# Prescribed List
# Post-listing Review

## Review of Surgical Guides and Biomodels
## Stage 2

### Report to the Department of Health and Aged Care

**FINAL REPORT**

5 June 2025

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# Abbreviations

| Abbreviation | Definition |
|---|---|
| **3D** | 3-dimensional |
| **AMA** | American Medical Association |
| **ANZAOMS** | Australian and New Zealand Association of Oral and Maxillofacial Surgeons |
| **BAOMS** | British Association of Oral and Maxillofacial Surgeons |
| **CMF** | craniomaxillofacial |
| **CPT** | Current Procedural Terminology |
| **department** | Australian Government Department of Health and Aged Care |
| **HRQoL** | health-related quality of life |
| **HTA** | health technology assessment |
| **IHACPA** | Independent Health and Aged Care Pricing Authority (formerly IHPA) |
| **IHPA** | Independent Hospital Pricing Authority |
| **KCE** | Belgian Health Care Knowledge Centre |
| **MBS** | Medical Benefits Schedule |
| **MDHTAC** | Medical Devices and Human Tissue Advisory Committee |
| **MOU** | Memorandum of Understanding |
| **MTAA** | Medical Technology Association of Australia |
| **NHMRC** | National Health and Medical Research Council |
| **NHS** | National Health Service |
| **NICE** | National Institute for Health and Care Excellence |
| **OMF** | oral and maxillofacial |
| **PL** | Prescribed List of Medical Devices and Human Tissue Products (formerly Prostheses List) |
| **PLR** | Post-listing review |
| **QOMS** | Quality and Outcomes in Oral and Maxillofacial Surgery |
| **RCT** | randomised controlled trial |
| **SM-ART** | Sydney Modified Alberta Reconstruction Technique |
| **SSDP** | Specialised Services Devices Programme |

| Abbreviation | Definition |
|---|---|
| **Stage 1** | Stage 1 of the post-listing review of surgical guides and biomodels |
| **TMJ** | temporomandibular joint |
| **TOR** | term of reference |
| **VSP** | virtual surgical planning |
| **WAP** | weighted average price |

# Glossary

| Term | Meaning |
|---|---|
| **Alveolar ridge augmentation** | Surgical procedure to adjust the alveolar ridge (i.e. the bony ridge of the upper and lower jaws), to help improve the size and shape of the ridge in preparation for a dental implant. |
| **Biomodel** | Derived from patient imaging data to replicate the geometry or morphology (i.e. the form or shape) of a biological structure (Lohfeld et al. 2005). Biomodels are used to replicate a patient's anatomical structures which, in a clinical setting, can aid in visualising abnormal or disturbed anatomy, diagnosis, surgical treatment planning and simulation, patient education, designing and fabricating patient-specific prostheses, and can serve as an intra-operative anatomical reference, including for surgeries involving the placement of an implant or prosthesis. They can be either digital representations, or physical 3D-printed models. |
| **Computer-assisted surgery** | The use of computers for planning, performing or assessing surgery. This can include intraoperative navigation, the production of cutting and drill guides and 3D-printed models, as well as patient-specific implants (Schramm et al. n.d.). |
| **Cutting guide** | A surgical guide which is customised to a patient's anatomy to enable 'intra-operative reproduction of pre-planned osteotomy cuts' (McAllister et al. 2018). |
| **Orthognathic surgery** | Corrective jaw surgery to 'realign disproportioned jaw bones to enable the best possible bite for mastication, speech and to balance the facial profile' (ANZAOMS (n.d.) Can be single or double jaw surgery. |
| **Surgical guide** | Patient-specific tools that are designed to transfer the planned surgical and prosthetic components of a procedure to the actual surgery (Poitros and Pena 2016). They are used to guide the precise cutting of bone or drilling of holes as needed for implantation (Francoisse et al. 2020). They include surgical templates, pilot guides, cutting and drilling guides, splints and jigs. |
| **Surgical splint** | Orthognathic surgical splints are surgical guides used in single or double jaw surgery to guide the mobile jaw segments into their virtually planned dental occlusion. These may be used to implant patient-matched implants or standard plates (definition supplied by the MTAA). |
| **Virtual surgical planning** | A planning procedure 'which uses digital clinical data for diagnostic, procedure selection and treatment planning purposes, including the forecast of potential outcomes' (Singh and Singh 2021). Surgical guides and biomodels may be produced as part of this process. Virtual surgical planning can be used in combination with other techniques such as 3-D printing, in order to produce implants and patient-specific surgical tools (Singh and Singh 2021) such as surgical guides or biomodels. |

# Executive Summary

Health Research Consulting (Hereco) was contracted by the Department of Health and Aged Care (the department) to review the evidence for the cost-effectiveness of surgical guides and biomodels listed on the Prescribed List of Medical Devices and Human Tissue Products (PL) and to use this to consider the appropriateness of the PL benefits for these devices.

This is Stage 2 of the post-listing review (PLR) of surgical guides and biomodels. Stage 1 considered the eligibility of surgical guides and biomodels for listing on the PL and the comparative clinical effectiveness of these devices. The PLR was a response to increased utilisation of these devices, concerns regarding appropriate use, uncertainty about their clinical and cost-effectiveness and uncertainty about their eligibility for listing on the PL. The definitions of the devices as used for Stage 1 are in the box.

**Definitions of surgical guides and biomodels from the Stage 1 PLR**

**Surgical guides** are tools designed to transfer the planned surgical and prosthetic components of a procedure to the actual surgery. They are contoured to each patient's specific anatomy and are designed to avoid critical structures. This enables precise cutting of bone or drilling of holes as needed for the accurate placement of an implant in a pre-planned location. Surgical guides include surgical templates, pilot guides, cutting and drilling guides, splints and jigs.

**Biomodels** are derived from patient imaging data to replicate the geometry or morphology (i.e. the form or shape) of a biological structure. They can help clinicians to visualise abnormal or disturbed anatomy and are used for diagnosis, surgical treatment planning and simulation, patient education, and designing and fabricating patient-specific prostheses. They can also serve as an intraoperative anatomical reference, including for surgeries involving the placement of an implant or prosthesis. Biomodels can be either digital representations (virtual models) or physical models; however, the only biomodels listed on the PL – and therefore in scope for this review – are physical models.

Abbreviations: PL, Prescribed List.

The external consultant's Stage 1 PLR was completed in March 2023. With respect to eligibility for listing on the PL, the report concluded that surgical guides and biomodels were eligible for complex but not simpler procedures and that there was insufficient evidence to determine the comparative clinical effectiveness of the devices. A review of the cost-effectiveness evidence was recommended.

In response to the Stage 1 PLR findings, from 1 February 2024 the department implemented a new condition for surgical guides and biomodels on the PL to restrict use to complex craniomaxillofacial (CMF) surgeries and to limit use to a maximum of 3 surgical guides and 3 biomodels per episode of care. Monitoring of these conditions is ongoing by the department.

## Post-listing review Stage 2 Terms of Reference

The department commenced Stage 2 of the PLR in November 2024. The Terms of Reference (TOR) for the review are:

1. Review the evidence for the use of surgical guides and biomodels currently listed on the PL, with a focus on cost-effectiveness to nominated comparator in CMF procedures.

2. Conduct an analysis of the PL benefits for devices in scope:
    a. Surgical guides used for implanting a device in CMF procedures on the PL
    b. Biomodels used for implanting a device in CMF procedures on the PL
    c. Surgical guides and biomodels in combination for implanting a device in CMF procedures on the PL
3. Subject to findings from TORs 1-2, provide recommended actions and outcomes about appropriate benefits for consideration by the delegate.

# Summary of comparative cost-effectiveness findings

## Methodology

The evidence for the cost-effectiveness of surgical guides and biomodels was assessed using a multipronged approach consisting of:

- review of key documents provided by the department, stakeholders and sponsors
- targeted systematic literature review – bibliographic database searches and grey literature searches to identify published studies reporting on cost or cost-effectiveness outcomes
- search for health technology assessments (HTAs) that have evaluated costs or cost-effectiveness
- search for primary studies in reference lists of relevant publications
- search of clinical trials registries to identify unpublished or ongoing studies
- review of pricing in other jurisdictions including the public system and internationally.

There were 21 primary studies eligible for inclusion in this Stage 2 PLR: 3 modelled economic analysis; 3 randomised controlled trials (RCTs) and 15 non-randomised comparative studies. Two HTAs were also included.

## Findings – modelled economic analyses

The 3 modelled economic analyses identified in the systematic review all considered the same surgical indication – mandibular reconstruction – and although they considered somewhat different clinical outcomes and health states, they broadly included different complications and total operative or ischemia time as the key outcomes that distinguish virtual surgical planning (VSP) from usual care (freehand surgery). All 3 studies explicitly stated that VSP included the manufacture of custom cutting guides and plates; 2 studies also mentioned the generation of biomodels.

The clinical inputs to the 3 modelled economic analyses were derived from small, non-randomised and largely retrospective studies. Overall, the authors of 2 analyses concluded that VSP was cost-effective, and the authors of the third analysis concluded that VSP was more costly and less effective. However, the findings should be interpreted in the context of the uncertain clinical impact of VSP due to the low-level evidence from which the model inputs were derived.

