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Printed Titanium Implants in UK Cranio-Maxillofacial Surgery: Part I – Access to digital planning and perceived scope for use in common procedures

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Abstract

Introduction and Aims: This first part, of a two-part study, examines perceived applications for and barriers to using printed titanium in light of current caseloads, funding pathways and use of digital planning; aiming to demonstrate the scope for printed titanium in modern practice and guide industry upon the needs of UK surgeons.

Methods: A cross-sectional study was undertaken over 14 weeks; performed electronically with support from the British Association of Oral and Maxillofacial Surgeons and a national trainee-led recruitment team. Ethical approval was obtained at the lead centre.

Results: One-hundred and thirty-two participants joined the study (70% consultants, 25% specialty registrars and 5% other), approximating a 29% response rate from consultant/registrar BAOMS members throughout mainland UK. Eighty-eight percent used CAD-CAM design, with highly-variable funding/access, design/manufacturing workflows (in-house/outsourced). Eighty-eight percent were involved with trauma, 61% orthognathic and 52% oncology-reconstruction surgery.

Favourite applications for printed titanium were orbital floor repair (89%) and free-flap jaw reconstruction (87%). Most participants also cited maxillary / zygomatic osteotomies and cranioplasty (range 61-73%). Although a popular application (78%), the evidence base in temporomandibular joint surgery is limited. Those performing orthognathic surgery perceived more indications compared to those who did not (p=0.013). Key barriers include cost, turnaround time/logistics and need to train in traditional techniques.

Conclusions: Printed titanium is useful for both common and niche procedures but specifically limited in emergency trauma. Most have experience in CAD-CAM surgery but technical understanding appears unclear. Limiting factors include variable funding/production pathways, perceived costs and logistics: in-house design can minimise these. In part II, we quantify perceived benefits/limitations and whether surgeons' understanding/knowledge is sufficient to rationalise these.

Keywords: 3D printing; additive manufacture; Laser sintering; Selective laser melting / SLM; Printed titanium; Indications; Applications; Osteosynthesis; Patient-specific implants / PSI; Fibular flap, Waferless osteotomy, Orbital floor repair

Introduction

Numerous techniques exist for fabrication of computer-aided design – computer-aided manufacture (CAD-CAM) implants; but commonly additive manufacture ('3D-printing') or

subtractive manufacture ('milling'). Furthermore, many materials are available, including titanium and cobalt-chromium alloys, or polymers such as polyether ether ketone (PEEK) (1). Titanium is a historically-favourable material for biocompatibility, osseointegration and strength. Additional benefits of additive manufacturing in titanium relate to predictability, accuracy, tailored biomechanics and development of novel surgical techniques (some but not all of which are shared with subtractive manufacturing). However, turnaround time, technical demands and intraoperative adjustability are limiting factors (2). The 2018 commission on the "Future of Surgery" focusses on 3D planning/printing, stating "the surgeon of the future will be required to know how to introduce new technologies, evaluate them and report outcomes for their patients." (3).

Although many options exist, this study focuses specifically on 3D-printed (additively manufactured) titanium for the reasons aforementioned. The study provides a national picture on the perceived scope for using printed titanium in common/routine procedures. This paper (part 1) focusses on access to digital design, general clinical workload and perceived indications/barriers to use.

Methods

Drawing upon methodology of previous UK surveys of oral and maxillofacial surgeons (4,5), this cross-sectional study was designed in collaboration with and vetted by the British Association of Oral and Maxillofacial Surgeons (BAOMS) targeting UK oral and maxillofacial (OMF) surgeons as potential end-users of printed titanium implants. The electronic 59-question survey was constructed using Jisc online surveys (Bristol UK) and evaluated participant's access to / uptake of digital design and perceptions of 3D-printed ("additively-manufactured") titanium. The study was approved by the Faculty of Life Sciences and

Education, University of South Wales ethical committee (ref: 18AG1001LR). Following successful piloting in South Wales (response rate of 85%; *n*=17/20), a national team of study representatives was assembled through the BAOMS Fellows-in-Training (FiT) group from 12 of 15 regions ('deaneries') to invite survey participants at a regional level. Electronic invites were also distributed to the BAOMS membership on two occasions. Although primarily aimed at future end-users (consultants/fellows and registrars/FiTs on pathways to certificates of completion of training), other membership categories were included to capture valuable responses from hospital-grades also potentially involved with relevant surgical procedures. The survey was open for 14 weeks.

