Annals of Medicine and Surgery 66 (2021) 102420

Contents lists available at ScienceDirect

Annals of Medicine and Surgery

journal homepage: www.elsevier.com/locate/amsu

Technical Note

Patient-specific implants for craniomaxillofacial surgery: A manufacturer's experience

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ARTICLE INFO

Keywords:
Additive manufacturing
Patient-specific
Polymethylmethacrylate
Porous high-density polyethylene
Titanium mesh

ABSTRACT

Additive manufacturing technologies have enabled the development of customised implants for craniomaxillofacial applications using biomaterials such as polymethylmethacrylate (PMMA), porous high-density polyethylene (pHDPE), and titanium mesh. This study aims to report an Australian manufacturer's experience in developing, designing and supplying patient-specific craniomaxillofacial implants over 23 years and summarise feedback received from clinicians. The authors conducted a retrospective review of the manufacturer's implant database of orders placed for custom craniomaxillofacial implants between 1996 and 2019. The variables collected included material, country of order, gender, patient age, and reported complications, which included a measure of custom implant "fit" and adverse events. The development of critical checkpoints in the custom manufacturing process that minimise clinical or logistical non-conformities is highlighted and discussed. A total of 4120 patient-specific implants were supplied, of which 2689 were manufactured from PMMA, 885 from titanium mesh, and 546 from pHDPE. The majority of the implants were used in Australia (2260), United Kingdom (412), Germany (377), and New Zealand (338). PMMA was the preferred material for cranial implants whereas pHDPE was preferred for maxillofacial applications. Age or gender did not influence the material choice. Implant "fit" and adverse outcomes were used as a metric of implant performance. Between 2007 and 2019 there were 37 infections (0.98%) and 164 non-conformities recorded of which 75 (1.8%) were related to implant 'fit'. Our experience demonstrates a safe, reliable, and clinically streamlined manufacturing process which supports surgeons that require bespoke craniomaxillofacial solutions for reconstruction surgery.

1. Introduction

Following the advent of additive manufacturing technology in the mid-1980s [1,2], patient computed tomography scan data could be used to develop anatomically-correct models of the craniofacial skeleton [3,4]. Consequently, skilled prosthetists were able to fabricate anatomically matched implants from a choice of alloplastic materials before scheduled craniofacial reconstruction surgery. Surgeons were then presented with a set of design options to pre-operatively customise and manufacture a patient-specific implant within a safe, and reliable quality system framework. Such a process obviates the need for intraoperative craniomaxillofacial implant fabrication.

Currently, craniomaxillofacial implants are digitally designed and directly fabricated without the use of physical anatomical models and prosthetists due to advances in computing power, 3D modelling software and manufacturing technologies. Advanced design tools also permit a collaborative approach to implant design, involving real-time communication between the implant designer and the surgeon, which ensures surgeon confidence in the final product as well as the correctness of the implant's anatomical contour [5,6].

Such devices, which are referred to as "patient-specific implants" (PSIs), offer several distinct advantages: PSIs are engineered to precisely match the margins of the bony defect which improves the stability of fixation; PSIs may offer superior restoration of cosmesis, which is of critical importance in craniofacial surgery; and, PSIs are manufactured pre-operatively with reference to a 1:1 scale model of the patient's craniofacial defect and avoids intraoperative fabrication methods, which may improve surgical workflow efficiencies and patient outcomes.

Anatomics (Anatomics Pty Ltd, East Bentleigh, Melbourne, Australia)

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https://doi.org/10.1016/j.amsu.2021.102420
Received 11 April 2021; Received in revised form 18 May 2021; Accepted 22 May 2021
Available online 2 June 2021

was the first to market with PSIs manufactured using additive manufacturing technologies [4,7,8] and has accrued over twenty years of manufacturing experience. Anatomics supplies products to a global network of partner distributors and healthcare providers. The PSIs are manufactured within the framework of an ISO 13485 certified quality management system. The choice of implant material (PMMA, titanium mesh, pHDPE) and implant profile is based upon the surgeon's design inputs.

This study aims to describe the evolution of the critical design and manufacturing processes in the supply of Anatomics' PSIs. We also report the non-conformity and adverse event rate using Anatomics' entire post-market surveillance data from 2007 to 2019.

