PUBLIC HEALTH FOUNDATION OF INDIA

ASSOCIATION OF HEALTHCARE PROVIDERS INDIA

Indian Institute of Science

Indian Institute of Space Science and Technology

Certificate Course in

Healthcare Technology (CCHT)

Module 3 : Technology- led Health Care Part 2

Smart materials enabling smart devices in healthcare

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Smart materials enabling smart devices in healthcare

Learning Objectives:

- To gain basic understanding about smart materials
- To identify smart material components in selected healthcare devices
- To understand the working principle of piezoelectric, SMA and SMPs.
- Identifying piezoelectric, SMA and SMPs components in selected healthcare devices
- To identify the factors that influence the performance of these smart devices (through case studies)
- To delineate research interventions to improve the capabilities/build new capabilities in smart devices (through comprehending suggested research articles)

Overview of Session:

Smart devices in healthcare are believed to increase physicians' productivity, efficiency, and accuracy and to improve patients' access to medical care. These devices facilitate the collection of crucial information in real-time about patients' or users' health, both continuously and non-invasively. New opportunities for remote and continuous healthcare monitoring in non-clinical settings are rapidly emerging. It's important that physicians and healthcare personnel become familiar with the strengths and limitations of today's smart devices. This module outlines 'smart devices in healthcare' and is formulated with the following learning outcomes.

- Learners can define smart materials with respect to stimuli and response
- Identify smart materials in selected healthcare devices
- Understand the working technology of these smart devices
- Learners will identify and appreciate functional role of smart materials in these devices
- Acquire knowledge on performance enhancement in these devices
- Appreciate advantages of being physician-scientist

Detailed reading content:

As you may be aware, smart devices in Healthcare are believed to increase physician's productivity, efficiency and accuracy and to provide improved access for patients to modern medical care. These Healthcare devices facilitate the collection of crucial information in real-time about patient's or in general the user's health both continuously and non-invasively. With the emerging opportunities for remote and continuous healthcare monitoring in non-clinical settings, it becomes important that Healthcare personnel become familiar with the capabilities and limitations of today's smart device. This module is framed to provide the learners with the following outcome. Learners can define smart materials with respect to stimuli and response, they can identify smart materials in selected Healthcare devices and understand the working technology of these devices. Learners will also identify and appreciate the functional role of smart materials in these devices and Acquire knowledge on the performance enhancement in these devices and finally the lecture will close by discussing the advantages of being a physician-scientist.

This module starts with a brief introduction to health care technology which is leading to the current medical revolution. Then being a materials chemist, I will talk about materials design, the paradigm shift from chance discoveries to customised design of materials and their transition as building units for devices. To introduce smart materials, I'll use common examples from nature and the concept of biomimetics in medical devices. Then about how we can take smart materials to smart devices by listing a few devices commonly used and depicting the functional role of smart materials inside those devices. I will also be discussing the basic theory of piezoelectric material, Shape Memory Alloy and Shape Memory polymer and will sum up the module by introducing a few very common examples of the application of these smart materials in healthcare devices. Now let's start with the introduction. As you are aware, Healthcare Technology can be any technology, device or digital solution designed to improve patients' health. Healthcare Tech development has major benefits and leads to highly improved Medical devices, that means products for performing a therapeutic or diagnostic action by physical means, in vitro diagnostic systems, and non-invasive assays analysing biomarkers of pathologies in biological samples. With the advancement in materials science especially in nanomedicine, photonics, biomaterials along with those in robotics and digital health, presently a medical revolution is ongoing. From a science driven revolution now it has moved to a technology driven solution. In my lecture I will be talking about selected smart materials which initiated materials revolution in Medical Technology whereas the technological revolution which we currently observe will be discussed in some other module.

Now let us travel some two decades back in time. On September 7, 2001 something unimaginable until then happened in the field of medical technology, doctors in the US performed the first long distance surgery, a laparoscopic cholecystectomy on a patient in Strasbourg France and the patient was discharged without any complications two days later. It was the first robotic surgery, demonstrating the ability to perform complex surgical manipulations from remote locations, most importantly note that the barriers imposed by geographical distances are no more valid. The access to medical expertise including surgical expertise can be made available throughout the globe, thanks to information technology

Now let's take a closer look. Obviously tele surgeries require a secure, reliable and fast network connecting the doctor's hand movements in place A (US in this case) to the devices located in the patient's body (in Strasbourg). How do these devices perform the job? So that question leads us to the advancements in materials science and technology which have provided us with functional materials and recently the smart materials so that devices that are smart could emerge.

The graphic visualisations of the human body (head here) and its organs by German scientist, gynaecologist and author Dr Fritz Kahn as a way to explain complex functions is depicted here. Man-machine analogy is an interesting and important aspect both in robotics and physiology and interested ones can read more from web resources.

To start talking about materials, it would be a good start from Dmitri Medeleev, the Russian chemist and the inventor of the periodic table of elements. One of his important quotes on materials is worth mentioning here. So both having a material and a plan for the utility of the material are equally important. When it comes to materials for healthcare, starting from the simplest syringes, catheters or latex gloves, to high-tech devices, for instance full body 3D scanners or neurostimulators the demand for materials are also highly diverse. Since materials require combining of atoms to molecules and in varying numbers and proportions, there is no wonder that in earlier times many of the materials were encountered by mere chances whereas currently we do understand the relationships between the materials and processes and thereby able to custom design materials for specific applications. In the present times, we do have the capability to design and develop so called advanced functional materials like smart materials or the completely artificial property possessing metamaterials for applications in the diverse fields, a few of them as listed here.

What are functional materials? These are materials with specific properties and we can tailor the properties of these materials to suit the applications. For example, a magnetic material, a ceramic material, or a piezoelectric material etc. Our discussion is towards smart devices/components for healthcare and hence I will now give a brief introduction to smart materials. Smart materials are functional materials that produce an output in response to a stimulus in a reversible and optimal manner. The stimulus can be light, heat, pressure, magnetic field and so on. The response can be a change in shape, color, electric conductivity, etc. These materials offer huge advantages to materials chemists in that these materials and their 'smartness' are tailorable and tunable, a synthetic chemist can do that. In my lab, we work on one or more categories of smart materials for medical to space applications.

Another important contemporary concept is biomimicry. Here we try to get inspired and learn from nature for the development of new functional materials and thereby better performing devices. For example, in the context of this course, energy-health relationships and the challenges in healthcare delivery in remote areas due to limited or no access to energy is something you people may well appreciate. The solar cells inspired by photosynthesis in plants is one among the bioinspired approaches to solve the energy issue. Other examples include high strength fibres inspired by spiders, multifrequency radars inspired by bats, camouflage skins inspired by squids etc. The very fact that the designs of nature is a result of prolonged optimisation leads to maximum efficiency and perfection in the devices if we are able to mimic nature in its totality.

Biomimetics is applicable/has been applied to medical devices? The answer is yes. Bioinspired surgical instruments, prosthesis and orthoses are documented in literature. However, we are far behind nature in this process and what is demanded in a holistic process where each stage demands high precision right from the product ideation to the compliance followed by designing testing and up to marketing of the product. Now let's link the bioinspired approaches and the medical device industry. The bioinspired approaches applied in any sector owes a lot to the field of biology, chemistry, materials science, medicine and engineering for the design and fabrication of advanced devices. The major processes in the most highly regulated sector namely the medical devices sector can be divided into two - the first part comprising the research and discovery where the materials scientists need to closely work with physicians and the second part where the design & development happens leading to commercialisation. The stringent quality measures and product requirements vary from product to product. A few examples of bioinspired devices that have appeared in the market are listed - synthetic vascular grafts, electronic pacemaker, coronary stents and LVA devices are representative examples. The bottom line is that the discovery/application of bioinspired devices is a burgeoning area of research and we can add more advantage in the devices by bringing in smart material components.

The remaining part of the lecture will focus on smart materials, the definition, science behind the working of smart materials and some of the components used in healthcare devices which have smart materials in them. Smart materials have the ability to reversibly modify one or more of their functional or structural properties in response to a stimulus or a change in the surrounding environment. In other words, they are materials or systems which are capable of sensing and responding to the environment around them in a useful and predictable manner. They differ from the control loop mechanism in that the same material adapts itself to suit the changing environment. That means the functions of sensing, adaptability, memory and other multiple functionalities are in-built in a smart material. For a better clarity this cartoon depicts the critical components in a smart material - a sensing device, a communication network, a decision-making unit and an actuating device. This actuating unit can be inherent to the material or externally coupled to it. The stimulus can be temp, pressure, electric field or magnetic field whereas the response of the material can be a change in shape, viscosity, color, dipole moment etc. Examples of smart materials are optical fibres, piezoelectric polymer/ceramics shape memory alloys, shape memory polymers and so on.

This table lists a few of the input-output and the terminologies in the smart material domain. It may be noted that those responses in the green dotted box are sensors and those in the red box are actuators (we can derive useful work out of them). The learners can get a better understanding of the concepts from the suggested readings.

In the remaining lecture I will be talking specifically on three categories of smart materials namely piezoelectric materials, shape memory alloys and smart polymers with examples of their utility in medical devices.

Before that, one important point I wanted to remind you is to nurture the physician scientist inside you because we require such people to bridge the gap between medicine and science so as to revolutionize the medical device sector and advance the medical knowledge. A noteworthy point is that more than 50% of the nobel prizes in physiology and medicine were bagged by physician scientists. Going back and forth between science and medicine should happen naturally and that is one of the reasons for floating this course.

Piezoelectric materials - the word originated from the Greek root piezein meaning pressure and Latin word electrum meaning electricity- piezoelectric materials produce an electric current in response to mechanical stress. The process is reversible and hence when we apply an electric current to these materials, they will actually change their shape/deform slightly. We can find many piezoelectric materials in nature and we can synthesise them in the laboratories as well. They make the critical component in an ultrasound scanning machine- namely the transducer component. From diagnostic testing to detect fetal heartbeat for the first time to surgical devices that can treat rare cancers, these ultrasound transducers play a key role in healthcare today. In a piezoelectric material, when compression and tension generate voltages of opposite polarity that are proportional to the amount of force used, the phenomenon is called direct piezoelectric effect. There is another phenomenon called Inverse piezoelectric effect which refers to the reverse property — where a piezoelectric material contracts or expands in accordance with the polarity and strength of an electric field. The voltage or mechanical change create very small expansion, but with a huge impact on technology. Common Devices include electric lighters, microphones, transformers, ultrasonic transducers and actuators.

