Level 3 Industrial Case Study

Fast mass-production of medical safety shields

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Summary

Selection of sterilizable transparent materials suitable for fast production of medical safety shields was conducted based on the analysis of merit indices, namely, minimal weight and minimal cost at given stiffness. Due to the need for permanent wear, the design was motivated by low mass, comfortable for long-term usage head fixation, and simple assembly, and high production efficiency.

Table of Contents

What is the scope?

Extraordinary circumstances of the COVID-19 pandemic significantly changed the landscapes in businesses, activities, and everyday life. New challenges emerged in the production, supply, and trading of many goods such as personal safety means and protection wear. This extra demand directly affected the capabilities of hospitals to limit the spread of infection between medical personnel. The efficiency of goods like face filtering masks and transparent full face medical shields is discussed and doubted by some specialists [1]. However, even imperfect extra protection reduces the risk for medical personnel in hospitals, paramedical staff and volunteers, and, ultimately, ordinary citizens.

The most recent, comprehensive review of face shields for infection control [2] concluded these products were mainly considered and regulated as labor protection equipment against mechanical impacts and that at least in 2016 there were no standards (only recommendations) posing the norms on face/eye protection against infection [3]. Other aspects of personal protection equipment safety against biohazard are covered by a number of norms [4, 5].

Although transparent full face medical shields (Figure 1) are undoubtedly less efficient than hermetic face masks protecting eyes and nose, the emergency demand for these is estimated at millions of pieces worldwide. During COVID-19, the answer was needed within a few weeks. Alternative stock reserves of medical shields, from the sport, diving, or professional stonemason, woodworking, and metalworking areas, are minimal.

a) b) c)

Figure 1. Example of personal protection equipment: a) full face shield (Medical Supplies and Equipment Co., Katy, Texas 77450, USA); b) construction worker goggles Archimedes 91862 (Technoplast Ltd., St. Petersburg, Russia); c) full face shield (FabLab, Skolkovo Institute of Science and Technology, Moscow, Russia)

Meanwhile, stringent border controls over international trading traffic, introduced by many governments in combination with obvious logistic limitations, prevent fast supply from traditionally low-cost sources (China, Indonesia) with industrial infrastructure for mass-production for global demand built up over decades. The current context conjures up memories of World War II context when all available national manufacturing resources and manpower were mobilized for low-cost mass production. Low-cost mass fabrication practices from that epoch may turn out to be relevant, with obvious adaptation to the modern technological, communication and logistic landscape.

The following aspects need to be taken into account:

- Consider big cities which are the most affected by COVID-19, such as Milan, Madrid, London, New York and Moscow. These are deeply deindustrialized, while external supplies of raw materials and tools are subject to delays or entirely disrupted.
- Manpower is mainly quarantined (self-isolated) or has limited access to production workshops.
- Nevertheless, some stock reserves of raw materials remain readily available in local manufacturing plants and transit warehouses or at least in commercial centers.

- As a universal rule, big cities are also centers of academic science concentrated in universities. Materials Science and Engineering Departments support fabrication centers and laboratories equipped with traditional and modern tools for shaping metal, polymer and composite materials.
- CAD/CAM production paradigm suggests that a small number of designers (quarantined at home) and workers (granted access to workshops and focused on performing the most complex fabrication operations) can generate a significant volume of simple parts for further manual assembly by a community of volunteers or users on or off site.
- The transportation and delivery of parts and the collection of assembled ready products can be organized via automated delivery.

How to tackle the problem?

By applying the "as simple as possible" design principle to medical face shields, we suggest cheap, easily accessible materials, along with small and medium scale laser cutters widely available in university workshops and fabrication laboratories. The design aimed to enable permanent wear of this means of protection, by reducing weight and providing comfortable fixation to head. We have taken into account the aspects of minimal tooling and the use of "assembling by final user" or "distributed volunteer labor" and sterilization.

Material selection and safety audit

Material selection for a transparent medical face shield requires the following steps [6]:
i) translation of design requirements, ii) screening against the material attribute limits, iii) ranking of materials in terms of performance indices; and iv) expert assessment and local testing (Figure 2).

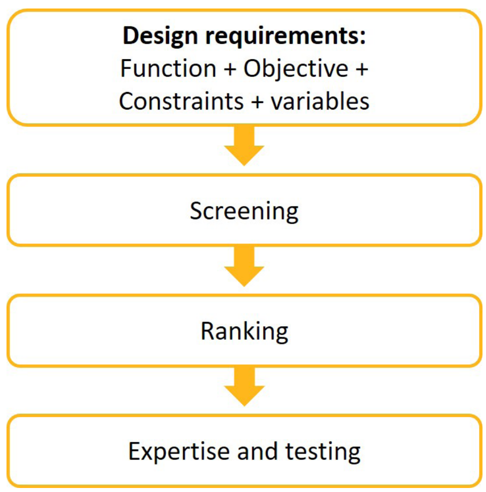


Figure 2. Material selection process.

