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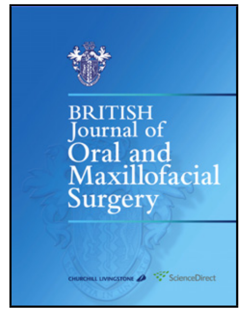

Printed Titanium Implants in UK Cranio-Maxillofacial Surgery: Part II – Perceived performance (outcomes, logistics and costs)

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Abstract

Introduction and Aims: This second part explores perceptions/understanding of clinical performance, turnaround and costs for printed titanium implants/plates in common procedures; evaluating both ‘in-house’ and ‘outsourced’ CAD-CAM pathways.

Methods: A cross-sectional study was conducted over 14 weeks; supported by the British Association of Oral and Maxillofacial Surgeons and a national trainee-led recruitment team.

Results: One-hundred and thirty-two participants took part (demographic data is reported in part I).

For fibular-flap mandibular reconstruction, most (69-91%) perceived printed titanium as superior to intraoperatively/pre-operatively hand-bent plates for surgical duration, accuracy, dental restorability and aesthetics. There was less consensus over complications and plate-failure risks. Most perceived printed plates as superior to traditional wafer-based maxillary osteotomy for surgical duration (61%) and maxillary positioning (60%). For orbital floor repair, most perceived improved surgical duration (83%, especially higher-volume operators p=0.009), precision (84%) and ease (69%) of placement. Rarely (<5%) was any outcome rated inferior to traditional techniques for any procedure.

Perceived turnaround times and costs were variable, but greatest consensus for 2-segment fibular-flap reconstructions and orbital floor repair. Industry estimates were generally consistent between two company representatives but 'manufacturing-only' costs differed when using 'in-house' (departmental) designers.

Conclusions:

Costs and turnaround times are questionable barriers since few understand 'real-world' figures. Designing 'in-house' can dramatically alter costs. Improved accuracy and surgical duration are common themes but biomechanical benefits are less-well understood. This study paints a picture of potentially routine applications and benefits of printed titanium, capacity for uptake, understanding amongst surgeons and areas for improvement.

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

Introduction

A national survey was distributed to UK OMF specialists to quantify their experience of using CAD-CAM implants. The scope for using printed titanium in common procedures, based upon perceived surgical indications, barriers to use and current surgical workloads is reported in part I of this study ***(editorial team please insert reference for part I of this series)***.

This second part of the study explores the scope for using printed titanium in common OMF procedures based upon end-users' perceptions of clinical performance in three common procedures (2-segment fibular free-flap reconstruction of the mandible, waferless Le Fort 1 maxillary osteotomy and orbital floor repair). Furthermore, we ascertain the current understanding of turnaround times and costs (perceived versus actual) using outsourced commercial providers, and how these compare to implants produced through an 'in-house' implant design pathway. By evaluating these clinical, technical and logistical factors, the study aims to provide a national consensus on the clinical value of printed titanium and expected standards from commercial suppliers.

Methods

This cross-sectional study of 132 clinicians was conducted in collaboration with the British Association of Oral and Maxillofacial Surgeons (BAOMS) and an OMF trainee-based national study team. Details of the study methodology have been reported ***(editorial team please insert reference for part I of this series)***. The study was approved by the Faculty of Life Sciences and Education, University of South Wales ethical committee (ref: 18AG1001LR).

Statistical techniques

All statistical analyses were conducted using R software (R Core Team (2020)). The following statistical methodologies were utilised and their usage described within the 'Results' section: ANOVA and ordinal logistic regression. The normality of data distribution for ANOVA was evaluated using the Shapiro-Wilk test; and in all cases, the normal distribution assumption was questionable ($p<0.05$). We therefore used a suitable non-parametric alternative namely, Kruskal-Wallis test with Dunn's multiple comparison test. The main underlying assumptions for the ordinal logistic regression modelling were satisfactory.

Results

Clinical outcomes

Beginning with perceived outcomes of those involved with mandibular reconstruction in oncology (*n*=68), 62 felt that for the "duration of surgery", printed titanium plates were superior to ("somewhat better" or "much better" than) bending a plate intraoperatively and 52 felt that printed plates were also superior to a pre-bent reconstruction plate. For "dimensional accuracy of the reconstruction in relation to the surgical plan", 59 perceived printed plates to perform superiorly to bent plates. Furthermore, the majority felt that printed plates were superior for "positioning of the fibula bone segments" for successful dental implant placement (*n*=51) and facial aesthetics (*n*=47).

The majority (*n*=54) perceived printed plates to be "about the same" for "duration of hospital stay".

There was less consensus over complication rates overall and plate failure. Half (*n*=33) felt that complication rates overall would be the same as with a traditional bent reconstruction plate, with one-third (*n*=22) feeling that printed plates would perform superiorly. There was similar uncertainty regarding plate failure, where a quarter of participants were "unable to comment" (*n*=18), 26 rated plate failure "about the same", and 22 rated plate failure as superior to traditionally bent plates. Few however (n=2) felt that printed plates would perform inferiorly to ("somewhat worse" or "much worse" than) hand-bent plates for any outcome (Fig 1).

Of those involved with orthognathic surgery (*n*=80), the majority felt that waferless Le Fort 1 osteotomy would be superior to the traditional wafer, intermaxillary fixation and intraoperative plate-bending approach for "duration of surgery" (*n*=49) and "positioning of the maxilla" (*n*=48) (Fig 2). Perceptions of dental occlusion were less clear; almost half (*n*=36) expected accuracy of dental occlusion to be "about the same" and 14 felt unable to comment. Over one-third (n=28) expected the occlusion to be superior but 4 felt that waferless osteotomy would produce a worse occlusion. Very few (*n*=4) felt that the duration of hospital stay would be superior with waferless surgery, but rather the majority expected it to be "about the same" (*n*=65) or felt "unable to comment" (*n*=10).

