CES Selector Case Studies:
Medical Forceps

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1 Introduction

1.1 CES Selector Case Studies

This set of case studies illustrate the use of a selection methodology, implemented using CES Selector™. CES Selector is used for advanced teaching and research and at industrial companies to select materials and processes, compare research data to reference data and present data in a visual way. CES Selector and EduPack have many similar functions and so this case study might also be of interest to those with CES EduPack, however, CES Selector has access to more advanced data and additional functionality, such as a performance index wizard, a comparison tool for materials substitution and the ability to create your own databases.

CES EduPack and CES Selector can be used to select candidate materials for a wide range of applications: mechanical, thermal, electrical, and combinations of these. Each case study addresses the question: out of all the materials available to the engineer, how can a short list of promising candidates be identified?

The analysis, throughout, is kept as simple as possible whilst still retaining the key physical aspects which identify the selection criteria. These criteria are then applied to materials selection charts created by CES Selector, either singly, or in sequence, to isolate the subset of materials best suited for the application. Do not be put off by the simplifications in the analyses; the best choice of material is determined by function, objectives and constraints and is largely independent of the finer details of the design.

There is no pretense that the case studies presented here are complete or exhaustive. They should be seen as an initial statement of a problem: how can you select the small subset of most promising candidates, from the vast menu of available materials? They are designed to illustrate the method, which can be adapted and extended as the user desires. Remember: design is open ended—there are many solutions. Each can be used as the starting point for a more detailed examination: it identifies the objectives and constraints associated with a given functional component; it gives the simplest level of modeling and analysis; and it illustrates how this can be used to make a selection. Any real design, of course, involves many more considerations. The 'Postscript' and 'Further Reading' sections of each case study give signposts for further information.

1.2 Are the case studies realistic? Is this used in Industry?

Industrial Context

As well as for Research, CES Selector is used widely in Industry to facilitate the rational selection of materials for commercial projects. Please see below for links to these case studies.

NCS Lab, an Italian research and development company, recently carried out their own selection project for medical forceps. This applied CES Selector to a real industrial project focused on replacing a metal with a polymer, allowing efficient preliminary design and saving NCS time and money. How a Powerful Material Selection Tool Enables Successful Design at NCS Lab.

Other case studies relevant to Biomedical Materials:

- How Tecumseh use systematic materials selection to reduce costs while enhancing quality and reliability
- How Victrex Polymer Solutions are demonstrating the benefits of aerospace materials
- Novo Nordisk: Materials information technology in industry

2 Materials for Medical Forceps

Medical forceps are a device used to grasp objects that are too small for a surgeon to hold. The forceps in this case study also have a small-diameter tube (known as a cannula) through which other devices are passed into the body to perform procedures such as cauterization, which uses a high voltage electrical current to stop bleeding. This case study is concerned with the selection of the material for the handles of these forceps. (Figure 1).

Figure 1 - Representation of a Medical Forceps

2.1 Design Requirements

Materials used in a medical context are typically required to meet a complex set of constraints. Some constraints, such as the need to maintain precision dimensions, relate to general engineering properties. Others are more specialized – for example, the need to withstand very harsh treatment through repeated sterilization at high temperature and pressure, or to meet regulatory requirements on biocompatibility. As well as constraints (which must be met) there are a series of competing design objectives that the designer must minimize or maximize. These are detailed below.

- **Biocompatibility** (USP class VI or ISO 10993)
- **Good sterilizability** (steam autoclave)
- **Mechanical toughness** (impact strength)
- **Electrical insulator**
- **Dimensional stability in the presence of water**
- **Processing** (injection molding)
- **Mechanical stiffness and strength in bending**

Objectives:

- **Minimize cost** for a specified stiffness – To increase the competitiveness of product
- **Minimize volume** for a specified stiffness – To increase comfort and convenience for the surgeon and to allow precision motion by avoiding bulky handles

2.2 The Model

Medical equipment is most easily and rapidly cleaned using a steam autoclave. All medical equipment requires sterilization if it comes into contact with the body, and will undergo many sterilization cycles during its lifetime. For this product 5,000 sterilization cycles were specified at 134°C and 2.5 bar: these requirements equate to a 'Good' or 'Excellent' rating in CES Selector.

The handles must withstand everyday wear and tear in an operating room, including impact with the instrument tray. A reasonable impact strength would be >7 kJ/m2.

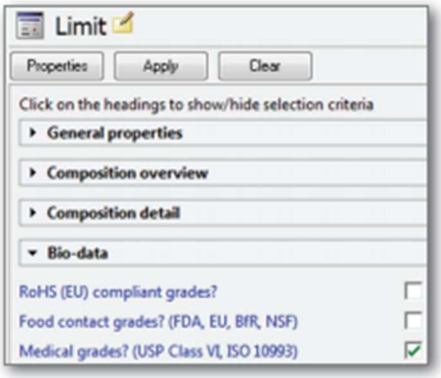
Good insulation ensures the high voltage current used for cauterization is not conducted through the handle. Materials were limited to those with a higher resistivity: a minimum of 1e12 µΩcm was found to be appropriate.