**Summary of clinical and cost outcomes from modelled economic analyses of VSP versus usual care**

| Study ID | Gardiner (2024) | Kurlander (2023) | Fatima (2019) |
|---|---|---|---|
| **Population** | Mandibular reconstruction – oncology only | Mandibular reconstruction | Mandibular reconstruction |
| **Country** | USA | USA | USA |
| **Time horizon** | 35 years | Operative and operative complications | Operative and operative complications |
| **Complication rate (vs. UC)** | 20% less hardware failure[a] | 0.3% more flap loss<br>0.8% less microvascular complications<br>8.6% less SSO | 0.6% more flap loss<br>6.6% more mandible infection |
| **Operative or ischemia time (vs. UC)** | 53 mins less | 34.8 mins less | 24.15 mins less |
| **Health utility (vs. UC)** | 0.10 QALY higher | 0.32 QALY higher | NA |
| **Cost difference (vs. UC)** | US$7,020 more | US$10,401 more | US$7,099 more |
| **ICER** | $68,383 per QALY[b] | $32,503 per QALY[c] | Dominated (higher cost and worse health outcomes) |

Source: Gardiner et al. (2024), Kurlander et al. (2023), Fatima et al. (2024)
Abbreviations: ICER, incremental cost-effectiveness ratio; mins, minutes; NA, not applicable; QALY, quality-adjusted life year; SSO, surgical site occurrence; UC, usual care; USA, United States of America; VSP, virtual surgical planning; US$, US dollars.
**a** Hardware failure was defined as hardware exposure, bone exposure, osteoradionecrosis or cutaneous fistula, requiring surgical intervention.
**b** Considered cost-effective by the study authors based on a willingness-to-pay threshold of $100,000, which is higher than commonly accepted.
**c** Considered cost-effective by the study authors based on the empirically accepted threshold of $50,000 per QALY.

## Findings – comparative cost-effectiveness

In addition to the modelled studies, primary comparative studies that reported cost outcomes were also included. There was a high risk of selection bias in most of these studies due to their unadjusted and retrospective design, therefore the summarised outcomes below are based solely on the 3 RCTs and one matched observational study.

Two RCTs in patients undergoing Le Fort osteotomy demonstrated a statistically significant reduction in operative time, favouring the use of patient-specific surgical guides and biomodels. The third RCT was conducted in partially edentulous patients undergoing prosthetic restoration and found no statistically significant differences in operative time between groups. None of the RCTs used surgical guides or biomodels that are listed on the PL.

The Australian observational study (Mazzola et al. 2020) found a statistically significant reduction in operative time and hospital length of stay for the unmatched cohort (N=138, not shown), favouring VSP, but no statistically significant differences in these outcomes in the matched subset (N=32).

**Summary of findings from RCTs and matched observational study reporting cost outcomes**

| Study ID N | Indication | Quality of evidence | Planning time | Operative time | Health outcomes | Cost |
|---|---|---|---|---|---|---|
| RCTs | | | | | | |
| **Omara (2021)**<br>**N=20** | Orthognathic surgery – Le Fort II osteotomy | Low | NR | **Favours SG&BM**<br>**2.23 h less, p <0.001** | NR | Favours UC<br>≈A$530, statistical significance NR |

| Study ID N | Indication | Quality of evidence | Planning time | Operative time | Health outcomes | Cost |
|---|---|---|---|---|---|---|
| **Schneider (2019a) N=21** | Orthognathic surgery – Le Fort I osteotomy & bilateral split osteotomy of the mandible | Low | NR | **Favours SG&BM 40 min less, p =0.041** | NR | Favours UC ≈A$670, statistical significance NR |
| **Schneider (2019c) N=73** | Dental – partially edentulous | Low | **Favours UC +7.2 mins, p <0.05** | No significant difference | No significant difference in QoL at 7 days | Favours UC ≈A$670, statistical significance NR |
| Matched observational cohort | | | | | | |
| **Mazzola (2020) N=32** | Reconstructive orthognathic – osseous free flap | Low | NR | No significant difference | No significant difference in surgical complications | No significant difference |

Abbreviations: A$, Australian dollars; h, hours; mins, minutes; NR, not reported; QoL, quality of life; RCT, randomised controlled trial; SG&BM, surgical guides and biomodels; UC, usual care.
**Bold** indicates statistical significance.

Operative time was the most consistently reported outcome of potential use for the purposes of comparative costing. Although reduced anaesthesia time might be beneficial for patients and could have flow on effects in reducing costs due to higher surgical throughput and lower staff costs, whether these efficiencies translate in real-world settings is uncertain. Patient relevant outcomes such as complications, reoperations and quality of life were infrequently reported in studies that also reported cost outcomes.

## Conclusions

The ability to make definitive conclusions from the evidence for surgical guides and biomodels is complicated by the complexity of the intervention (which often included any/all of VSP, use of 3-dimensional (3D) printed surgical guides and/or biomodels, other 3D printed tools and patient-matched implants) and the interaction of the physical guides and models with the VSP procedure itself and changes that may entail to the surgical procedure. The aspect of the intervention leading to a clinical effect is difficult to disentangle and as such, outcomes cannot be solely attributed to the physical surgical guides and biomodels. Furthermore, most studies did not clearly specify which surgical guides and biomodels were used or how many, therefore linking the evidence directly to PL listed devices is challenging.

A further methodological difficulty is the range of indications within CMF surgery for surgical guides and biomodels. The evidence was predominately for orthognathic (jaw) osteotomies and maxilla and mandibular reconstructions, for both benign and malignant pathologies. These are likely to be considered complex CMF procedures and therefore within scope, although the Stage 1 PLR noted that simple single jaw surgery is not considered complex. The next most common indication in the literature was dental implants, which are generally considered simple procedures and would therefore not be within scope.

For the remaining indications listed in the Stage 1 PLR as appropriate surgeries for the use of surgical guides, there was a lack of evidence on cost-effectiveness. This is not unexpected given many of these indications are uncommon or rare and therefore present greater challenges for undertaking clinical

research, particularly prospective comparative studies. However, these indications are likely to be the more complex and individualised surgeries where the use of surgical guides and biomodels is of greatest value, but evidence from RCTs is unlikely to ever be available due to small and heterogenous patient populations.

Overall, the use of surgical guides and biomodels in CMF surgery tended to cost more than usual care; however, the actual costs were poorly reported, and the costs of the devices were infrequently separated from that of the virtual planning system. The applicability of cost studies from other jurisdictions is usually low given the variation across health systems, and this is particularly the case for the studies identified, with the exception of the Australian matched observational study by Mazzola et al. (2020).

No convincing data were identified to support that the use of patient-matched surgical guides and/or biomodels is more effective or safer than conventional procedures without the use of such devices. This limits the ability to determine whether the current PL benefit for surgical guides and biomodels is relative to the clinical effectiveness, and highlights the need for more and/or higher quality evidence for both the clinical effectiveness and relative costs of surgical guides and biomodels to inform PL benefits.

RCTs have shown that surgical guides and biomodels provide added value in complex CMF surgeries by reducing operative time. Based on the available evidence, this does not appear to be the case for less complex procedures, such as dental implant surgery. This brings into question the value of surgical guides and biomodels for dental implants that are not part of a complex CMF procedure involving facial reconstruction or correction of significant jaw deformities.

## Options for consideration by the department

A range of options are presented to ensure the benefits for surgical guides and biomodels represent value for money on the PL. The options are not mutually exclusive, can be combined in multiple ways and include options that set benefits both directly (i.e. considering the benefits of surgical guides and biomodels in isolation) and indirectly (i.e. considering surgical guides and biomodels within the total benefits paid for a procedure).

### Options for deriving appropriate benefits

Options A1 to A4 are the most direct with respect to deriving benefits; several were suggested in the Stage 1 PLR. Two of these proposed options have limited viability. Option A1 is not feasible due to limitations in the evidence base, which has not established the clinical benefits of surgical guides and biomodels compared to usual care. Option A2 is not deemed feasible given the lack of transparency regarding public prices and international reimbursement.

Therefore, the options deemed potentially feasible to implement are A3 and A4. It is noted that option A3 may be challenging due to the use of higher-cost titanium in commercially supplied surgical guides. Consideration could be given to identifying titanium surgical guides on the PL and setting a different benefit for them.

**Summary of potential options for deriving appropriate benefits for surgical guides and biomodels on the PL**

| # | Option | Rationale |
|---|---|---|
| **A1** | Establish benefits relative to the clinical effectiveness of surgical guides and biomodels | PL listing criteria specify that 'the benefit amount for the medical device must be proportionate to the clinical effectiveness of the device'. This approach to benefit setting is hampered by the limited and confounded evidence base for surgical guides and biomodels. |
| **A2** | Align PL benefits for surgical guides and biomodels with the public sector or with internationally reimbursed prices | Although this option aligns with the benchmarking of all devices in Part A of the PL to public prices, it is unable to be implemented beyond the benefit reductions that have already occurred due to a lack of publicly available price data. |
| **A3** | Establish benefits that reflect the cost of production of surgical guides and biomodels | The cost of materials and 3D printing of surgical guides and biomodels is modest relative to the PL benefits. Furthermore, these devices are made-to-order and have reduced costs in terms of inventory, warehousing and waste compared with off-the-shelf devices. A benefit that is established on the basis of published costs for in-house facilities – with an additional commercial profit margin – would be substantially lower than the current benefit. However, different costs may need to be introduced for titanium surgical guides (as opposed to plastic biomodels and surgical guides) as these cannot be produced in house and production costs are significantly higher. |
| **A4** | Establish benefits for surgical guides and biomodels that are proportionate to other costs associated with the implantation procedure | Deriving a benefit for surgical guides and biomodels that is proportional to the total episode benefit (either restricted to prostheses or including medical services) provides a transparent mechanism to set a benefit that reflects the added value attributable to the addition of surgical guides and biomodels to the overall procedure. Using mean values, taken from all episodes where surgical guides and biomodels were used, could be easily implemented but might not accurately reflect the heterogeneity of use. A more complex mechanism that allows for differences in benefits according to surgical complexity would be more difficult to implement. |

Abbreviations: 3D, 3-dimensional; CMF, craniomaxillofacial; PL, Prescribed List; VSP, virtual surgical planning.

