0
Use unknown brand	6	8.5	14	23.0
Use other	8	11.3	4	65.6
Did not answer	0	0	1	1.6
Ref. Q.4. (Includes those using adhesive for more than one purpose)				
Used for skin graft fixation	65	91.5	18	29.5
Used for wound closure	6	8.5	16	26.2
Used for fixation of dressings	15	21.1	19	31.1
Used for other	11	15.5	33	54.1
Ref. Q.5.				
Had problems applying adhesive	29	40.8	27	44.3
Did not have problems applying adhesive	41	57.7	33	54.1
Don't know or no reply	1	1.4	1	1.6

Table 13(a)

SURGICAL USE OF ADHESIVE SURVEY

	Plastic Surgeons		Oral and Maxillo-Facial Surgeons	
	Number	Percentage	Number	Percentage
Ref. Q.6. (a) Those who had problems applying adhesive Total number	29		27	
Said a precision applicator would help	25	86.2	23	85.2
Said a precision applicator would not help	3	10.3	4	14.8
Did not know	1	3.4	0	0
(b) Those who did not have problems applying adhesive Total number	33		41	
Said a precision applicator would help	25	75.8	19	46.3
Said a precision applicator would not help	6	18.2	16	39.0
Did not know	2	6.1	4	9.8
No reply	0	0	2	4.9
Ref. Q.7. Based on those NOT using adhesive Would consider using superior adhesive	70	79.5	206	78.0
Would not consider using superior adhesive	11	12.5	23	8.7
Did not know	2	2.3	0	0
Did not answer	5	5.7	35	13.3
Would consider using superior adhesive	66	93.0	61	100.0
Would not consider using superior adhesive	3	4.2	0	0
No reply	2	2.8	0	0

Table 13(b)