Statistical techniques

All statistical analyses were conducted using R software (R Foundation for Statistical Computing, Vienna, Austria). The following statistical methodologies were utilised and their usage described within the 'Results' section: Chi-square test of independence, two-sample t-test and ANOVA. The normality of data distribution for the t-test and ANOVA were evaluated using the Shapiro-Wilk test; and in all cases, the normal distribution assumption was questionable ($p<0.05$). Therefore a suitable non-parametric alternative was used accordingly; Wilcoxon rank sum test for t-test and Kruskal-Wallis test with Dunn's multiple comparison test for ANOVA.

Results

Survey response and functionality

One-hundred and thirty-two complete responses were received (including 17 from the pilot): 128 (97%) from OMF surgeons, the remaining 3% consisted of 2 technicians, 1 plastic surgeon and 1 foundation trainee. The vast majority were fellows/consultants (70%, n=92)

and FiTs/registrars (25%, n=33); approximating to a response rate of 29% for these two target membership groups (the remaining 5% were early-years trainees or non-training middle-grades). Regional representatives obtained half of all participant responses (52%, *n*=69), whilst other participants were recruited through BAOMS mail-shots alone. Participants were located almost exclusively in the UK mainland (1 located in the Middle-East) (Fig 1).

General CAD-CAM experience

The cohort was generally experienced in virtual surgical planning and implant design. Of 132 participants, 27 (20%) used in-house services only, 39 (30%) outsourced only and 50 (38%) using either route. Sixteen (12%) did not use CAD-CAM surgery (7 consultants, 7 registrars and 2 junior trainees). In total, 77 (58%) respondents used local/in-house CAD facilities. Of these, the staff involved varied: most commonly the departmental technician operating the software, sitting with the surgeon guiding the process (*n*=35) whilst in some cases the surgeon operates the software (*n*=19). A few describe both operating software (*n*=7), the surgeon alone (*n*=8), the technician alone (*n*=2) or another approach (*n*=6). Furthermore, most report their department's ability to produce resin models (*n*=75), resin surgical guides (*n*=67), pre-bent osteosynthesis plates (*n*=62) or pressed orbital/cranioplasty implants (*n*=54). However, few appear to independently provide true CAD-CAM implants: with direct access to milling in 6 and metal 3D printing in just 3 cases.

Use of outsourced design services was common (67%, n=89). Of these, most (*n*=71) describe live interaction with the technician: usually web-conferencing with ability to control the technician's software (*n*=35) or no direct software control (*n*=23). Some used text/messenger systems with (*n*=6) / without (*n*=5) design software control but rarely a physical meeting or other approach (*n*=2). These 89 participants were asked which staff

were involved and were allowed to select more than one option, resulting in 96 responses. Typically, it is the surgeon and commercial technician designing the implant together (*n*=52), sometimes with the addition of a departmental technician (*n*=31) but rarely the commercial and departmental technicians alone (*n*=3). In some cases (*n*=10) the implant is designed entirely by the commercial technician and later approved by the surgeon.

Of those using CAD-CAM (n=115/132), local funding routes for using 3D-printed implants vary regionally; most report complete cost-reimbursement by the NHS (84%, *n*=97) with more than three-quarters of these reporting no need for specific funding requests (77%, *n*=75). Nine (8%) report the need to part-fund printed implants with additional funding sources (charity/departmental/other). Nine (8%) were uncertain or described other arrangements.

General case loads

Exploring potential 'routine' applications, reported surgical workloads were as follows: 116 (88%) involved with trauma surgery, 80 (61%) with orthognathic surgery and 68 (52%) with bony oncological reconstruction. Annual workloads of specific procedures are illustrated in figures 2 and 3.

Prosthetic reconstruction of the condyle/TMJ in oncology was performed infrequently. Of the 68 involved with oncology surgery, half perform up to 5 joint replacement cases per year (*n*=34) and half do not formally reconstruct the joint at all (*n*=33). Beyond oncology, 39 (30%) were involved with general TMJ surgery.