## Options for conditions on benefits payable

Following the Stage 1 PLR, conditions were implemented on the PL for listed surgical guides and biomodels. Retaining, refining or altering these conditions could have an impact on the overall cost of benefits paid for surgical guides and biomodels. These options may pose the highest implementation challenges as conditions are not widely used within the PL. Furthermore, some options may have the unintended consequence of having a greater impact on more complex surgeries than simpler surgeries, despite evidence and stakeholder feedback that the use of surgical guides and biomodels is of greater value in more complex surgeries.

**Summary of potential options for conditions on benefits payable for surgical guides and biomodels on the PL**

| # | Option | Rationale |
|---|---|---|
| **B1** | Retain conditions on the maximum number of surgical guides and biomodels that can be used per procedure | Implementation of this condition caps the number of surgical guides and biomodels that are payable per episode but may have inadvertently set an effective floor volume, encouraging greater use of these devices than is required for simpler procedures. This approach also impacts complex surgeries more than simpler procedures, despite evidence of greater value of surgical guides and biomodels in complex procedures. |
| **B2** | Create a new condition allowing a single benefit for surgical guides or biomodels per procedure rather than per item | Planning is the major cost input in the development of surgical guides and biomodels and occurs at the procedure level rather than the device level. Restricting to a single benefit payable per procedure would reflect the additional value of using VSP to produce all surgical guides and biomodels required for that procedure. |

| # | Option | Rationale |
|---|---|---|
| **B3** | Implement a stratified approach, where benefits payable for surgical guides and biomodels are reduced for each additional product used | A stratified approach, similar to that in place for pathology services on the MBS, would contain costs for surgical guides and biomodels and could be implemented alone or in addition to the current cap on the number of devices payable per episode, or in combination with other options. |
| **B4** | Implement a tiered approach, where benefits payable for surgical guides and biomodels are higher for more complex surgeries | A tiered approach could be based on MBS fees for the procedure in which the surgical guides or biomodels are used, with the aim of establishing benefits that increase with increasing surgical complexity. |
| **B5** | Create a condition that surgical guides or biomodels only attract a benefit when used without a patient-matched implant | This restriction is proposed as a mechanism to remove the 'double dip' benefit premiums associated with claiming both patient-matched implants and surgical guides and biomodels. It risks favouring simpler procedures. |

Abbreviations: MBS, Medicare benefits schedule; PL, Prescribed List; VSP, virtual surgical planning.

## Other options for the department to consider

At present, surgical guides are in different subcategories on the PL with different benefits and limited clinical rationale for this grouping. As part of the PL reform activities, a revised structure for the Plastic and Reconstructive Category of the PL was proposed. This structure was developed in collaboration with clinical experts and a clinical working group, and subject to review by industry and sponsors. The proposition was to bring all patient-matched CMF devices together into a single product group and remove anatomical distinctions for CMF surgical guides. There is a strong clinical justification for this, and it would facilitate many of the other options presented.

Deeper consideration of surgical guides and biomodels was limited in the regrouping activities because the PLR had been initiated, therefore further options for grouping as proposed in the Stage 1 PLR are included (C2 and C3).

**Summary of potential options for regrouping surgical guides and biomodels on the PL**

| No. | Option | Rationale |
|---|---|---|
| **C1** | Implement changes to surgical guides, biomodels and patient-matched implants as proposed under PL reform activity | Creation of a new product group for patient-matched devices for craniofacial reconstruction that brings together all patient-matched implants, surgical guides and biomodels would ensure that components of kits are co-located and facilitate greater consistency in benefit setting across these products. |
| **C2** | Group dental surgical guides and biomodels with dental implants | Relocation of dental surgical guides and biomodels to the endosseous implants group would enable a different benefit to be set for dental compared to CMF surgical guides and biomodels, in recognition that the clinical evidence relating to dental implants suggests no advantage over standard surgery. |
| **C3** | Separate splint guides from cutting and drilling guides | Creation of a separate subgroup for splints would recognise the notable differences between surgical splints (which are not readily identifiable on the PL) and surgical cutting and drilling guides. |

Abbreviations: CMF, craniomaxillofacial; PL, Prescribed List.

Rather than considering benefits for each device, the total benefits associated with a VSP procedure can be considered. Although the options for removing surgical guides and biomodels (wholly or partially) from the PL (D1 or D2) appear to result in them no longer receiving a benefit on the PL, stakeholders have argued that the additional benefit that patient-matched implants attract in the Plastics and Reconstructive category of the PL already provides a benefit for the associated surgical guides and biomodels. This is contrasted with patient-matched orthopaedic devices, which do not attract a higher benefit than off-the-shelf devices and where surgical guides and biomodels have been deemed ineligible for listing.

**Summary of potential options that change the benefits associated with a VSP 'package'**

| No. | Option | Rationale |
|---|---|---|
| **D1** | Remove biomodels from the PL | Reduces overall benefit for procedures involving surgical guides and biomodels. Biomodels do not strictly meet PL eligibility requirements and their value-add has not been definitively demonstrated. These devices can be considered part of the manufacturing process for patient-matched implants rather than essential to implanting a device. |
| **D2** | Remove surgical guides and biomodels from the PL | Reduces overall benefit for procedures involving surgical guides and biomodels. This approach aligns with other implants on the PL, such as knee, hip and spine, which do not provide PL benefits for surgical guides and biomodels. Patient-matched implants in the Plastic and Reconstructive category on the PL already attract a higher benefit than off-the-shelf implants and therefore any added value of surgical guides and biomodels is already accounted for in the benefit for the patient-matched implant. Most surgical guides and biomodels on the PL are packaged as part of a kit with the patient-matched implant. |
| **D3** | Lower the benefit of patient-matched implants to be the same as standard implants | Lowering the benefit for CMF patient-matched implants would align with other patient-matched implants on the PL, which do not attract a premium over off-the-shelf implants. This approach also recognises that surgical guides and biomodels are often provided as parts of kits, and it would prevent the VSP process, which is currently 'absorbed' in the benefit for patient-matched implants as well as for surgical guides and biomodels, from being funded multiple times in a single procedure. |

Abbreviations: PL, Prescribed List; PLR, post-listing review.

Given the lack of evidence and overwhelming association with simple procedures, the removal of surgical guides and biomodels that are specifically for dental implant surgery could be considered (option E1).

**Option for dental implant surgery**

| No. | Option | Rationale |
|---|---|---|
| **E1** | Remove surgical guides and biomodels for dental implant surgery from the PL | Removes benefits associated with procedures where clinical effectiveness is not demonstrated. PL eligibility criteria are not met for surgical guides or biomodels that are used for '*simpler procedures*'. Surgeons consulted during the Stage 1 PLR considered dental implant surgery and alveolar ridge augmentation as 'simpler'. |

Abbreviations: PL, Prescribed List; PLR, post-listing review.

# 1 Background

## 1.1 Context for the review

The Prescribed List of Medical Devices and Human Tissue Products (the PL) is a list of devices and products that private health insurers must pay a benefit for when they are provided to a privately insured patient in a hospital or hospital substitute setting. The arrangements for listing products on the PL help to ensure that the benefits paid by insurers are relative to comparative clinical effectiveness and are comparable to prices paid in other sectors.1

As part of recent reforms to the PL, the Australian Government Department of Health and Aged Care (the department) developed a Post-listing Review (PLR) Framework that outlines the processes for conducting reviews of medical devices listed on the PL.[1] PLRs may be triggered by a number of issues including, but not limited to, concerns about eligibility or inappropriate grouping on the PL, inappropriate or inconsistent use in practice, or concerns about comparative safety, comparative clinical effectiveness or comparative cost-effectiveness.

### 1.1.1 Post-listing review of surgical guides and biomodels – Stage 1

The PLR of surgical guides and biomodels is one of 4 pilot reviews supported by the Prostheses List Advisory Committee (PLAC), now the Medical Devices and Human Tissue Advisory Committee (MDHTAC). Surgical guides and biomodels were selected in response to:

- rapid growth in use of these devices – PL benefits paid by health insurers rose from $1.6 million in 2016–17 to $20.6 million in 2021–22
- reports suggesting overuse and inappropriate use
- uncertainty about comparative clinical effectiveness and cost-effectiveness
- uncertainty about eligibility on the PL – whether the devices are considered essential to implanting another device.

The review of surgical guides and biomodels is being conducted in two stages. In Stage 1 the terms of reference (TOR) were:

1. Analyse the role in clinical practice of surgical guides and biomodels currently listed on the PL, including future trends in clinical use.
2. Review the evidence base for the use of surgical guides and biomodels currently listed on the PL, with a focus on comparative clinical effectiveness and clinical benefits.
3. Consider the current utilisation of surgical guides and biomodels listed on the PL.
4. Based on the findings of 1, 2 and 3, advise if surgical guides and biomodels meet the eligibility criteria for listing on the PL. Findings regarding eligibility may differ between products and clinical circumstances.

[1] The Prescribed List Post-listing Review Framework. Australian Government Department of Health and Aged Care. December 2024.

## Stage 1 PLR findings

The external consultant's Stage 1 PLR was completed in March 2023.2 The definitions of surgical guides and biomodels from the Stage 1 PLR are reproduced in Box 1.

**Box 1 Definitions of surgical guides and biomodels from the Stage 1 PLR**

**Surgical guides** are tools designed to transfer the planned surgical and prosthetic components of a procedure to the actual surgery (Poitros and Pena, 2016). They are contoured to each patient's specific anatomy and are designed to avoid critical structures. This enables precise cutting of bone or drilling of holes as needed for the accurate placement of an implant in a pre-planned location (Francoisse et al. 2020). Surgical guides include surgical templates, pilot guides, cutting and drilling guides, splints and jigs.

