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RESEARCH ARTICLE

MAXILLOFACIAL PROSTHETICS PART - II: MATERIALS AND TECHNOLOGY. A REVIEW OF PAST, PRESENT AND FUTURE TRENDS

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Abstract

An ideal maxillofacial prosthetic material must have excellent tissue receptivity.Fabrication of maxillofacial prostheses presents various problems, such as obtaining impressions, mold construction, coloration and characterization to resemble human skin, also, the range of mechanical properties and degree of permanence desired in materials poses a challenge. Prosthetic materials should be translucent, color stable with a tendency to stain, easy to clean and be flexible conjunct to the skin which it adheres to. In addition, it must be able to adhere securely and comfortably and exhibit a fine line marginal contact.In this article the authors have tried to explain in detail about all maxillofacial prosthetic materials that have been used and are being used, with a note on the most recent 3D printing technology being researched currently for facial prostheses.

Introduction:-

Polymers and elastomers are the mainstay of modern prosthetic reconstruction. "Poly(methyl)methacrylate, poly-dimethyl-siloxane, and poly-ether-urethanes" have been used and they meet the demand for biocompatibility, durability, color stability, and easy manipulation[1,2].Regardless of the approach taken, appropriate criteria for an ideal material must be established to guide the research effort, thus,numerous researchers have assembled data from physical, mechanical, chemical and biological tests of materials[3]. As a result, several important criteria have been listed for an ideal material.

Generally, these criteria fall under two categories[3,4,5,6]-
1. Processing Characteristics
2. Performance Characteristics

Processing Characteristics[3,4,5,6]:
The basic requirement of a prosthetic material is that, it-
1. Should allow inexpensive fabrication.
2. Should be castable andshrinkage free.
3. Should have adequate pot life (working time).
4. Should have adequate viscosity.

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Performance Characteristics[3,4,5,6]

Tensile strength, elongation at break, modulus, and tear strength together define resistance of prosthesis to rupture. Although, high values of strength, toughness, and tear strength, or low values of hardness and modulus, are desirable, highest or lowest values of these are not a goal, because a material possessing these properties in extreme would be unacceptable for use.

Ideal Physical and Mechanical Properties[2,7,8,9]

1. High edge strength allowing thin margins
2. High elongation, abrasion resistance, tear and tensile strength
3. Low glass transition temperature imparts flexibility
4. Low specific gravity, surface tension and thermal conductivity
5. Non-inflammable
6. Non-absorbent
7. Translucent
8. Light weight

Ideal Processing Characteristics[2,7,8,9]

1. Adjustability
2. Post-processing chemical inertness
3. Dimensional stability during and after processing
4. Longpot life
5. Low processing temperature and short processing time
6. Long shelf life

Ideal Biological Properties[2,7,8,9]

1. Non-toxic, non-allergenic and non-carcinogenic
2. Inert to solvents and adhesives
3. Permeable to moisture release from underlying tissue
4. Resistance to growth of microorganisms
5. Maintained consistency during use

Considerations in Material Selection:

The range of mechanical properties and degree of permanence desired in materials present a challenge. An ideal material must allow accurate forming and retain fine details without distortion, additionally;it must be translucentto allow tinting to simulate pastel skin tones. It must be durable and resistant to outdoor weathering[1,2,7].

It should be flexible, i.e.; as the underlying facial musculature contracts and relaxes; the prosthesis should undergo similar movements. In addition, it must adhere securely and exhibit a fine line marginal contact[10].

Acrylic polymers are used extensively in fabrication of intraoral prostheses and for someselective immediate facial prostheses. Soft, flexible auto-polymerizing copolymers are used in chair-side refitting and relining procedures[10,11,12].

Some formulations of room temperature vulcanizing (RTV) silicones are difficult to color intrinsically, have reduced tear strength andpoor processing characteristics. Curing can be accelerated in a dry heat oven at 85° - 150°C[10,11,12].

Heat/high temperature vulcanizing (HTV) silicones exhibit higher tear strength. Metal molds or high-density stone contained-in-metal molds are preferable because of the high viscosity and compression molding technique used[10,11,12]. Adequate color stability, controlled intrinsic coloration, and satisfactory edge strength are a few of the clinically important qualities obtainable with these.