Risk of plate failure and complication rates overall were not perceived as advantageous with waferless osteotomy; half felt these to be the "same" as with conventional surgery (*n*=38 and *n*=41 respectively), a third felt "unable to comment" (*n*=26 and *n*=23 respectively). Just one participant perceived printed plates to perform worse.

Of those involved with orbital floor repair in trauma (*n*=116), the majority perceived printed orbital implants to be superior for duration of surgery (83%, *n*=96), accuracy of placement (84%, *n*=98) and ease of placement (69%, *n*=80) (Fig 3).

The Kruskal-Wallis test was used to demonstrate significant differences between multiple categories of annual frequency of orbital floor repair ("up to 5 per year / 6-10 per year / 11 or more per year") in the perceived duration of surgery with printed implants. Those who perceived duration of surgery as shorter/superior tended to be higher-volume operators, with a trend noted between intermediate and highest (Kruskal Wallis: "up to 5 per year" versus "11 or more per year"; p=0.003 and "6-10 per year" versus "11 or more per year"; p=0.064). Regarding seniority, there was a trend for consultants to be more than twice as likely as registrars to rate duration of surgery as superior. Here, an ordinal logistic regression model was utilised with Likert ratings treated as ordinal response and seniority (consultant and registrar) as predictor with registrar as baseline. The odds ratio for consultants was 2.283; p=0.056; 95%CI: 0.981 - 5.315. Regarding duration of hospital stay however, the majority felt this stay would be the same as with 'off-the-shelf' implants (86%, *n*=100).

A small majority felt the risk of damage to orbital contents to be the same as with 'off-the-shelf' implants (54%, *n*=63) but more than a third (37%, *n*=43) felt the level of risk to orbital contents to be superior. Almost a half (46%, *n*=53) perceived complication rates as superior, or "about the same" (42%, *n*=49) whilst 13 (11%) felt unable to comment.

Turnaround time

The minimum turnaround time from pre-operative CT scan to insertion of the sterile implant was estimated by all 132 participants for three surgical procedures. The mode estimated turnaround time for 2-segment fibular free flap reconstruction of the mandible was 7-9 days, waferless Le Fort 1 osteotomy 13-15 days and orbital floor repair 4-6 days (Fig 4). Of the three procedures, there was greatest consensus on turnaround for 2-segment fibular free-flap reconstruction of the mandible and orbital floor repair (albeit still variable) and least consensus for waferless Le Fort 1 osteotomy; 10 (8%) having "no idea". Two industry representatives from market-leading CMF implant companies (supplying printed titanium implants commercially) were asked to provide their company's turnaround times. Both agreed on 10-12 days for fibular flap reconstructions and waferless Le Fort 1 osteotomy. Representative responses for orbital floor repair differed by one ordinal time category; one estimated 10-12 days and the other 7-9 days (Fig 4).

Costs

All participants estimated the total production cost (planning, manufacture and delivery of the guide(s) and implant ready for surgical use) through a fully outsourced (commercial) service for the three procedures of focus, as well as relative cost savings by planning/designing the implant "in house" (using commercial services for manufacturing only). Akin to turnaround times, estimates were juxtaposed with actual figures provided by two company representatives (Fig 5). Most had their own ideas of costs, providing cost estimates for 2-segment fibular free-flap reconstructions (90%, *n*=119), Le Fort 1 waferless osteotomy (82%, *n*=108) and orbital floor repair (77%, *n*=101), but the remainder having "no idea" (Fig 5). Similar numbers had ideas of cost savings through in-house design and planning (88%, *n*=116 for 2-segment fibular free-flaps / 80% , *n*=106 for Le Fort 1 waferless osteotomy / 73%, *n*=96 for orbital floor repair. Participant estimates were wide-ranging, with no clear consensus.

Based upon the company representatives' estimated cost for each procedure, a 'typical' actual (industry-reported) cost for each procedure was calculated as a median of the total range between the minimum and maximum possible cost of the two representative answers; '2-segment fibular flap reconstruction of the mandible' equates to a typical cost of £3750.50, 'waferless Le Fort 1 maxillary osteotomy' – typical cost of £2250.50 and 'orbital floor repair' – typical cost of £2000.50. There was a difference between the two company representatives of two ordinal cost categories for '2-segment fibular free-flap reconstruction of the mandible' and 'waferless Le Fort 1 maxillary osteotomy', equating to an actual cost difference between the two companies of £501 to £1499 for each of these procedures. The two company representatives were closer in their costings for 'orbital floor repair', being one ordinal cost category apart (an actual cost difference between the two companies of £1 to £999). The savings possible through in-house planning and implant design were also different between the two companies. One company representative predicted 'in-house' savings of 11-20% for both '2-segment fibular free-flap reconstruction of the mandible' and 'waferless Le Fort 1 maxillary osteotomy' and a saving of 21-30% for 'orbital floor repair'. The other predicted much greater savings of 51-60% reduction for 'fibular free-flap reconstruction of the mandible', 41-50% reduction for 'waferless Le Fort 1 maxillary osteotomy' and 61-70% reduction for 'orbital floor repair'.

Participants were asked to estimate up-front set-up costs for developing an in-house digital planning and implant design service within their own NHS department. Thirty-nine (30%) had "no idea", otherwise estimates ranged from £0-£100,000 with no clear consensus (Fig 6).