**Biomodels** are derived from patient imaging data to replicate the geometry or morphology (i.e. the form or shape) of a biological structure (Lohfeld et al. 2005). They can help clinicians to visualise abnormal or disturbed anatomy and are used for diagnosis, surgical treatment planning and simulation, patient education, and designing and fabricating patient-specific prostheses. They can also serve as an intraoperative anatomical reference, including for surgeries involving the placement of an implant or prosthesis. Biomodels can be either digital representations (virtual models) or physical models; however, the only biomodels listed on the PL – and therefore in scope for this review – are physical models.

Abbreviations: PL, Prescribed List.

With respect to eligibility for listing on the PL,[3] the Stage 1 PLR concluded that of the 5 PL listing criterion, surgical guides and biomodels only partially met criterions 4 and 5.

- Criterion 4: Essential to, and specifically designed as an integral single-use aid, for implanting a product:
    - **not met** for surgical guides or biomodels when used in *procedures that do not involve implantation* of a product on the PL
    - **met** for surgical guides and biomodels used for *complex craniomaxillofacial (CMF) procedures*
    - **not met** for surgical guides or biomodels for *simpler procedures*.
- Criterion 5: The product has been compared to alternative products on the PL or alternative treatments and

  (i) assessed as being, at least, of similar clinical effectiveness; and

  (ii) the cost of the product is relative to its clinical effectiveness:
    - **insufficient evidence** to determine if criterion 5(i) or 5(ii) is met.

Although the Stage 1 PLR did not define simple and complex procedures, and noted that clinical circumstance may render a simple procedure complex, the report provided a list of procedures considered by surgeons during consultation to be complex CMF procedures that would necessitate use of surgical guides:

- orthognathic surgery (double jaw and complex single jaw – e.g. with segmentation)
- facial trauma surgery

[2] Prostheses List Post-Listing Review: Review of surgical guides and biomodels currently listed on the Prostheses List. Final Report. 3 March 2023.
[3] PL eligibility criteria are described in The Prescribed List of Medical Devices and Human Tissue Products Guide. Department of Health and Aged Care. Draft, December 2023.

- temporomandibular joint (TMJ) disorder surgery
- cancer resection and reconstruction
- correction of cleft and craniofacial deformities (e.g. craniosynostosis conditions)
- cranial vault reconstruction and cranioplasties
- surgery for rare conditions (e.g. fibrous dysplasia, anodontia)
- dental surgery where it is part of a CMF procedure (for example, where multiple teeth are replaced as a result of trauma, cancer resection, cleft and palate procedures).

The same surgeons considered that simple procedures where surgical guides and biomodels were not essential included:

- simple single jaw orthognathic surgery
- simple orbital surgery
- sinus lift procedures
- alveolar ridge augmentation
- dental implants (e.g. following tooth extraction).

With respect to comparative clinical evidence, a targeted systematic literature review was undertaken considering only surgical guides and biomodels listed on the PL at the time. Thirteen studies were included, all relating to a single product (ProPlan, now known as TruMatch). The level of evidence was low (National Health and Medical Research Council [NHMRC] level III-2), most studies were at moderate risk of bias (9 were retrospective) and with small patient numbers (18 to 138). The report concluded that 'the findings indicate improved or comparable outcomes for virtual surgical planning (VSP) groups where surgical guides and/or biomodels had been used, when compared to the comparator group (e.g. surgery conducted with a freehand surgical technique)'.

The Stage 1 PLR provided suggestions for the department to consider. These are listed in Box 2.

**Box 2 Suggestions to the department from the Stage 1 PLR of surgical guides and biomodels**

Clarifying PL eligibility criteria (and giving examples of eligible and ineligible types and usage of surgical guides and biomodels). This could include the development of regularly updated guidelines driven by expert clinicians.

Addressing some of the eligibility issues raised in the context of concurrent work, to reorganise or recategorise products currently listed on the PL.

Clarifying the role of and pricing structures for surgical guides and biomodels supplied as individual products and as elements of 'kits' or bundles currently listed on the PL.

Considering alternative funding structures for virtual surgical planning.

In consultation with relevant clinical experts, placing limits on the benefits payable through the PL, for example:

- specifying the MBS categories or items for which surgical guides and biomodels are eligible for benefits through the PL mechanism
- limiting the number of surgical guides and biomodels for which a PL benefit is paid per separation
- considering alternative approaches to listing of benefits, such as stratified or tiered approaches.

Investigating, and taking actions to address, areas where benefits may be claimed inappropriately (e.g. in the absence of a prosthesis, or where the procedure could be performed outside of a hospital or hospital-substitute setting).

Conducting an economic analysis (e.g. IHACPA review) to:

- review the benefit amounts specified on the PL for the listed surgical guides and biomodels, for example to determine if the benefits listed on the PL are consistent with the cost of manufacture
- explore whether the benefits paid are proportionate to other costs associated with implantation of prostheses (including other items supplied as part of kits)
- determine whether the costs of products are comparable to the minimum prices available in the public sector and overseas.

Exploring options for future consultation and governance arrangements to ensure any changes and guidance to the sector are appropriately informed by stakeholder input.

Abbreviations: IHACPA, Independent Health and Aged Care Pricing Authority; MBS, Medicare Benefits Schedule; PL, Prescribed List.

## Department response and implementation of Stage 1

The department considered the Stage 1 PLR and conducted further consultation with clinical experts. Following this, a new condition for surgical guides and biomodels was implemented, effective from 1 February 2024, to restrict use to complex CMF surgeries.

PL reimbursement for surgical guides and biomodels was restricted to use in admitted patients undergoing procedures involving insertion of implantable medical devices listed in the Plastic and Reconstructive category in the following subcategories:

- 07.01 – Craniomaxillofacial Reconstruction & Fixation
- 07.02 – Craniomaxillofacial Implants
- 07.03 – Dental Implants (only applies if the dental implantable medical device is explicitly identified in the product name or description of the billing code for the surgical guide or biomodel and is used in hospital)

- 07.04 – Distractor Systems.

To be eligible for reimbursement:

- at least one valid MBS item must be used that covers the implantation of at least one of the implantable medical devices listed in either of the subcategories above, and
- the surgical guides and biomodels must be used intraoperatively to aid device implantation, and not for virtual planning, preparation or manufacturing of patient-specific implants.

The condition also limits PL benefit reimbursement to a maximum of 3 surgical guides and/or 3 biomodels per episode of care (i.e. a total of 6 benefits and a maximum of 3 each per episode).

The department has committed to monitoring the impact of the condition and undertook a short consultation on the requirements specific to dental implants in March 2024. No changes were made following this consultation; however, monitoring and review is ongoing.

### 1.1.2 Post-listing review of surgical guides and biomodels – Stage 2

The department commenced Stage 2 of the PLR in November 2024. The TOR for the review are:

1. Review the evidence for the use of surgical guides and biomodels currently listed on the PL, with a focus on cost-effectiveness to nominated comparator in CMF procedures.
2. Conduct an analysis of the PL benefits for devices in scope:
    a. Surgical guides used for implanting a device in CMF procedures on the PL
    b. Biomodels used for implanting a device in CMF procedures on the PL
    c. Surgical guides and biomodels in combination for implanting a device in CMF procedures on the PL.
3. Subject to findings from TORs 1-2, provide recommended actions and outcomes about appropriate benefits for consideration by the delegate.

Health Research Consulting (Hereco) was contracted by the department to review the evidence for the cost-effectiveness of surgical guides and biomodels and to use this to consider the appropriateness of the PL benefits for these devices. The services to be provided to inform the department in the Stage 2 PLR are listed in Table 1.

**Table 1 External HTA evaluation services to be provided in Stage 2**

| Service | Description |
|---|---|
| 1 | Review the evidence for cost-effectiveness of surgical guides and biomodels currently listed on the PL (separately and in combination) to implant a device compared to standard care, or alternative therapeutic approaches:<br>• Review the following key documents provided by the department:<br>  ○ information and submissions obtained from sponsors<br>  ○ information and submissions obtained from stakeholders<br>  ○ other utilisation and economic data<br>  ○ any relevant clinical guidelines<br>  ○ any relevant existing reports<br>• Undertake a search of key clinical trials registries (ANZCTR, Clinicaltrials.gov) for ongoing clinical trials which may provide relevant evidence in the short to medium term<br>• Conduct a targeted, systematic literature review of the evidence on cost effectiveness of surgical guide and biomodels and any pivotal clinical evidence or clinical guidelines not captured through the above sources. Include both domestic and relevant international data.<br>• Undertake a search of HTA agencies for reviews on the cost effectiveness of surgical guides and biomodels<br>• Consider appropriate perioperative, clinical and patient-centered outcomes in relation to the cost and value of surgical guides and biomodels<br>• Review comparable public pricing and international pricing of surgical guides and biomodels in CMF procedures |
| 2 | Summarise the knowledge/evidence to address the following questions:<br>• Are surgical guides and biomodels cost-effective compared to standard care or other therapeutic approaches when used to implant a device in CMF procedures?<br>• Is the current PL benefit for surgical guides and/or biomodels relative to the clinical effectiveness?<br>• Can any conclusions/recommendations be made from the evidence? |
| 3 | Provide a scope of options and suggest methods to derive appropriate benefits for surgical guides and biomodels. |
| 4 | Guided by the PL Post listing review framework, present the information and evidence from services 1 to 3 in a report to support the department to assess what actions or policy initiatives should be considered with regards to the benefit setting for surgical guides and biomodels in CMF procedures.<br>Present options, for the department to consider, to ensure the benefit for surgical guides and biomodels represents value for money on the PL when used to implant a device in CMF procedures. |

Abbreviations: ANZCTR, Australian New Zealand Clinical Trials Registry; CMF, craniomaxillofacial; HTA, health technology assessment; PL, Prescribed List.