The fundamental mathematical relationships in piezoelectric material reveals that in the direct piezoelectric effect the polarisation P is directly proportional to the applied stress (ie force applied per unit area) whereas in the converse effect the strain is directly proportional to the applied voltage E. The proportionality constant d, is called the piezoelectric constant is a third rank tensor so the directions are also important while discussing piezoelectric property of a component. For any piezoelectric material the properties need to be explained on the basis of the cartesian coordinates X, Y and Z. Usually the Z axis if fixed and called the poling axis and the piezoelectric properties are discussed wrt to this axis which is also called the 3-axis which indicates the direction of polarisation.

The unique coupling of electrical and mechanical properties leads to the smart performance of piezoelectric material. A detailed discussion is beyond the scope of this lecture.

Now comes the fundamental question - Why only certain materials show piezoelectricity? A straightforward answer is that a material's ability to be piezoelectric is directly related to its crystalline structure. When the static crystal structure is disturbed by as little as 10%, the atoms are disturbed, and a charge is created. This brings in the materials scientists/synthetic chemists role of creating new piezoelectric materials by careful atomic manipulations in well-designed crystal structures. We will now take the specific example of the ultrasound transducer and see how the smart piezo component helps in generating the output from the device. Diagnostic transducers act as both a transmitter and receiver of ultrasound and are able to produce beams which can be directed in various ways to improve the quality of the images that we see on screen. The primary component of the transducer is made from a piezoelectric material which means they are able to convert one form of energy to another, in this case electrical energy into mechanical energy and vice versa.

Components and assembly of a simple single element circular transducer is illustrated.

Although there are many types of transducers ranging from a simple single element to electronic multi-array probes which have hundreds of elements, the basic components and construction of these different types of transducers are principally the same.

The main components of a typical ultrasound transducer consist of: physical housing assembly, electrical connections, piezoelectric element, backing material, acoustic lens, and impedance matching layer. The physical housing contains all the individual components including the crystal, electrodes, matching layer, and backing material. It provides the necessary structural support and acts as an electrical and acoustic insulator. Electrical connections, two of them, are formed on the front and back face of the crystal by plating a thin film of gold or silver on these surfaces. These thin electrodes are connected to the ultrasound machine which generates the short burst of electrical pulses to excite the crystal and through the piezoelectric effect generates a pulse of ultrasound energy. Now the crucial component is the piezoelectric crystal - What is it made of? You have seen that quartz is a naturally occurring material with piezoelectric properties and hence was extensively used in the development of early machines. But Research over the years has provided some better performing man-made ceramics such as lead zirconate titanate (PZT) which is now commonly used. PZT is more efficient, has better sensitivity, and can easily be shaped also. With many types of ultrasound transducers available, which one to be selected before performing an ultrasound investigation is a crucial decision. WE should pay much attention in selecting the most appropriate transducer for the application. How can one do that? We now know that a piezoelectric transducer produces ultrasound because the material used to manufacture the transducer vibrates when an AC voltage is applied. This vibration creates very high-frequency air pressure waves; at rates of 10MHz or higher. To produce ultrasound waves at these frequencies most medical applications of ultrasound use lead zirconate titanate or Barium Titanate ($BaTiO_3$) ceramics as the piezo element. These same materials can also work in reverse, to detect ultrasonic waves and convert the energy from those waves into an electric signal. Now the fitness for purpose is decided on the basis of transducer type and operating frequency.

Ultrasound transducers are described by their type and operating frequency which can range from 2 MHz up to 20 MHz. The selection is based on their 'fitness for purpose for which the end user needs to recognize that different applications require an appropriately selected transducer which is best suited for a particular investigation. Frequency and depth of penetration are critical parameters. It is to be noted that higher frequencies (meaning lower wavelengths) will have lower depth of penetration and vice versa. Caution here; a trade-off exists between the image resolution and the penetrating depth. To provide an example, a 12 MHz transducer has very good resolution, but will not penetrate very deep into the body compared to a 3 MHz transducer which can penetrate deep into the body. However, the resolution for the 3MHz one is not as good as 12 MHz one. Thus the bottom line is that for general use, the highest frequency transducer which will reach the required depth should always be selected for use.

How do you determine a transducer's operating frequency? The operating frequency is critically governed by the thickness of the piezoelectric crystal. For maximum efficiency the crystal should be operating at its 'natural' or 'resonant' frequency, which is a material dependent property. This max efficiency occurs when the thickness of the crystal corresponds to half a wavelength ($\lambda/2$). Since wavelength and frequency are inversely related, thinner piezoelectric materials should produce higher resonant frequencies. Typical diagnostic ultrasound elements are between 0.2 mm and 1 mm thick.

Work out the numerical with this simple equation and understand the relationship between the thickness t of the piezoelectric transducer and its operating frequency f, Remember that wavelength is inversely proportional to frequency. You can also find out these specs for the probe which your hospital/medical centre is using.

Now we move on to the next category of smart material namely shape memory alloys. Shape memory alloys (SMAs in short) are a group of metallic materials that have the unique ability to recover a previously defined shape when subjected to heat or a mechanical stimulus. We call it the thermomechanical load. They find immense applications in consumer products like sunglasses to a large number of medical devices- for example, in orthodontics, coronary stents, artificial myocardium, bone staples, jaw plates and a lot many cardiovascular and surgical devices. Shape memory alloys have a "memory" and hence can go back to a predetermined shape upon action of a stimulus. But if we impose a restriction on the material from going back to its shape, they generate high restitution forces. Although a relatively wide variety of alloys exhibit the shape memory effect, only those that can recover from a large amount of strain or generate considerable restoration force are of commercial interest. To mention a few, alloys based on Ni-Ti and on Cu, such as Cu-Zn-Al and Cu-Al-Ni. In medical applications, Ni-Ti based alloys are most frequently and specifically NiTinol because of the combination of good mechanical properties with shape memory. There are two functional properties for SMA- namely shape memory effect and superelasticity and both arise from the crystallographic (atom-level) features. When we apply the stimulus, these alloys undergo a solid-to-solid, reversible phase transformation where the two phases have distinct physical, mechanical, thermal properties. Also, they have the ability to both sense and actuate and hence are multifunctional.

Coming to the science behind the material, NiTi SMA accommodates a large amount of inelastic deformation by atomic lattice rearrangements called discrete forward and reverse phase transformation. This thermoelastic diffusionless martensitic transformation (MT) occurs at slightly above room temperature. (in fact the transition temp can be varied with alloy composition). Upon cooling, the SMAs undergo a first order structural transition from the high temperature austenite phase to the low temperature martensite phase. It is important to remember that the martensitic transformation is a displacive phase transition and it occurs by coordinated shifts of atoms and there is no long-range diffusion during the phase change.

If the shape recovery is obtained after removal of the load, it is superelasticity and if recovery occurs upon application of heat it is a shape memory effect. Thus it is understood that the governing parameters for a thermoelastic NiTi SMA is stress, temperature and the thermal-mechanical loading histories. How to make the material/actuator stable? Two solutions are listed here - Solution 1: Thermomechanical “training” (e.g., cycling, reverse loading…) and Solution 2: Alloying and microstructural control (e.g., precipitation hardening). Physicians working with SMA components need to discuss their experience with materials scientists for improving/customising the properties. The stress-strain plot of a normal metal (ie: without Shape memory property), and the other two for shape memory effect and superelasticity respectively. In case 1 the material suffers a permanent deformation whereas in 2 heating will restore the original shape and in 3, i.e. superelasticity, unloading will lead to the shape restoration. The temperature for this shape recovery in the case of superelasticity should be above the austenite start temperature.

Analogous to these SMAs, we have another category of smart materials in the polymer category having shape memory behaviour and widely used in medical devices. They are the shape-memory polymers (SMPs) which can revert to their original shape at a designed temperature (the most commonly employed). These materials gain the property by virtue of their architecture combined with processing parameters. For activating the SME, the use of body heat, external heat, lasers, magnetic particles, moisture, and light are generally used. However, in comparison to SMAs, the restoration forces exerted by SMPs are much smaller.

Here a comparison between shape memory polymers and shape memory alloys are made. In attributes like shape recovery, density, transition temp., changes of elastic modulus, ease of processing and cost, SMPs dominate the SMAs. However, the response time, durability and the magnitude of restoration forces are not that good for SMPs. SO choice of the material becomes highly specific to the envisaged application. The wide range of monomers, polymerisation techniques and properties like biodegradability, bioresorbability, drug eluting properties etc that can be brought in for the polymers make research in the field of SMPs highly attractive.

This cartoon shows the basis of classification of SMPs in terms of switch behaviour, namely, one-way and two-way SMPs. In the first case the SMP can automatically recover its shape to its permanent shape when exposed to an external stimulus and this shape remains unchanged when the external stimulus is terminated (or reverse

stimulus applied); Here there is one cycle of programming and one-time shape recovery. In the case of a two-way shape memory polymer, it can automatically change between two trained shapes when they are triggered by two external stimuli, here heating and cooling. The science behind this behavior is rather exciting and the deeper look into the polymer has revealed that the SMproperty depends on the formation of well separated hard and soft phases in a single elastic network. The hard phase acts as net-points, which determine the permanent shape, while the soft phase acts as the switch to immobilize the temporary shape and provide the inner force for its recovery. Further details are beyond the scope of this lecture.
Since we are discussing thermally activated SMPs, the critical parameter is the shape memory transition temperature (switching temp or Tsw). Depending on the polymer class and architecture it can be a transition temperature (T_{trans}) or a melting temperature (T_m). This graph shows the glassy to rubbery transitions occurring in an amorphous polymer where the transition temp. is the glass transition temp (T_g) below which the material will be in a glassy state and above which the material shows a rubbery behaviour. The common examples of polymers with shape memory property are Polyurethane (PU), Polylactic acid (PLA) based and Poly caprolactone (PCL) based polymers. When the SMPs are deformed by applying a load above the Ttrans and then cooled, the soft phase is fixed and the internal stress is stored. Upon re-heating to above Ttrans, the internal stress will be released and enable the recovery of the polymer to its permanent shape. For 2WSMPs, switching between different shapes is possible when the two switch temperatures (above and below a critical value) are applied.These are some of the devices in healthcare which use SMPs.- especially smart resorbable sutures, orthodontic braces, vascular stents and as embolization plugs.