Perceived indications for and barriers to 3D-printed titanium

Orbital floor repair is the most popular indication, cited by 118 (89%) of all 132 participants, followed by free-flap jaw reconstruction (87%, *n*=115) and temporomandibular joint (TMJ) arthroplasty (78%, *n*=103). Over half (61-73%, *n*=80-97) cited Le Fort maxillary osteotomy, zygomatic osteotomy and cranioplasty whilst one-third to half (34-43%, *n*=45-57) cited middle/upper-third and pan-facial fractures, mandibular osteotomy and genioplasty. Condyle fractures were a weaker indication (21%, *n*=28) and 13 (10%) cited some specific indications, including but not limited to: “complex deformity (not routine) / asymmetrical / revision orthognathic surgery”, “cosmetic / onlay”, “craniofacial / skull-base resections / reconstructions”, “craniofacial distraction”, “non-union mandibular fractures” and “composite facial transplantation”.

Perceived numbers or types of surgical indications were independent of the participant’s grade (e.g. consultant versus registrar): “number of indications”, Wilcoxon rank sum, $p>0.05$; “type of indication”, Chi-square test of independence, $p>0.05$. However, number of indications did relate to subspecialty practice; those involved with orthognathic surgery purporting more indications for printed titanium implants than those who were not (Wilcoxon rank sum; $p=0.013$). This association was not seen in oncology/trauma ($p>0.05$) and types of perceived indications were also unrelated to individuals’ subspecialty practice (Chi-square test of independence: all subspecialties $p>0.05$).

Perceived barriers/limitations to printed titanium implants (categories listed in figure 4) related mostly to cost and ‘turnaround’ logistics. Novelty-related issues were less important (Fig 4). Eleven (8%) elaborated on ‘other’ limitations, including (but not limited to): “relative disinterest/buy-in from managers”, “lack of Trust support”, “quite a bit of

micromanagement is required on my part", "loss of skill for the surgeon" and loss of teaching "conventional" techniques.

Kruskal-Wallis test was used to demonstrate significant differences between multiple categories of use of virtual surgical planning ("in-house / outsourced / both / neither") in the perceived number of limitations of printed implants. Participants with 'in-house' experience/facilities perceived significantly fewer barriers/limitations than those using commercial/outsourced services only ($p=0.003$) or those not using CAD-CAM implants at all ($p=0.045$).

Discussion

This cross-sectional study was designed to maximise the distribution and response rate amongst the main stakeholders (OMF surgeons). The survey evaluated the wider scope for printed titanium based upon perceived surgical indications and workloads within various OMF subspecialties rather than just evaluating the 'obvious' applications. This maximised the response rate and provided a dataset more representative of the specialty as a whole. The study therefore focussed on the three commonest areas of subspecialty practice: head & neck oncology, orthoganthic and trauma (7). Methodology involved a collaborative approach with BAOMS, strongly supported by a trainee-based national study team, achieving a 29% response rate from target participants; existing consultants and 'consultants of the future' (registrars on pathways leading to a certificate of completion of training). The national response rate was lower than that of the regional pilot study and as a trainee-led study, a proportionally greater response from registrars was expected. However, the overall response rate was comparable to other surveys of surgical specialists (8) and specifically in the case of registrar participants, a similar number responded as with

a recently published benchmark study through BAOMS on the management of mandibular third molar teeth (9). Furthermore, it is acknowledged that voluntary surveys can be limited by self-selection bias; those interested are more likely to respond (10). It is for this reason the survey was distributed through the main BAOMS mailing list, rather than thorough subspecialty interest groups (which may have provided a higher proportional response rate but might have increased the influence of self-selection bias on the study). The study design included multiple regional representatives to encourage uniform survey participation from clinicians with varying interests in CAD-CAM surgery. Subjectively, participants were evenly distributed on the UK mainland, meaning that responses likely represented regional variations in practice (apart from one participant with practice both in the UK and abroad, currently based in the Middle-East). Ireland (Northern/Republic of) was not represented, possibly because there was no volunteer regional representative. This study design incorporating BAOMS' vetting process, endorsement, electronic mailing and crucially, trainee regional representatives provides a model for other studies.

The study has revealed the absence of a standardised NHS in-house implant design pathway with individual roles and responsibilities. For quality control, this is an area for concern. The enforcement of ISO13485 medical device regulations (MDR) in May 2021 may better bridge the interface between in-house designers and external manufacturers (11,12). MDR guide the creation of a quality management system for designers/manufacturers of implantable devices, including printed osteosynthesis plates (class IIb) (13). Surgeons must source the device from a reputable supplier, check for CE marking, report adverse events with the Yellow Card system, retain implant identifier data and provide the patient with an 'implant card' (14). NHS OMF laboratories should be MDR-compliant with appropriately-

audited quality control measures but as long as working within their institution, can refrain from independent ISO13485 certification through the “Health institution exemption” (15).