## Targeted consultation

Sponsors and stakeholders were invited to submit information for the PLR in response to the TORs. The list of sponsors and stakeholders contacted is provided in Appendix A (Table App. A.1); 16 stakeholders and 10 sponsors responded to the request for information.

A draft report on the evidence for the cost-effectiveness of surgical guides and biomodels was circulated to stakeholders in March 2025. Stakeholder feedback was incorporated into the final version where required for clarity.

# 2 Review of cost-effectiveness evidence

## 2.1 Methodology

The research question to focus the Stage 2 PLR is:

> Review the evidence for cost-effectiveness of surgical guides and biomodels currently listed on the PL (separately and in combination) to implant a device compared to standard care, or alternative therapeutic approaches.

The evidence for the cost-effectiveness of surgical guides and biomodels was assessed using a multipronged approach consisting of:

- review of key documents provided by the department, stakeholders and sponsors
- targeted systematic literature review – bibliographic database searches and grey literature search to identify published studies reporting on cost or cost-effectiveness outcomes
- search for health technology assessments (HTAs) that have evaluated costs or cost-effectiveness
- search for primary studies in reference lists of relevant publications
- search of clinical trials registries to identify unpublished or ongoing studies
- review of pricing in other jurisdictions including public system and internationally.

Full details of the methodology are provided in Appendix C.

### 2.1.1 Systematic literature review

The systematic bibliographic database searches (both generic and device-specific approaches) identified 1,055 unique records for screening (Appendix C.1.2), of which 53 were reviewed at full text. Of these, 16 primary studies were eligible for inclusion in the current report (Table App. C.3). Thirty-seven studies were excluded, as shown in Table App. C.4 with reasons for exclusion. Systematic reviews were not eligible for inclusion, but two were selected for sourcing primary studies (Table App. C.5).

### 2.1.2 Grey literature search

A targeted search of HTA agencies and key clinical guideline repositories identified 10 relevant HTA reports (Table App. C.8); 8 were excluded from further analysis and 2 were eligible for inclusion. A search of clinical trials registries was undertaken.

### 2.1.3 Studies from stakeholder submissions

All studies reporting economic or cost outcomes submitted by stakeholders for the Stage 2 PLR were tabulated, along with those from Stage 1 submissions and the Stage 1 PLR. These are listed in Appendix C.4 (Table App. C.10), along with the primary studies included in the two HTAs and the two selected systematic reviews. A total of 52 studies are listed, of which eight were eligible for inclusion.

### 2.1.4 Summary of studies from all sources

Combining the studies identified from the bibliographic search, stakeholder submission and reference lists from included studies, 16 duplicates were removed and a total of 21 primary studies were eligible for inclusion in the Stage 2 PLR: 3 modelled economic analysis; 3 randomised controlled trials (RCTs) and 15 non-randomised comparative studies (although 5 were low-level evidence and not presented in this Stage 2 PLR) (Appendix C.5, Table App. C.12).

## 2.2 Summary of the evidence

### 2.2.1 Included modelled economic analyses

Three modelled economic studies were identified in the systematic review (Gardiner et al. 2024; Kurlander et al. 2023; Fatima et al. 2019). In all 3, the participants were patients undergoing mandibular reconstruction surgery, which is likely to be considered complex craniofacial surgery. The intervention was virtual surgical planning (VSP) compared to freehand surgery (usual care). All 3 studies explicitly stated that VSP included the manufacture of custom cutting guides and plates; 2 studies also mentioned the generation of biomodels (Gardiner et al. 2024; Fatima et al. 2019). None of the studies explicitly named a commercial product in their model. The studies are summarised in Table 2.

Two studies were cost-utility analyses that reported cost-effectiveness in terms of cost per quality-adjusted life year (QALY). The analysis reported by Fatima et al. (2019) was termed a cost-effectiveness analysis by the authors, though the outcomes were not expressed in natural health units. Model inputs and findings are described for each study individually.

**Table 2 Characteristics of the economic analyses identified in the systematic review**

| Study ID | Gardiner (2024) | Kurlander (2023) | Fatima (2019) |
|---|---|---|---|
| **Perspective** | Health care<br>USA | Hospital or insurer/payer<br>USA | Payer<br>USA |
| **Time horizon** | 35 years (3% discount rate) | No time dimension | No time dimension |
| **Economic evaluation type** | Cost-utility analysis (Markov) | Cost-utility analysis (decision analysis) | Cost-effectiveness analysis (decision analysis)[a] |
| **Participants** | Mandibular reconstruction surgery in advanced oral cavity cancer | Mandible reconstruction surgery | Mandible reconstruction surgery |
| **Intervention** | VSP including patient-specific stereographic models, cutting guides and pre-milled fixation plates | VSP and computer-assisted design and manufacturing of custom cutting guides and pre-milled plates (commercial) | VSP including stereolithographic model and custom plates and/or cutting guides |
| **Comparator** | Usual care | Usual care | Usual care |
| **Health states** | Cancer recurrence, hardware complication, “normal life”, death | Total flap loss, microvascular compromise, surgical site occurrence | None |
| **Funding** | NR | NR | NR |
| **Author COIs** | One author is on the editorial board of the journal. | No COIs declared for authors. | No COIs declared for authors. |

Source: Fatima et al. (2019); Gardiner et al. (2024); Kurlander et al. (2023)
Abbreviations: COI, conflict of interest; EE, economic evaluation; NR, not reported; USA, United States of America; VSP, virtual surgical planning.
**a** Results were presented as the difference in costs alongside the difference in effectiveness.

### Gardiner (2024)

The hypothesis for the Gardiner et al. (2024) analysis was that the higher initial costs for VSP would be offset by increased effectiveness as measured by QALYs when accounting for long term postoperative complications. Model input parameters were derived from a literature search and institutional data (Table 3). The institutional data consisted of prospectively collected data on 241 patients operated between 2012 and 2021 (40 with usual care and 61 with VSP) with at least 2 years' follow up. Most parameters were derived from institutional data due to the lack of published data. Key model inputs were reduced operative time (53 minutes shorter) and reduced rates of hardware failure requiring surgical intervention at 2 years (20% lower)4 for VSP compared to usual care.

Cost data for individual aspects of VSP were not reported separately and the study did not report whether the VSP planning and printing was undertaken in-house or commercially.

**Table 3 Model input parameters (Gardiner 2024)**

| Parameter | Value (SD) | Source |
|---|---|---|
| Event rates | | |
| **VSP operative time (minutes)** | 774 (0.05) | Fatima et al. (2019); Tarsitano et al. (2016); Institutional data |
| **Usual care operative time (minutes)** | 721 (0.05) | Fatima et al. (2019); Tarsitano et al. (2016); Institutional data |
| **VSP deviation** | 0.03 (0.015) | Efanov et al. (2018); Ma et al. (2021); Institutional data |
| **VSP hardware failure** | 0.16 (0.07) | Swendseid et al. (2020); Institutional data |
| **Usual care hardware failure** | 0.36 (0.11) | Institutional data |
| **Recurrence** | 0.21 (0.05) | De Almeida et al. (2016) |
| **Death from recurrence** | 0.80 (0.10) | Paleri & Kelly (2008) |
| Costs (USD) | | |
| **VSP procedure** | $7,500 ($1,000) | Institutional pricing |
| **Remission** | $1,800 ($40) | Centers for Medicare & Medicaid Services |
| **Clinic visit** | $92.05 ($15) | Centers for Medicare & Medicaid Services |
| **Pectoralis major flap** | $1,700 ($1,500 -1,900) | Jackson et al. (2016) |
| **Removal of portion of mandible due to infection** | $950 ($830 – 1,080) | Jackson et al. (2016) |
| **Removal of mandibular hardware** | $750 ($600 – 820) | Jackson et al. (2016) |
| **Intravenous antibiotics** | $85 ($68 – 95) | Jackson et al. (2016) |
| Utility scores | | |
| **Death** | 0 | |
| **After adjuvant** | 0.793 (0.025) | De Almeida et al. (2016); Ren et al. (2022); Noel et al. (2015) |

[4] Hardware failure was defined as hardware exposure, bone exposure, osteoradionecrosis, or cutaneous fistula, and surgical interventions required (washout/debridement or hardware removal). The total cost for repair of hardware failure was estimated to be $4,900, which included clinic visits, intravenous antibiotics, removal of portion of mandible due to infection, and removal of mandibular hardware.

| Parameter | Value (SD) | Source |
|---|---|---|
| **Hardware failure** | 0.63 (0.025) | De Almeida et al. (2016) |

Source: Gardiner et al. (2024) Table 1
Abbreviations: SD, standard deviation; USD, United States dollars; VSP, virtual surgical planning.

The results of the base case analysis are shown in Table 4. The authors noted a marginal difference in effectiveness between the groups, and that the cost difference was similar to the cost of VSP itself. In one-way sensitivity analyses, the model was sensitive to patient age and VSP cost; however, only thresholds of $100,000 and $150,000 were reported and these are higher than generally used by Australian decision makers.

**Table 4 Base case results (Gardiner 2024)**

| | Cost (USD) | Incremental cost | Effectiveness (QALY) | Incremental QALY | ICER (cost/QALY) |
|---|---|---|---|---|---|
| **Usual care** | $42,478.04 | | 8.27 | | |
| **VSP** | $49,498.37 | $7,020.04 | 8.37 | 0.10 | $68,382.62 |

Source: Gardiner et al. (2024) Table 3
Abbreviations: ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life year; USD, United States dollars; VSP, virtual surgical planning.

