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# DESIGN AND PRODUCTION OF CUSTOM-MADE PROSTHETIC IMPLANTS IN PECTORAL RECONSTRUCTION IN PATIENTS WITH POLAND SYNDROME USING INTEGRATED CAD / CAM SYSTEMS

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## ABSTRACT

### 1.1. Background
Poland Syndrome is a rare congenital condition characterized by deformities affecting soft and skeletal tissues of thorax and ipsilateral upper limb. Psychophysical integrity, especially for young people, is influenced by early diagnosis and an effective therapeutic strategy. Reconstructive surgery is the gold standard treatment and developing custom-made implants could dramatically change the outcomes for those patients.

### 1.2. Methods
The study aims to develop an entire production process which starts from morphological data acquisition to definitive implant production through 3D-printing processes. Data were acquired from 10 male patients affected by Poland Syndrome.

### 1.3. Results
An MRI acquisition protocol was developed, leading to the creation of the first 3D-model and custom-made prototype then evaluated directly on the patient.

### 1.4. Conclusions
Nowadays, impressive personalized healthcare experiences can be achieved with software and 3D-printing techniques. The advantages of custom-made implants are unquestionable, though a cost-benefit analysis should be evaluated in detail.

## 2. INTRODUCTION
Poland Syndrome is a rare congenital condition characterized by unilateral deformities affecting soft and skeletal tissues of thorax and ipsilateral upper limb. The main diagnostic criterion is the unilateral, partial or complete, lack of the pectoralis major muscle. Rib cage deformities are often present and vary from mild forms of asymmetric pectus excavatum/carinatum up to the absence of multiple costal arcs and/or complex sternal deformities (Romanini et al., 2016).

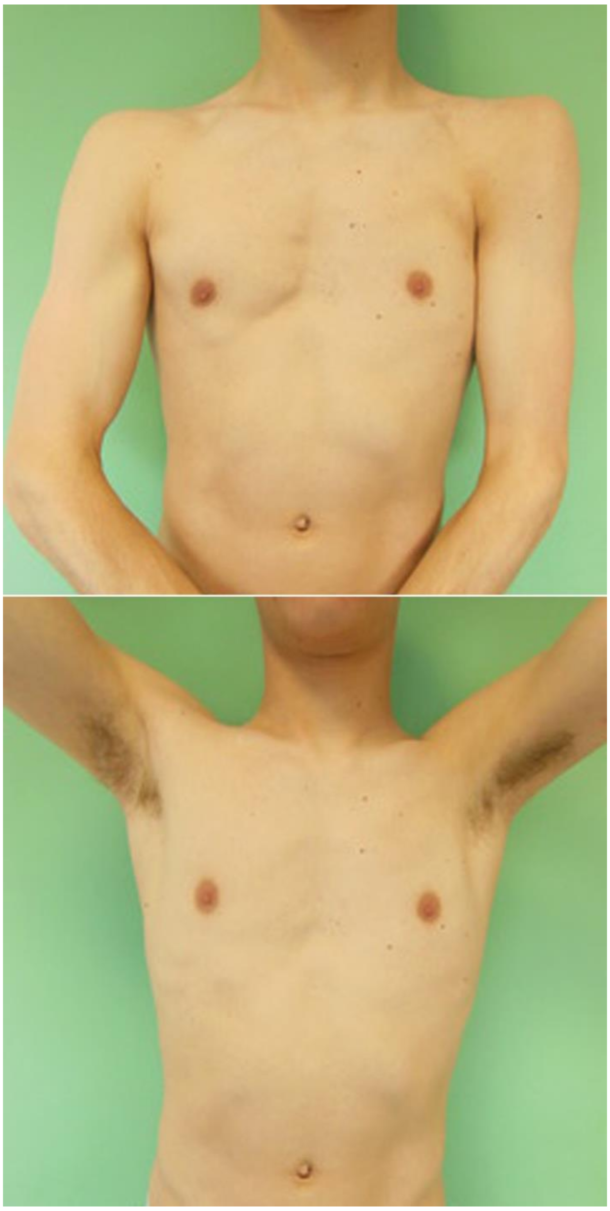

Figure 1: Example of mild Poland Syndrome chest deformity of a young male patient.