Here's a recap of the session. We analyzed some of the very common medical devices/components that are being used on a routine basis for patient care. Going deep into the molecular level explanation of the performance of these devices we identified that there are smart materials – materials which can respond to an external stimulus in a controllable and reversible manner- which are responsible for the output from these devices. We discussed three distinct categories of smart materials- piezoelectrics, shape memory alloys and shape memory polymers and their applications in medical devices/procedures. The science behind the smartness was explained. Further improvements and discovery of new smart components in these devices are possible with the feedback from the end users to the materials researchers. Finally, to wrap up the session, these are the take home messages.
Healthcare technology, aiming to improve the health of patients, is in search for new devices that can revolutionize medicine. Smart devices are being developed at a faster pace to provide more personalized, less invasive, safer and much more efficient diagnostic/treatment approaches for patients and are crucial units in the Internet of things (IoT) for healthcare.

Understanding the fundamentals science behind the working of these smart devices can facilitate their performance enhancement and troubleshooting.

Thank you for joining the session!

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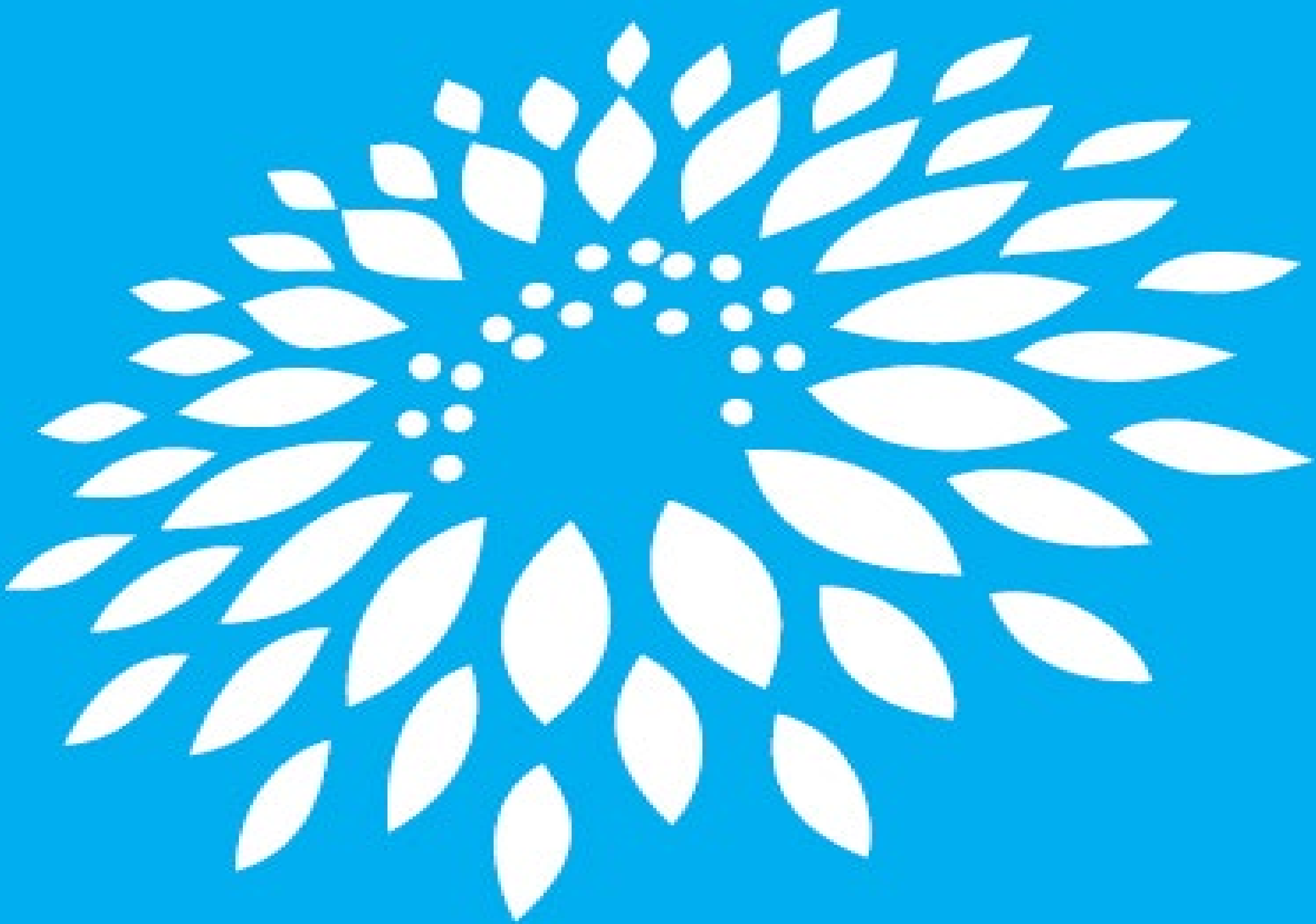
Food for Thought

- Identify minimum three medical devices from literature that incorporate a smart material component. Explain the working of the devices and emphasise the sensor/actuator role of smart material in them.
- Discuss the conditions where the device can underperform and suggest ways to enhance the performance of the selected devices (from a science perspective)

Presentations



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CERTIFICATE COURSE IN
HEALTHCARE TECHNOLOGY

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Sreejalekshmi is a Combinatorial Synthetic Organic Chemist by training and currently Associate Professor at the Indian Institute of Space Science and Technology (IIST) in Thiruvananthapuram. She obtained her PhD in 2006 and after a short post doctoral stint at Sree Chithra Tirunal Institute of Medical Sciences and Technology (SCTIMST), Thiruvananthapuram in 2007, joined as a founding faculty member of IIST. In addition to her core research interests in the Computational design, synthesis and screening of combinatorial libraries for medicinal and materials science applications, she works in the area of Smart Materials, especially for theranostics development. Very recently, in collaboration with medical professionals and industry partners, her group is elaborating their research in the broad area of Space Life Sciences – focusing on the development of tools for personalized medicine.

She is a member of several professional bodies including ACS, SPSI, MRSI, IEEE, ISNM and has 4 patents and over 50 publications in international/national journals and proceedings.

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- To identify smart material components in selected healthcare devices
- To understand the working principle of piezoelectric, SMA and SMPs.
- Identifying piezoelectric, SMA and SMPs components in selected healthcare devices
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- To delineate research interventions to improve the capabilities/build new capabilities in smart devices (through comprehending suggested research articles)

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Identify smart materials in selected healthcare devices

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Learners will identify and appreciate functional role of smart materials in these devices

Acquire knowledge on performance enhancement in these devices

Appreciate advantages of being physician-scientist

Subtopics

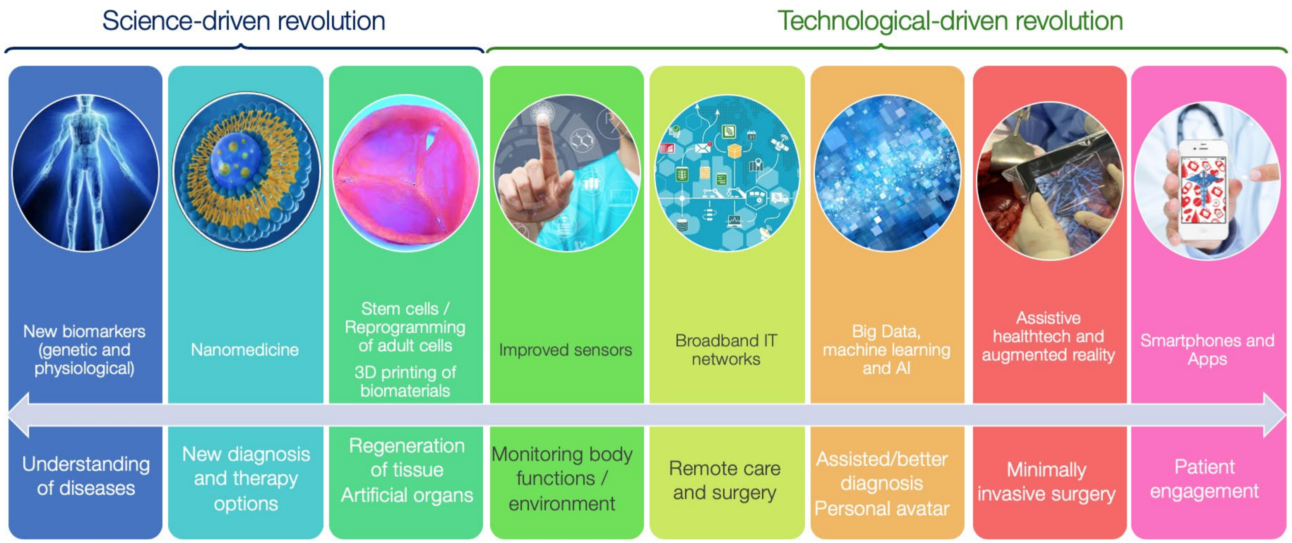
- Healthcare technology- leading to Medical revolution
- Materials design: from chance discoveries to customized design. Materials as building units for devices.
- Introduction to smart materials: Definitions and common examples from nature
- Biomimetics in medical devices.
- Smart Materials to smart devices – the transition.
- Smart devices in healthcare - functional role of smart materials in healthcare devices
- Basic theory of Piezoelectric materials, Shape Memory Alloys and Shape Memory Polymers and their applications in healthcare devices

Introduction

Healthcare technology - any technology, device or digital solution designed to improve the health of patients

Search for new devices that can revolutionize medicine

Smart devices: more personalized, less invasive, safer and much more efficient approaches for patients



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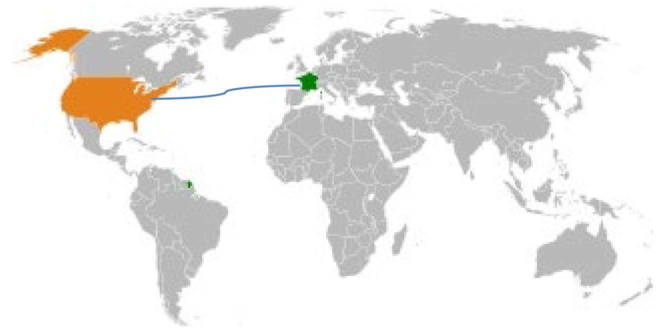
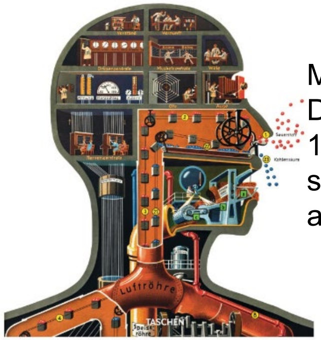


September 7, 2001: First robotic surgery
September 9, 2001: The patient was discharged from the hospital - with no complications

Complex surgical manipulations from remote locations

Potential uses of such remote, robotic technology are boundless –in search and rescue missions, scientific discovery missions, and countless other arenas…

Thanks to information technology!