### Kurlander (2023)

The hypothesis for the Kurlander et al. (2023) analysis was that the added cost of VSP would be justified by the surgical outcomes compared with the conventional technique. Model input parameters were derived from a systematic review and meta-analysis conducted by the authors (Padilla et al. 2021). The published systematic review reported no statistically significant differences between VSP and usual care for the health states included in the model (total flap loss, microvascular complications, surgical site occurrence) (Padilla et al. 2021). Of the 27 studies included in the systematic review, 26 were retrospective case series. The institutional data used to supplement the finding from the Padilla et al. (2021) review were not described. In the modelled analysis, a higher rate of successful procedures and a lower rate of complications was applied to the VSP group without consideration of the statistical significance nor clinical relevance of these differences (Padilla et al. 2021 found no statistically significant differences between groups in flap loss, osseous flap non- or mal-union, microvascular complications or surgical site occurrence).

Utility values were obtained through a survey of 14 plastic surgeons. The survey used a visual analogue scale without transformation into preference-based measures and is therefore considered another major weakness of this study.

Costs for individual components of VSP were stated and derived from a commercial supplier. A higher cost was applied to usual care to account for a longer operative time based on the meta-analysis (Padilla et al. 2021).

**Table 5 Model input parameters (Kurlander 2023)**

| Parameter | Value | Source |
|---|---|---|
| Event rates | | |
| **Successful procedure VSP** | 0.696 | Padilla et al. (2021); institutional data |
| **Successful procedure UC** | 0.621 | Padilla et al. (2021); institutional data |

| Parameter | Value | Source |
|---|---|---|
| **Total flap loss VSP** | 0.031 | Padilla et al. (2021); institutional data |
| **Total flap loss UC** | 0.028 | Padilla et al. (2021); institutional data |
| **Microvascular complication VSP** | 0.025 | Padilla et al. (2021); institutional data |
| **Microvascular complication UC** | 0.033 | Padilla et al. (2021); institutional data |
| **SSO VSP** | 0.235 | Padilla et al. (2021); institutional data |
| **SSO UC** | 0.321 | Padilla et al. (2021); institutional data |
| Costs (USD) | | |
| **Bone graft with microvascular anastomosis; fibula** | $2,832.42 | Centers for Medicare & Medicaid Services |
| **Split thickness autograft, trunk, arms, legs; first 100 sq cm or less** | $806.91 | Centers for Medicare & Medicaid Services |
| **Ear, nose, mouth, and throat malignancy with major complication or comorbidity** | $15,916 | Centers for Medicare & Medicaid Services |
| **10 mm screws** | $1,100 | Commercial supplier |
| **2.0 mm recon plate (UC)** | $3,150 | Commercial supplier |
| **Premilled plate (VSP)** | $9,644 | Commercial supplier |
| **Cutting guides (VSP)** | $5,580 | Commercial supplier |
| **OR time surcharge (UC)** | $1,584.47 | Per minute cost of $19.09 and Padilla (2021) |
| Utility scores | | |
| **Successful procedure** | 0.83 | Clinician survey |
| **Total flap loss** | 0.52 | Clinician survey |
| **Microvascular complication** | 0.71 | Clinician survey |
| **SSO** | 0.67 | Clinician survey |

Source: Kurlander et al. (2023) Table 1, Table 2 and Table 3.
Abbreviations: OR, operating room; SSO, surgical site occurrence; UC, usual care; USD, United States dollars; VSP, virtual surgical planning.

The results of the base case analysis are shown in Table 6. In one-way sensitivity analyses, the utility values for successful outcome and surgical site occurrence had the greatest impact.

**Table 6 Base case results (Kurlander 2023)**

| | Cost (USD) | Incremental cost | Effectiveness (QALY) | Incremental QALY | ICER (cost/QALY) |
|---|---|---|---|---|---|
| **Usual care** | $26,087 | | 16.93 | | |
| **VSP** | $36,488 | $10,401 | 17.25 | 0.32 | $32,503 |

Source: Kurlander (2023) Table 4
Abbreviations: ICER, incremental cost-effectiveness ratio; QALY, quality adjusted life year; USD, United States dollars; VSP, virtual surgical planning.

### Fatima (2019)

The hypothesis for the Fatima et al. (2019) analysis was that the higher front-end costs with use of VSP technology from generation of models, custom plates, and/or cutting guides would be offset by reduced operative time and reduced probability of downstream complications, both acute and delayed. Model input parameters were derived from a literature review. The authors chose to use ischemia time rather than

operative time due to its association with flap survival and overall complication rate. In this model, with the exception of ischemia time, all clinical outcomes favoured usual care.

Costs for VSP were derived from the literature review and costs for individual aspects of VSP were not separately defined.

**Table 7 Model input parameters (Fatima 2019)**

| Parameter | Value | Source |
|---|---|---|
| Event rates | | |
| **Ischemia time (UC)** | 91.76 min | Wang et al. (2016); Weitz et al. (2016); Culie et al. (2016) |
| **Ischemia time (VSP)** | 67.61 min | Wang et al. (2016); Weitz et al. (2016); Culie et al. (2016); Toto et al. (2015) |
| **Infection (UC)** | 0.242 | Wang et al. (2016); Culie et al. (2016) |
| **Infection (VSP)** | 0.308 | Wang et al. (2016); Culie et al. (2016) |
| **Total flap loss (UC)** | 0.077 | Wang et al. (2016); Culie et al. (2016) |
| **Total flap loss (VSP)** | 0.083 | Wang et al. (2016); Culie et al. (2016) |
| **Flap salvage** | 0.040 | Toto et al. (2015) |
| **Other or no complications (UC)** | 0.883 | Wang et al. (2016); Culie et al. (2016); Toto et al. (2015) |
| **Other or no complications (VSP)** | 0.877 | Wang et al. (2016); Culie et al. (2016); Toto et al. (2015) |
| Costs (USD) | | |
| **VSP** | $7,812 | Weitz (2016); Culie (2016); Centers for Medicare & Medicaid Services |
| **Ischemia time (UC)** | $2,462 | Culie et al. (2016); Macario (2010); Zweifel (2015) |
| **Ischemia time (VSP)** | $1,814 | Centers for Medicare & Medicaid Services, Institutional data |
| **Infected mandible** | $274 | Centers for Medicare & Medicaid Services, Institutional data |
| **Flap salvage** | $342 | Centers for Medicare & Medicaid Services, Institutional data |
| **Other or no other delayed complication** | $171 | Centers for Medicare & Medicaid Services, Institutional data |
| **Flap loss with regional flap reconstruction** | $4,903 | Centers for Medicare & Medicaid Services, Institutional data |
| **Flap loss with bone flap reconstruction** | $4,228 | Centers for Medicare & Medicaid Services, Institutional data |
| **Flap loss with var and soft tissue graft reconstruction** | $1,565 | Centers for Medicare & Medicaid Services, Institutional data |
| **Flap loss with debridement only** | $274 | Centers for Medicare & Medicaid Services, Institutional data |

Source: Fatima et al. (2019) Table 2.

Abbreviations: UC, usual care; USD, United States dollars; VSP, virtual surgical planning.

In the Fatima et al. (2019) analysis, VSP was more costly and less effective than usual care (i.e. usual care dominated VSP). In sensitivity analysis, the model was most sensitive to the cost of VSP and it was estimated that VSP material costs would need to be reduced to $712 to match the total costs of usual care.

**Table 8 Base case results (Fatima 2019)**

| | Cost (USD) | Incremental cost | Effectiveness (flap loss per 1000) | Effectiveness (mandibular infection per 1000) |
|---|---|---|---|---|
| **Usual care** | $2,957 | | 77 | 243 |
| **VSP** | $10,057 | $7,099 | 83 | 308 |

Source: Fatima (2019) Table 2.
Abbreviations: USD, United States dollars; VSP, virtual surgical planning.

## Summary of modelled economic analyses

The 3 modelled economic analyses identified in the systematic review all considered the same surgical indication – mandibular reconstruction – and although they considered somewhat different clinical outcomes and health states, they broadly included surgical complications and operative times as the key outcomes that distinguish VSP from usual care. However, the clinical inputs differed across the studies. Only the systematic review that informed Kurlander et al. (2023) was published (Padilla et al. 2021) and the authors noted the low level of evidence (included studies were overwhelmingly retrospective case series). Further, the published systematic review identified no statistically significant differences between VSP and usual care with respect to surgical site occurrence, hardware failure or flap loss. Therefore, the low level of evidence leads to very high uncertainty regarding the clinical impact of VSP and the model outcomes should be interpreted in this context.

**Table 9 Summary of clinical and cost outcomes from modelled economic analyses of VSP versus usual care**

| Study ID | Gardiner (2024) | Kurlander (2023) | Fatima (2019) |
|---|---|---|---|
| **Population** | Mandibular reconstruction – oncology only | Mandibular reconstruction | Mandibular reconstruction |
| **Country** | USA | USA | USA |
| **Time horizon** | 35 years | Operative and operative complications | Operative and operative complications |
| **Complication rate (vs. UC)** | 20% less hardware failure[a] | 0.3% more flap loss<br>0.8% less microvascular complications<br>8.6% less SSO | 0.6% more flap loss<br>6.6% more mandible infection |
| **Operative or ischemia time (vs. UC)** | 53 mins less | 34.8 mins less | 24.15 mins less |
| **Health utility (vs. UC)** | 0.10 QALY higher | 0.32 QALY higher | NA |
| **Cost difference (vs. UC)** | US$7,020 more | US$10,401 more | US$7,099 more |
| **ICER** | $68,383 per QALY[b] | $32,503 per QALY[c] | Dominated (higher cost and worse health outcomes) |

Source: Gardiner et al. (2024), Kurlander et al. (2023), Fatima et al. (2024)
Abbreviations: ICER, incremental cost-effectiveness ratio; NA, not applicable; QALY, quality-adjusted life year; SSO, surgical site occurrence; UC, usual care; USA, United States of America; US$, US dollar.
**a** Hardware failure was defined as hardware exposure, bone exposure, osteoradionecrosis or cutaneous fistula, requiring surgical intervention.
**b** Considered cost-effective by the study authors based on a willingness-to-pay threshold of $100,000, which is higher than commonly accepted.
**c** Considered cost-effective by the study authors based on the empirically accepted threshold of $50,000 per QALY.