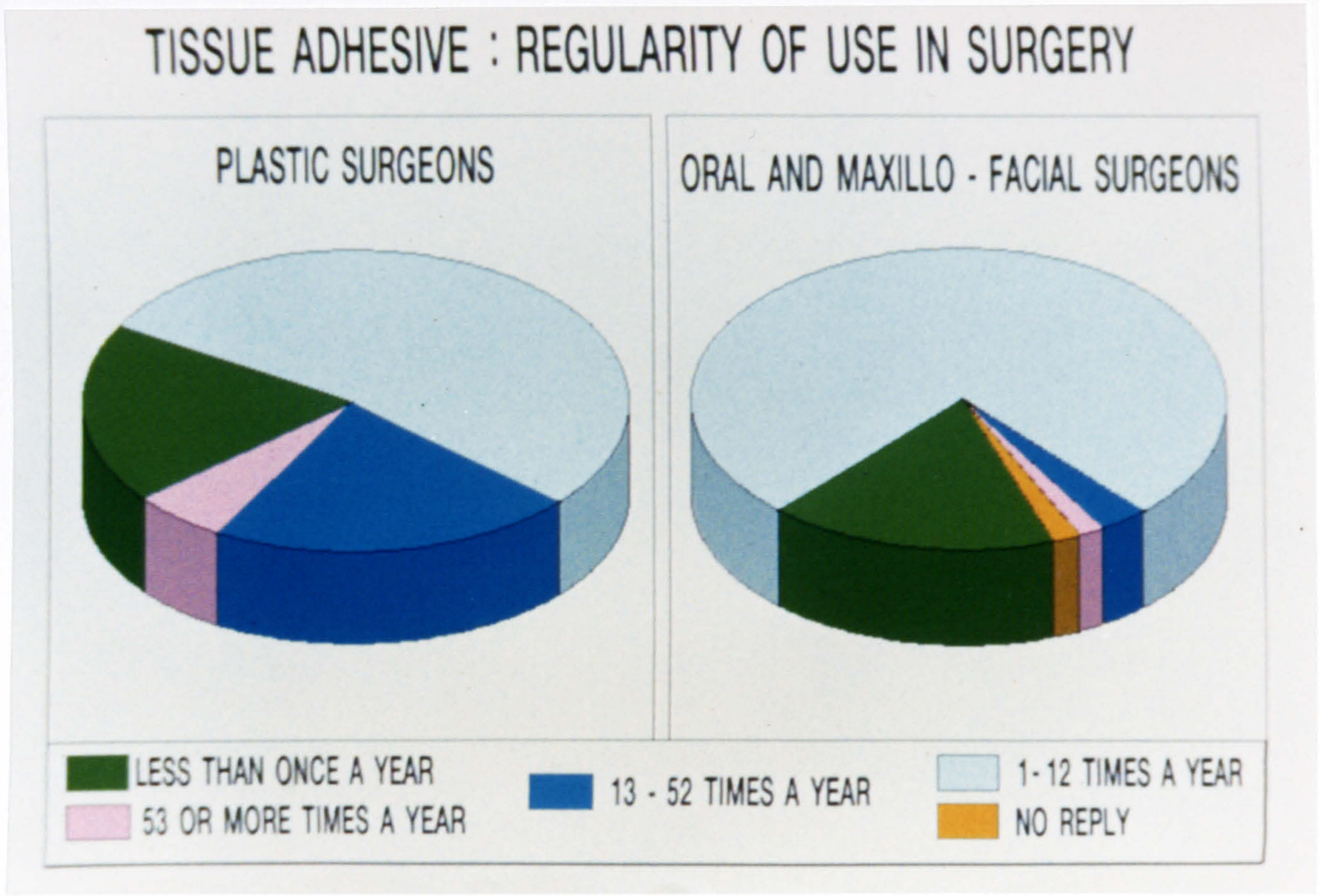

TISSUE ADHESIVE : REGULARITY OF USE IN SURGERY
PLASTIC SURGEONS
ORAL AND MAXILLO - FACIAL SURGEONS
LESS THAN ONCE A YEAR
53 OR MORE TIMES A YEAR
13 - 52 TIMES A YEAR
1 - 12 TIMES A YEAR
NO REPLY