Most centres with in-house planning facilities have resin 3D printers (but not titanium) and therefore are unable to deliver true CAD-CAM implants/plates independently. They can however produce sterilisable resin surgical guides and models required for the placement of CAD-CAM (including printed/milled titanium) implants, or for the use of pre-bent plates. Five-axis titanium milling machines start in the tens of thousands of pounds whereas titanium 3D printers in the hundreds of thousands so converting a typical NHS laboratory to a metal-printing facility is not an option for most. Some surgeons have in-depth understanding of titanium additive/subtractive-manufacture techniques by exposure facilities within local institutions but many have exposure to design processes and perhaps desktop polymer printing only. In this study, understanding of the term “3D printing” as “additive manufacture” is a prerequisite, with the survey clarifying the term on the first page accordingly and fortunately, the vast majority of participants were consultants or senior trainees which should help minimise any confusion. Nevertheless, we acknowledge that as with any study on user perceptions of novel technology, there may be uncertainties and a lack of knowledge for some. The current Intercollegiate Surgical Curriculum Syllabus for OMFS does not have a dedicated component on novel surgical technologies (including patient-specific CMF implants). Terms such as “CAD-CAM” or “3D printing” (and other technologies) do not feature in the document and may be a surprising finding for UK trainers and trainees alike (16).

Commercially-outsourced design had no standard format. The lack of standardisation in commercial workflows is a potential problem, particularly when the surgeon takes ultimate

responsibility for the surgery. Familiarity and control, with standardised roles/responsibilities appears important and explains why surgeons using in-house planning perceive fewer barriers to using printed titanium.

Funding routes are somewhat variable; an apparent 'postcode lottery' exists for printed CMF implants as seen with other specific procedures in UK maxillofacial surgery (17). In NHS England, individual funding requests (IFRs) are used when, "a clinician believes that their patient's clinical situation is so different to other patients with the same condition that they should have their treatment paid for when other patients would not" (18). Some may view the use of printed CMF implants as 'exceptional' (using the IFR route), whereas others see this as the standard of care or 'routine'. Put simply, funding may simply depend upon local interpretations of which route is appropriate.

Subspecialty workload data in combination with clinicians' perceptions of appropriate surgical indications will help the industry focus research and development on commercially viable applications in UK OMFS. For example, elective procedures for post-traumatic deformity/defects (e.g. zygomatic osteotomy / cranioplasty) are relatively uncommon and on frequency alone, one might argue that there is more commercial sense for the 3DP industry to focus closer upon the more frequent, acute trauma procedures. However, training requirements and the time required for planning, implant design and fabrication may preclude the use of printed titanium implants in acute trauma surgery whilst elective post-traumatic surgery is perceived as a stronger indication.

In this study, many cite temporomandibular joint (TMJ) replacement as a suitable application. TMJ reconstruction in mandibulectomy appears relatively uncommon but

printed reconstruction plates with anatomically-shaped condylar heads have been used by a European group without major complications at 5 years follow-up, in stark contrast to potentially disastrous glenoid fossa erosion and heterotopic ossification with condyle-only stock implants seen by other authors (19, 20, 21). Many surgeons would remain averse to condyle-only joint replacement for this reason. In UK total TMJ replacement, printed patient-specific prostheses would be used 'off-licence', requiring a signed disclaimer by the surgeon (2). Only subtractively-manufactured/milled custom or 'off-the-shelf' prostheses are readily available. Ackland et al. report that additively manufactured titanium possesses biomechanical advantages over prostheses manufactured by other techniques such as milling (22). Risk of failure can be reduced as transfer of force between implant and bone can be optimised; finite-element analysis can be used in combination with additive manufacturing to determine the alloy composition, porosity/tetrahedral structure and macro-structure, controlling stiffness and minimising implant failure or screw loosening / stress shielding (23, 24). TMJ replacements are increasingly popular because of the favourable outcomes seen (25) but at present, it remains a niche procedure nationally. Thirty-nine (30%) participants were involved with non-oncological TMJ surgery, however most do not undertake complex (arthroplasty) surgery; performed by less than 20 consultants in the UK (26). Even if printed titanium arthroplasties are clinically superior (lighter, cheaper or biomechanically superior) to milled TMJ prostheses, it may take considerable time before the evidence base is sufficient for widespread adoption amongst a tertiary-care network.