Low water absorption helps to maintain the tight dimension tolerances necessary for the handles; water absorption causes the handle volume to increase changing the shape of the part. An appropriate limit for water absorption after 24 hrs would be < 0.5%.

Ergonomics and aesthetics are important to ensure that the handles are comfortable for the surgeon to hold; these can cause the shape to be complex. It must be possible to process the material to achieve this shape: injection molding is the most likely process. The surface finish should also be pleasing to touch and maintain a clean appearance whilst being used in a tough environment.

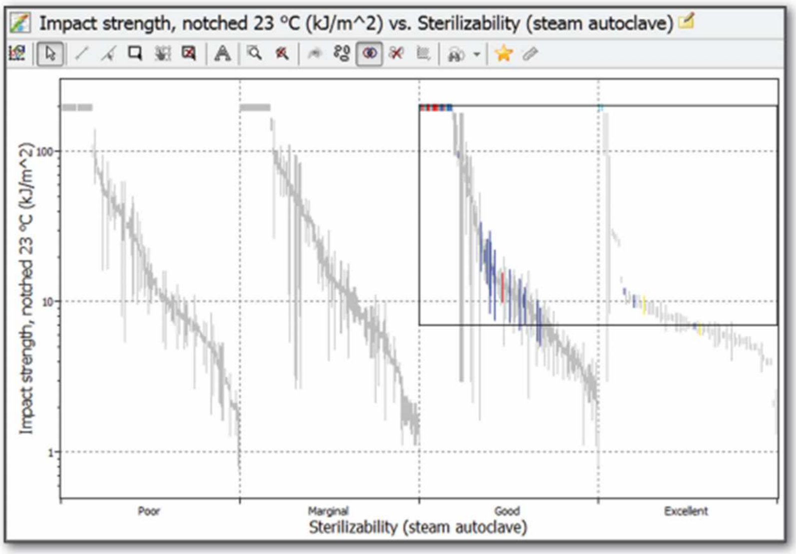
When pressure is applied to the handles to activate the device the handles should not deflect excessively (thus increasing the force necessary to activate the device leading to increased fatigue). The device should be strong enough not to break under the required loading.

2.3 The Selection



In this example we will investigate polymers. We do this by using the polymer subset. (The CES Medical Selector edition adds to this database properties of interest in medical device design). We either use the "limit table" (*illustrated left: In this instance the constraint on Biocompatibility, a property of particular interest in medical devices*), or perform a "box selection" on graphs of the relevant attributes (*illustrated below: In this instance the constraints on sterilizability and mechanical toughness. Simply select the top-right of the graph to ensure that only materials with high values of both properties are considered*).

With constraints applied, CES Selector narrows the choice to just over 60 polymers. It is now easy to graphically display the objectives in order to observe the trade-off between them for the remaining materials. The "Performance Index Finder" tool within CES Selector is a visual tool that helps to specify design objectives. It generates the performance index (a formula describing the combination of properties that must be minimized in order to make an optimal choice for a particular design objective) based on the function and loading of the part. The user does not need to understand the underlying math.



For this example the function and loading is of the form of a 'Beam in bending'.

The Performance Index Finder determines that our objectives are optimally met by minimizing