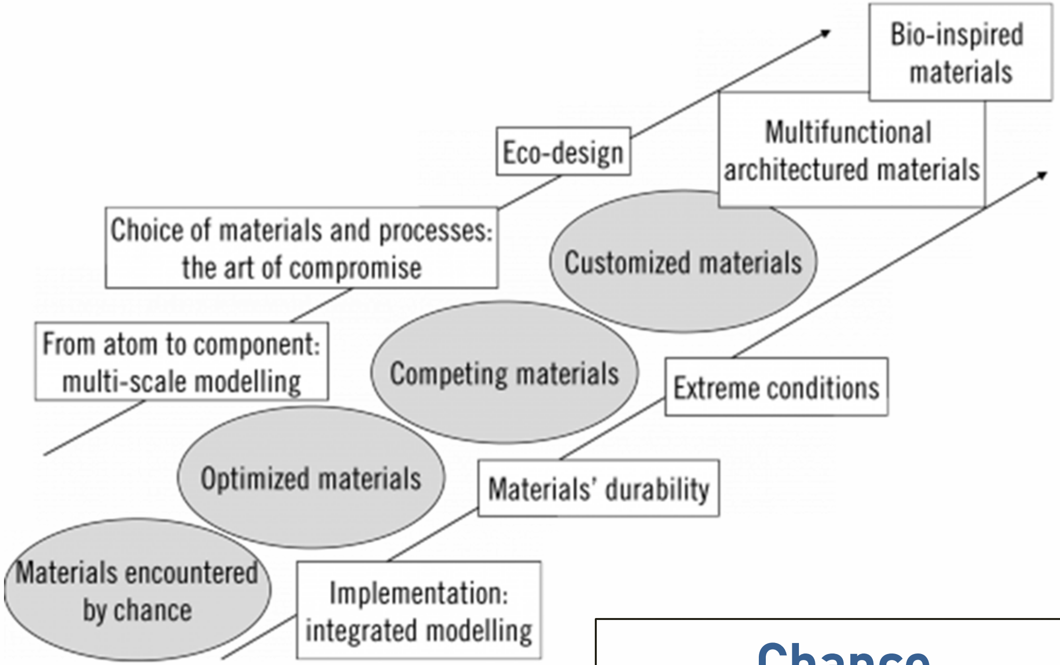
Man-machine analogy Dr Fritz Kahn (1888-1968), a German scientist, gynaecologist and author

Let’s take a closer look:
Telesurgeries require a secure, reliable and fast network connecting the two points (surgeon to patient) and a robotic system capable of translating the surgeon's hand movements in location A to the devices inside the patient in location B

How does these devices perform the job?
Materials science and technology advancements have made **functional materials to smarter materials and hence smarter devices** could emerge

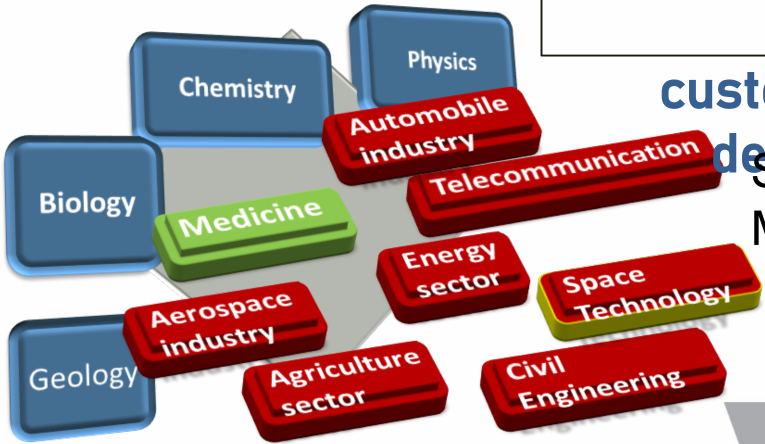
The edifice of science not only requires material, but also a plan. Without the material, the plan alone is but a castle in the air- a mere possibility; whilst the material without a plan is but useless matter

- D.Mendeleev



https://books.openedition.org/cdf/3643

Chance discoveries to customised design



Smart materials
Metamaterials

Functional Material

I can perform specific functions

I play key roles in the modern world

Looking for special applications??

I'm born with specific properties

You can design, synthesize and tailor my properties

I can exist as a single molecule, assembled structures, part of polymer/ceramic or nanoparticles

I'm there in a whole lot of devices

Diagnostics, health monitoring and therapeutics

Fitness tracking wearable with other health-oriented consumer connected devices

Functional materials: Able to perform a certain "functions" under a determined stimulus.
SMART MATERIALS: Able to perform "functions" under a determined stimulus, whereas the functions/properties are **REVERSIBLE**

Smart materials are also tailorable and tunable (a synthetic chemist can do that)
Can be designed for specific, controlled property changes

BIOMIMICRY: Nature Inspires Development of Functional Materials

Engineers and scientists are trying to understand the art of biomimicry for decades.

Egs: solar cells inspired by plant leaves; high-strength fibers inspired by spider silk; multifrequency radars inspired by bats; camouflage skins inspired by squids

Biomimetics in Medical Devices?

Designs of nature – result of prolonged optimization

Bioinspired inspired surgical instruments, prostheses and orthoses

Functional design – modular part of a device has only one responsibility and performs that responsibility with the minimum of side effects on other parts

Holistic design - demands precision in every stage — right from product ideation → compliance → designing → testing and marketing of the product


Energy-health nexus and the challenges in health delivery due to absence of reliable access to energy

Bioinspired functional materials discovery





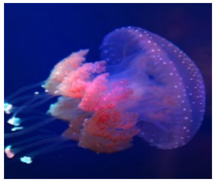
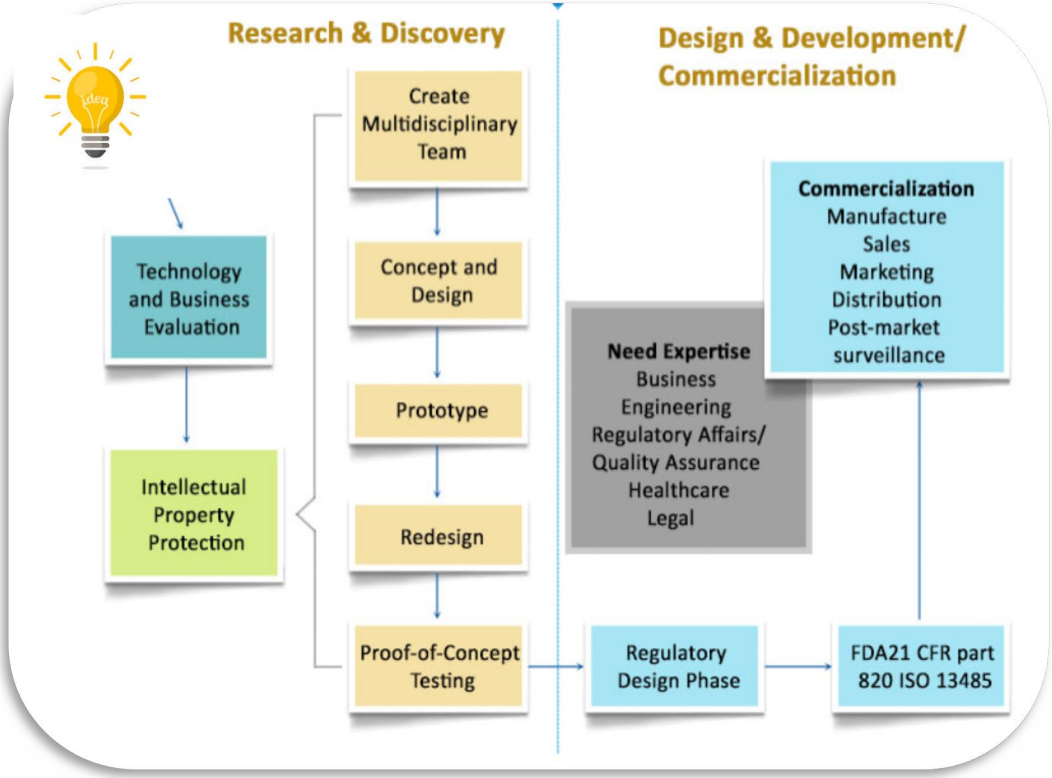


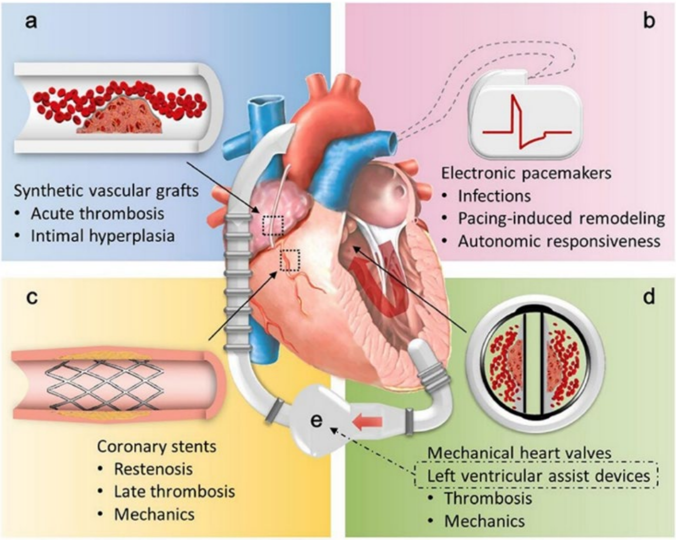
Image credits:
https://www.undp-capacitydevelopment-health.org/
https://www.biotechnews.com.au/
https://www.smithsonianmag.com/innovation/
https://www.telegraph.co.uk/