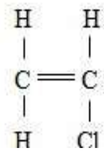
Materials in Maxillofacial Prosthesis:

Vinyl Polymers and Copolymers:

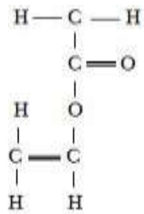
These are the most widely used plastics for prostheses. In the elastomeric form, vinyl exhibits properties superior thannatural rubber in flex life, resistance to sunlight and aging. Copolymers of vinyl chloride and vinyl acetate are more flexible but less chemical resistant than polyvinyl chloride[13].

Vinyls are derivatives of ethylene. Thus, the formula for vinyl chloride is[14]:

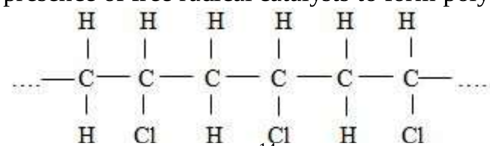
$$(CH_2 = CH_2)$$



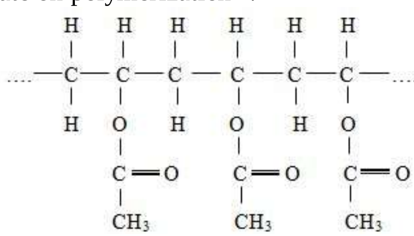
and for vinyl acetate[14]:



Vinyl chloride is polymerized in the presence of free radical catalysts to form polyvinyl chloride[14]:



And vinyl acetate forms polyvinyl acetate on polymerization[14]:



Polyvinyl chloride is tasteless and odorless, clear and hard resin. It darkens when exposed to ultraviolet light, and requires heat and light stabilization to prevent discoloration during fabrication and use[13,15]. Example – EVA Flexible Copolymer, OP-TEK® Flex, Duraflex®, Proflex, or Orfitrans™ Excel.

Acrylic Resin:
Poly(methyl)methacrylate is a hard, transparent resin of remarkable clarity and stability. These can be injection and compression moulded.Both intrinsic and extrinsic coloration can be utilizedto achieve basic skin color and they do not discolor in ultraviolet light[16,17,18].

Heat-polymerizing methyl methacrylate is preferred over the auto-polymerizing. Facial prostheses made of this material remain serviceable for up to 2 years, but they require occasional surface repainting[19,20,21].

It allows feather margins, easy alterations, adhesive compatibility, easy cleaning and bonding with other plastics[20,21].

Rigidity is the primary disadvantage, making them less useful in highly mobile tissue beds and in undercut areas. Psychologically, acrylic is less acceptable by the patient[21,22].

Acrylic Co-Polymers:
These are soft and elastic but are not widely accepted because of poor edge strength, durability and degradation under sunlight and difficult processing and coloration. They also readily acquire dust and stains[23,24]. Example- Palamed – Kulzer.

Polyvinyl Chloride Co-Polymers:
Their earliest form was vinyl plastisol, introduced in 1940[13]. These contain vinyl resins and a plasticizer. In its plastisol stage it is a thick liquid to which pigments are incorporated. Vinyl resins are partially dissolved by plasticizer when heated, resulting in a flexible prosthesis[14,25].

Recently a copolymer of 5-20% vinyl acetate with the remaining percentage being vinyl chloride has been introduced. This copolymer is more flexible but, less chemically resistant than polyvinylchloride itself[14,25,26].

The primary disadvantage is plasticizer migration and loss, resulting in discoloration and hardening of the prosthesis.

Edges tear easily and require reinforcement with nylon mesh. They get easily stained and degrade on exposure to ultraviolet light, peroxides and ozone and absorb sebaceous secretions. Their clinical service may extend from 1-6 months[26].

Latex:
They were once used extensively forfabrication of life-like facial prosthesis. However, it changes color rapidly and the finished product is weak, degenerating rapidly with age. Hence its use as a prosthetic material is limited[11,12,13].

Ter-PolymerLatex:
These materials are under investigation. It consists of two latexes based on acrylate monomers with formaldehyde as a cross-linking agent[27,28].

Prostheses are fabricated by dip-casting over male models. The mechanical properties achieved are in the desired range for an extra-oral prosthetic material[29].