2. Materials and methods

2.1. Manufacturing methods

2.1.1. Biomodel

Each patient underwent a high-resolution planning CT scan following a biomodelling protocol [9]. Medical imaging data in DICOM format were transferred to a workstation running AnatomicsPro software (Anatomics, East Bentleigh, Australia) for processing before manufacturing a 1:1 scale BioModel of the osseous craniofacial anatomy from resin (Accura, 3D Systems, Rock Hill, SC, USA) using stereolithography (SLA250, 3D Systems).

2.1.2. Polymethylmethacrylate (PMMA)

The Anatomics PMMA PSI is a transparent, non-porous, biologically inert, strong implant (Fig. 1). The PMMA PSI is thermally polymerised under pressure in a boiling water bath to cure the methacrylate and minimise residual methacrylate monomer to negligible levels. The implant clarity allows the surgeon to easily visualise implant placement, dural stitching, and any fluid collection that may occur under the implant.

The PMMA PSI fits in the craniofacial defect to eliminate a visible or palpable margin. Fibrous encapsulation of the implant ensures simple removal in cases of recurring pathology requiring revision surgery. Three-millimetre diameter perforations are placed in patterns over the implant body. Implant thickness is patient-specific, and CT derived, ranging from 4mm to 7mm and never thicker than the adjacent bone. Fixation "pilot" holes of 1.4mm diameter surround the implant periphery to accommodate the required screw or plates. Additionally, the PMMA PSI can be designed to accommodate CranioFix™ fixation (Aesculap, Tuttlingen, Germany).

2.1.3. Titanium mesh

The Anatomics titanium PSI is a grey, porous, biologically inert, strong metallic mesh (Fig. 1). The PSI is 0.6mm thick and placed over the defect margins making it most suitable for defects with poorly defined margins. Countersunk holes of 2.0 mm diameter create a uniform mesh pattern across the PSI and allow for screw fixation, fluid perfusion and tissue suturing.

The mesh is attached with commercially available screws. Fixation is possible at any location provided there is sufficient underlying bone. The precise location of the screws is at the treating surgeon's discretion.

Fig. 1. Cranial Biomodel with a patient-specific implant in situ. Implants are made from (Left) Porous high-density polyethylene (StarPore®), (Centre) Polymethylmethacrylate, (Right) Titanium mesh.

2.1.4. Porous high-density polyethylene (pHDPE)

The Anatomics StarPore® PSI is a white, porous, biologically inert, strong polymer implant (Fig. 1). The interconnecting porous ("Pore-") architecture is created from a sub-millimetre star ("-Star") shaped particle that permits tissue ingrowth into the implant. StarPore® PSIs are sintered at high temperature to create an omnidirectional porous network that has greater than 50% porosity. The sintered particles also afford the strength, malleability, and biological porosity of the implant (unpublished data).

The porous nature of the implant permits tissue integration and implant vascularisation, which may improve implant stability and reduce infection risk. The StarPore® PSI fits in the craniofacial defect to eliminate a visible or palpable margin. Perforations of 3.0mm diameter are placed in patterns over the implant body. Implant thickness is patient-specific, and CT derived, ranging from 4mm to 7mm and never thicker than the adjacent bone. Fixation with mini-plates and screws or CranioFix® is possible anywhere around the implant periphery with no need for pre-drilled holes.

For facial applications, StarPore® implants can be used to reconstruct lost bone or augment existing bone as an "on-lay" to achieve the required cosmesis. Each implant is designed and manufactured to the exact patient-specific morphology to restore craniofacial cosmesis.

2.1.5. Post-processing

The PSIs were verified, cleaned, sterilised, and packaged under an ISO13485 quality system at Anatomics (Anatomics, East Bentleigh, Victoria, Australia) for delivery to the hospital. The surgeon may opt to take delivery and sterilise PMMA and titanium mesh devices at their respective institution. StarPore® implants were supplied sterile. Each PSI was supplied with a BioModel so that the surgeon can validate PSI fit, prepare the donor site accordingly and demonstrate the surgery to the patient and their next of kin. The implant 'fit' was assumed if the craniomaxillofacial reconstruction surgery was performed within six months of the planning CT scan.