MEDICAL DEVICES: THE PROCESSES



Recommended Reading:
ISO 13485:2016 — Medical devices — A practical guide; 2017; ISBN 978-92-67-10774-5

Bioinspired approaches: owe much of their current development in biology, chemistry, materials science, medicine and engineering to the design and fabrication of advanced devices.



https://doi.org/10.1016/j.cclet.2017.03.033

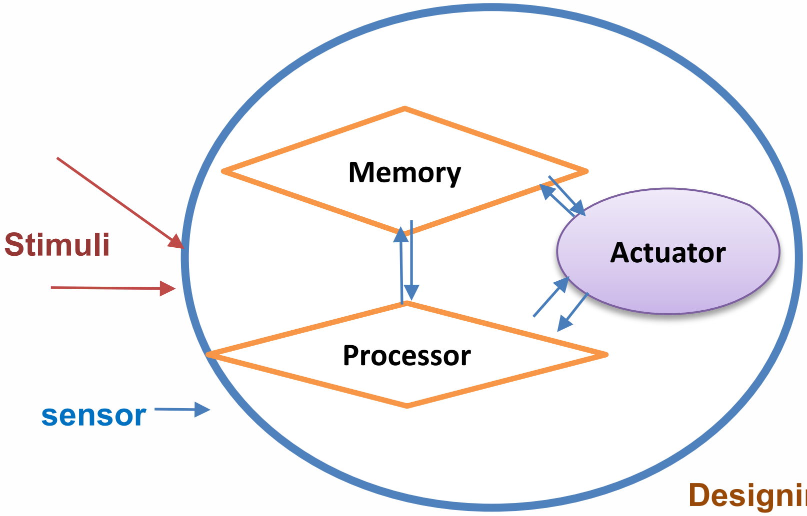
The application of bioinspired devices is a burgeoning area of research

SMART MATERIALS: AN INTRODUCTION

Smart Materials – ADVANCED FUNCTIONAL MATERIALS - ability to REVERSIBLY MODIFY one or more of their functional or structural PROPERTIES IN RESPONSE TO STIMULUS or to changes in conditions of their surrounding environment

'Material (or system) that can sense and respond to the environment around them in a useful and predictable manner'

Differs from control loop mechanism - material adapts itself to suit the environment - self-adaptability, self-sensing, memory and multiple functionalities



- (i) A sensing device to perceive the external stimuli
- (ii) A communication network
- (iii) A decision-making device
- (iv) An actuating device, which could be inherent in the material or externally coupled with it

Designing a material with sensor, processor and actuator functions

Stimuli – temperature, pressure, electric field, magnetic field,..
Response – change in shape, viscosity, color, dipole moment,….
Optical fibres, peizo electric polymers, ceramics, SMAs, SMPs,….

Output / Input	Charge current	Magnetization	Strain	Temperature	Light
Electric field	Permittivity Conductivity	Electromagnetic effect	Converse piezo effect	Electric caloric effect	Electric-optic effect
Magnetic field	Magnetic electric effect	Permeability	Magneto-striction	Magneto caloric effect	Magnetic-optic effect
Stress	Piezoelectric effect	Piezomagnetic effect	Elastic constant	------	Photoelastic effect
Heat	Pyroelectric effect	-----	Thermal expansion	Specific heat	--------
Light	Photovoltaic effect	-----	Photostriction	-------	Refractive index

sensor   actuator

Suggested reading:

1. Rogers, C. A., Barker, D. K. & Jaeger, C. A., Introduction to smart materials and structures. In Smart Materials, Structures, and Mathematical Issues, ed. C. A. Rogers. Technomic, Lancaster, PA, 1989
2. Smart Materials; Mel Schwartz (Ed), CRC PRESS, 2009

SMART MATERIALS IN HEALTHCARE DEVICES

We will discuss about

1. Piezoelectric materials
2. Shape Memory Alloys
3. Smart Polymers

Physician-Scientists: The Bridge between Medicine and Science

Medical Devices – has vital roles in acquiring patients' data and advancing medical knowledge

Physicians involved in science research

More than 50% of the Nobel prizes in physiology and medicine have been awarded to physicians engaged in science

For a physician-scientist, going back and forth between medicine and science is natural and almost necessary

PIEZOELECTRIC MATERIALS

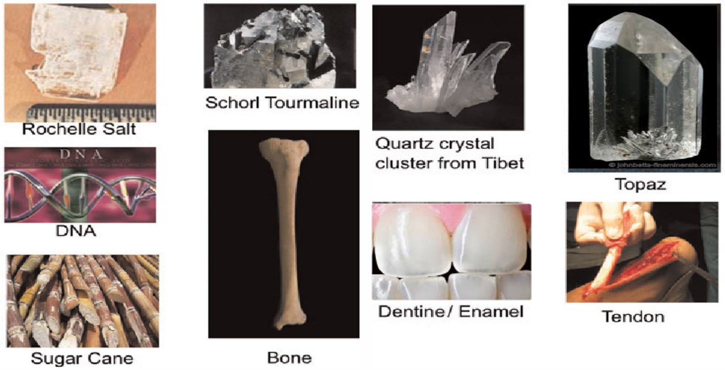
Materials that produce an electric current (output) in response to a mechanical stress (input).

A reversible process

When we apply an electric current to these materials, they will actually change shape slightly

Can be Natural or Synthetic materials

NATURALLY OCCURING PEIZOELECTRICS



Ultrasonic devices

Image credits: wikipedia.org/

Jacques (left) with his brother Pierre and their parents Eugène Curie and Sophie-Claire Depouilly

The term ‘piezoelectricity’ originates from the Greek word ‘*piezein*’, which means *to press or squeeze, and* Latin word ‘*electrum*’ — electricity
Discovered in 1880 by French scientists Pierre and Jacques Curie when they discovered that applying pressure to certain crystals caused them to produce an electric charge

PIEZOELECTRIC EFFECT

In a piezoelectric material, compression and tension generate voltages of opposite polarity that are proportional to the amount of force used – direct piezoelectric effect.

Inverse piezoelectric effect refers to the reverse property — where a piezoelectric material contracts or expands in accordance with the polarity and strength of an electric field.

The voltage or mechanical change create very small change in dimension of the material, but with a huge impact on technology.

Devices include electric lighters, microphones, transformers, ultrasonic transducers and actuators.

Useful links:
http://core.materials.ac.uk/repository/doitpoms/tlp/piezoelectrics/piezoelectric_compression.swf
http://core.materials.ac.uk/repository/doitpoms/tlp/piezoelectrics/gas_lighter.swf
http://core.materials.ac.uk/repository/doitpoms/tlp/piezoelectrics/ultrasound.swf

Ultrasonic devices

$P = d\,\sigma$, direct effect

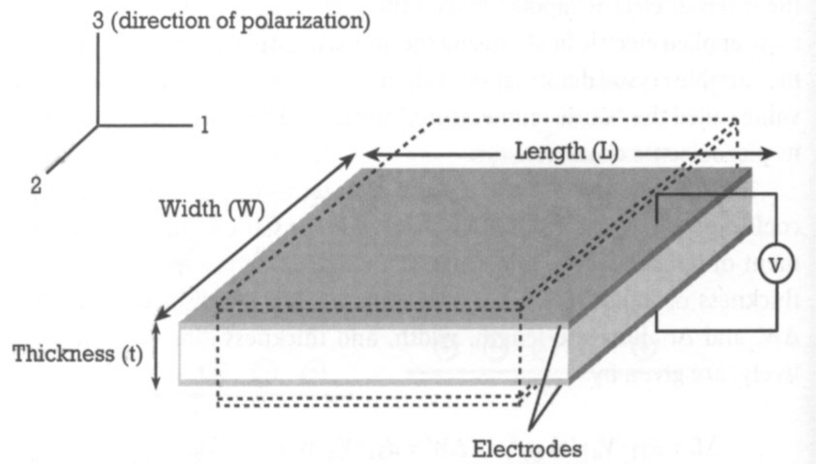
$\varepsilon = d\,E$, converse effect

P : polarization (pC/m^2)

σ : stress (N/m^2)

ε : strain

d: piezoelectric coeff (pC/N or m/V)



Piezoelectric Material Specifications

	Electrical Properties				ElectroMechanical Properties							Mechanical Properties						
	Relative Dielectric Constant*	Dielectric Dissipation Factor*	Curie Temp.	Max. Recom-mended Working Temp.	Coupling Factors			Piezoelectric Coefficients				Compliance		Young's Modulus	Poisson's Ratio	Mechanical Quality Factor	Density
	K_{33}^T	Tan δ	T_c		k_p	k_{33}	k_{31}	d_{33}	d_{31}	g_{33}	g_{31}	S_{11}^E	S_{11}^D	Y_{11}^E	Υ	Q	ρ
			[°C]	[°C]				[10^{-12} m/V]		[10^{-12} m/N]		[10^{-12} m/N]		[GPa]			[g/cm^3]
P1	3650	2.0	200	<110	0.58	0.70	0.34	650	-280	20	-8.7	14.2	12.5	70	0.3	TBD	7.8

*Measured at 1 kHz frequency

Why certain materials show piezoelectricity?