This was carried out as follows:

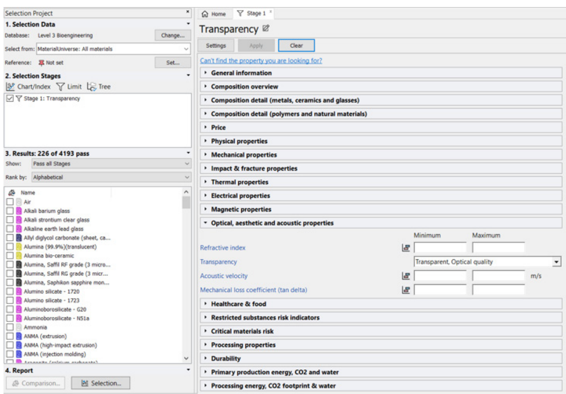
i) Translation

- **Function:** Stiff panel (plate) resisting the bending force,
- **Objective:** a) Minimize mass; b) Minimize cost,
- **Constraints:** Non-negotiable constraints: * transparency: transparent or optical quality * non-allergic and non-toxic in the contact with skin *Area AxB is specified * must not be brittle,
- Negotiable constraints: * must withstand limited bending force with small distortions * must not yield, buckle or fail under own weight and limited bending force

- **Free variables:** * plate thickness * material choice.

ii) Screening

The constraint on transparency significantly reduces the number of candidates – from more than 4000 down to 226 as shown in the Figure 3a (Level 3 Bioengineering> Chart/Select>Materials Universe: All materials>Limit>Optical, aesthetic and acoustic properties>Transparency). The candidates which passed the “transparency” filter represent different classes of materials (Figure 3b) including senseless fibers and particulates and technical ceramics like sapphires and quartz and various glasses. Ceramics and glasses will be further excluded because of brittleness and obvious technological difficulties in application of shaping processes. By limiting the material class to polymers and elastomers, the candidate number can be further refined to only 129 materials for the ranking stage (Chart/Select > Materials Universe: All materials > Tree > Polymers: plastics, elastomers).



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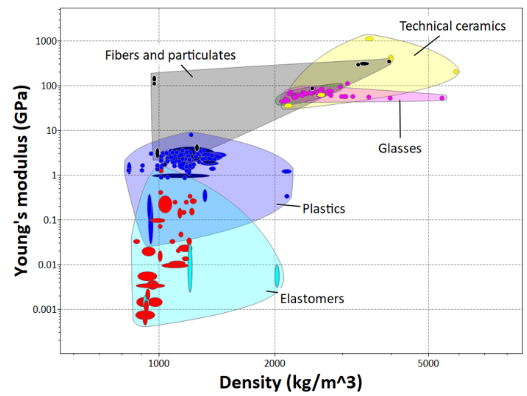

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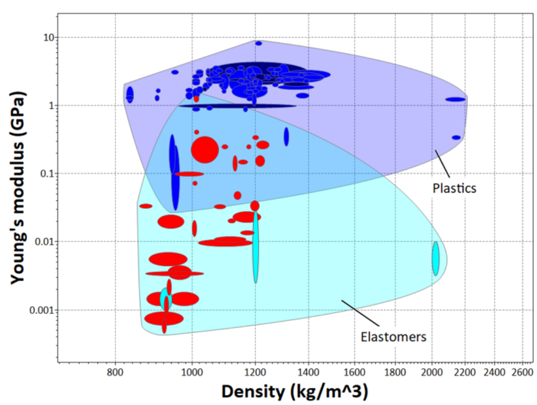


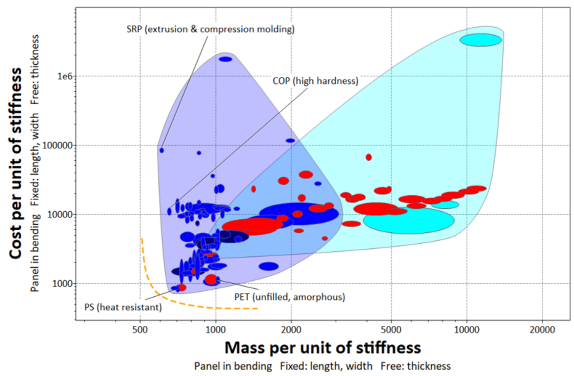
c)

Figure 3. Material selection for transparent medical face masks. Screening stage: a) the list of candidate materials passed “transparency” filter; b) bubble charts for all transparent materials and c) for polymers and elastomers, [7].