2.2. Data collection

Data on every implant manufactured was captured in Anatomics post-market surveillance database. Variables included gender, age, material, cranial region, material, country, and date. Post-market surveillance data on the implants delivered by Anatomics, including clinician feedback, was captured through the Anatomics' quality system from 2007 to 2019. All PSIs described in this study were manufactured by Anatomics and supplied directly to the healthcare provider either by Anatomics or through a partner distributor. Clinician feedback on PSIs was directly communicated to Anatomics. For medical confidentiality and privacy reasons, details of the indications for craniofacial reconstruction and the clinical progress were not disclosed to Anatomics by the healthcare providers.

2.3. Data Analysis

Data was summarised by separating the implants into two groups: cranial and facial. Within each group, the implants were separated by material: PMMA, titanium mesh, pHDPE. For each subgroup, the number of units and materials utilised per year was summarised. Comparisons between age, gender, country and material use were summarised.

Note that Anatomics is not the sole provider of PSIs in each of the countries listed in this study. Post-market feedback is summarised as adverse events or non-conformities and is available if the surgeon wishes to report feedback. Clinical non-conformities include the number of implants that did not "fit" and implant designs that were not optimal. An unsatisfactory implant "fit" was recorded if the surgeon was unable to deploy the PSI or required substantial intraoperative modification, due to a geometrical mismatch between the craniofacial defect and the PSI. Logistical non-conformities included handling, labelling, and packaging errors; miscommunications during the ordering process that led to an implant not meeting a surgeon's specification; and, late deliveries. The total number of adverse events, namely explants secondary to infection and haematoma, are also reported.

3. Results

Material usage between 1996 and 2019 is illustrated in Fig. 2. PMMA and titanium mesh were both available to surgeons for PSI from 1996, whereas pHDPE (StarPore®) was introduced after 2007. Demographic data for 96 implants (54 PMMA, 38 titanium mesh, and 4 pHDPE) was not recorded and not included in this analysis. Total implants by country and material preference (Fig. 3) include: Australia (2242), UK (412), Germany (376), Finland (337), New Zealand (335), Malaysia (87), Singapore (73), Colombia (58), Portugal (46), Chile (30), Hong Kong [21], Netherlands [18], Sweden [16], Spain [15], UAE [14], India [13], Greece [11], (China = Bulgaria = Turkey = 1). Patient age range was 2–95 with median age 47 for 4104 implants and was not associated with material choice. Gender (2587 male:1557 female patients) was not associated with material choice (chi-squared = 4.5, p = 0.10). pHDPE (n = 137) was the most popular material for facial implants (Fig. 4), whereas PMMA (n = 2325) was most frequently used for cranial PSIs after 2008 when all three materials were available (Fig. 5). Out of 3749 implants delivered between 2007 and 2019, the total clinical and logistical non-conformities were 98 (2.6%) and 66 (1.8%), respectively. The adverse event rate was 1.0% (39), of which 37 and 2 explants were recorded citing infection and haematoma, respectively. There were 75 cases where the implant did not "fit" and 21 cases where the surgeon provided negative feedback on the appearance of the implant. Non-conformities and adverse events were not recorded for 371 implants delivered between 1996 and 2006.

4. Discussion

In a patient-specific and surgeon led design process, the motivation is to improve surgical workflow optimising the 'fit' of the PSI and minimising the adverse event rate [10,11]. The process provides a surgeon with a list of safe and viable design options to tailor the implant to their patient and is aimed at reducing surgical complexity by incorporating both patient and surgeon-specific considerations into pre-operative planning and the implant design. Consequently, we have identified the key checkpoints that must be completed to ensure an optimal 'fit'.

The first checkpoint is to ensure a high-resolution CT scan of the relevant anatomy is performed. CT integrity determines the quality of the output from the biomodelling process. For craniofacial applications, our scanning recommendations include a slice thickness of 0.5–0.625 mm, a spacing of 0.4–0.625 mm, gantry tilt of zero degrees, low milliamperage for bone, and higher milliamperage when soft tissue definition is required. The field of view should only include the structures of interest to the surgeon. Therefore, clinicians are requested to obtain pre-operative CT data using Anatomics' biomodelling scanning protocol [9] and plan to proceed to surgery with the PSI within six months of the planning CT used for biomodelling. Following, engineers use 3D modelling software to verify the CT data to check the accuracy and correct orientation before proceeding to biomodelling.