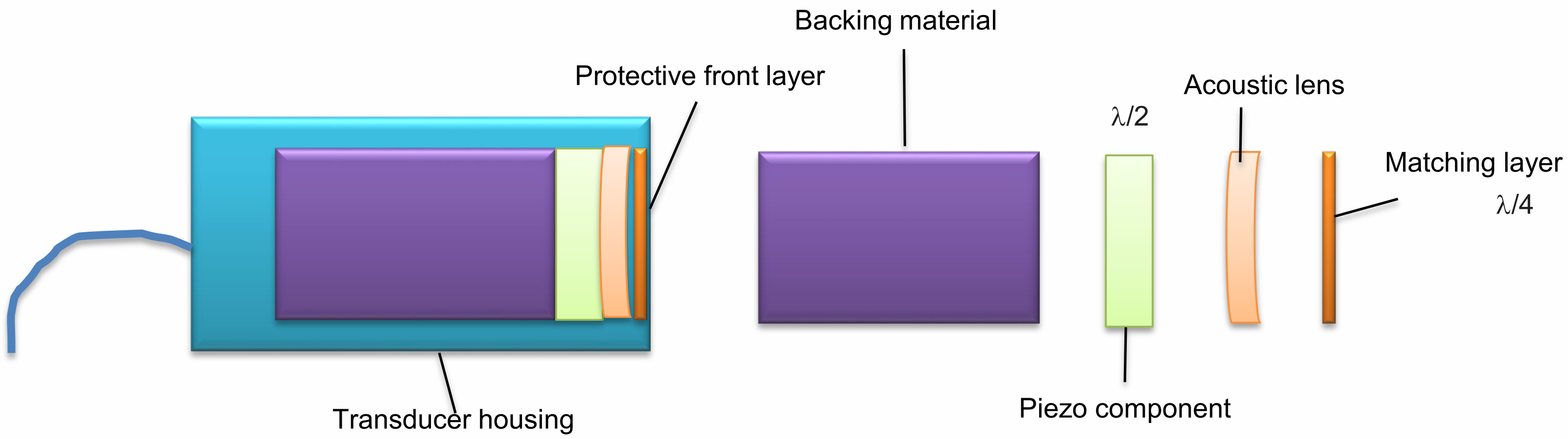
A material's ability to be piezoelectric is directly related to its crystalline structure.
When the static crystal structure is disturbed by as little as 10%, the atoms are disturbed, and a charge is created.

ULTRASOUND TRANSDUCER

1. Basic components that are used in the construction of a typical diagnostic ultrasound transducer.
2. Understand the role of piezoelectric material in an ultrasound transducer.
3. Understand how ultrasound images are formed.
4. List the different types of electronic array transducers.

https://radiologykey.com/

Components and Assembly of a Typical Transducer



Components	Functional role
Physical housing assembly	structural support and acts as an electrical and acoustic insulator
Electrical connections	a thin film of gold or silver plated for conducting
Piezoelectric element	acts both as a transmitter and receiver of ultrasound
Backing material	eliminate the vibrations from the back face
Acoustic lens	to focus ultrasound waves
Impedance matching layer	to provide acoustic matching

How to select the most appropriate transducer?

Piezoelectric transducer produces ultrasound due to vibration of the piezo element when an AC voltage is applied.
This vibration creates very high-frequency air pressure waves; at rates of 10MHz or higher.

Most medical applications of ultrasound use lead zirconate titanate ceramics (PZT) or $BaTiO_3$ as the piezo element.

The same material also work in reverse: detect ultrasonic waves and convert the energy from those waves into an electric signal.

Fitness for purpose - type and operating frequency

FREQUENCY & DEPTH OF PENETRATION

The depth of penetration is related to the frequency of the ultrasound wave (range from 2 MHz up to 20 MHz)

Higher frequencies have a shorter depth of penetration.

Lower frequencies have a longer depth of penetration.

Caution! Trade-off between image resolution and the penetrating depth

For example, a 12 MHz transducer has very good resolution, but cannot penetrate very deep into the body compared to a 3 MHz transducer which can penetrate deep into the body

But the resolution is good for the transducer operating at 12 MHz.

In general use, the highest frequency transducer which will reach the required depth should always be employed

How to determine a transducer’s operating frequency?

The operating frequency of a transducer is critically governed by the thickness of the piezoelectric crystal.

For maximum efficiency the crystal should be operating at its ‘natural’ or ‘resonant’ frequency.

Natural frequency occurs when the thickness of the crystal corresponds to half a wavelength ($\lambda/2$).

Thinner piezoelectric materials produce higher resonant frequencies

Typical diagnostic ultrasound elements are between 0.2 mm and 1 mm thick.

Let
λ = wavelength; c = acoustic velocity; f = frequency; thickness = λ /2 (at fundamental resonance) and λ = c/f, then thickness= c/(2f) and solving for f, we get

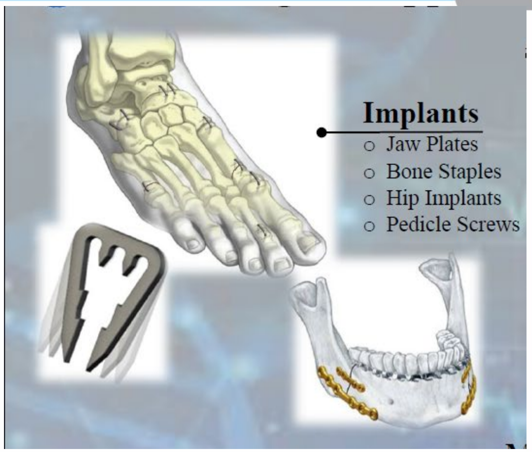
$$f = c/(2 \times \text{thickness})$$

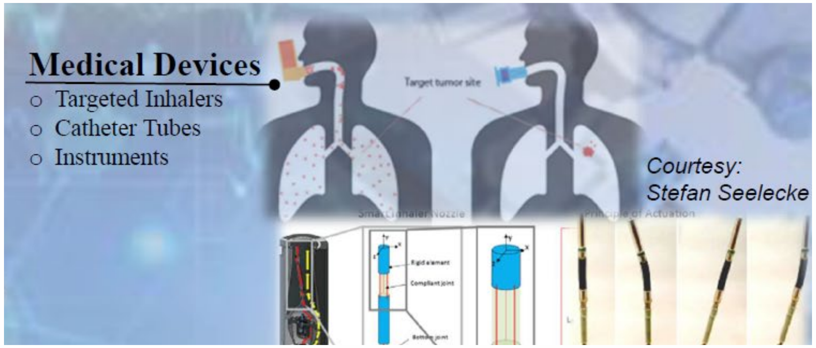
A transducer operating at a resonant frequency of 2 MHz would have a thickness around 1 mm.

Calculate the thickness of a piezo transducer operating at a frequency of 7.5 MHz.

Neumann D, Kollorz E. Ultrasound. 2018 Aug 3. In: Maier A, Steidl S, Christlein V, et al., editors. Medical Imaging Systems: An Introductory Guide [Internet]. Cham (CH): Springer; 2018. Chapter 11. Available from: https://www.ncbi.nlm.nih.gov/books/NBK546144/ doi: 10.1007/978-3-319-96520-8_11

SHAPE MEMORY ALLOYS (SMAs)





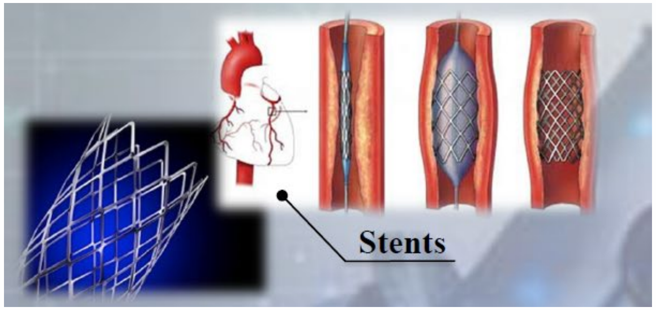
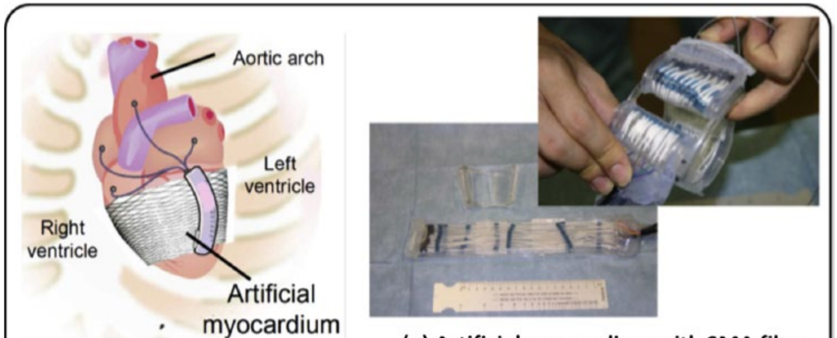
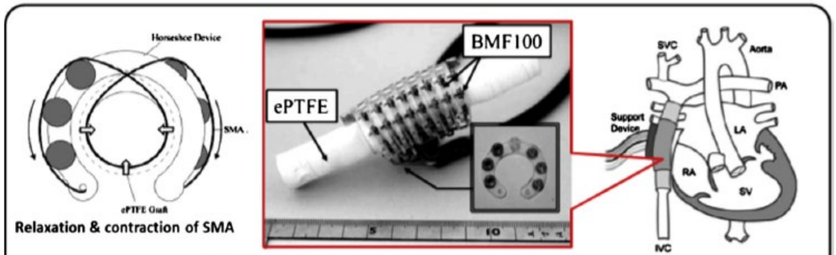


Image courtesy: NASA



(a) Artificial myocardium with SMA fibre



(b) Artificial Fontan circulation support device with SMA fibre

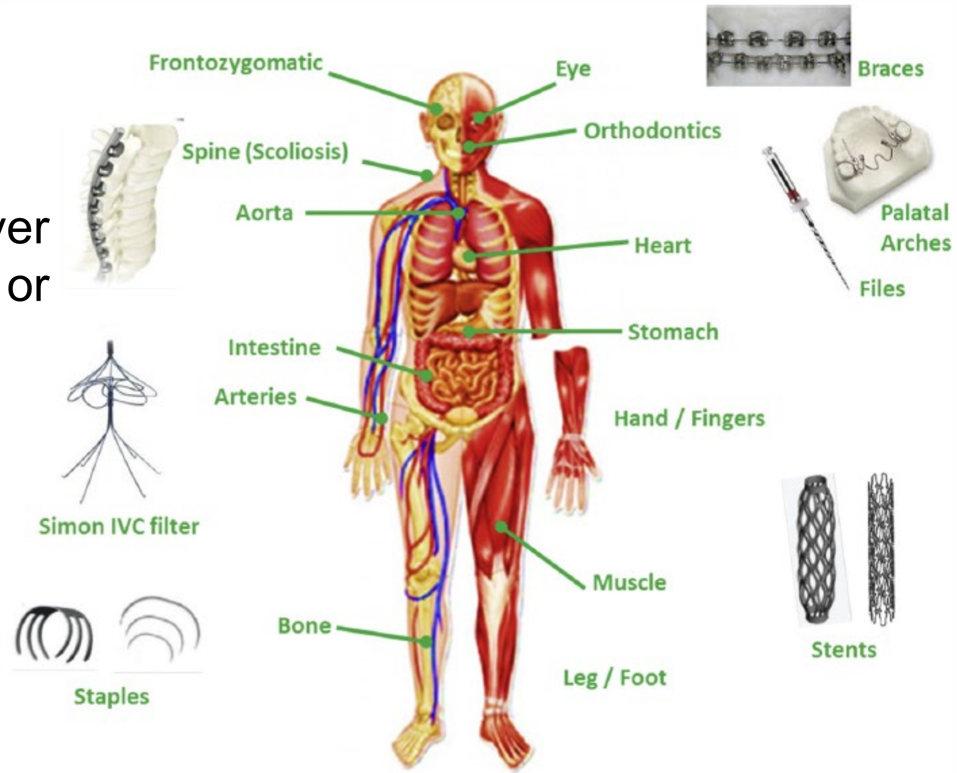
J. Mohd Jani et al. / Materials and Design 56 (2014) 1078–1113

SHAPE MEMORY ALLOYS (SMAs)

Alloys that have a "memory."