Figure 66

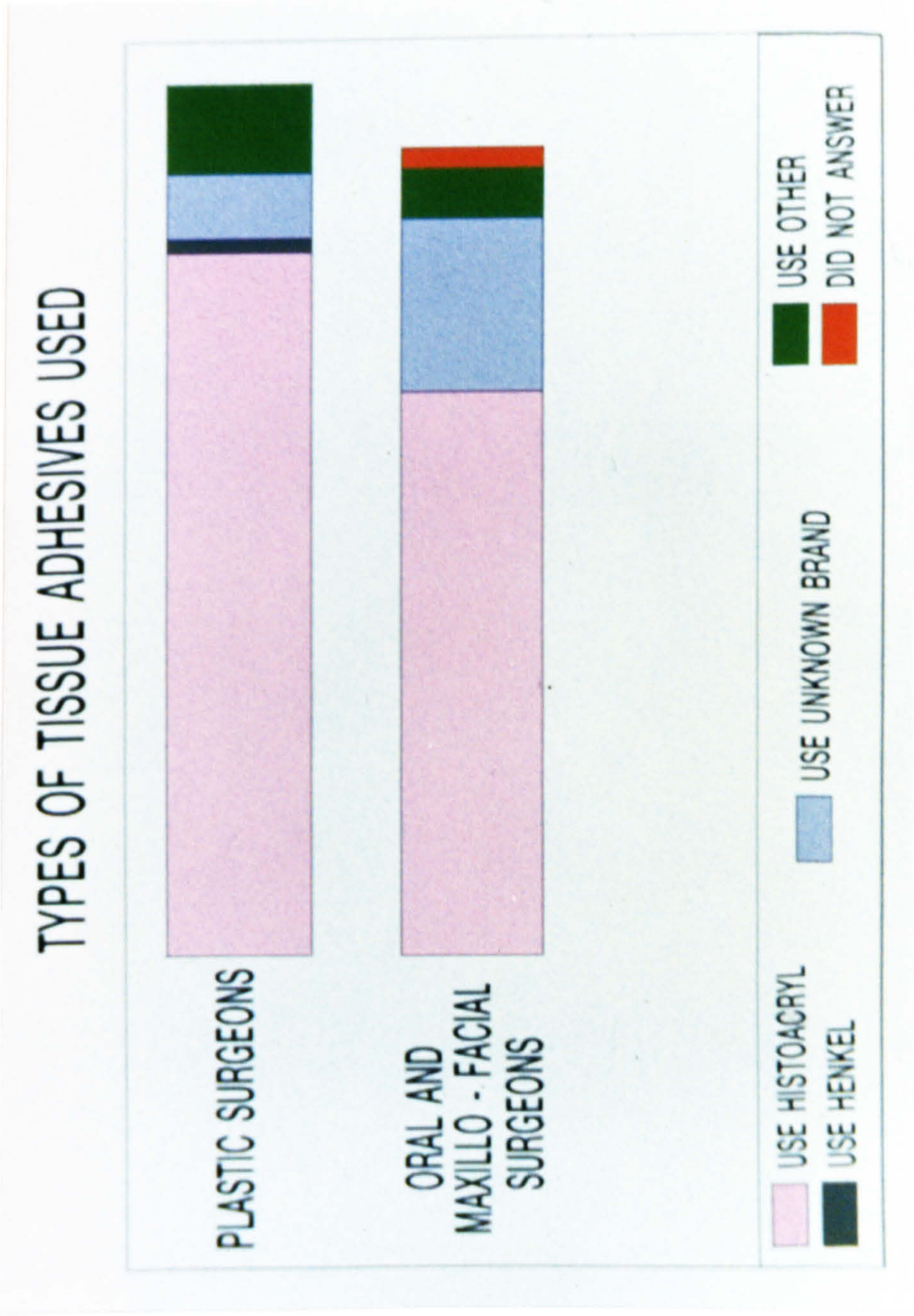

TYPES OF TISSUE ADHESIVES USED
PLASTIC SURGEONS
ORAL AND MAXILLO - FACIAL SURGEONS
USE HISTOACRYL
USE HENKEL
USE UNKNOWN BRAND
USE OTHER
DID NOT ANSWER