Finally, the majority (80%, n=106) expressed a wish to learn more about printed titanium CMF implants by interest in attending a course ('yes'/'no'), irrespective of their involvement in certain subspecialties (Chi-square test of independence: oncology, orthognathic and/or trauma; $p>0.05$ in all cases).

Discussion

Histograms of Likert scale ratings of performance/outcomes of printed titanium, in all three procedures demonstrated meaningful trends in opinion with an identifiable central peak/mode in all outcome categories. Participants showed less certainty (by use of the "don't know" rating) of outcomes for waferless Le Fort 1 maxillary osteotomy in comparison to the other two procedures and may simply reflect a relative lack of experience/understanding of this novel procedure.

Duration of surgery was considered advantageous by the majority for all 3 procedures, mirrored by other responses relating to positional accuracy (and in the case of orbital floor implants specifically, ease of insertion). Anatomical accuracy of implant placement with printed plates shortens surgical time in mandibular reconstruction and this association is supported by perceptions of our study participants (1,2). With perceived improvements in accuracy of free-flap mandibular reconstruction, the majority also felt that dental implant-based prosthetic rehabilitation and facial aesthetics were likely to be more successful, reflecting the findings of other authors evaluating implant-supported prostheses (3,4) and facial symmetry/aesthetics (5); especially relating to lower border morphology (6–10).

In Le Fort 1 maxillary osteotomy, planning and intraoperative positioning of the maxilla relative to the cranial base is subjective, especially with two-dimensional cephalometry which is insensitive to facial asymmetries (11). Several participants felt that waferless (printed-plate) osteotomies were particularly suited to asymmetries and other complex deformities specifically, supporting their overall opinion that maxillary positioning is superior with this approach although benefits to dental occlusion were not as strong. Both traditional wafer (occlusally-driven) and waferless (computer-guided positioning of maxillary bone with printed plates) osteotomies can produce occlusal discrepancies/inaccuracies. Further work would include evaluating if surgeons feel waferless Le-Fort 1 osteotomy is equally suited to bimaxillary or single-jaw procedures. This would determine surgeons' faith in the ability of printed plates to produce the desired occlusion as in bimaxillary procedures a final wafer with the second (mandibular) osteotomy could otherwise compensate for any occlusal discrepancy incurred following the maxillary movement.

For orbital floor repair, the fact that high-volume (experienced) and possibly more-senior surgeons perceive greater time-saving benefits from printed implants may be attributed to their greater experience with difficult/lengthy cases or simply a greater appreciation from a high case-load for small/marginal but clinically significant gains in all complexities of orbital trauma. Although most felt printed implants are easier to insert, perceived risk of damage to orbital contents was generally the same as with an 'off-the-shelf' implants, suggesting risk is more related to prior dissection of the orbit rather than implant placement itself.

Most participants had no strong feelings regarding the risk of cyclical/biomechanical plate failure of printed versus traditionally bent osteosynthesis plates; many felt unable to comment but very few (2 or less for each procedure) felt that printed titanium would be inferior to conventional osteosynthesis plates. This may reflect a lack of awareness of the reported benefits in the literature of printed titanium over off-the-shelf plates and milled implants (2). Printed plates can be designed with the aid of finite-element analysis (FEA) to tailor the plate's stiffness in specific anatomical regions; minimising stress shielding / screw loosening and stress concentrations, and therefore plate fractures in mandibular reconstruction (12–14). Similarly, a benchtop model under loading conditions demonstrated that printed miniplates significantly lowered the risk of failure in Le Fort 1 maxillary osteotomies when compared to hand-bent miniplates (15).

General complication rates in free-flap mandibular reconstruction and maxillary osteotomy with printed plates were felt to be equivocal to using hand-bent plates but favourable in orbital floor repair. Long-term complications of orbital floor repair usually relate to inadequate recreation of the orbital floor and medial wall leading to globe malpositioning (e.g. exophthalmos) (16). It follows that the perceived improved accuracy in implant placement contributes to fewer long-term complications.

Part I of this series established that implant design and manufacture costs appear to be the greatest concern (essentially a 'deal-breaker'), despite the fact that participants frequently had little/no understanding of typical figures ***(editorial team please insert reference for part I of this series)***. Cost comparisons between printed titanium and conventional off-the-shelf plates have been reported in the literature. Specifically with free-flap reconstruction of the mandible, an Italian author group conducted a prospective cohort study of 20 patients with printed titanium implants versus 20 undergoing intraoperative (free-hand) plate bending. They concluded that total costs were at least equivocal on the basis that their operative facilities cost €30/minute and the statistically significant time savings of using their novel implants (an average of 33.1minutes) equated to the cost of the actual implant (including planning costs). When accommodating for different complexities of surgeries between the two cohorts (because the printed implant group were overall more complex based upon number of fibula segments in the reconstruction), the time savings per fibula segment appeared more significant and thus producing net cost savings. Overall procedural costs (ignoring differences in surgical complexity), excluding the cost of the inpatient stay, were on average €3500 per case in the printed plate group and €3450 per case in the freehand bent plate group (17). Another author reported a saving in their case study of €932, also because of reduced surgical duration (18).