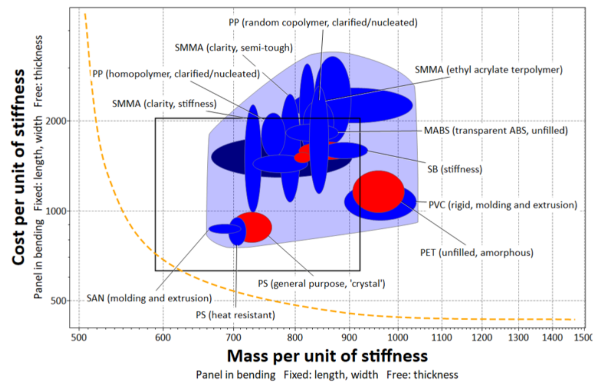
iii) Ranking

The mask screen itself is a panel in bending. The performance indices tables are available in Granta EduPack, Level 3 Bioengineering (Learn>Material Selection>Performance Indices). The performance indices relevant for minimal mass $\frac{\rho}{E_f^{\frac{1}{3}}}$ and cost $\frac{C_m \cdot \rho}{E_f^{\frac{1}{3}}}$ of bent panel were chosen as the axes for bubble chart (Figure 4a).

Here ρ is density, E_f is flexural modulus and Cm is the price per unit mass. The bottom left corner is the region of interest which corresponds to light cheap material solutions. A sample of the best 19 candidates from that region is depicted in the Figure 4b. Yellow dashed line represent the trade-off for best weight (SAN) and cost (SMMA) solutions.



a)



b)

Figure 4. Material selection for transparent medical face masks. Ranking stage: a) 129 candidates; b) 19 candidates (red - optical quality; blue – transparent), [7].

iv) Expertise and testing

A list of the most attractive candidates is given in Table 1, in the order of ascending value of cost per unit stiffness. The top three candidates for both performance indices are Polystyrene (heat resistant), Polysytrene (general purpose, crystal), and Styrene acrylonitrile (molding and extrusion).

Table 1: Performance of candidate materials (top two candidates in respect of each performance indices are highlighted in grey), [7].

N	Material	Cost per unit of stiffness, USD/ GPa⅓·m³	Mass per unit stiffness, kg/GPa⅓·m³ (Place in the order of ascending mass)	Comments
1	Polystyrene PS (heat resistant)	767 - 953	692 - 718 (2)	Poor wear and fatigue resistance
2	PS (general purpose, 'crystal')	787 - 989	697 - 759 (3)	
3	Styrene acrylonitrile SAN (molding and extrusion)	841 - 902	663 - 710 (1)	Poor wear resistance
4	Polyvinyl chloride PVC (rigid, molding and extrusion)	933 - 1240	890 - 1040 (11)	
5	Polyethylene Terephthalate PET (unfilled, amorphous)	988 - 1360	907 - 1010 (12)	Not suitable for negative temperatures
6	Styrene-methyl methacrylate copolymer SMMA (clarity, stiffness)	992 - 2260	716 - 743 (4)	Susceptible for stress whitening
7	SMMA (clarity, semi-tough)	1070 - 2450	773 - 808 (6)	
8	SMMA (ethyl acrylate terpolymer)	1140 - 2610	825 - 859 (9)	
9	Styrene-Butadiene SB (stiffness)	1500 - 1690	845 - 936 (10)	
10	Polypropylene PP (homopolymer, clarified/ nucleated)	1520 - 2120	743 - 782 (5)	
11	PP (random copolymer, clarified/nucleated)	1680 - 2340	814 - 869 (8)	
12	Methyl methacrylate-acrylonitrile-butadiene-styrene MABS (unfilled)	1710 - 1950	784 - 878 (7)	

During the COVID-19 pandemic, there has been great emphasis not only on covering the face, but also on washing hands and stopping the spread of the virus. Alcohol-based hand sanitizers are now a common household item, and although protective visors are marketed as 'single-use', it would not be surprising to learn that cleaning products are being used to extend the life of the product. Considering this, Table 2 presents additional data relevant to the material's sterilizability and durability in organic solvents (Level 3 Bioengineering > Chart/Select > Materials Universe: All materials > Limit > Durability).