Figure 67

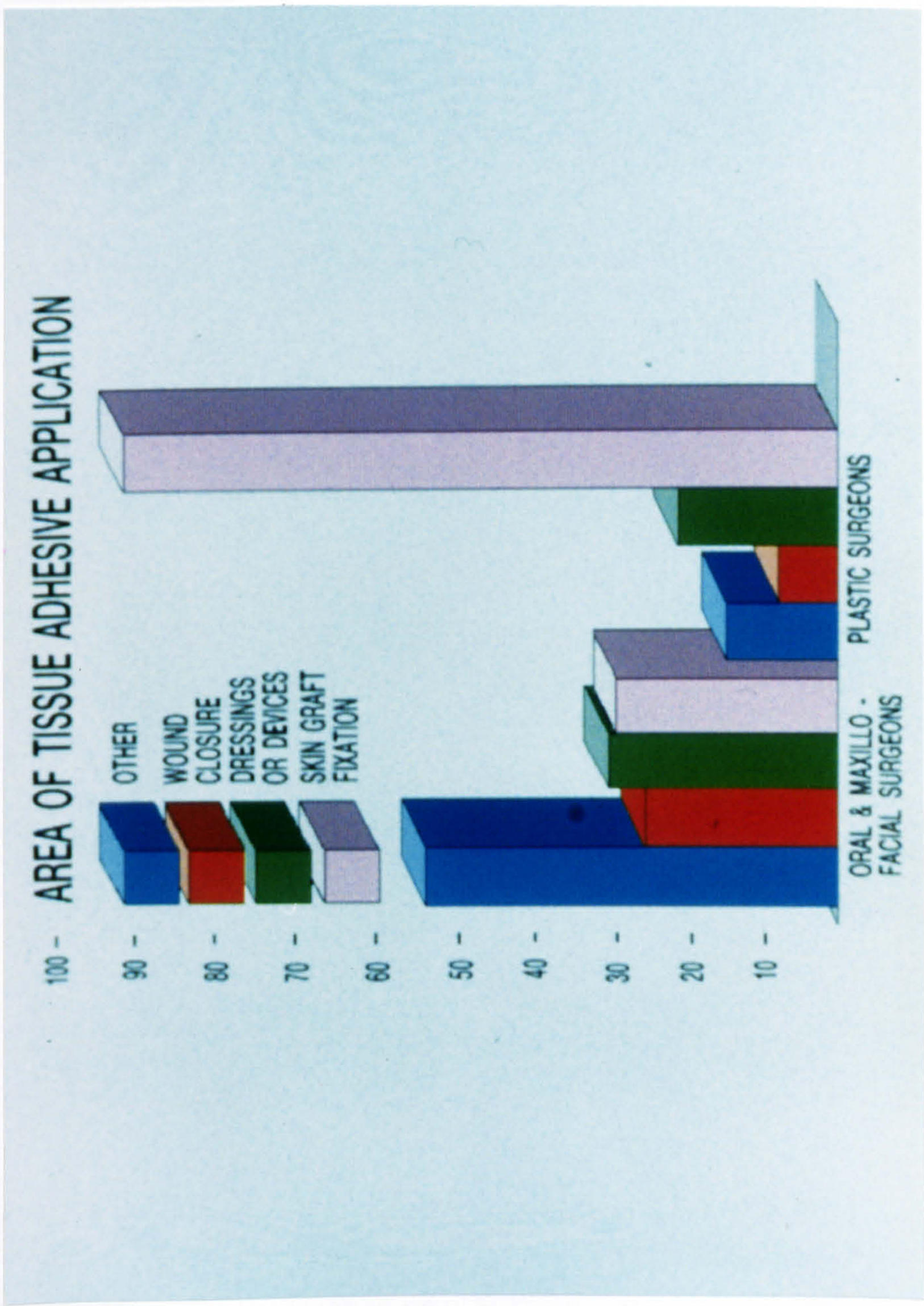

AREA OF TISSUE ADHESIVE APPLICATION
100
90
80
70
60
50
40
30
20
10
OTHER
WOUND CLOSURE
DRESSINGS OR DEVICES
SKIN GRAFT FIXATION
ORAL & MAXILLO - FACIAL SURGEONS
PLASTIC SURGEONS

Figure 68

The main type of tissue adhesive used by both groups of surgeons was Histoacryl. This can be attributed to adhesive being the only medical grade tissue adhesive on the market at the present time with a Medicines Commission product licence in the United Kingdom.*

Surgeons of both groups used unknown brand cyanoacrylate. Again both groups used other cyanoacrylates but did not specify the adhesive as asked in the questionnaire (Fig. 67).

Plastic surgeons predominantly used cyanoacrylate tissue adhesive to attach skin grafts. The oral surgeons used the adhesive more for wound closure and the fixation of dressings together with other unspecified applications in the oral and maxillo-facial area (Fig. 68).

The indication from both groups was that a precision method of application would be of benefit and that a superior cyanoacrylate tissue adhesive was required and would use it if available.

All the surgeons who returned the questionnaire said they would be interested in knowing the results of the survey. Both groups of surgeons provided constructive and complimentary comments to the questionnaire. The comments indicated considerable interest and support for the study and for future developments.

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*United Kingdom Product Licence No. 3551/0001

Review of patients from the Bradford fire

The three year review of those patients who had skin grafts attached by means of n-butyl 413 cyanoacrylate following extensive burns showed satisfactory results. From examination of the 15 patients it was confirmed that the grafts attached with n-butyl cyanoacrylate were comparable with skin grafts attached by conventional methods. The review demonstrated the benefits of this method of graft attachment. In emergency and life-saving surgery the use of cyanoacrylate functioned effectively providing good adhesion. No cases of premature termination of adhesion were seen in this study. The n-butyl 413 cyanoacrylate combined relatively low histotoxicity and adhesive strength coupled with haemostasis. Only minimal amounts of the adhesive are required for effective graft attachment. Precision controlled dispensing ensured optimal results. No adverse medical history was noted relating to the tissue adhesive used.

After all, when the historians of Science look back on our times with the perspective of the years, all that we do today will certainly be seen to have been wrong, irrelevant, or obvious.

G. H. Herbig
In Star Formation
Reidel 1977

GENERAL CONCLUSIONS

The need for prosthetic reconstruction and the use of biomaterials in the form of prostheses and devices have become an established method of treatment in keeping with advances in medical science. More people are now surviving disfiguring injuries and disease which would formerly have claimed there lives. There is a growing awareness of plastic and reconstructive surgeons in the value of facial and body prostheses and the advantages of this form of rehabilitation.

Despite the important contribution of this field to plastic surgery, facial prosthetics has remained the Cinderella of prosthetics. Little attention has been directed to the development of new materials and techniques. The importance of specifically structured materials cannot be over-emphasized.

This study has examined the materials available with particular reference to the use of silicone elastomers for prosthetic reconstruction. The physical properties of six currently used silicone elastomers were subjected to mechanical testing to define the optimum properties required for facial prosthesis. Variation of the ratios of polymer to catalyst were examined to determine modulus variations in the elastomers.