However, bony regrowth, scar tissue formation, soft tissue atrophy, and skin changes may develop between the time of planning CT and reconstruction surgery. The surgeon is asked to discuss the surgical reconstruction plan with the biomodelling engineers using a 1:1 scale patient-specific biomodel as a reference to minimise the risk of an implant mismatch. Before high-speed internet was available, a wax

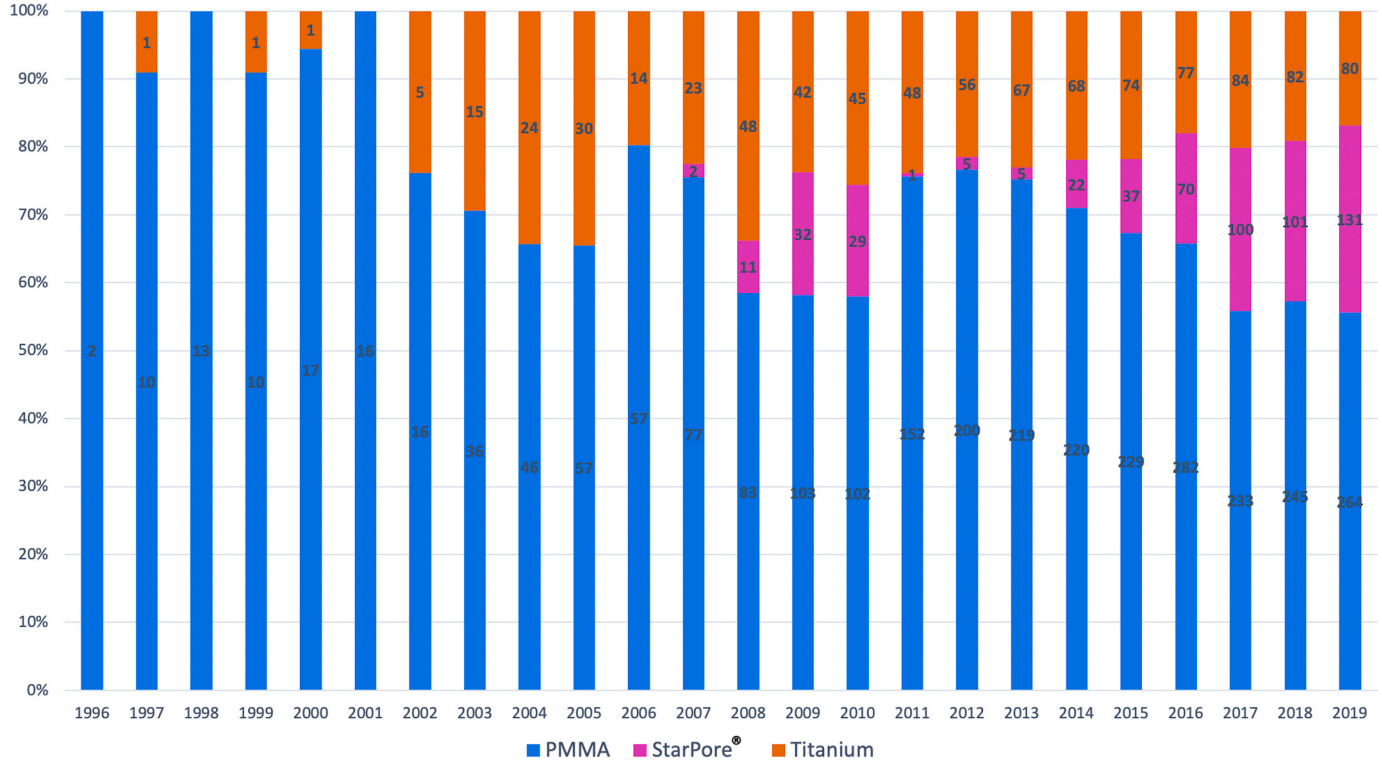

Fig. 2. Stacked 100% column graph demonstrating material usage over time.