In the present study, there was uncertainty and a lack of consensus for savings attainable by planning the surgery and designing the implants 'in-house' (excluding in-house design set-up costs) rather than through commercially-outsourced services. There was considerable difference between the two industry representatives in the typical savings to be made, suggesting that one manufacturer may be more amenable to providing a 'manufacturing-only' service to accompany in-house planning / design than the other. Consequently, the survey has provided a good basis for departments using in-house planning and implant design to 'shop around' for the best 'manufacturing-only' costs as these appear vary considerably. When considering the cost of setting-up a departmental / in-house planning and implant design service, there was again, uncertainty and a lack of consensus within the cohort. The Swansea unit has claimed to be the first NHS hospital in the UK to employ a full time 3D Scientist to work on 3D planning / design in CMF surgery. Despite further costs of computer hardware and software, their in-house service claims to save £50,000 per year on cases of mandibular reconstruction alone (not including other surgical applications) by avoiding outsourcing all planning and design work to a commercial provider (only additive manufacturing of the mandibular reconstruction plate is outsourced) (19). In 2018, the Swansea unit presented a total annual set-up cost (for the first year) of approximately £85,000 based upon: sourcing laboratory space, appropriate computer facilities (£1200), a Maxillofacial Technician (£35,577) and Biomedical Science Technician (£29,626), Geomagic Freeform® software (3D Systems, USA, £5,000 per year), Mimics software (Materialise, Belgium, £6140) and a resin (polymer) printer (for fabrication of anatomical models and drill/cutting guides, £4,500) (20). Adoption of similar models on a regional basis in the UK is likely improve the financial viability of printed implants, as well as a logistically-favourable design workflow for surgeons, with reliance on commercial providers for additive manufacturing only.

Conclusions

Although a major concern, costs and logistics are questionable barriers to the use of printed titanium implants since few have a good understanding of these. Estimates and actual savings to be made by designing implants 'in-house' (rather than fully-outsourced) vary considerably; in-house design laboratories should 'shop around' for the best contractual agreements with manufacturers.

Accuracy of bony reconstruction and reduced duration of surgery are positive themes common to many procedures. Biomechanical benefits however are less well recognised. Perceived impact upon complication rates overall appears to be procedure-specific (favourable for orbital floor repair but less clear for waferless Le-Fort 1 maxillary osteotomy) whilst 'hospital stay' was typically unremarkable all-round.

This survey has identified some key areas in which the industry can focus research and development to improve the clinical evidence base and application of printed titanium in CMF surgery. The study has also identified some key areas in which surgeons' knowledge and understanding of printed titanium can be improved. This warrants a pilot training scheme for educating surgeons in printed CMF implant design, production, logistics and surgical applications.

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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 1. Perceived outcomes of printed titanium implants for free-flap reconstruction of the mandible in comparison to traditional plating techniques.

Figure 2. Perceived outcomes of printed titanium implants in waferless Le Fort 1 maxillary osteotomy in comparison to traditional hand-bent implants.

Figure 3. Perceived outcomes of printed titanium implants for orbital floor repair in comparison to hand-bent “off-the-shelf” implants.

Figure 4. Participants’ estimates versus company representatives’ actual turnaround times for 2-segment fibular free flap reconstruction of the mandible, waferless Le Fort 1 maxillary osteotomy and orbital floor repair. Ordinal question responses (estimated time ranges) are on the vertical axis ranging in a linear fashion from the lowest (“1-3 days”) to highest (“>30 days”) possible time range, followed by “no idea” at the terminal end of the axis (shaded grey). Industry representative’s estimates are represented by dotted blue lines (where differing) and the median of their responses is represented by a solid red line.

Figure 5. Participants’ estimates and company representatives’ actual costs and ‘in-house savings’ (% cost reduction) for 2-segment fibular free-flap, waferless Le Fort 1 osteotomy and orbital floor repair. Cost estimates on the Y-axis increase in a linear fashion (ordinal cost ranges in £500 increments and saving ranges in 10% increments). Participants with “no idea” are shaded grey.

Figure 6. Estimated up-front set-up costs for developing an ‘in-house’ digital planning and implant design service.