Hand and upper limb anomalies generally include clinical presentations of increasing severity from an hypoplastic hand without morphologic and functional anomalies to symbrachydactyly with absent or non-functioning fingers (Catena et al., 2012). Reconstructive thoracic surgery is mandatory when functional impairment or severe chest wall deformities are present. Fortunately, in most cases chest wall deformities are mainly “cosmetic” and characterized by the lack of the anterior axillary pillar, subclavicular hollow and dislocation of the nipple-areola complex due to agenesis of the pectoralis major muscle. Cosmetic and social aspects of this pathology are not negligible. Early diagnosis and timing in therapeutic approach are essential for patient psychophysical integrity, especially for young people (Baldelli et al., 2016; Romanini et al., 2018). Reconstructive surgery with autologous adipose tissue associated or not with a pectoral implant is the least invasive and most suitable surgical choice, especially if performed in teenagers. However, male pectoral implants available on the market do not suit the particular anatomic conditions characterizing Poland Syndrome. This project aims to develop specific custom-made design implants for patients affected by this malformation by processing data acquired by Magnetic Resonance Imaging rather than three-dimensional volume-rendered computed tomographic scans (Chavoin et al., 2018).

## 3. METHODS

Ten male teenagers with Poland syndrome were selected from patients with no thoracic functional impairment and no functional specialist reconstructive surgery required; in particular, they were also not candidate for reconstruction with pectoral implants available on the market due to their anatomical characteristics. Data regarding patient age and physical characteristics are shown in Table 1.

Table 1: Descriptive data of the 10 patients in the study

| | **Min** | **Max** | **Mean** | **Std. Deviation** |
|---|---|---|---|---|
| *Age (years)* | 16 | 40 | 27 | 8,804 |
| *Height (cm)* | 170 | 182 | 176 | 3,335 |
| *Weight (Kg)* | 54,0 | 76,0 | 68,5 | 7,2971 |
| *BMI* | 18,7 | 24,2 | 21,7 | 1,8690 |

An overall view of the presentations of the selected patients, ranked according to their thorax, breast, nipple-areola complex (TBN) classification (Romanini et al., 2016), is shown in the following pie chart (Figure 2).

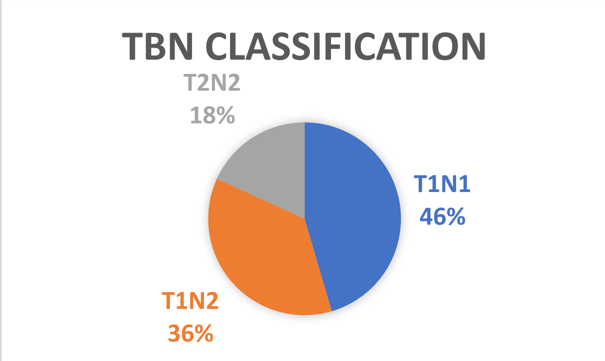


Figure 2: Percentages of TBN ranks of selected patients.

Utilization of CT imaging to acquire the necessary morphoanatomical data was strongly limited by the high amount of radiations to which the patients could be exposed. MRI was the most effective choice for the purpose thanks to high resolution and negligible impact on the patient. An MRI acquisition protocol for the chest was developed in cooperation with the production company and performed at different radiological centres, based on residency of the patients. Finding the best projection to gather most of the morphological data was the main difficulty.