Table 2: Sterilizability of candidate materials is given in comparison with the exposure to ethylene oxide (EtO) gas and rated as excellent, good, marginal and poor, [7]

N	Material	Sterilizability			Durability- Organic solvent
		Ethylene oxide	Gamma radiation	Steam autoclave	
1	Polystyrene PS (heat resistant)	Marginal	Excellent	Poor	Unacceptable
2	PS (general purpose, 'crystal')	Marginal	Excellent	Poor	Unacceptable
3	Styrene acrylonitrile SAN (molding and extrusion)	Marginal	Good	Poor	Unacceptable
4	Polyvinyl chloride PVC (rigid, molding and extrusion)	Excellent	Marginal	Poor	Limited use
5	Polyethylene Terephthalate PET (unfilled, amorphous)	Excellent	Excellent	Poor	Limited use

Although both types of PS and the SAN candidate have the best trade-off between the two performance indices, their durability when exposed to an organic solvent is deemed unacceptable. The next best materials in terms of cost per unit of stiffness are Polyvinyl Chloride (PVC) and Polyethylene Terephthalate (PET), also included in Table 2. Since high temperatures are required for steam autoclave sterilization (121°C and 132°C are commonly applied worldwide, though higher temperatures are also used for metal surgeon instruments), most polymers are excluded, hence the 'poor' result across Table 2. Out of the five top candidates, the choice of PET for full face mask is justified due to the excellent sterilizability with help of ethylene oxide and gamma radiation, as well as an improved 'limited use' with organic solvents.

While the final choice should be defined after the analysis of local prices, stock resources and available equipment for fast shaping, PET has the additional benefit that is it of optical quality and was selected as the candidate as the most accessible in the situation of pandemic emergency.

Shaping and assembling recommendations are given in Appendix 1.

Conclusions

COVID-19 pandemic dramatically challenges society to find technical solutions for the fast mass production of low-cost personal safety means to protect medical personnel and ordinary citizens. When supplies are limited by the restrictions on trading and transportation and workforce quarantined, these technical solutions must rely on the designs suggesting simple tools operated by a minimal number of operators. CAM technology realized as the cutting of sheet materials using widely available in university workshops and fabrication laboratories is viewed as optimal for fast mass production of parts to be assembled by a community of volunteers or end-users at the site.
More details are here: https://www.mdpi.com/1660-4601/17/10/3418 [9].

Acknowledgments

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[9] https://www.mdpi.com/1660-4601/17/10/3418

Appendix 1. Production requirements for design: shaping and assembling

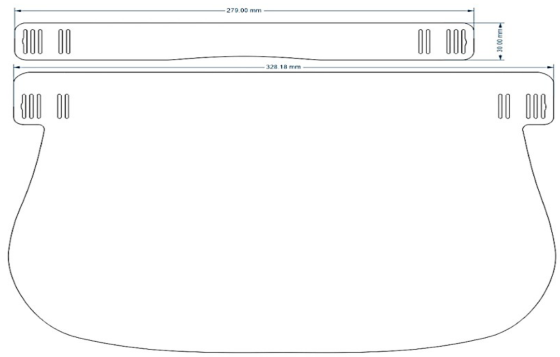
The guidelines for fast low cost mass-production are:

A. All designs should be as simple as possible. This means both minimal number of parts and simplest design of each part.
B. All materials applied should be as cheap and as more affordable as possible.
C. All technologies applied should be as simple as possible to achieve the highest productivity relying on simplest tooling for shaping and no tools for assembling and unqualified manpower (any end-user such as oldsters, housewives and teenagers).
D. The number of technological steps, pre- and post- treatments should be minimized. This includes material synthesis, shaping and joining or assembling.
E. The transportation of parts should be minimized along the production chains. Following these guidelines, the design was based mainly on the cutting of PET sheets and elastic fabric band. The layout of the pattern ready for laser cutting of front flap and forehead strip is represented in the Figure 5. This pattern was used to cut PET lists having 0.5 mm thickness (or 0.3 mm version is 35 mm shorter and 30 mm narrower). This material has been justified in terms of optical quality and minimal cost (although, other candidates provide advantages in terms of minimal mass) above and it is relatively affordable in local conditions. Other materials from the Table 1 are

merely suitable if affordable from local suppliers since they also possess adequate rigidity. When changing the material, one needs to experimentally adjust the laser power and cutting speed only. Drawings do not need to be changed, that is an important and obvious advantage.