Figures

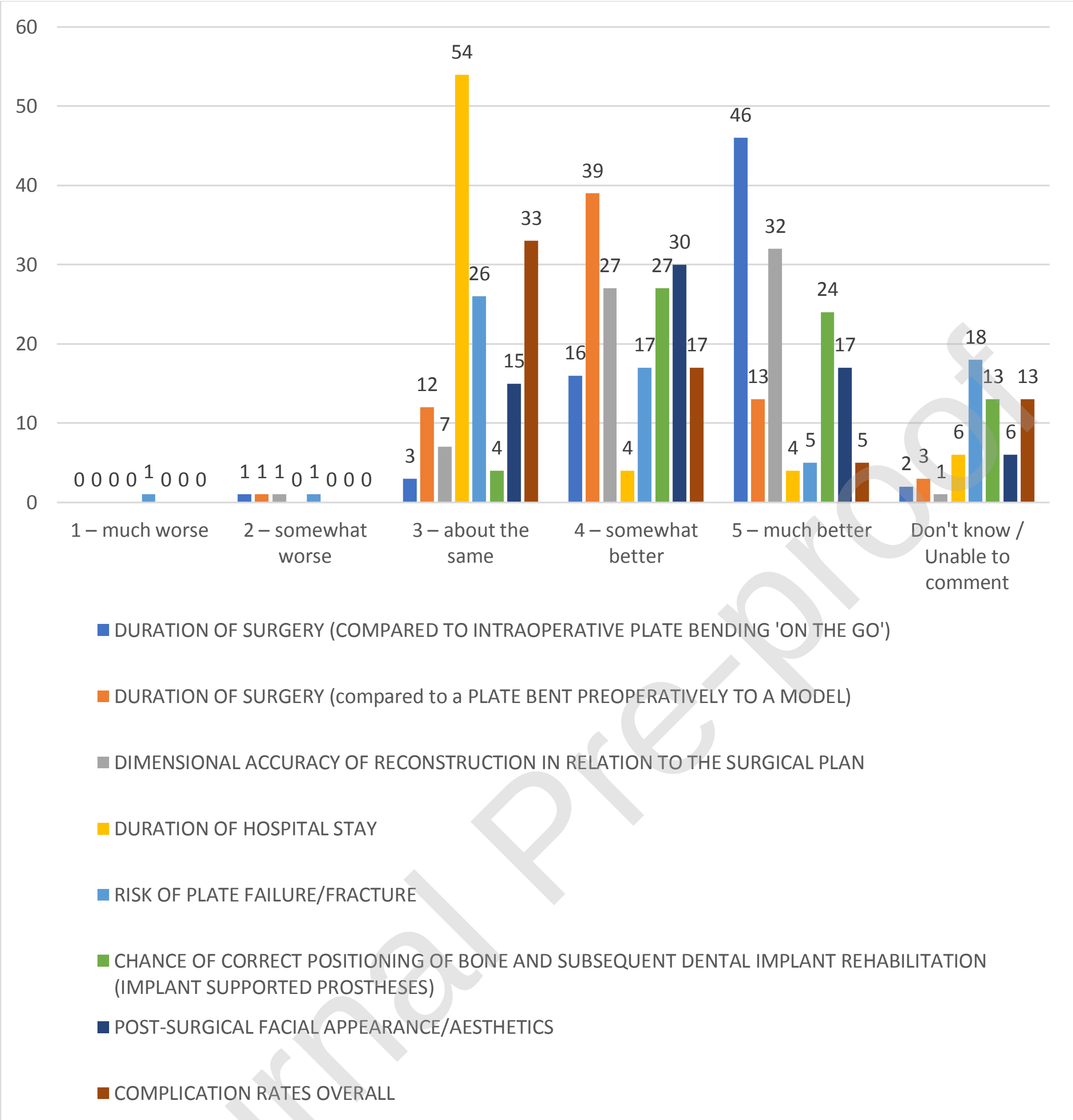
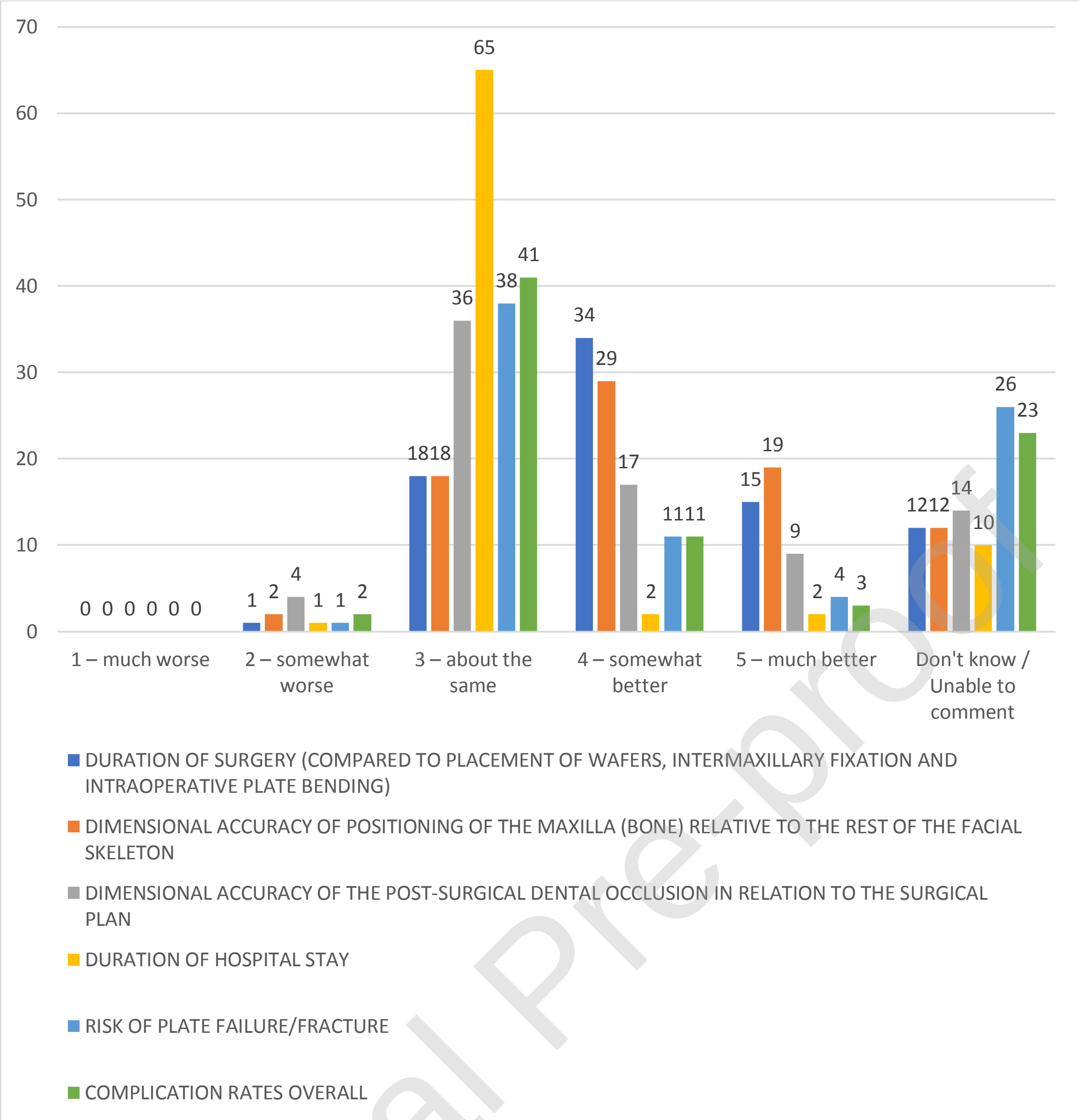