Table 2: Descriptive data and comparison of measures in affected/not-affected chest sides; distances are expressed in cm.

| | **Min** | **Max** | **Mean** | **Std. Deviation** |
|---|---|---|---|---|
| ***G-C Distance*** *Poland side* | 14,0 | 19,5 | 16,4 | 1,6964 |
| ***G-C Distance*** *not-affected side* | 15,5 | 22,0 | 19,0 | 2,0261 |
| ***S-C Distance*** *Poland side* | 8,5 | 11,0 | 9,7 | 0,9443 |
| ***S-C Distance*** *not-affected side* | 9,5 | 12,5 | 11,0 | 1,0395 |
| ***Areola Diameter*** *Poland side* | 1,2 | 3,0 | 2,3 | 0,5190 |
| ***Areola Diameter*** *not-affected side* | 1,9 | 3,2 | 2,6 | 0,4315 |

High resolution and a large enough window were necessary to fully acquire data regarding muscle insertion and chest wall and soft tissue morphology, alongside the sequence to correctly discriminate the area of interest from negligible anatomical structures. Patient height and body-type limitations were an exclusion criterion, since MRI acquisition window was limited. 18 channels Siemens body coil excluded patients with a chest which exceeded frame edges. The technology adopted for the production process and data acquirement is the same utilized in several surgery contexts: neurosurgery with polyetheretherketone (PEEK) cranioplasties, mammoplasty with the development and production of silicone implants through dipping techniques. The possibility of thin film deposition with physical vapor deposition (PVD) sputtering technique could be considered as a next step.

## 4. RESULTS

The complete production process of a custom-made 3D-printed implant was developed, analysing possible benefits on 10 male patients affected by Poland Syndrome with no thoracic functional impairment and no functional specialist reconstructive surgery required. The process can be divided in several steps, from morphological data acquisition to device testing with the patient and subsequent surgical implantation. The first custom-made 3D-models, based on the selected patients, reached the prototype production phase.

### 4.1. Morphological Data Acquisition

Through a strict collaboration between Radiologists and Clinicians, an MRI acquisition protocol was designed. MRI imaging must include the whole area of the pectoralis major muscle with scans from the upper clavicular origin to the lower abdominal one (clavicle-to-diaphragm). T1 and T2 isotropic sequences are preferred with repetition times (TR) of 500-600ms and 4000ms respectively, and echo times (TE) of 10-15ms and 150ms respectively. Slices have a maximum width of 1mm, with voxel's dimensions of 1mm x 1mm x 1mm. Patient should be supine with arms resting alongside the body to limit respiratory artefacts while right-left axial scanning is performed with 1,5 Tesla magnet. An example is reported in Figure 3.

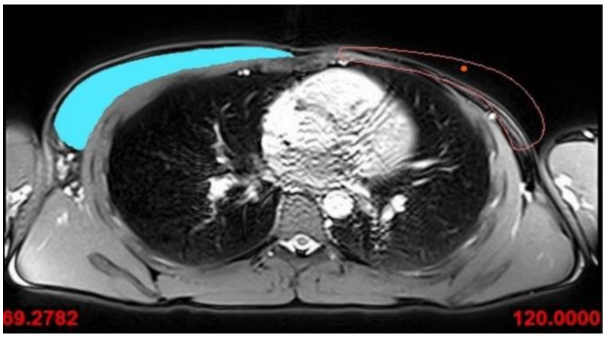


Figure 3: MRI slice with highlight of contralateral pectoralis muscle (blue) and mirror outlining

### 4.2. Data Elaboration

DICOM files were imported in Mimics Suite® software (Materialise NV, Leuven, Belgium). Segmentation and thresholds to identify tissues of interest were defined (Figure 4).

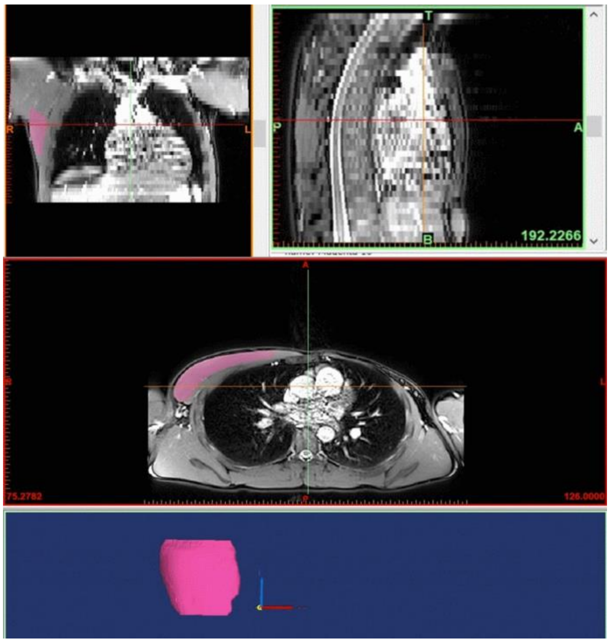


Figure 4: DICOM data elaboration from MRI imaging, identification of pectoralis area (pink highlight) and extrapolation of the pectoralis muscle area