The ability to remember and recover their original shapes with load or temperature.

- Exhibit a solid-to-solid, reversible phase transformation
- Change in physical, mechanical, thermal properties
- Sense and actuate (multifunctional)



J. Mohd Jani et al. / Materials and Design 56 (2014) 1078–1113

Nitinol is popular due to its biocompatibility and superelasticity.
Used to manufacture stents, guide wires, stone retrieval baskets, filters, needles, dental files, and other surgical instruments.

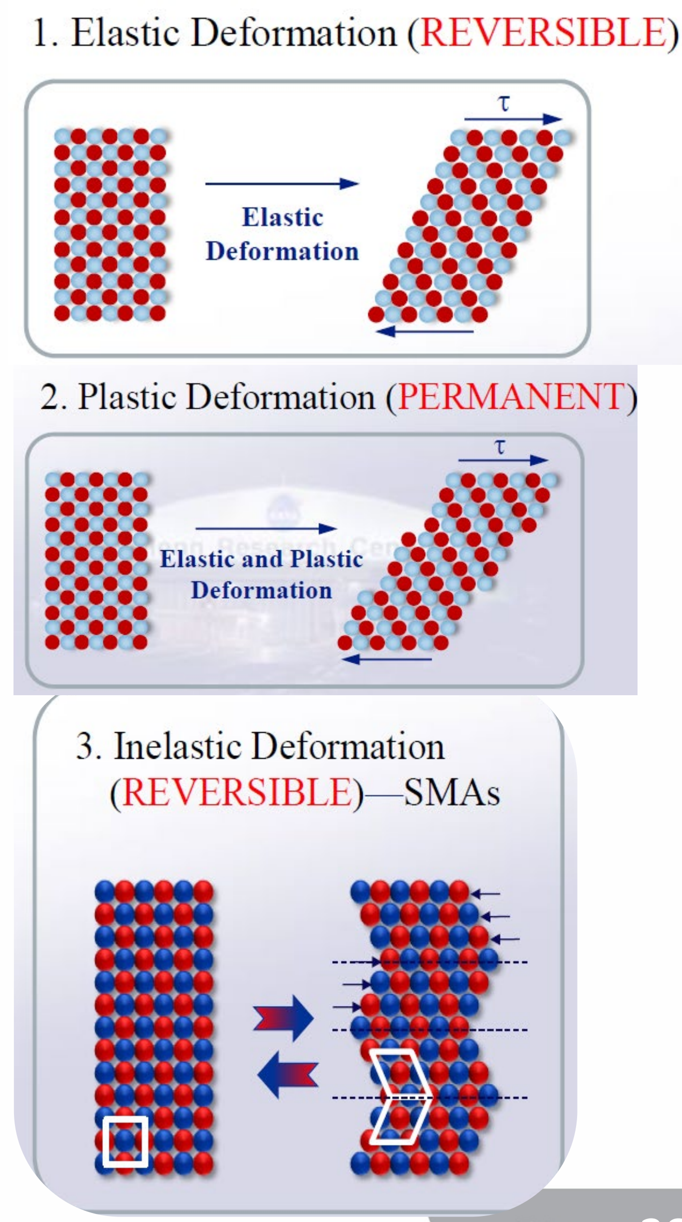
Phase Transformation:

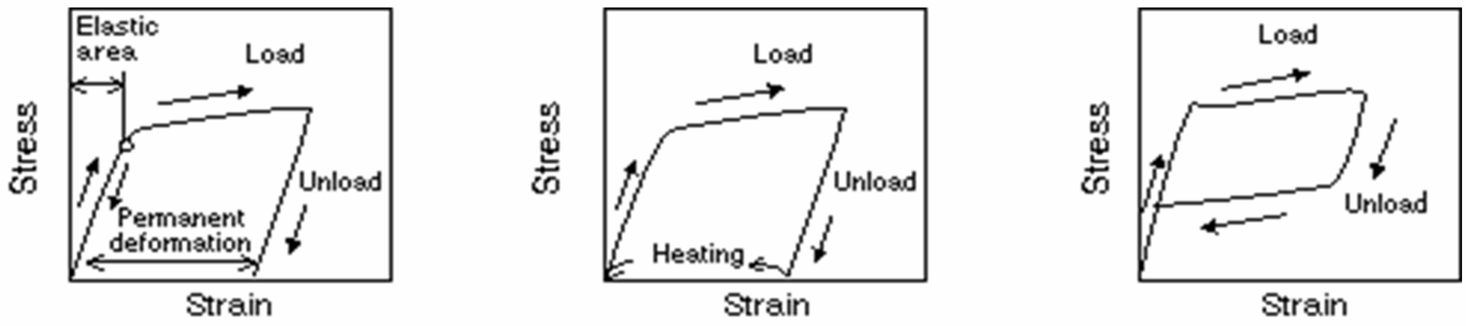
Solid-to-solid, diffusionless, martensitic phase transformation between a high temperature, high symmetry **austenite phase** (generally cubic) and a lower temperature, low symmetry **martensite phase** (e.g., monoclinic, tetragonal, or orthorhombic).

How to make the material/actuator stable?

- Solution 1: Thermomechanical "training" (e.g., cycling, reverse loading…)

- Solution 2: Alloying and microstructural control (e.g., precipitation hardening)





① Normal metal ② Shape-memory effect ③ Superelasticity

SUPERELASTICITY (PSEUDOELASTICITY)	SHAPE MEMORY EFFECT
Phase transformation between the austenitic and martensitic phases	
Reversible response to STRESS	Return to the old configuration (trained shape) BY HEATING
Realize the reverse deformations without temperature application, only due to instability of their structure	Controlled superelastic materials
ISOTHERM PROCESS, above A_s	HEATING & COOLING
MARTENSITE UNSTABLE , RETURNS BACK TO AUSTENITE ON STRESS REMOVAL (excessive strain can lead to conventional plastic flow (dislocation glide), which will be irreversible	

	AUSTENITE	MARTENSITE
Youngs modulus	30–83 GPa	20–45 GPa
Ultimate Tensile Strength	800–1900 MPa	800–1900 MPa
Elongation at Failure	20–25%	20–25%
Recoverable strain	8–10 %	8–10%
Poisson Ratio	0.33	0.33

Property	NiTi	Stainless Steel
Recovered Elongation	8%	0.8%
Biocompatibility	Excellent	Fair
Torqueability	Excellent	Poor
Density	6.45 g/cm^3	8.03 g/cm^3
Magnetic	No	Yes
Resistively	80 to 100 micro–ohm*cm	72 micro–ohm*cm

Useful link:
https://www.medicalexpo.com/medical-manufacturer/stent-3677.html

SHAPE MEMORY POLYMERS (SMPs)

Shape-memory polymers (SMPs) can revert to their original shape at a designed temperature.

Polymer architecture + processing parameters

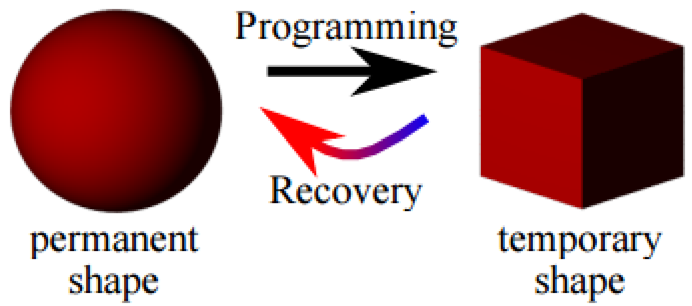
For activating the SME, the use of body heat, external heat, lasers, magnetic particles, moisture, and light are used.

In comparison to SMAs, the forces exerted by SMPs are much smaller.