Figure 1.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3 – about the same
4 – somewhat better
5 – much better
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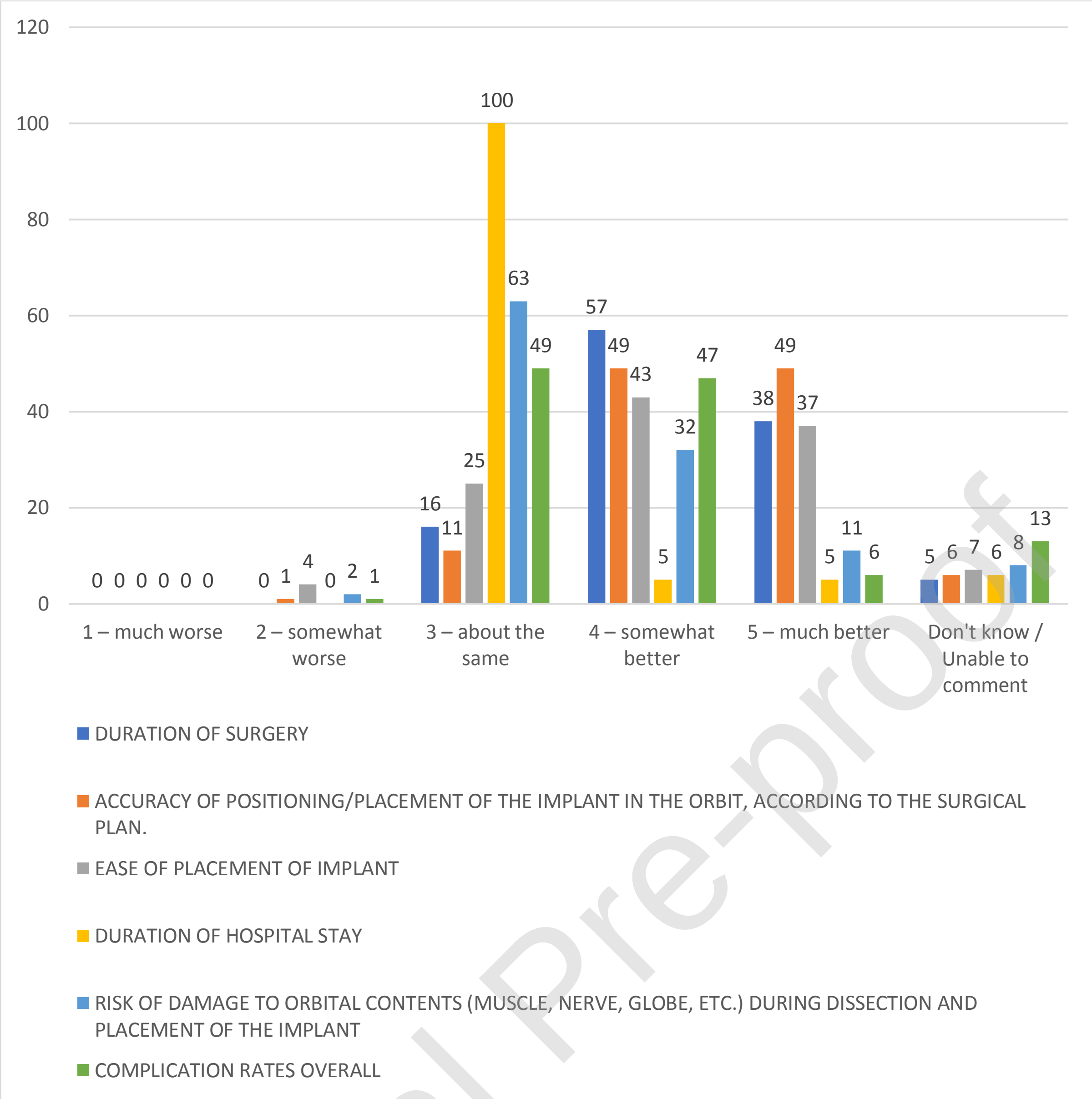
DURATION OF SURGERY (COMPARED TO PLACEMENT OF WAFERS, INTERMAXILLARY FIXATION AND INTRAOPERATIVE PLATE BENDING)
DIMENSIONAL ACCURACY OF POSITIONING OF THE MAXILLA (BONE) RELATIVE TO THE REST OF THE FACIAL SKELETON
DIMENSIONAL ACCURACY OF THE POST-SURGICAL DENTAL OCCLUSION IN RELATION TO THE SURGICAL PLAN
DURATION OF HOSPITAL STAY
RISK OF PLATE FAILURE/FRACTURE
COMPLICATION RATES OVERALL

Figure 2



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0 0 0 0 0 0
0 1 4 0 2 1
16 11 25 100 63 49
57 49 43 5 32 47
38 49 37 5 11 6
5 6 7 6 8 13
1 – much worse
2 – somewhat worse
3 – about the same
4 – somewhat better
5 – much better
Don't know / Unable to comment
DURATION OF SURGERY
ACCURACY OF POSITIONING/PLACEMENT OF THE IMPLANT IN THE ORBIT, ACCORDING TO THE SURGICAL PLAN.
EASE OF PLACEMENT OF IMPLANT
DURATION OF HOSPITAL STAY
RISK OF DAMAGE TO ORBITAL CONTENTS (MUSCLE, NERVE, GLOBE, ETC.) DURING DISSECTION AND PLACEMENT OF THE IMPLANT
COMPLICATION RATES OVERALL

Figure 3.