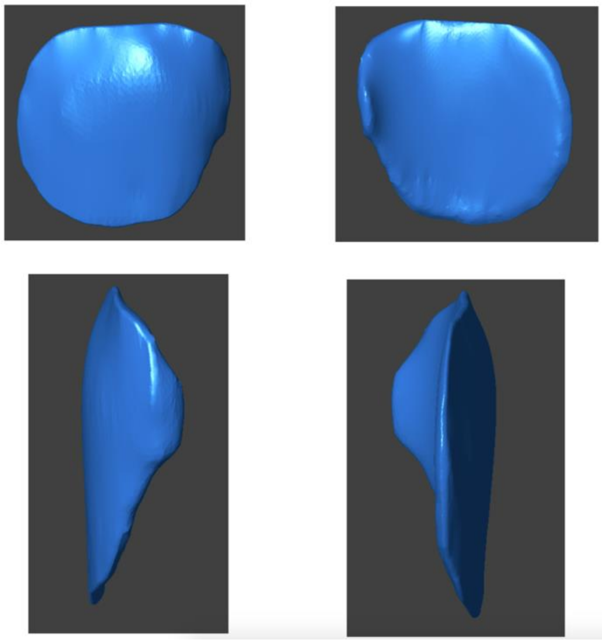

Figure 5: 3D model obtained through Mimics elaboration (standard sections: front, back, right and left)

The procedure must consider pectoralis major muscle asymmetry alongside possible thoracic plan deformations and characteristics of vascular district. Proceeding to 3D-printing requires a stereo lithography interface format file (STL file) adequately corrected to avoid missing edges and/or surfaces overlaps, etc. (Figure 5) A software with haptic functionalities (like Geomacic Freeform® or equivalent open source software) was adopted to transform STL files into CAD format, allowing finite element method (FEM) analysis of the model to test physical properties and performance. 3D modelling capabilities of such software can also be utilized in revision phase by the clinician to better fit the model to the specific patient.

**4.3. Prototype Realization**

An aluminium mould was designed with CAD software and a first prototype was obtained with technical silicone polymer (Figure 6). The mould consists in two pieces obtained through computer numerical control (CNC) process, specifically treated to achieve an adequate texturization of the implant.

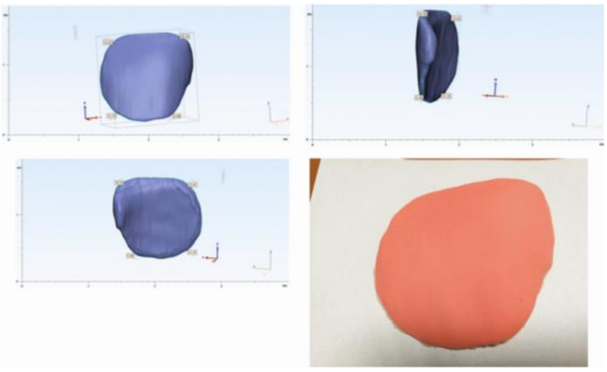

Figure 6: CAD design of mold and implant prototype in technical silicone polymer (pink element)

**4.4. 3D Model Check**

Technical and clinical checks were performed on the designed model. First step was to scan the prototype and virtually insert it in patients MRI images to check if all the project characteristics have been maintained over the printing process (Figure 7).