### 2.2.2 Included randomised controlled trials reporting costs

Three RCTs were identified in the systematic review for evidence of comparative costs or cost-effectiveness (Schneider et al. 2019a, Schneider et al. 2019c, Omara et al. 2021). All 3 RCTs were small, single-centre, open-label and reported cost outcomes. The clinical interventions in the trials differed; 2 were Le Fort osteotomy's (Type I [Schneider et al. 2019a] and Type II [Omara et al. 2021]) and one was dental implants (Schneider et al. 2019c). Le Fort osteotomies are likely to be considered complex procedures; however, the implantation of dental implants in partially edentulous adults are more likely to be classified as simple.

The study characteristics are summarised in Table 10. None of the studies used surgical guides or biomodels that are listed on the PL. The Schneider (2019c) study was designed to compare different approaches to surgical planning as opposed to comparing the use of surgical guides and/or biomodels against free-hand surgery; however, it was included due to a lack of eligible studies. The control group was described in the study as 'free-hand implant placement.'

The Schneider et al. (2019c) study was reported in 4 separate publications;[5] only outcomes relating to cost and time reported in Schneider et al. (2019c) were extracted.

**Table 10 Characteristics of RCTs that compared surgical planning using patient-specific surgical guides and/or biomodels versus conventional surgical planning**

| Study ID | Omara (2021) | Schneider (2019a) | Schneider (2019c) |
|---|---|---|---|
| **Study design** | Single-centre, open label RCT | Single-centre, open label RCT | Single-centre, open label RCT |
| **Study size** | N=20 | N=21 | N=73 |
| **Country** | Egypt | Germany | Switzerland |
| **Population** | Non-syndromic patients with maxillary-zygomatic deficiencies associated with infraorbital hypoplasia, but normal nasal projection<br>Excluded patients with previous extensive jaw surgery, cleft palate or temporomandibular joint dysfunction | Healthy adult patients with skeletal class II malocclusion treated with bimaxillary surgery<br>Excluded patients with a history of facial trauma, hemifacial microsomia, craniosynostosis, or degenerative or inflammatory conditions | Partially edentulous adults in need of an implant-supported prosthetic restoration<br>Excluded if the remaining dentition did not allow adequate stability of a tooth-supported radiologic template and surgical guide; changes in the residual dentition during the prosthetic treatment that rendered the matching of the initial and final dental conditions impossible for the superimposition software |
| **Follow up** | 1-week post-operation | NR | NR |
| **Intervention** | Quadrangular Le Fort II osteotomy (QLFIIO) using patient-specific surgical guides and pre-bent titanium miniplates | Le Fort I osteotomy of the maxilla and bilateral sagittal split osteotomy of the mandible using VSP, individualised splints and patient-specific biomodels | 1: Digital planning and patient-specific surgical guides following development of a plaster model<br>2: Digital planning and patient-specific surgical guides without plaster model |

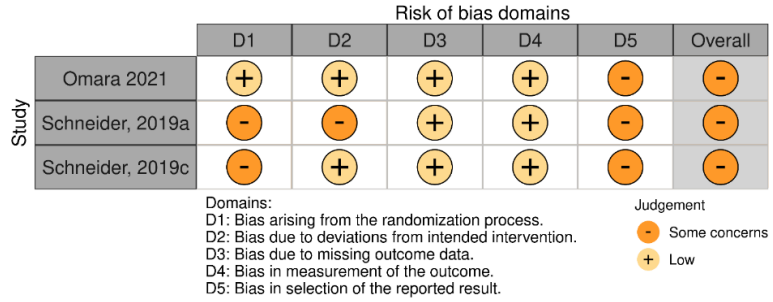
[5] Also reported by Sancho-Puchades et al. (2019), Schneider et al. (2018) and Schneider et al. (2019b).

| Study ID | Omara (2021) | Schneider (2019a) | Schneider (2019c) |
|---|---|---|---|
| **Comparator** | QLFIIO using conventional intermediate interocclusal wafers with intraoperatively adapted titanium miniplates. | Le Fort I osteotomy of the maxilla and bilateral sagittal split osteotomy of the mandible using conventional planning and plaster models to produce splints | Conventional planning with a plaster model |
| **Outcomes** | Angular deviations<br>Operative time<br>Cost | Angular differences for the maxilla and mandible (post-operative)<br>Intraoperative accuracy<br>Operative time<br>Cost | Surgical complications or deviations<br>Operative time<br>Cost<br>Pain[a]<br>Quality of life[a]<br>Accuracy |
| **Funding** | No specific grant | NR | Self-funded |
| **Author COIs** | No COIs | No COIs | Software and study materials provided by Dentsply Sirona and Swissmeda. Dr Schober is a part-time employee of Swissmeda |

Source: Omara et al. (2021); Schneider et al. (2019a); Schneider et al. (2019c).
Abbreviations: COI, conflict of interest; NR, not reported; QLFIIO, Quadrangular Le Fort II osteotomy; RCT, randomised controlled trial; VSP, virtual surgical planning.
**a** Assessed during the first 7 postoperative days using non-validated questionnaires with visual analog scales to quantify the answers.

Risk of bias was assessed with the Cochrane risk of bias tool for randomised trials (Sterne et al. 2019) against the outcome of operative time. All 3 studies were considered to have 'some concerns' overall. Two studies provided insufficient details regarding randomisation and allocation concealment (Schneider et al. 2019a; Schneider et al. 2019c); none of the studies provided a table of the baseline characteristics of the patients to demonstrate adequacy of the randomisation. Insufficient information was provided in all 3 studies to establish whether analyses were pre-planned. Therefore, risk of bias assessment was hindered by lack of information rather than specifically indicating high risk of bias. Due to their small size, all studies had low statistical power.

**Figure 1** **Risk of bias summary**




Source: Prepared using McGuinness LA and Higgins JPT (2020) 'Risk-of-bias VISualization (robvis): An R package and Shiny web app for visualizing risk-of-bias assessments', *Res Syn Meth*, 1- 7, doi: 10.1002/jrsm.1411.

## Findings from the randomised controlled trials

The outcomes of the trials are presented in Table 11. Operative time was the most widely reported outcome proposed to counter the higher cost outlay of patient-specific surgical guides and biomodels. Across the 3 RCTs, 2 reported a statistically significant reduction in operative time. The actual saving differed greatly depending on the complexity, and hence length, of the operations. The mean time saved was 2.23 hours for the more complex Le Fort II osteotomy and 40 minutes for the less complex Le Fort I

osteotomy. Dental implant surgery did not demonstrate a statistical difference in operative time and tended to favour conventional surgery for this outcome. Neither of the studies that reported reduced operative time also reported on planning time.

Costs were higher in the intervention group in all studies due to higher hardware costs that were not offset by reduced operative time. Details of how costs were calculated were lacking, with the exception of Schneider et al. (2019c) where a detailed cost analysis was undertaken including items and tariffs for individual components of the interventions.

In the 2 studies that reported accuracy based on deviations between the surgical plan and post-surgical result, all outcomes favoured the intervention. The clinical significance of these findings is uncertain. In a separate publication, no difference in quality of life was found between dental implant surgery planned using conventional methods compared to computer-aided planning (Sancho-Puchades et al. 2019).

**Table 11 Outcomes of RCTs that compared surgical planning using patient-specific surgical guides and/or biomodels versus conventional surgical planning**

| Study ID Surgery | Outcome | Intervention (mean) | Conventional planning (mean) | Summary | Statistical significance |
|---|---|---|---|---|---|
| | **Time** | | | | |
| **Omara (2021) Le Fort II osteotomy** | Operative time | 4.9 h (SD 0.62) | 7.13 h (SD 0.6) | - 2.23 h | p <0.001 |
| **Schneider (2019a) Le Fort I osteotomy** | Operative time | 162 min | 202 min | - 40 min[a] (CI 1.8–79.8) | p =0.041 |
| **Schneider (2019c) Dental restoration** | Operative time | 1: 51.2 min (IQR 32.5)<br>2: 54.0 min (IQR 32.1) | 44.9 min (IQR 41.8) | 1: 6.3 min<br>2: 9.1 min | NS |
| | Planning time | 1: 13 min (IQR 10.5)<br>2: 12.7 min (IQR 2.0) | 5.5 min (IQR 7.1) | 1: 7.5 min<br>2: 7.2 min | p <0.05 |
| | **Cost** | | | | |
| **Omara (2021) Le Fort II osteotomy** | Total | US$1,115 | US$790 | US$325 | NR |
| | Operative | US$440 | US$580 | US$-140 | NR |
| | Hardware | US$460 | US$6 | US$454 | NR |
| **Schneider (2019a) Le Fort I osteotomy** | Planning total | €884 | €481 | €403 | NR |
| | Planning without hardware | €479 | €481 | €-2 | NR |
| **Schneider (2019c) Dental restoration** | Total | 1: 2,268 CHF<br>2: 1,946 CHF | 1,567 CHF | 1: 701 CHF<br>2: 379 CHF | NR |
| | Hardware (surgical splint) | 1: 463 CHF<br>2: 409 CHF | 0 CHF | 1: 463 CHF<br>2: 409 CHF | NR |

| Study ID Surgery | Outcome | Intervention (mean) | Conventional planning (mean) | Summary | Statistical significance |
|---|---|---|---|---|---|
| | **Angular deviations/ Accuracy** | | | | |
| **Omara (2021) Le Fort II osteotomy** | Sn-orb. R | 0.19° (SD 0.03) | 1.08° (SD 0.45) | -0.89 | p <0.001 |
| | Sn-orb. L | 0.15° (SD 0.04) | 0.93° (SD 0.37) | -0.78 | p <0.001 |
| **Schneider (2019a) Le Fort I osteotomy** | SNA angle | 0.6° (SD 9) | 1.8° (SD 12) | -1.2° (CI 0.6, 1.8) | p <0.001 |
| | SNB angle | 0.7° (SD 9) | 1.9° (SD 12) | -1.2° (CI 0.5, 1.9) | p =0.002 |
| | ANB angle | 0.5° (SD 9) | 1.6° (SD 12) | -1.1° (CI 0.6, 1.7) | p <0.001 |