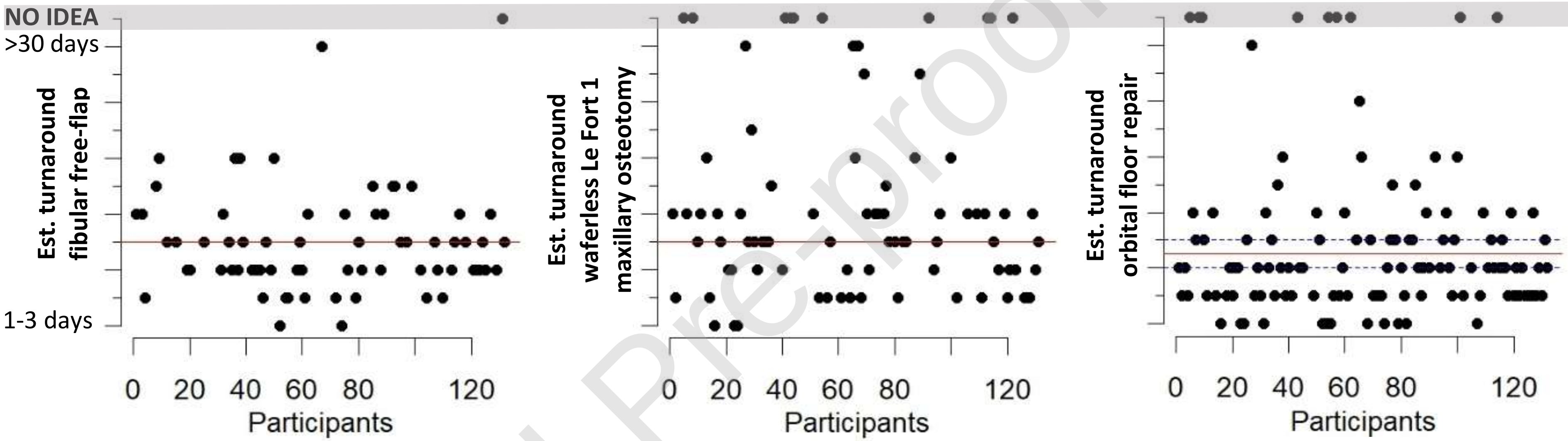
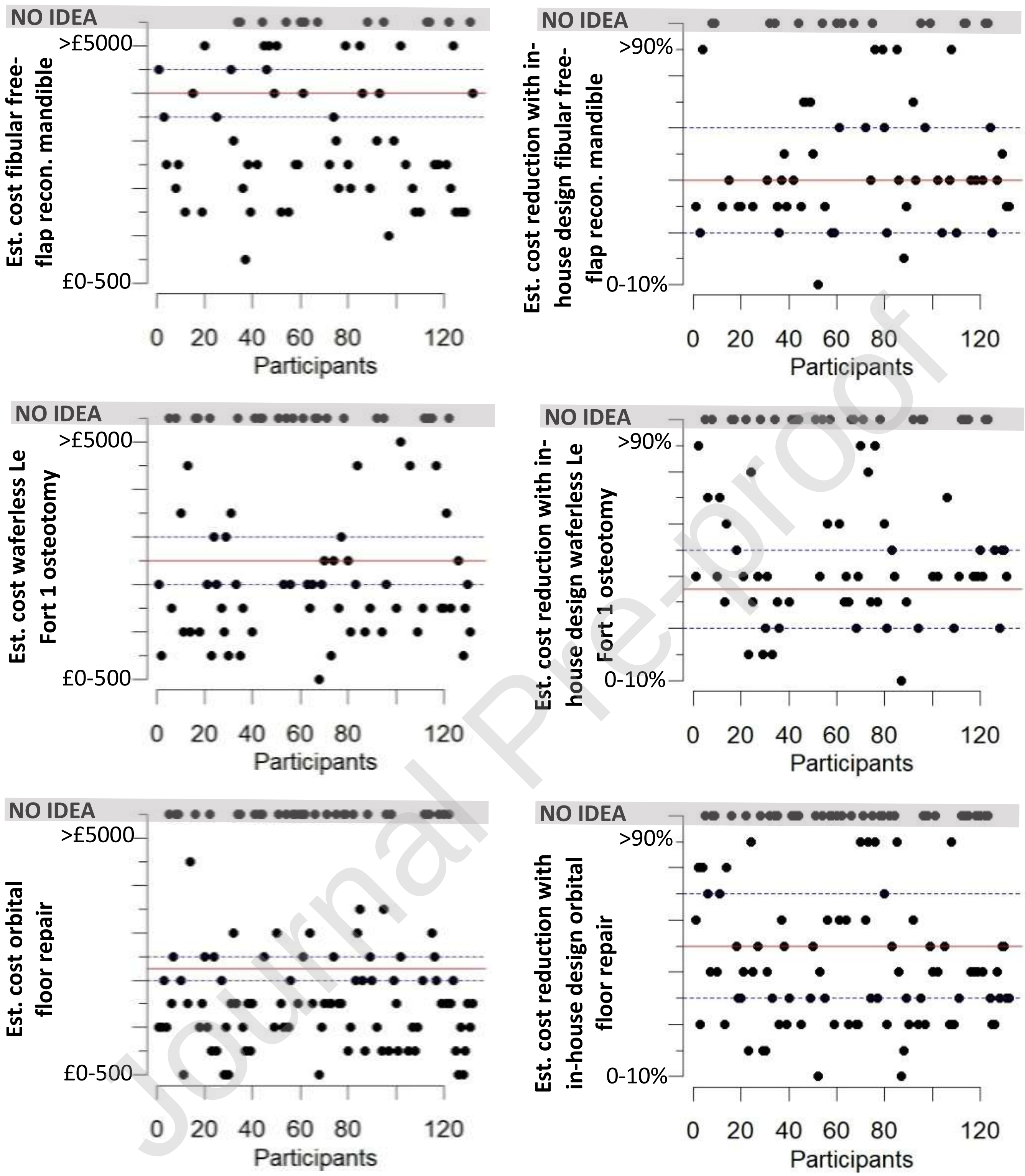