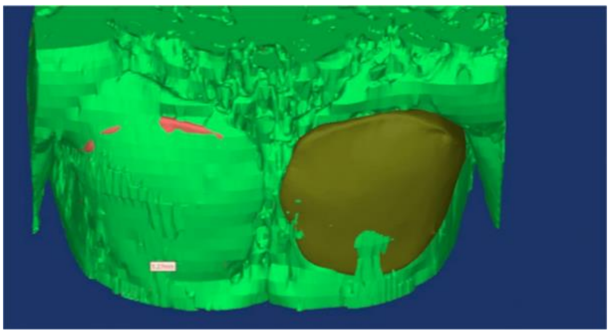

Figure 7: Reconstructed prototype inserted in patient chest MRI

FEM, a numerical method which allows to solve mathematical and physical problems with complex geometry, was performed with medical grade silicone parameters. Static constraints and standard loads can be applied to test physical interactions between implant, skeleton and surrounding tissues. Clinical observations, supported by computer mechanical analyses, are the focal point of model check-up which must be tested directly on the patient (stretchable t-shirt) with particular concern to necessary surgical techniques. An example of technical silicone prototype is reported in Figure 8.

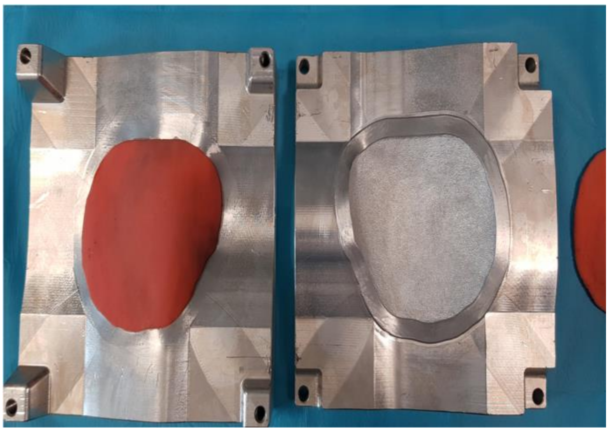

Figure 8: Prototype of the implant realized in technical silicone with aluminium mould

**4.5. Implant Production**

After revision and acceptance of the 3D-model, definitive long-term implant production initiates. Different techniques can be applied in production process: moulding and dipping were the two techniques considered by production company. Moulding technique is considered the most appropriate choice and medical grade silicone, due to its reliability, biocompatibility, stability over time and extensive utilization in breast implant surgery and production industry was selected. Silicone mechanical characteristics required consist in high flexibility and tear resistance: elastomeric silicone with hardness value of 6-12 Shore, tensile strength range of 3-5 MPa, elongation value of approximately 1075% and tear strength of at least 11 kN/m was selected to achieve high tensile strength and a realistic feel with an adequate density. The two sides of the mould (Figure 8) are then assembled, silicone is treated to remove air and introduced in the mould with a pump to avoid bubble formation (trapped air should escape through specific outlets). Mould can be adapted to offer different types of texturization (Figure 9) through an automatized engraving process operated by a software which considers peeks/indentations ratio and engraving uniformity. Filled mould undergoes a 5 minutes thermal curing process at 150° Celsius, which allows temperature-induced chemical changes in silicone, and a stabilization phase of 3 hours. Mould is then opened and the silicone implant is removed, removing macroscopic residues.

Figure 9: Selection of 6 texture types of mould surface

Newly created implant will be sanitized in specific clean-rooms and washed with pyrogen-free, double distilled water. The most appropriate sterilization process depends on medical silicone type. High performance liquid chromatography (HPLC) and Fourier transform infrared spectroscopy (FTIR) analyses will be performed to verify superficial contamination and eluates alongside tests to check sterilization and possible cyclodextrin residues. Alternatively, a Delrin model can be created from definitive 3D-model and a standard dipping production process can be applied obtaining an implant which is similar to those produced for mammoplasty purposes, with some shape limitations.