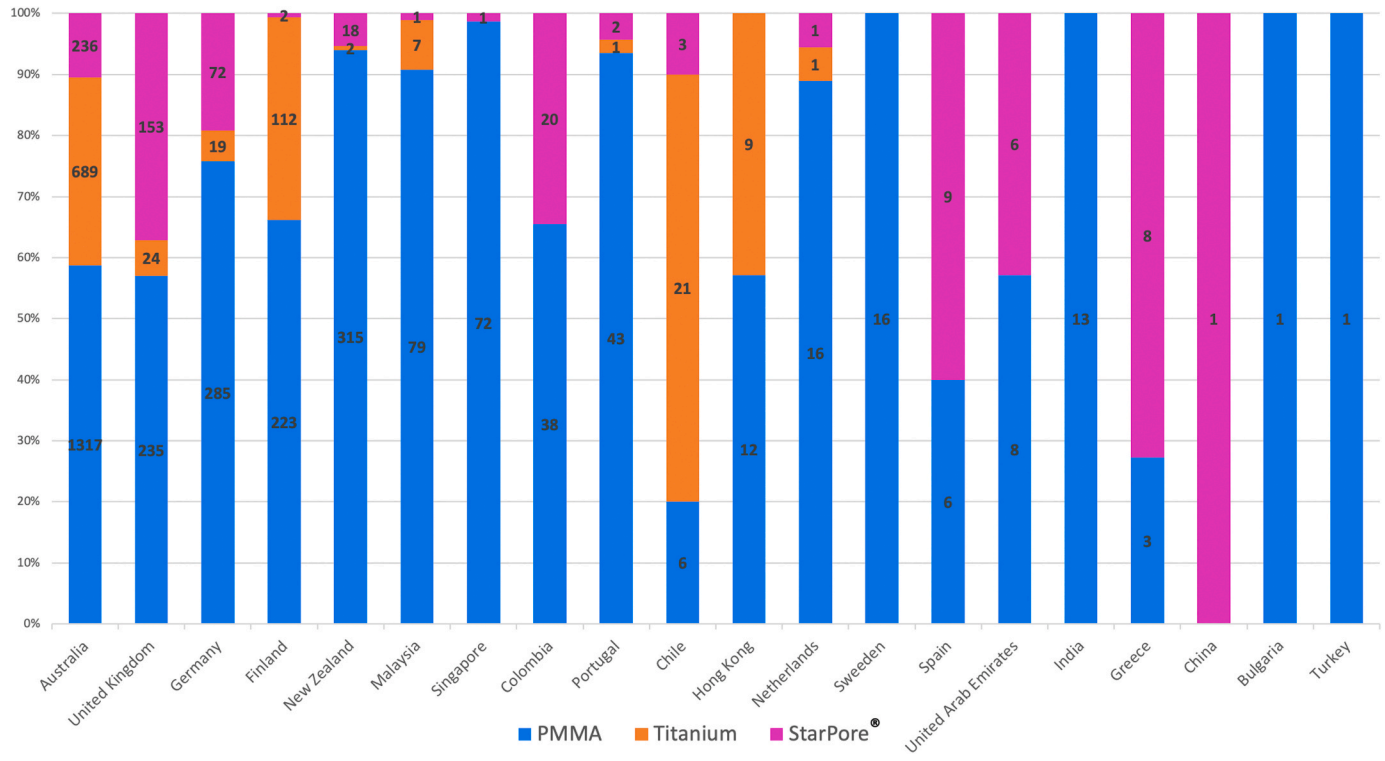

Fig. 3. Stacked 100% column graph demonstrating usage patterns by country.