NO IDEA
>30 days
1-3 days
Est. turnaround fibular free-flap
Est. turnaround waferless Le Fort 1 maxillary osteotomy
Est. turnaround orbital floor repair
0 20 40 60 80 120
Participants

Figure 4.



NO IDEA
>£5000
£0-500
Est. cost fibular free-flap recon. mandible
0 20 40 60 80 120
Participants
NO IDEA
>90%
0-10%
Est. cost reduction with in-house design fibular free-flap recon. mandible
0 20 40 60 80 120
Participants
NO IDEA
>£5000
£0-500
Est. cost waferless Le Fort 1 osteotomy
0 20 40 60 80 120
Participants
NO IDEA
>90%
0-10%
Est. cost reduction with in-house design waferless Le Fort 1 osteotomy
0 20 40 60 80 120
Participants
NO IDEA
>£5000
£0-500
Est. cost orbital floor repair
0 20 40 60 80 120
Participants
NO IDEA
>90%
0-10%
Est. cost reduction with in-house design orbital floor repair
0 20 40 60 80 120
Participants

Figure 5.

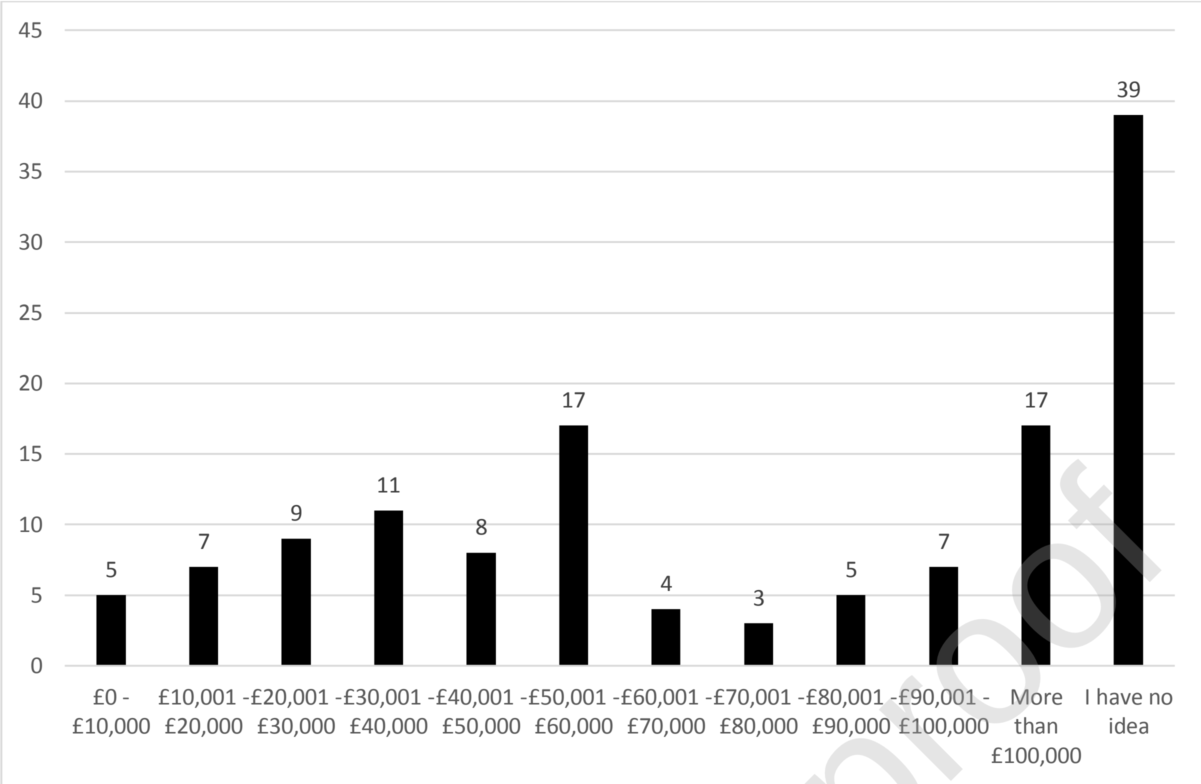

45
40
35
30
25
20
15
10
5
0
5
7
9
11
8
17
4
3
5
7
17
39
£0 - £10,000
£10,001 - £20,000
£20,001 - £30,000
£30,001 - £40,000
£40,001 - £50,000
£50,001 - £60,000
£60,001 - £70,000
£70,001 - £80,000
£80,001 - £90,000
£90,001 - £100,000
More than £100,000
I have no idea

Figure 6.