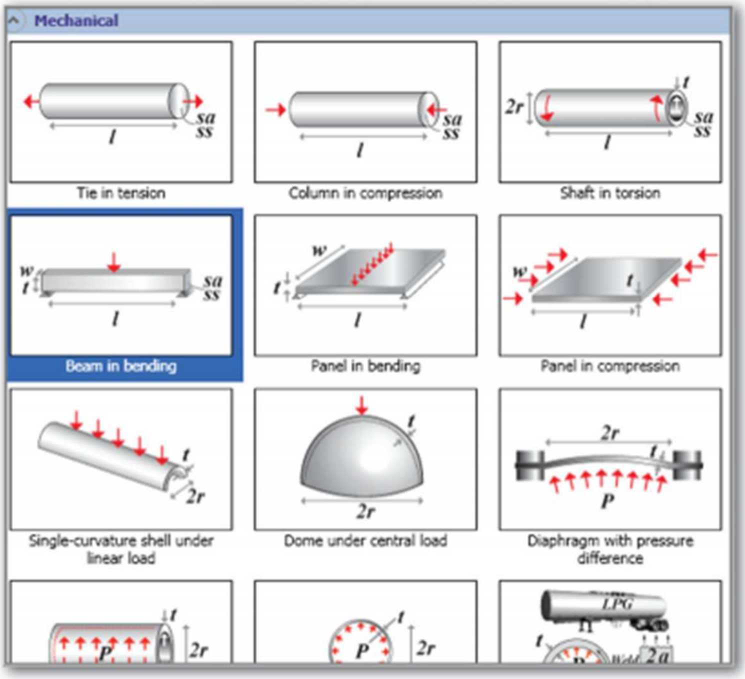
Cost = (ρ x c_m) / √E

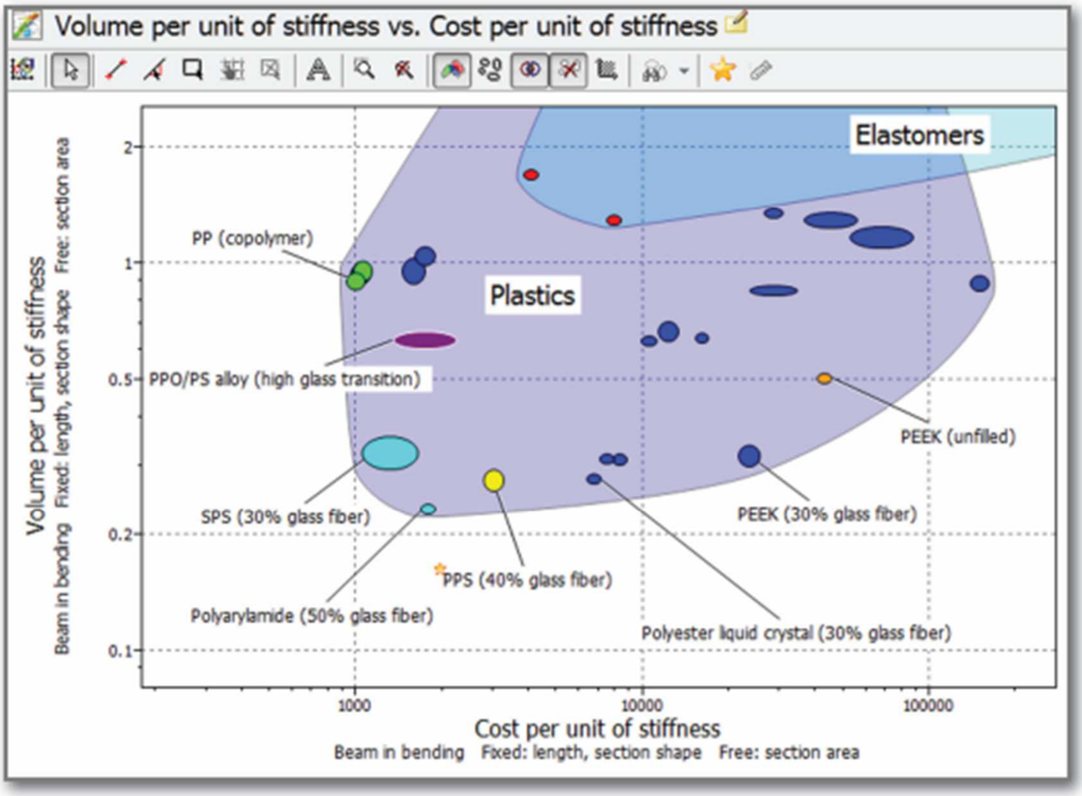
And

Volume = 1 / √E .

CES Selector automatically plots a graph for these objectives so that the trade off between them for the different materials can be seen.

Right: *The performance Index Finder tool offers a simple graphical menu from which the user can select the function and loading options.* Below: *Selection chart for optimizing the cost and volume performance indices for potential materials. Materials closest to the axes are optimal for the objectives shown. The light blue materials were not available for medical use when the original selection was performed in 2003.*





2.4 Conclusions

CES Selector, combined with a user's materials expertise, suggests the following conclusions:

- Initially, unfilled PEEK (PEEK Classix, orange in figure) was being considered for use. The chart shows that PEEK is a valid option, but it is neither particularly low cost nor particularly low volume, so not an optimal choice.
- Unfilled polypropylene copolymer (green in figure) is the cheapest option, but the forceps handles will need to be bulky to have adequate stiffness and strength.
- PEEK carbon fiber composites (e.g., Endolign) had been considered, and would give a substantial bulk reduction compared to unfilled PEEK. They do not feature on this selection chart as they fail to pass the processing or electrical resistivity criteria.
- Polyester Liquid Crystal-based materials do feature on this chart, offering 0.3 of the volume of polypropylene, but cost more and have a poor surface finish.
- A similar volume reduction is available with glass filled PPS (Fortron, yellow on chart), with a lower cost penalty.
- An intermediate choice is PPO/PS alloy (medical grade Noryl, purple in figure), which has about twice the bulk of Polyester Liquid Crystal or PPS, but a third of the material cost.

The Surgical Innovations Group chose Ticona's Fortron (40% glass filled PPS, yellow in figure) for their forceps in 2003[2]. In light of these results, it is clear that this material was then at the apex of the cost-vs-volume trade-off curve, and the optimum choice. Since the original study was performed, new medical grades have become available (light blue in the figure). Consequently, both Polyarylamide (IXEF) and SPS (Xarec) could be considered as candidate materials.

2.5 Further reading

Ashby, M.F., '*Materials Selection in Mechanical Design*', (2005), Butterworth Heinemann, Oxford.

'Composites Technology', December 2003.

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