Ouellette reported that the unnatural milky, see-through appearance of prosthetic devices fabricated from ter-polymer latex could be eliminated by secondary spraying of the outer surface with an oil dye[30].

Chlorinated Polyethylene:
These are thermoplastic elastomers available as thin sheets in a variety of shades. The sheet is heated and placed between heated metal mould halves and the prosthesis is formed in a hand press.The prosthesis can be colored with oil-soluble dyes[31,32]. Chemically, CPE closely resembles polyvinyl chloride. It is resistant to environmental degradation and can be developed into soft, tough elastomers without the need for plasticizer[33,34].

Lewis and Castleberry reported similarity of this material to polyvinyl chloride in both chemical composition and physical properties[6,34].

Polyurethane Elastomers:
These serve a variety of commercial uses and can be synthesized with wide range of physical properties.

They arise from 2 major reactants. In the presence of a catalyst, polymer terminating with an iso-cyanate is combined with one terminating with a hydroxyl group. Varying number of iso-cyanates will change the physical properties of final product[13].

Commercially, Epithane -3 is the only polyurethane used in facial restorations. It consists of a soft polyol component, a hardand toxic iso-cyanate component and an organotin catalyst. Their flexibility is wellsuited to defects with movable tissue beds. They can be colored both intrinsically and extrinsically and superior cosmetic results can be obtained[35].

Extrinsic colors wear off rapidly on exposure to ultraviolet light and surface oxidation.

Clinical usefulness is generally less than 6 months. Polyurethanes have poor compatibility with existing adhesive systems[35].

Isophorone Polyurethane:
A unique polyurethane elastomer based on a cycloaliphatic diisocyanate monomer is being developed and tested. It is a three-component kit comprising an isocyanate terminated prepolymer, a triol as the cross – linking agent, and an organotin catalyst. These have unusually high strength compared to other aliphatic polyurethanes. The aliphatic nature of the polymer improves resistance to sunlight degradation[36,37].

Other Polyurethanes:
Goldberg et al, reported synthesis of a series of polyurethane elastomers based on aliphatic diisocyanate and a polyether macro-glycol. The elastomers displayed high strength and elongation necessary for maxillofacial applications and exhibited satisfactory resistance to ultraviolet light[35,36,37].

Silicone Elastomers:
These were introduced in 1946, but are being used as prosthetic materials only for the past few years.

Silicones consist of alternate chains of sodium and oxygen which can be modified by attaching various organic side groups to the silicon atoms or by cross linking the molecular chains.They exhibit good physical properties over a range of temperatures and can be cured at room temperature or under high temperatures[38,39].

Silicones are classified into 4 groups according to their applications[40]:
1. **Class I:** Implant grade.
2. **Class II:** Medical grade. This material is used for fabrication of maxillofacial prosthesis.
3. **Class III:** Clean grade.
4. **Class IV:** Industrial grade.

Silicones can also be classified according to temperature of vulcanization[40]:
1. High/Heat Temperature Vulcanizing (H.T.V)
2. Room Temperature Vulcanizing (R.T.V)
3. H.T.V Silicones

HTV silicone is usually a white, opaque and viscous material. The catalytic agent is dichlorobenzoyl peroxide or platinum salt depending on condensation or addition polymerizationrespectively[2,7]. Pure, finely divided silica particle of about 30 microns are added as fillers. A small amount of methyl vinyl or methyl phenyl siloxyradical varies the relative softness and tear strength[8,11,12,13].

After milling to blend the catalyst and coloring pigments, the material is packed under pressure and cured at 180ºC for 30 minutes[13].

Available as1 or 2-component system[29,41,42]:
Catalyst- Dichloro-benzoylperoxide/ platinum salt.
Silica- As filler with particle size 30µm.
Various types of HTV Silicones[43,44,45]:
1. Silastic S-6508, 382 and 399 (Michigan).
2. Silastic S-6508 in raw stage is similar to sticky modelling clay. It must be vulcanized at 260°F and formed in pressure moulds.
3. Silastic 382 is an opaque white fluid with a viscosity resembling thick honey.
4. Silastic 399 resembles white petroleum jelly in its raw state. Easily spatulated,non-flowing.
5. Silastic 382 is tougher, non-flowing, easier to handle.