Conclusions

The majority of surgeons have current experience of CAD-CAM CMF implant surgery, whether using in-house and/or outsourced planning but almost always reliant upon commercial additive manufacturing. Personnel involved and the format of planning/design is variable. In-house design appears more conducive to using printed titanium, such that developing ISO13485-compliant/certified in-house facilities will improve its uptake.

Funding of printed titanium depends on local health authorities and may relate to local interpretations of 'exceptional' versus 'routine' treatments. A stronger evidence base demonstrating clinical and quality-of-life benefits (through prospective multi-centre studies) is needed to establish if printed titanium should be the 'standard of care' for all rather than for the 'exceptional'.

Amongst the main subspecialties, sui procedures for large-scale application of printed titanium (based upon practiced frequency and favourability as a surgical indication) include fibular-flaps, Le Fort maxillary osteotomies and orbital floor repair. Furthermore, niche/complex deformity applications (zygomatic osteotomy, cranioplasty, onlay augmentations and other craniofacial applications) should not be overlooked by the industry, since deformity surgeons perceive more applications than others.

Clinicians may well understand the concepts of additive/subtractive manufacture yet be uncertain over which technique is currently used in the specific case of TMJ replacements. Alternatively like other surgeons internationally, they may simply feel at face-value that printed titanium is well-suited to this purpose. Furthermore, we have identified that the specialty training syllabus does not specifically include the "use of novel surgical

technologies" (this is therefore an assumed component of training). We propose that these issues and the general CAD-CAM knowledge base of UK surgeons is further explored within an educational workshop and focus group.

Acute facial trauma surgery often precludes the use of printed implants because of the planning and fabrication time involved, as well as training requirements for surgeons. Printed plates/implants have more relevance in elective trauma surgery (e.g. middle / upper-facial-third trauma).

Costs and production logistics are the greatest concerns. Part 2 evaluates the participants' understanding/knowledge of these factors (and therefore the legitimacy of these concerns) as well as perceived benefits and clinical outcomes.

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Conflict of Interest

None.

Ethics statement/confirmation of patient permission

The study was approved by the Faculty of Life Sciences and Education, University of South Wales ethical committee (ref: 18AG1001LR). Patient permission not applicable

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Figure Captions

Figure 1. Locations and frequencies of 131 UK-based study participants. Interactive map accessible at: https://www.easymapmaker.com/map/79cbf56222a17cd353d1a4543642001d (5).

Figure 2. Numbers of participants performing free-flaps for jaw reconstruction in oncology, orthognathic procedures and acute trauma procedures by annual frequency of the procedure.

Figure 3. Numbers of participants performing cranioplasty, zygomatic osteotomy and panfacial fracture surgeries by annual frequency of the procedure.

Figure 4. Barriers (and occasions reported) to using printed titanium implants.