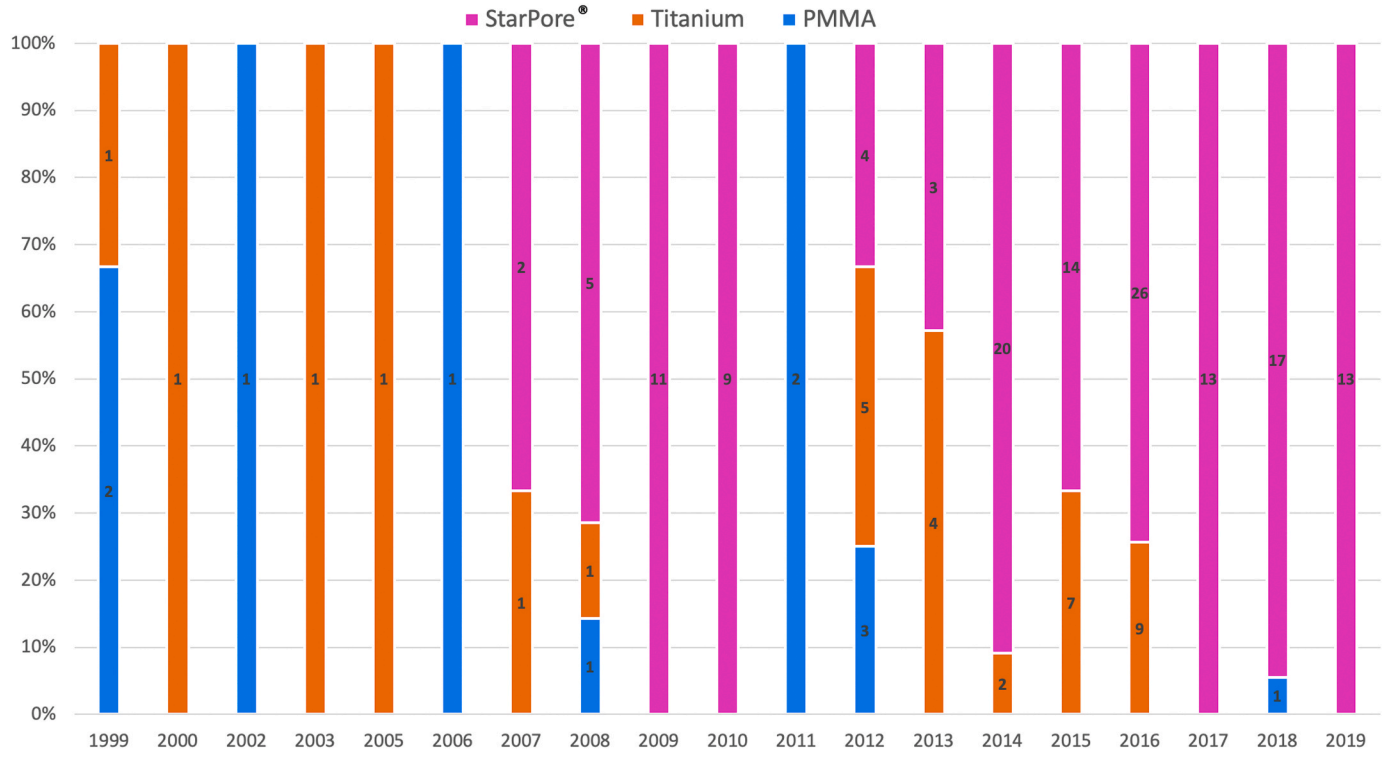

Fig. 4. Material usage for facial implants.

master of the implant was sent to the surgeon alongside the 1:1 scale biomodel to facilitate such a discussion. Currently, the surgeon is invited to attend an online planning session to visualise the anatomy, osteotomies, and implant design. Pre-operative planning incorporates a thorough assessment of the clinical case, surgical preferences, and implant material properties (Table 1). The surgeon may also specify fixation methods, drainage holes, suture anchor points, bone resection templates, drill guides, delivery time, contour, or implant profile to tailor the PSI to optimise the 'fit' and optimise surgical ergonomics.