SE-4524U:
This silicone requires moderate to high temperatures for initiation of cross-linking reaction[42]. The Silastic 44514 and 44515 available from Dow Corning are of the same type. Organic peroxide initiates the cross-linking reaction, therefore, prosthesis must be fabricated at a temperature high enough to cause decomposition of the peroxide catalyst[42,45]. Lontz et al have found that when bis-2,4-dichlorobenzoyl peroxide is used as catalyst, prosthesis can be processed at 100˚C. Amount of catalyst and fabrication temperature affect the properties of the finished prosthesis[42].

PDMSiloxane:
This HTV silicone has physical and mechanical properties that exceeds values considered clinically acceptable[45,47].

Q7-4635, Q7-4650, Q7-4735, SE-4524 U:
These are new generation of HTV silicones, which have improved mechanical and physical properties[45,47].

Siliastic S-6508:
In the raw state it is similar to sticky modeling clay. It must be vulcanized at 260°F and formed in pressure moulds[45,47].

R.T.V. Silicones:
RTV silicones are designed for rapid room temperature curing. They are short-chain silicone polymers with cross-linking agent such as tetra-ethoxysilane,withstannous octoateas catalyst.

After addition of catalyst and careful introduction into the mould, it is allowed to cure for 30 minutes. The prosthesis is removed from the mould and thoroughly cleaned with chloroform before proceeding towards extrinsic coloration and characterization[2,7,8,11,48,49].
It includes[12,13]-
A filler- Diatomaceous earth particles.
A catalyst-Stannousoctoate.
A cross linking agent- Tetra-ethoxysilane.

Silastic 382,399:
Thesepolymerize by condensation reaction. These are colorstable, biologically inert, and retain their physical and chemical properties at wide temperature ranges[50]. These are much easier to process and moulds of dental stone can be used. Silastic 399 is translucent and Silastic 382 is opaque and white[51].

Silastic 891:
It is also known as SilasticMedical Adhesive Silicone Type A and is a methyltriacetoxysilane-cross-linked silicone. It is a translucent, non-flowing paste, which polymerizes at room temperature on contact with moisture[52,53]. It does not contain solvents, plasticizers, or catalyst and can be processedin gypsum moulds. Metal moulds are not recommended as it may react with acetic acid, which is liberated as a by-product of polymerization. The color stability is good and is compatible with a wide range of colorants[53,54].

Cosmesil:
Cosmesil is an RTV silicone which can be processed to a varying degree of hardness. This material shows higher tear strength at failure than MDX 4-4210[50,51].

A-2186:
It is a recently developed material whose physical and mechanical properties are inferior compared to MDX 4-4210[50,51].

Polyderm:
Polyderm is an RTV silicone consisting of short chain dimethyl polysiloxane polymers, cross-linking agent and highly dispersed fillers. It is specially formulated for facial and body prosthetics. It is supplied as basic skin shade and clear base, which can be characterized by addition of intrinsic pigment. Extrinsic pigments are supplied with the kit[50,51].

Materials of the 3rd Millennium:
According to Remerdale E.H. these are expected to be translucent with pigmentation ability to match any skin color[9]. They should have following characteristics-
1. Increased elongation.
2. Increased tear strength.
3. Should be easily mouldable (clay like consistency).
4. Cured with light.
5. They should readily accept extrinsic coloration.
6. High temperature – metal moulds should not be necessary.

MDX 4-4210:
This is a medical-grade silicone elastomer most popular among clinicians. Moore reported that it exhibits improved qualities of coloration and edge strength[54].

It is based primarily on a modified polydimethylsiloxane structure;polymerization involves addition of Si-H groups to Si-vinyl units. A platinum catalyst initiates the cross-linking reaction;sensitive to amines, sulphur and tin compounds, inhibiting curing of the material. It is not as opaque as other highly filled silicones[55].
It is available as a two-component kit. It has chloroplatinic acid catalyst and hydro-methylsiloxane as cross-linking agent[56].

Recent Advances:
Silicone Block Copolymers:
These have been introduced to improve tear strength, low percent elongation and susceptibility to bacterial growth[56].

Foaming Silicones:
A gas forms bubbles within the polymerizing silicone which is eventually released; leaving a spongy material causing an increase in volume by as much as sevenfold[42,43,44].

The purpose is to reduce the weight of the prosthesis; however, it has reduced strength and is susceptible to tearing, which, can be partially overcome by coating it with another silicone.