Figures

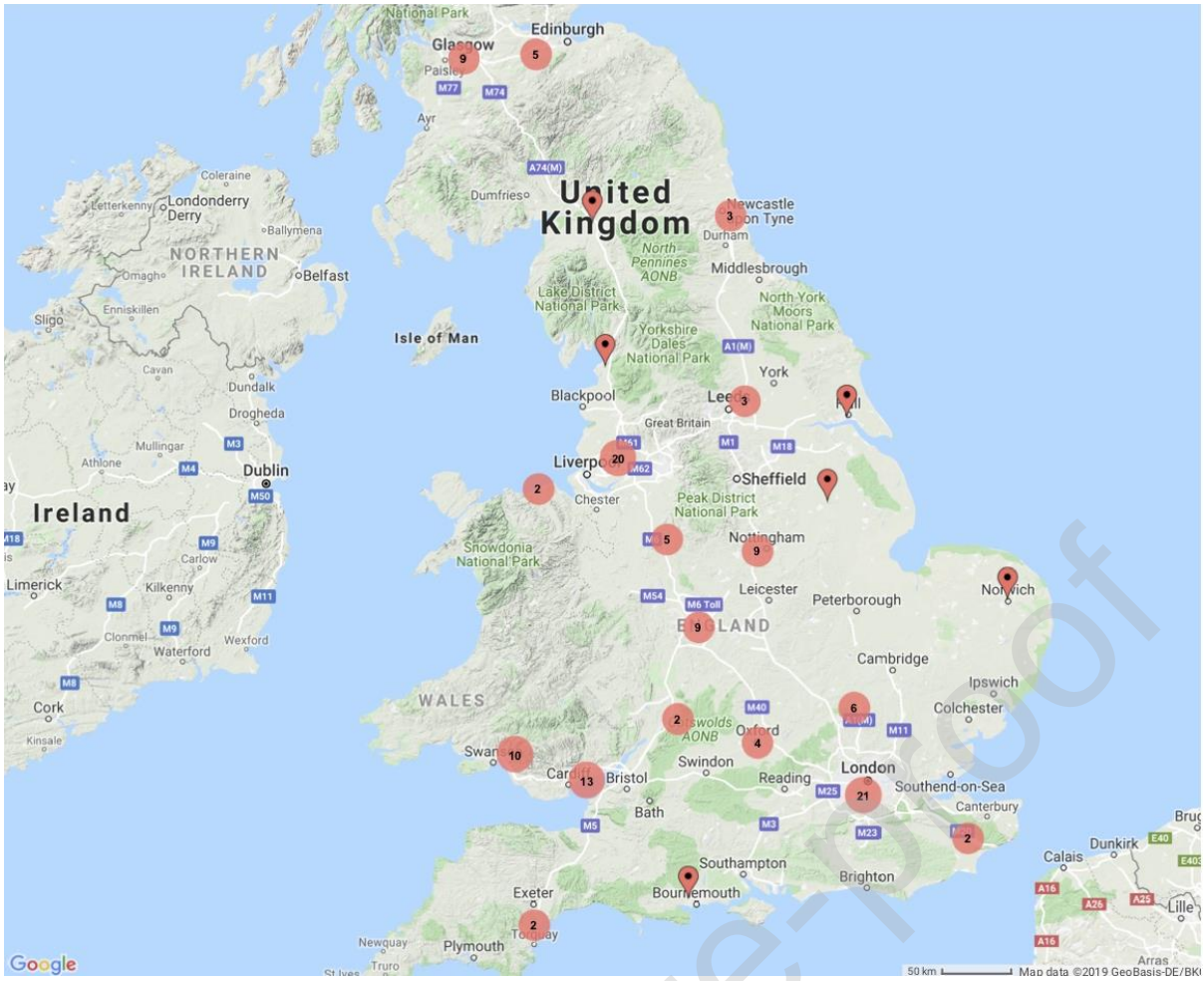

Figure 1.