## 5. CONCLUSION

Alongside yearly changes in guide lines and evidence-based medicine, technology and bioengineering evolve to assist medical professionals in obtaining ever better outcomes for patients. 20 years ago, utilizing imaging techniques to obtain a custom-made silicone implant was inconceivable. Even if Poland Syndrome does not necessarily cause significant functional impairment, it has a huge impact on psychophysical integrity, especially for young people. The possibility to create an implant which perfectly fits patient anatomy could substantially improve cosmetic results leading to a better social acceptance, specifically for mild forms. Coating the silicone implants with thin films of several materials with high-biocompatibility is considered a possible next step for the study. A recent study by Chen K. et colleagues analysed the reliability of 3D surface imaging to evaluate breast shape and volume with results similar to MRI in terms of precision and accuracy, thus an application of this technology in data acquirement phase could be considered afterwards. Regarding highly debilitating presentations, different approaches are necessary for either cosmetic and functional purposes: presentations with severe thoracic defects, pectus carinatum and pectus excavatum can determine serious functional impairment and a multidisciplinary surgical equipe is necessary (plastic and reconstructive surgeons, thoracic surgeons) (Romanini et al., 2016).

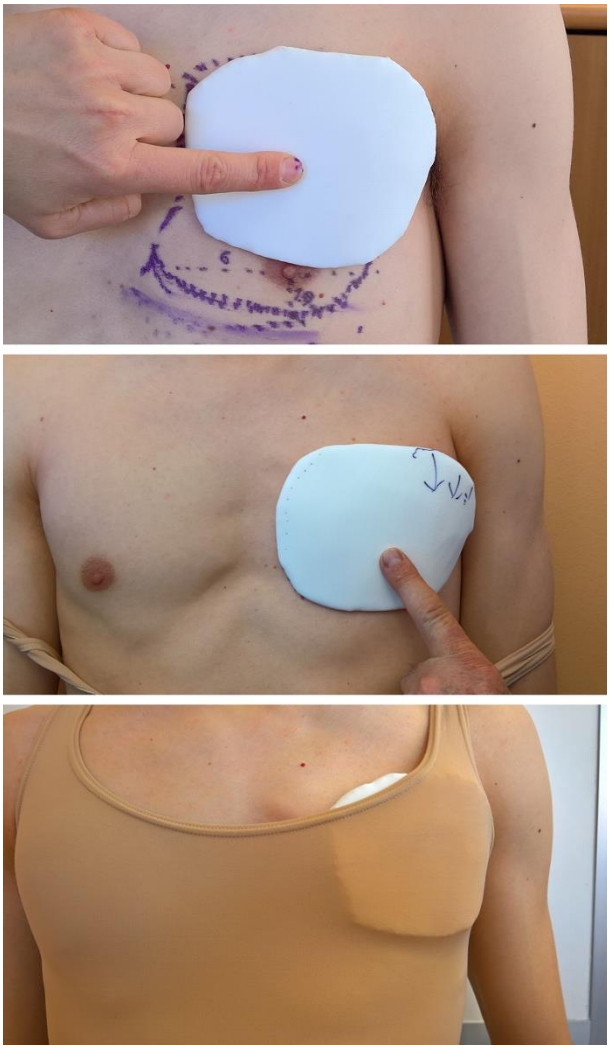

Figure 10: Prototype revision phase on the patient showing (from top to bottom picture) markings on the affected area and confrontation with prototype; clinician observations and device adaptation; implant testing with stretchable t-shirt

Even though 3D-printing of silicone devices is unquestionably promising in this area, a cost-benefit analysis must be considered. Clearly depending on the medical environment, is it public or private, the pursue of custom-made implants still relies on financial capabilities of the patient (in case of private healthcare) or structure (in case of public healthcare). Elaborating different 3D-models, aluminium moulds and/or Delrin models during the project obviously raised costs of the definitive implant. However, general costs and amortisation of the equipment/machines could be cut by the flexibility of the machines themselves, which could be utilized for elaboration, 3D-printing, moulding and dipping in several contexts (neurosurgery, plastic surgery, maxillofacial, etc.). Therefore, the cohort of people who could benefit from this particular kind of implants is small (especially the mild presentations) and the higher cost could be afforded by a public healthcare system.

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