The second checkpoint is to specify the surgical approach, exposure,

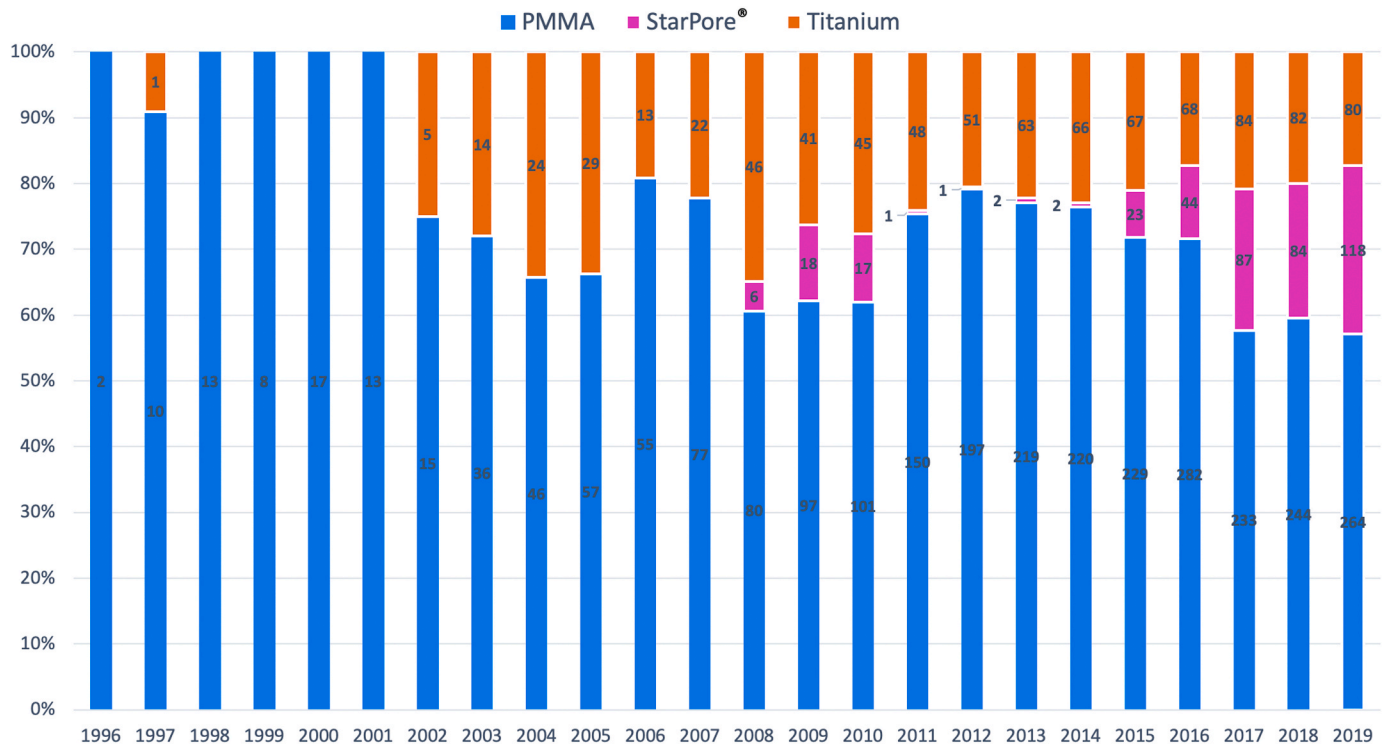

Fig. 5. Material usage for cranial implants over time.

Table 1
Properties of prefabricated materials used in craniofacial reconstruction.

Material	Strengths	Weaknesses
Titanium mesh	Non-inflammatory Non-corrosive Strong Malleable Overlay implant Simple screw fixation	Cost Image artefact Thermal conductivity Extrusion risk
PMMA	Strong Heat resistant Inert Transparent Radiolucent Lightweight Inlay implant	Poor osseous integration Thin flanges not viable on implant
pHDPE (StarPore®)	High tensile strength Resists compression yet flexible Easily fixed with screws Porosity permits tissue ingrowth Easily contoured with a scalpel Easily contoured using power-equipment without fragmenting Osseointegration Radiolucent Lightweight Inlay implant Thin flanges viable on implant	Cost Explantation may be difficult

and extent of soft tissue dissection overlying the craniofacial defect, which is ultimately the prerogative of the surgeon. Firstly, a 3D virtual model of patient anatomy is prepared from CT data and presented to the surgeon to verify that the modelled bony surface approximates the surgical plan. Secondly, implant margins are designed so bulky soft tissue masses do not impede that fit. Surgeons may choose to limit the margins of the PSI, which may simplify surgical 'fit' and limit the size of the surgical flap. In cases of inadequate skin coverage, such as sunken craniectomy flaps, the patient-specific design can incorporate lower implant profiles so that the skin flap can be appropriately stretched over the PSI to ensure a satisfactory cosmesis.