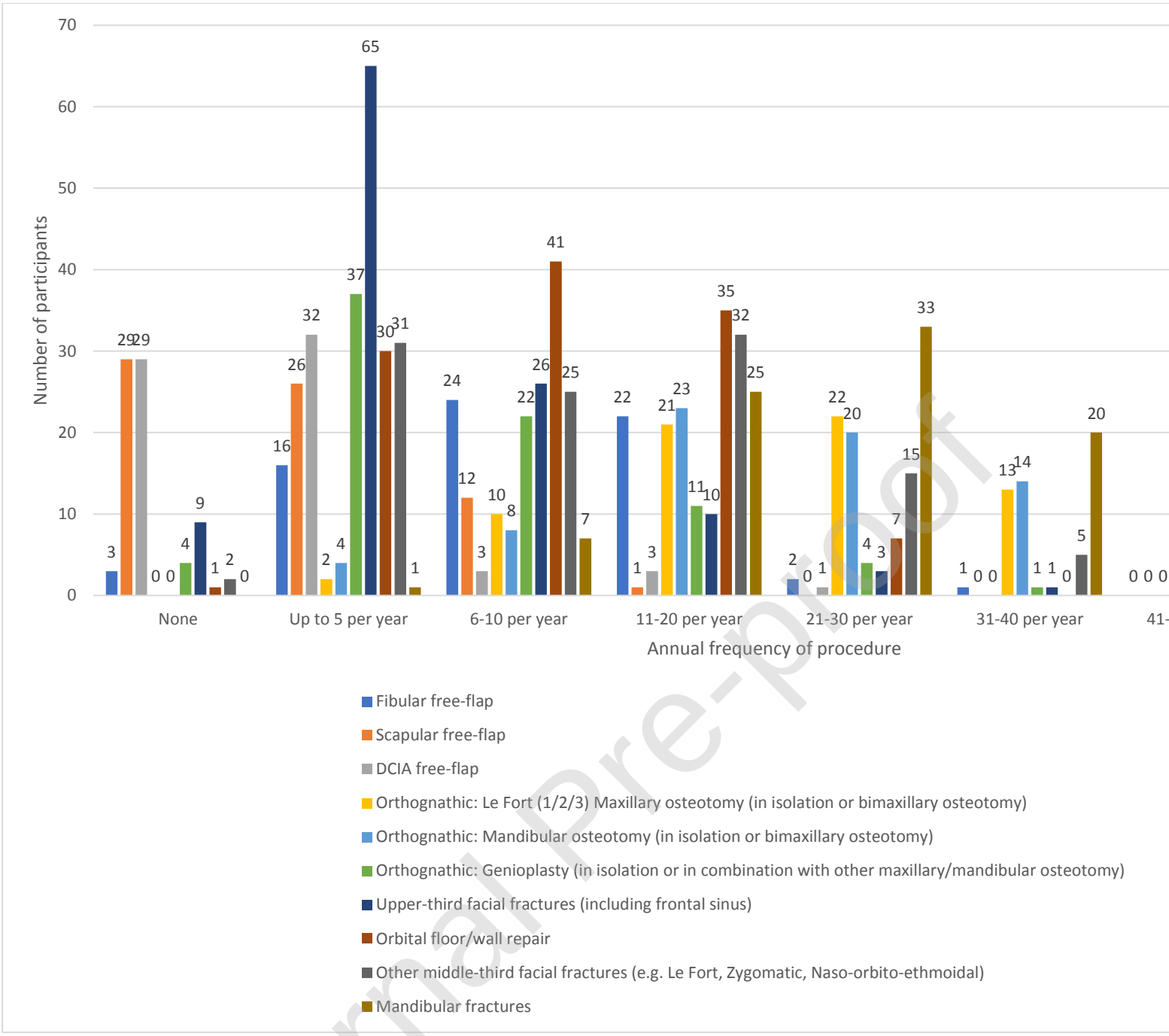

Figure 2.