This adds strength but increases stiffness[45,46,56]. Eg. Silastic 386.

SiphenylenePolymer:
It is another siloxane copolymer with phenyl and methyl groups and exhibits significant improvement with respect toedge strength, coloration, and lowmodulus of elasticity relative to other RTV silicones[10,56].

Primers:
Various primers such as 1200, 1205, S-22602, 4040, Z6032, Z6076 are available. Primers are used to promote bond between silicone and other maxillofacial material. S-2260 and A-4040primer were found most effective in bonding Medical Adhesive Type A to polyurethane sheets. A-4040 primer has greatest bond strength when bonding Silastic 891 to Lucitone 199 denture-based resin andZ-6032 produce the highest bond strength between silicone elastomers and light activated resin[10].

Printable Silicones:
A 3D color image reproduction protocol has been developed for 3D printing of facial prostheses. It involves 3D scanning of the face using a photogrammetry system that captures both 3D topography and color information. Using a combination of software suites, raw scanned data can be modified and corrected by removing noisy polygons, along with color adjustment[57,58,59].

In order to add realism, fine textures (e.g. pores, wrinkles) are added over the 3D mesh using high- field mapping. Finally, thickness is added to get a solid printable model[57,58,59].

As with the surface topographic information, the color images may also require further processing before final colour printing, which involves, management of the 2D color image from the camera RGB to printer RGB pixel by pixel. When the color is finalised, surface texture mapping is done to map the new color image onto the 3D model. The penultimate step involves printing to produce the 3D model[57,58,59]. Which can be done by two methods-

1. **Silicone Infiltration.**
2. **Direct Printable Silicones.**

Silicone Infiltration:
A full color 3D printingtechnology called 3DPTM printing, also known as powder–binder printing has beendeveloped at MassachusettsInstitute of Technology and is licensed to Z Corporation and 3D Systems, it is based on inkjet printing, with a powder being deposited in consecutive layers, which is then selectively joined by ink- jetting with coloredbinderto print powder material in a fullcolor spectrum, layer by layer[57,59,60].

The powder can be made of gypsumin combination with plastic powder, starch, ceramic, glass or otherpowdered materials.

After printing color into the powder, infiltration with elastomeric polymer is carried out to produce aflexible, lightweight and lifelike prosthesis[60].

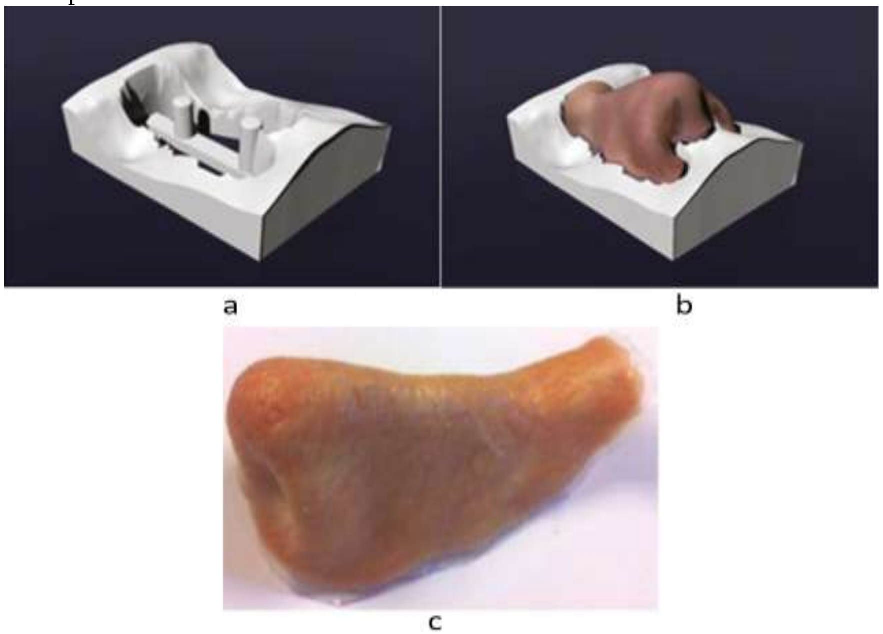


Fig 1:- a.Infiltration powder deposited in layers for nasal prosthesis. b.Infiltration of silicon in powder with basic color. c.Finished final nasal prosthesis with extrinsic coloring.