A facial prosthesis does not require to be of the same rigidity throughout its full anatomical form. Differing areas of flexibility in the ear and nose are examples. The orbital region may need an extra flexibility to utilize the topography of a defect. The elastomers were tested to determine comparative effects of fillers to

exploit the various hardness values. This consideration is of importance in supporting areas of a prosthesis. The effects of different methods of vulcanization of the elastomers examined can determine tear strength. This data relates to durability of a prosthesis and its term of use by the patient. The qualitative pigments which constitute the colouring of human skin have been simulated by organic pigments to form skin shade variations in the elastomers.

The pigments must remain stable during vulcanization and exposure to the environment. Clinical experience in this study confirms that pigments could be further improved by continued research into colour stability, together with chemical reaction between pigments and catalysts.

Of the elastomers examined SILSKIN has been established as the most satisfactory. The physical properties and performance during mechanical testing was less than the elastomers Polyshield and HV 25. However, the tensile, modulus and tear strength is considered acceptable for general prosthetic use. SILSKIN has been extensively used for our patients. A particular advantage of SILSKIN is its ease of pigmentation and management in both clinical and laboratory procedures. The material is now used extensively in the National Health Service and ~~produced~~ marketed in a laboratory kit for international use by a U.K. medical company.*

The clinical development of osseointegration implant techniques pioneered by BRÅMEMARK are now being applied to retention and attachment of facial prosthesis. This skin penetrating implant is only successful

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*Chas. F. Thackray Ltd., Leeds, West Yorkshire.

if the facial prosthetic material used as the superstructure has the physical properties quantified in this study. The same material criteria apply to the prosthesis used in the subcutaneous Samarium-Cobalt magnets developed by SWARTZ and TSUTSUI.

Patient selection for osseointegration attachment of facial prosthesis is of particular importance. Consideration should be given to the advantage gained in relation to the surgery and possible problems that can result. In most patients effective attachment and retention can be achieved by use of correctly matched prosthetic adhesive in relation to the prosthetic elastomer used. The attachment of prostheses and devices continues to increase throughout the medical area. The prosthetic adhesives currently available are limited mainly due to the problems of biological adhesion and the diverse range of polymers used for prostheses. There is now an impetus to develop new external adhesives to function effectively in a biological environment, with reference to the prosthetic material to be attached to the skin.

No single adhesive will be completely successful in all locations under all conditions. The same observations can be made in respect to more conventional industrial applications of adhesive. This study indicates the selection and match of prosthetic adhesives to obtain the best performance in topical adherence with a reasonable time duration. Patients find handling characteristics important. Clinical experience has shown that a simple to apply adhesive which functions well is more successful than complicated mechanical methods of attachment.

The use of cyanoacrylate as a tissue adhesive as an alternative to conventional skin suture has many advantages. The use of cyanoacrylate in the Vietnam War drew attention to the potential of tissue adhesive. Major fire disasters in the UK have also demonstrated the effective use of cyanoacrylate tissue adhesive and most of the surgical disciplines report its use in specific appliations.

It has been established that n-butyl cyanoacrylate is the most tissue tolerated of the cyanoacrylatesapplied to surgery. In this study a formulation of a n-butyl cyanoacrylate has been developed in collaboration with LOCTITE UK. The current status of the adhesive n-butyl 413 meets the clinical criteria regarding minimum histotoxicity and persisting adhesion and has been successfully used at this centre for skin graft attachment.

One of the main disadvantages of the use of cyanoacrylate in surgery has been the difficulty of its application. To overcome this problem a precision applicator has been developed jointly with LOCTITE UK. The applicator enables the surgeon to have precision control of the tissue adhesive. The first model of the applicator drew on industrial experience for adhesive dispensing. The pressure system was provided by compressed air and a pressure reservoir. This was most effective but required calibration and intricate tubing. In a modified development the pressure source was obtained from a CO_2 sparklet bulb to make the system less dependent on bottle or mains air supply.

The current model uses a peristaltic pump to provide the pressure required and a simple tubing system is employed which allows

the precision applicator to be quickly set up and functional. The UV light option gives the applicator an additional facility, as fluorescent agents are defined for the adhesive. The applicator has now eliminated the handling difficulties of cyanoacrylates in the operating theatre. It has considerable potential in military surgery. A rechargeable or battery unit used to drive the peristaltic pump would make the applicator a useful instrument for battlefield surgery. A similar use can be found for the applicator in veterinary surgery.