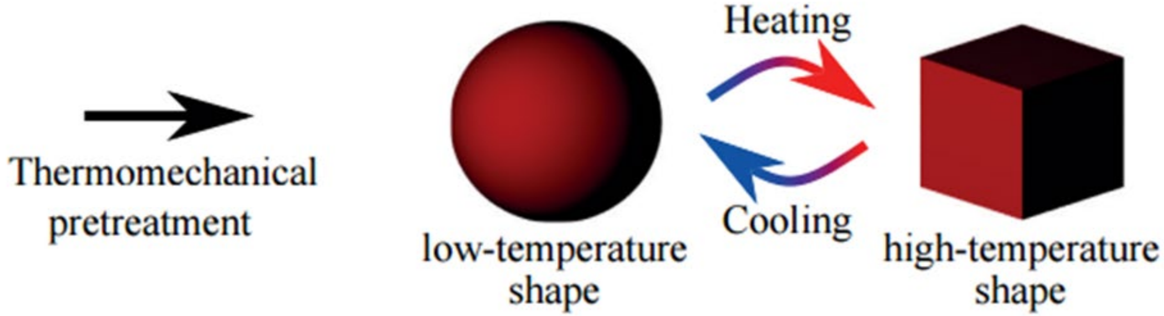
Comparison between SMP and SMA

Attribute	SMP	SMA (NiTi)
Density	1.13 – 1.25 g cm^{-3} (light weight)	6.4 – 6.5 gcm^{-3} for NiTi
Shape recovery	up to 400% of plastic strain	7–8% only
Transition temperature	wide range of *Tg*, from−70ºC to +100ºC	Lesser range; 52.54ºC - 60.90ºC for austenite 44.78ºC - 32.84ºC for martensite
Changes of elastic modulus	Large and reversible (as high as 500 times)	Comparatively smaller
Processing	Easy	Difficult
Cost	Low	High

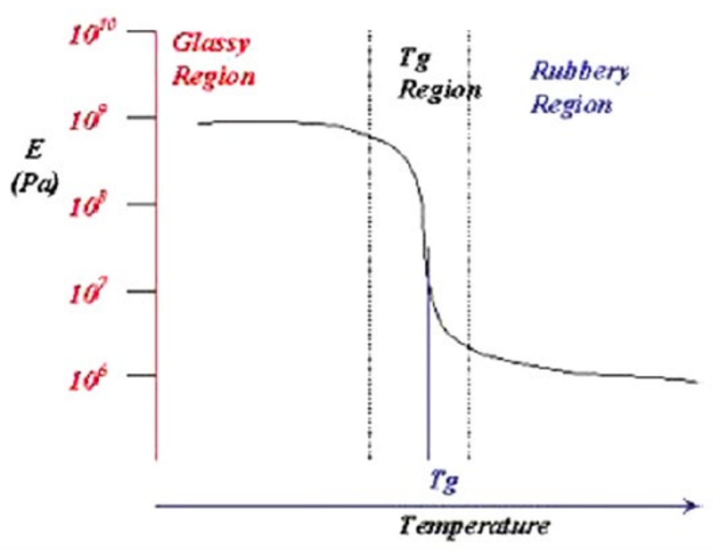
1-way SME

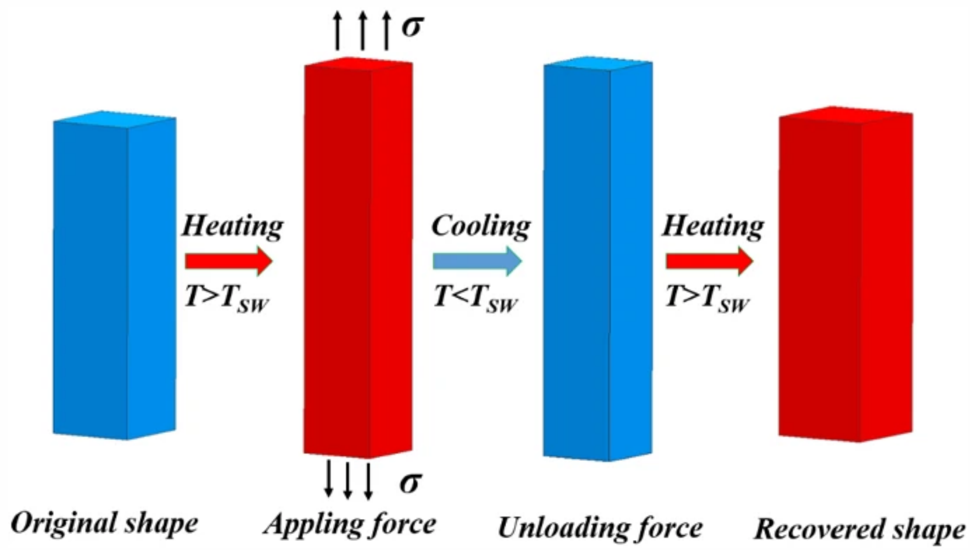


2-way SME



- Critical parameter for SMP - shape memory transition temperature (switching temp T_{sw})
- Polymer architecture – T_{trans} or T_m
- Examples – Poly Urethane, PLA based polymers, PCL based polymers



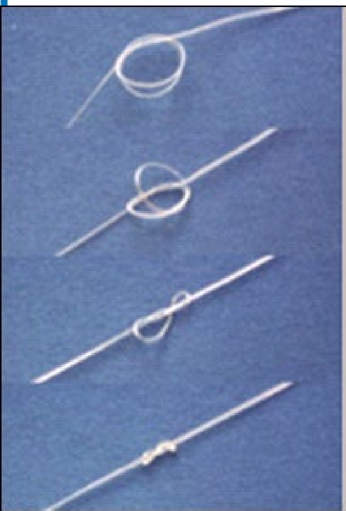


(1) **heating and shaping**: sample is deformed into a temporary shape under external load : $(T > T_{sw})$

(2) **cooling and fixing**: external load maintained and the temperature lowered to below T_{SW} : INTERNAL STRAIN LOCKED

(3) **Reheating**: sample is reheated to above T_{SW} and recovers the original shape

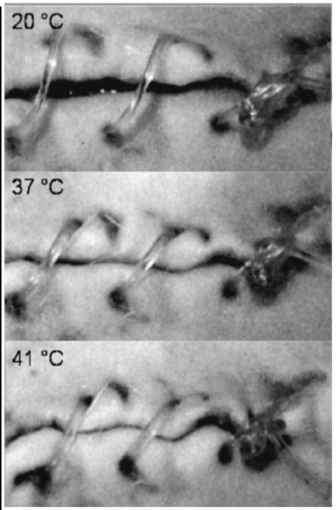
Smart sutures



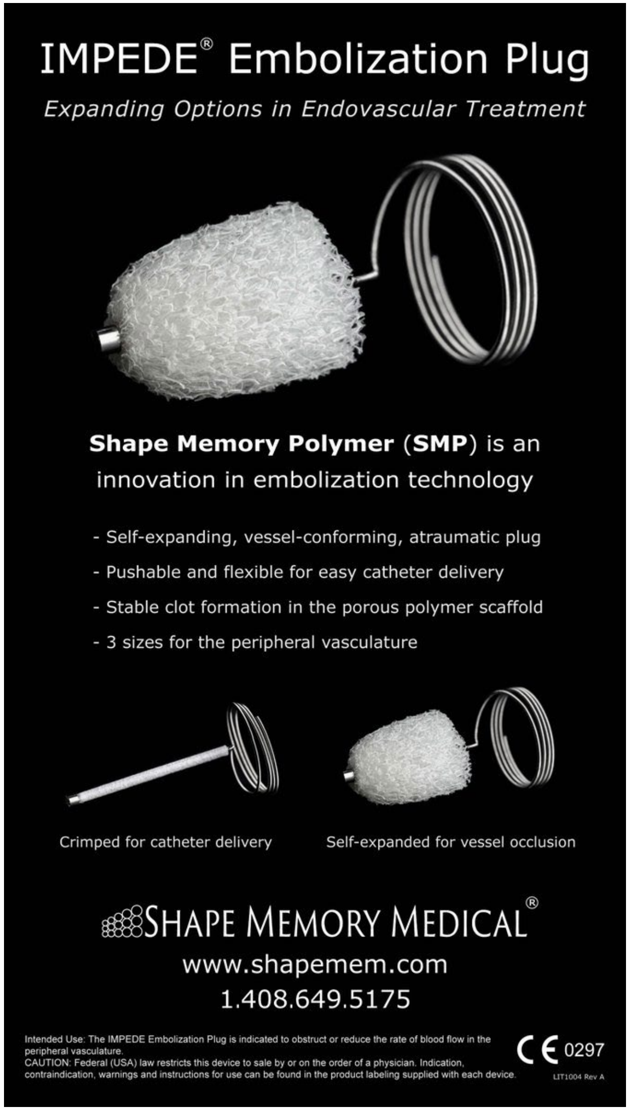
A fiber made of a new biodegradable plastic with "memory" can be used to tie a smart suture.

After forming a loose knot, the ends of the ends of the suture were fixed

The knot tightened in 20 seconds when heated to 40 degree C



Orthodontic braces
Vascular stents



Useful Resources

Advanced Healthcare Materials - an international, interdisciplinary journal on high-impact materials, devices, and technologies for improving human health – Publishers: Wiley

New Materials and Technologies for Healthcare; Edited By: Larry L Hench (University of Florida, USA), Julian R Jones (Imperial College London, UK) and Michael B Fenn (University of Florida, USA) https://doi.org/10.1142/p713 | November 2011

Biomaterials in Modern Medicine The Groningen Perspective; Edited By: Gerhard Rakhorst (University of Groningen, The Netherlands) and Rutger Ploeg (University of Groningen, The Netherlands) https://doi.org/10.1142/6562 | January 2008

Suggested Viewing

https://www.youtube.com/watch?v=s23_d-qeEn4
https://www.youtube.com/watch?v=p3z9FLYijrQ
https://www.youtube.com/watch?v=g6ZZaX-xDqg

https://www.intel.co.uk/content/www/uk/en/healthcare-it/solutions/videos/remote-healthcare-platform-video.html

https://igniteoutsourcing.com/healthcare/internet-of-medical-things-iomt-examples/

https://today.mims.com/7-bio-inspired-inventions-that-are-transforming-medicine

Recap

We analyzed some of the very common medical devices/components that are being used on a routine basis for patient care.
Going deep into the molecular level explanation of their performance we identified that there are smart materials – materials which can respond to an external stimuli in a controllable and reversible manner- which are responsible for the output from these devices.
We discussed three distinct categories of smart materials- piezoelectrics, shape memory alloys and shape memory polymers and their applications in medical devices/procedures.
The science behind the smartness was explained.
The improvements in these devices are possible with the feedback from the end users to the materials researchers.

Take home messages

Healthcare technology, aiming to improve the health of patients is in search for new devices that can revolutionize medicine.

Smart devices are being developed at a faster pace to provide more personalized, less invasive, safer and much more efficient diagnostic/treatment approaches for patients and are crucial units in the Internet of things (IoT) for healthcare.

Understanding the fundamentals science behind the working of these smart devices can facilitate their performance enhancement and troubleshooting.

Activity/ assignment

- Identify minimum three medical devices from literature that incorporate a smart material component. Explain the working of the devices and emphasise the sensor/actuator role of smart material in them.
- Discuss the conditions where the device can underperform and suggest
- ways to enhance the performance of the selected devices (from a science perspective)
- Provide suitable references to support your report.

For more Information please contact

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