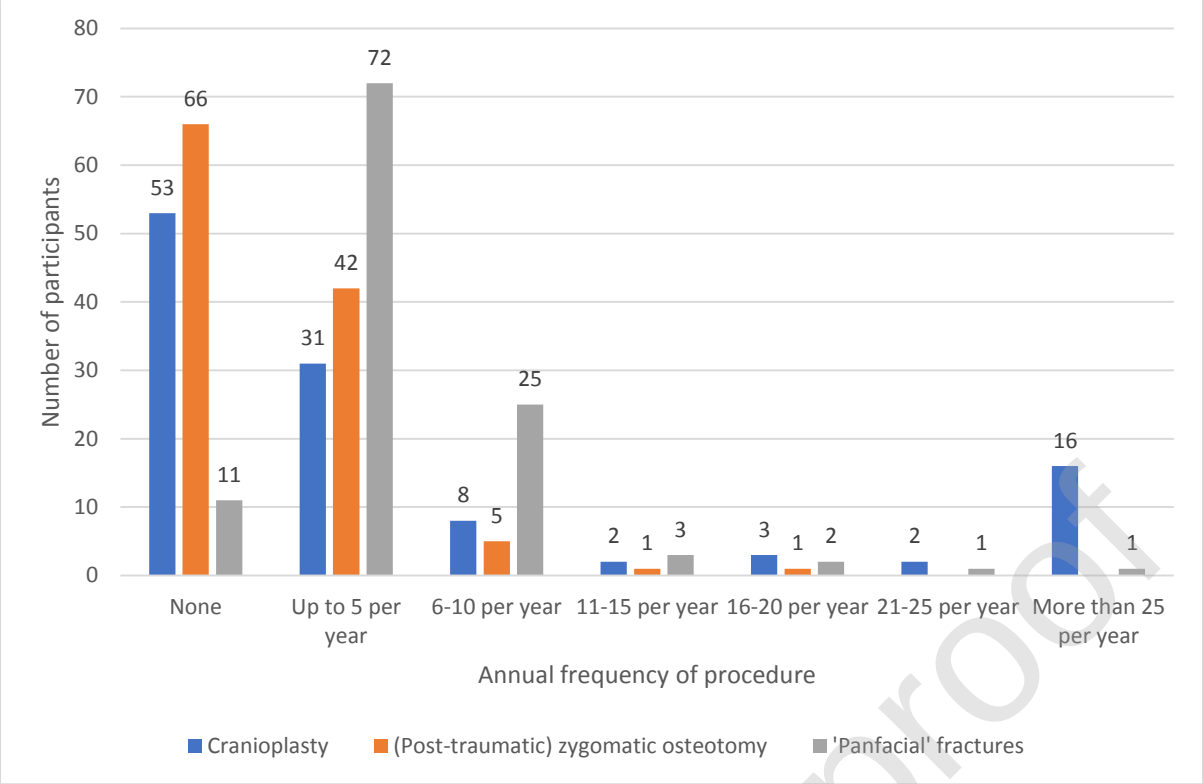

Figure 3.

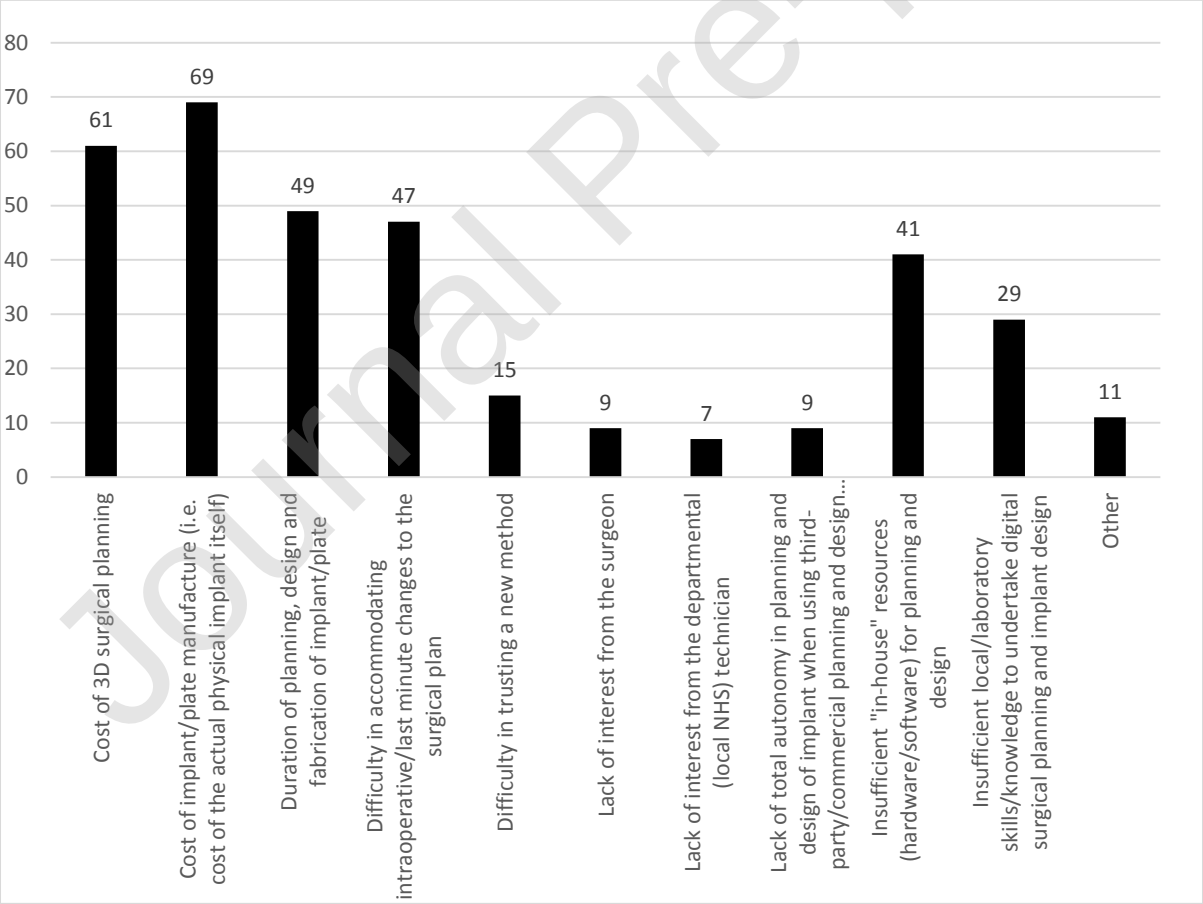

Figure 4.