Clinical trials of the applicator have been most successful. Surgeons and theatre staff complement its use. It is proposed to market the precision applicator with the proposal that it becomes an accepted instrument in the modern operating theatre.

The survey of surgeons confirmed the interest and need for an improved adhesive and a more satisfactory method of its application. The general interest of surgeons in the use of tissue adhesives and the increasing requests for information and assistance with surgical problems have encouraged this research.

Cyanoacrylates have made a distinct contribution as tissue adhesives. Continued study and further clinical experience will confirm their ultimate place in surgery.

SUGGESTIONS FOR FURTHER WORK

The physical and mechanical properties investigated in facial prosthetic elastomer could be further extended by considering the effects of pigment concentration on mechanical properties. Colour stability of pigments following differing methods of vulcanization together with ageing effects also need further investigation.

Room temperature vulcanizing silicone elastomers considered at present to have limited application in facial prosthetics need their physical and mechanical properties improved. This group of elastomers with enhanced properties would have considerable potential in the treatment of patients by further development of RIV systems.

Photochromatic pigments now available would be an effective method of skin colour compensation in differing environments. Investigation of these pigments as surface coatings on silicone elastomers would improve aesthetics in facial prosthetics.

Colour analysis by spectrophotometric measurement is now an established science. Hand held instrumentation for clinical use would enable a computed data base to be established of human skin colouring, providing mathematical colour simulation.

In examination of the literature and from animal and human studies there is considerable morphological evidence available concerning cyanoacrylates. Further histology now needs to be completed regarding the process of degradation. The hypothesis that histo-

toxicity is in part due to degradation into formaldehyde and cyano-acetate derivatives requires confirmation. Dr. Valerie Randall, of the University of Bradford has established a tissue culture system for skin cells and hair follicles, it is proposed to further test n-butyl 413 cyanoacrylate formulated for tissue bonding by this system.

Sterilization of cyanoacrylate by photosensitization methods indicated in this research by the use of protoporphyrin IX dimethyl-ester signify a considerable advance in sterilization technology. This method of sterilization could be used for other pharmaceutical compounds and requires further development.

The advantage of incorporating a fluorescent agent into cyano-acrylate tissue adhesive for UV light indication has been described.

Research is required into the toxicity and chemistry of fluorescent agents for medical use, in particular fluorescent agent L1-990. Heamostasis by topical application of bio-materials is developing in surgery. Heamostasis following topical application of cyanoacrylate occurs rapidly, this phenomenon is not fully understood. Investigation by electron microscopy may contribute to further understanding.

The use of cyanoacrylate as a tissue adhesive commends itself to veterinary applications. The problem of tissue closure and bone fixation in an uncooperative animal in a difficult environment would suggest a role for tissue adhesive. Clinical trials in veterinary surgery are indicated.

The Medical Bondmatic II applicator now designed to function efficiently with a paristaltic pump could be further developed by supplementing the electricity mains power supply with a battery power unit. The facility of both battery or mains power mode would further extend the use of the Medical Bondmatic II applicator. A mains power rechargeable unit could also be a design feature for future models of the Medical Bondmatic applicator.

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APPENDIX

Appendix

MICROBIOLOGY LABORATORY REPORT

Sterility Test n-butyl 413 Cyanoacrylate Tissue Adhesive

Introduction

Three specimens of n-butyl Cyanoacrylate 20_cP were submitted to the Department of Microbiology, Leeds General Infirmary, to test and check sterility (14.9.88).

Sample No I — 1 x 50ml pyrex glass conical beaker containing 20ml n-butyl 413 Cyanoacrylate. The specimen was sterilised by dry heat as described (Page 147: sterilising procedures).

Sample No II — 1 x 20gram polyethylene bottle containing 20ml n-butyl 413 Cyanoacrylate. The specimen was sterilised by gamma irradiation as described (Page 147: sterilising procedures).

Sample No III — 1 x 20gram polyethylene bottle containing 20ml n-butyl 413 Cyanoacrylate. The specimen was not sterilised and was as supplied clean by Research and Development Division, Loctite. No sterilisation procedures had been used.

Laboratory Procedure

(16.9.88)

Samples were taken using a sterile dry swab from the liquids in the three containers. Samples were also taken from the tops of the containers.

The swabs were plated onto chocolate plate CO_2 agar and blood plate anaerobic agar.

The plates were cultured for 48 hours at 37°C.

All samples were found to be sterile.