Direct Printable Silicones:

This technology is called as Drop-On-Demand (DOD) printing and is basedon platinum-catalysed addition polymerization, meaning the crosslinking Si-H groups react with the vinyl groupto form a 3D network[60,61,62].

A puresilicone free of solvents isused. This technologyuses single satellite droplets that are dosed onto theworking surface according to the STL mesh, and eachlayer (0.4 mm) is polymerized with ultravioletlight. After this the finished prosthesis is then coated with a suitable silicone polymer, is colored extrinsically and is finally cured at 200ºC[60,61,62].

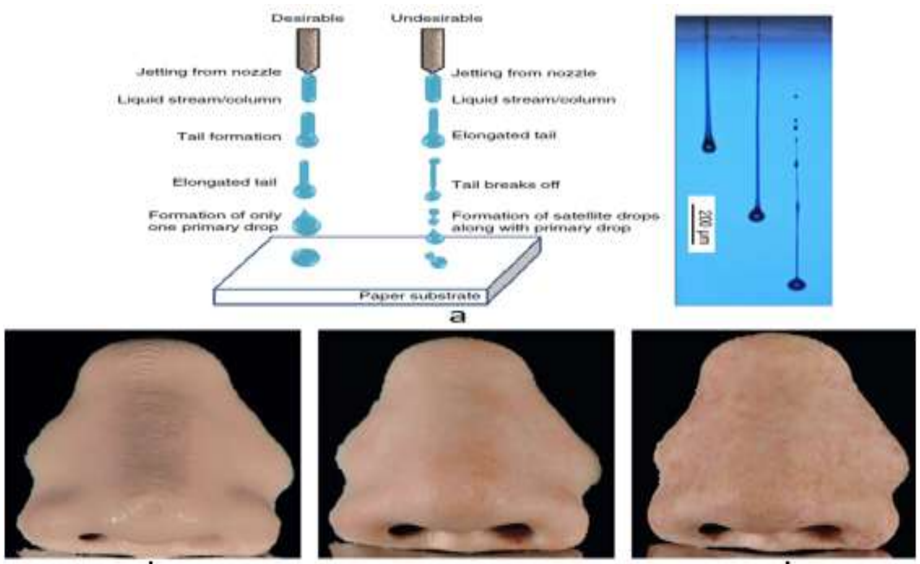


Fig 2:- a.Schematic diagram illustrating the formationof undesirable satellite droplets& photographic image of satellite droplets. b.Finished nasal prosthesis immediately after droplet addition in basic skin color, note the spread of silicone layers near bridge of the nasal prosthesis. c.Finishing of the nasal prosthesis. d.Final nasal prosthesis with definitive extrinsic coloration and characterization.

Conclusion:-

Patients with maxillofacial disfigurement experience a change in societal acceptance that greatly affects their psyche, and their expectation of a normal life collapses[63].

With continual advancement in prosthetic materials, coloring techniques and retentive mechanisms, a life like prosthesis is possible. The biggest impact of such prostheses is not only on the appearance but majorly on the psyche of the patient. The main objective is not only over all restoration but rehabilitation of the patient's quality of life[63].

Out of all the materials discussed here, it becomes obvious that no single material is ideal for every patient. Material selection largely depends on the type of defect and patient acceptance. Though, some materials do hold promise of long-term clinical use, but, still further development is required. Some of the problems inherent inall these materials are[64]:

1. The continued effect of environmental factors, vascularity and movements exhibited by natural tissues,cannot be duplicated.
2. The variations of skin tone due to various light sources and emotional factors cannot be duplicated.
3. Full facial movement of the non-defective side cannot be duplicated.
4. Various patient related factors that make the life of a prosthesis questionable.

The ultimate challenge is clinical performance, research should concentrate on two major goals-

1. Improving the physical and mechanical properties of the material.
2. Finding stable coloring agents and developing a scientific method of color matching.

When it comes tofabrication, 3D printing holds great promise in delivering an accurate and wellfitting prosthesis in a fraction of a time when compared to conventional techniques, but still the materials and coloration techniques involved require a lot of research and development.

Conflict of Interest:
None

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