Fixing back elastic band can be realized from potentially any flat elastic band or rubber ribbons available in a needlework and sewing store. The current design has a flat 20mm elastic fabric band with adjustable length for optimal personal comfort.

a)



b)

c)

Figure 5. Devised full face transparent shield – stages of fabrication a) ready product; b) pattern for laser cutting; c) laser cutting of forehead strip

In the 21st century, public workshops, fabrication departments, laboratories or workshop facilities in the universities, at schools and in after-school fablab clubs for children and youth became widely spread. Almost all of them have CAD/CAM equipment such as 3D printers and what is necessary for this particular design - a laser plastic cutter with suitable working characteristics. An option of cutting with a hot knife requires minimal training (less than 5 minutes) and intensive exhaust ventilation. That is hard to implement at flat, but it is still reasonable to work outside or in a countryside workshop in a warm climate with the personnel having proper PPE (Personal Protection Equipment).

The minimal set of equipment includes:
- a laser cutter[1] (available in a huge number of workshops) of any power, though the mastered regime suggests that optimal performance is achieved at 100 Won PET.
- a soldering iron as a hot knife.

1 It is also possible to shape the part using both a cutting press or a water-jet cutter

Equipment and recommendations for the production:

1. Cutting the sheet material for the front visor and forehead strip.
- A CO_2 laser cutter with any characteristics. If the maximum performance is required, it is optimal to use a nominally 100 W laser and an average speed of 105±10 mm/s (depending on actual layout of cut part within the sheet area) at 70% of power to avoid laser source degradation. A SYNRAD FSTI100SFB, 48.3V/21A laser tube was used in the present case. If the laser cutter can maintain the quality of curved surfaces at a higher speed and the laser lifetime can be consumed, it is advisable to increase both characteristics up to the limit to be experimentally found (Figure 6).
One should expect a production rate of about 6 cut parts per 4min 30sec at 900x600mm at each laser cutter. One person can operate two laser cutters simultaneously which results in up to 130 sets in an hour (fume-extraction time is added). Smaller machine will decrease the productivity.
Mechanical pattern cutters driven by pneumatic, hydraulic or mechanical actuators are undoubtedly much more performant but the production and repairing of cutting forms is the bottle neck stage in the present circumstances.

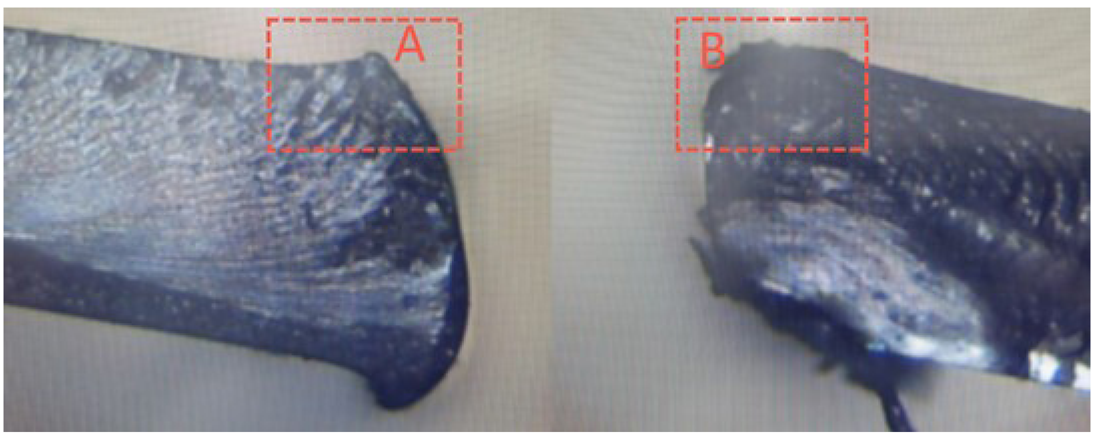


Figure 6. Laser cutting results in the sharp edges (A). Sandpaper processing: the final forehead strap cross-section is shown (B) (Image by Skoltech Advanced Imaging Shared Facility).

2. Cutting of fabric elastic band (or rubber ribbon).

-hot knife for cutting synthetic fabric or fabric elastic bands to simultaneously cut and secure the cut edge from unraveling. A cheap household soldering iron 80 … 400W ($3) with an initially thick but manually sharpened stinger was applied to reach the resulting performance of up to 1 cut per 2 seconds. The process requires appropriate fume extraction and proper PPE!

-CAM hot knife that is available in specialized sewing workshops.

-conventional scissors can be used to significantly accelerate cutting process up to more than 30 cuts per minute while cutting 3 tapes simultaneously. A guillotine-type hand cutter (60 cuts per minute, 6 tapes at the same time) is also an option. Mechanical cutting of fabric elastic band, however, deteriorates the performance of fabric elastic band due to the unraveling.

3. Assembling the front visor, forehead strip, and elastic band in all types of design is manual.

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