The third checkpoint involves optimising operational logistics. Processes such as biomodel validation, implant verification, post-processing, and shipping are performed under a strict quality system framework so that the PSI meets the surgeon's pre-operative plan on schedule for surgery. Nevertheless, the PSI may not meet its design requirements if the incorrect implant is delivered, the packaging is mishandled in transit, miscommunications occur between engineer and surgeon, and deliveries are delayed. Process verification and validation systems and post-market surveillance data are fed back to optimise the patient-specific manufacturing process, which is attested by the volume of implants delivered and the low complication rate over 23 years.

The fourth checkpoint is clinical validation. Upon receipt of the 1:1 scale biomodel and implant, the surgeon is able physically check the 'fit' in three dimensions. The biomodel may also be used for patient education or surgical rehearsal. Such a patient-specific process has previously been used to develop patient-specific tools and implants for other anatomical regions such as the spine [12–16], peripheral limb, cerebrovascular [17,18], brain tumour [19], and sternum [20–22].

Every biomaterial carries a risk of negatively affecting the clinical outcome. However, the relative risk of a biomaterial incompatibility is small compared to the combined influence of clinical indication, patient comorbidity, surgical technique, wound integrity, and postoperative self-care on clinical outcome. Overall complications rates following cranioplasty vary between 10.9 and 40.4% due to factors such as bone resorption (0.7–17.4%), surgical site infection (5–12.8%), seizure (3.4–14.8%), hydrocephalus (1.4–5%), postoperative haematoma (1.7–4.1%) and subdural hygroma (2.5%) suggesting that other variables may influence the adverse event rate other than the choice of biomaterial alone [23]. Even so, surgeons are quick to learn of, avoid, and report on the biomaterials that are consistently associated with poor outcomes. Such materials quickly become commercially unviable and therefore unlikely to remain in clinical practice over extended periods of time. Moreover, no single craniomaxillofacial implant material has emerged with the ideal biomimetic properties [24–26], and, as such, the choice of implant material should be tailored to optimise each clinical

case based on an assessment of the material properties (Table 1).

Limitations of this study include lack of long term follow up clinical data on every case in this series. A reporting bias is present as outcome data was only made available if clinicians reported their findings through Anatomics' post-market surveillance program. Patient demographics, clinical indication, postoperative outcome, and long-term outcome data were also not available due to healthcare privacy laws. However, we estimate that the reporting bias is low as PSI design requires the clinician and engineers to work closely together until surgical implantation; we estimate that the dataset in this series regarding implant 'fit' and 'adverse events' is complete.

Our current research efforts are dedicated to discovering new biomaterials and processes to provide clinicians with better patient-matched solutions. For example, the introduction of selenium or calcium sodium phosphosilicate nanoparticles into the StarPore® pHDPE scaffold promises optimised antimicrobial and bony integration properties of the material. Plasma treated StarPore® pHDPE particles have increased hydrophilicity, which improves cell attachment [27]. In addition, the advent of 3D-printed electronics expands the possibility of manufacturing sensors directly into patient-specific CMF implants for remote clinical monitoring.

In conclusion, our experience with customised solutions for reconstructive craniofacial surgery has evolved with developments in material science, computer-aided design, and advanced manufacturing. New materials and manufacturing processes were successively introduced within a quality system framework to provide treating clinicians with an inventory of safe, reliable, and clinically robust components to tailor customised craniofacial solutions for their patients.

Ethical approval

Not applicable.

Sources of funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for profit sector.

Author contribution

Study concept and design: Paul D'Urso.
Data collection: Robert Thompson, Ganesha Thayaparan.
Data Analysis: Ganesha Thayaparan, Philip Lewis.
Writing the paper: Ganesha Thayaparan, Philip Lewis, Paul D'Urso.

Research Registration number

1. Name of the registry: Research Registry
2. Unique Identifying number or registration ID: researchregistry6736
3. Hyperlink to your specific registration (must be publicly accessible and will be checked): https://www.researchregistry.com/browse-the-registry#home/registrationdetails/6072a10e3de19b001b45446c/

Guarantor

Paul D'Urso, Ganesha Thayaparan.

Consent

Not Applicable.

Provenance and peer review

Not commissioned, externally peer reviewed.

Declaration of competing interest

Robert Thompson is Vice President of Production at Anatomics Pty Ltd.

Paul D'Urso is Executive Chairman and shareholder at Anatomics Pty Ltd.

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