Source: Omara et al. (2021); Schneider et al. (2019a); Schneider et al. (2019c).
Abbreviations: ANB angle, A point to B Point Angle; CHF, Swiss francs; CI, confidence interval; h, hours; IQR, interquartile range; min, minutes; NR, not reported; NS, not statistically significant; SD, standard deviation; SNA angle, Sella-Nasion to A Point Angle; SNB angle, Sella-Nasion to B Point Angle; Sn-orb. R, right sella-nasion orbital angle; Sn-orb. L, left sella-nasion orbital angle.
**a** Reported as 40.8 in Figure 3 of Schneider et al. (2019a).

### 2.2.3 Non-randomised comparative evidence

The systematic review identified an additional 15 non-randomised comparative studies of patient-specific surgical guides and/or biomodels that reported cost as an outcome. All were level III-2 or III-3 based on the NHMRC levels of evidence6 and therefore at high risk of bias, particularly where no adjustments were made for baseline confounding (selection bias). Given the large volume of low-level evidence, only those studies that met the following criteria (relating to study size and relevance) are discussed further in the current report:

- more than 10 patients per arm
- commercially supplied patient-specific surgical guides and/or biomodels (i.e. not 3-dimensional [3D] printed in-house)
- compared surgery using patient-specific surgical guides and/or biomodels against usual care (surgery without VSP).

Six studies met these criteria (Mazzola et al. 2020; Lignon et al. 2021; Speed et al. 2024; Ravida et al. 2018; Rodríguez-Arias et al. 2022; Bolzoni et al. 2020); study findings are summarised in Table 12. All 6 studies were retrospective; baseline differences between patients selected for VSP compared to usual care were apparent and acknowledged by the study authors. In 5 studies, patients were undergoing mandibular reconstruction; the population in Ravida et al. (2018) was edentulous patients. All are considered complex procedures. Three studies used Johnson & Johnson's ProPlan/Trumatch software (Bolzoni et al. 2020; Mazzola et al, 2020; Rodrigues-Arias et al. 2022) and one used Stryker's VPS system (Speed et al. 2024). The remaining studies did not use PL-listed systems or devices.

One study was conducted in Australia (Mazzola et al. 2020) and this was also the only study to include an analysis of a matched cohort. Patients in this subset analysis (16 in each group) were matched according to

[6] Level III-2: a comparative study with concurrent controls (non-randomised experimental trial; cohort study; case-control study; interrupted time series with a control group). Level III-3: a comparative study without concurrent controls (historical control study; two or more single arm studies; interrupted time series without a parallel control group).

treating institution, site (mandible or maxilla), ablative procedure description, bone flap used (including scapula flaps), indication, complexity score and age within 5 years. The authors noted that the most complex cases (mainly secondary reconstructions where VSP is most strongly indicated) could not be matched and were therefore excluded.

The most frequently reported outcome across the 6 studies was operative time. This was statistically significantly lower, favouring VSP, in 4 of the 5 studies that reported this outcome. However, in the matched subset analysis reported by Mazzola et al. (2020), the difference in operative time was not statistically significant.

Pre-operative planning time was infrequently reported. No statistically significant differences in complications were reported.

Costs were reported variably; however, authors broadly considered that the higher costs for VSP were partially recouped due to shorter operative time.

**Table 12 Summary of outcomes and costs reported in non-randomised studies that compared commercial surgical planning with usual care (≥10 patients per arm)**

| Study ID<br>Country<br>Study type | Population | Intervention | VSP N | UC N | Planning time (days) | Operative time (min) | Ischemia time (min) | Length of stay (days) | Complications | Cost |
|---|---|---|---|---|---|---|---|---|---|---|
| **Mazzola (2020)**<br>**Australia**<br>**R, CC** | OFF mandible or maxilla reconstruction | C-VSP: BM, CG, CP | 29 | 99 | NR | **VSP: 507**<br>**UC: 562**<br>**p =0.042** | NR | **VSP: 10.0**<br>**UC: 13.0**<br>**p =0.009** | p =NS | VSP: $34,939 AUD<br>UC: $34,653 AUD<br>p =0.94 |
| **Matched subset** | OFF mandible or maxilla reconstruction | C-VSP: BM, CG, CP | 16 | 16 | NR | VSP: 498<br>UC: 518<br>p =0.27 | NR | VSP: 10.5<br>UC: 11.0<br>p =0.84 | VSP: 0<br>UC: 2<br>p =NR | VSP: $35,505 AUD<br>UC: $32,392 AUD<br>p =0.61 |
| **Lignon (2021)**<br>**France**<br>**MC, R, CC** | FFF mandibular reconstruction | C-VSP: BM, CG | 89 | 211 | VSP: 21<br>(range 7-321)<br>UC: NA | VSP: 545<br>UC: 540<br>p =0.28 | **VSP: 78**<br>**UC: 67.5**<br>**p =0.0015** | | p =NS | VSP: median €2,000<br>(range 600 – 3,800)[a]<br>UC: €400 – 1,000[a] |
| **Speed (2024)**<br>**USA**<br>**R, CC** | FFF mandibular reconstruction | C-VSP: BM, CG, CP | 44 | 52 | | **VSP: 417**<br>**UC: 474**<br>**p =0.011** | VSP: 110<br>UC: 121<br>p =0.93 | VSP: 5.64<br>UC: 6.81<br>p =0.24 | VSP: 5<br>UC: 14<br>p =0.065 | VSP $9,457 more |
| **Ravida (2018)**<br>**USA**<br>**R, CC** | Implant-retained fixed hybrid prostheses in edentulous patients | C-VSP: BM, CG | 26 | 19 | NR | NR | NR | NR | Early<br>VSP: 6<br>UC: 5<br>p =0.80<br>Late[b]<br>VSP: 18<br>UC: 13<br>p =0.95 | NS overall<br>VSP cost $659 more initially |
| **Rodríguez-Arias (2022)**<br>**Spain**<br>**R, CC** | FFF mandibular reconstruction | C-VSP: BM, CG, CP | 18 | 19 | **VSP: 34.6[c]**<br>**UC: 22.5[c]**<br>**p =0.039** | **VSP: 521**<br>**UC: 623**<br>**p =0.018** | NR | VSP: 21.8<br>UC: 24.3<br>p =0.06 | VSP: 10<br>UC: 7<br>p =NS | Equivalent |
| **Bolzoni (2020)**<br>**Italy**<br>**R, CC** | FFF mandibular reconstruction (benign only) | C-VSP: BM, CG | 15 | 10 | | VSP: 510<br>UC: 558<br>p=0.1 | NR | **VSP: 12.3**<br>**UC: 16.6**<br>**p=0.008** | NR | VSP: €22502.7 ± 2035.6<br>UC: €22482.8 ± 2120.3<br>p=0.98 |

Abbreviations: BM, biomodel; CC, comparative cohort; CG, cutting guide; CP, custom (patient-specific) plate; C-VSP, commercial virtual surgical planning; FFF, fibular free flap; MC, multicentre; NA, not applicable; NR, not reported; NS, not statistically significant; OFF, osseous free flap, R, retrospective; UC, usual care; VSP, virtual surgical planning.
**Bold** indicates statistical significance.
**a** Includes the cost of hardware.
**b** Implant failure rates did not differ per patient (VSP: 5 patients [19.2%], UC: 4 patients [21.1%], p=0.88); however, they did differ per implant (VSP: 5 implants [3.3%], UC: 22 implants [19.8%% survival], p<0.001).
**c** Refers to days to surgery.

### 2.2.4 Unpublished or ongoing clinical trials

The search of clinical trial registries did not identify any active or completed studies of relevance to the Stage 2 PLR with comparative cost or cost-effectiveness as specified outcome measures.

Two active studies were identified with outcome measures that could potentially be used in an economic analysis. The first is a multicentre, open label RCT conducted in France (CURVE; NCT04725396) that aims to compare fibula free-flap mandibular reconstruction with or without VSP in patients with oral or oropharyngeal cancer indicated for segmental mandibulectomy. In this trial, VSP includes the production of surgical cutting guides required for mandibular resection and fibula free-flap conformation, and the production of preformed plates for flap osteosynthesis. Duration of operation, quality of life and functional outcomes are prespecified outcome measures. Target enrolment is 132 patients and estimated study completion is September 2025.

The second is an RCT from Egypt that enrolled 28 patients and is no longer recruiting (NCT06588075). The aim of the study was to compare zygomaticomaxillary complex fracture reduction and fixation using either a full digital workflow with customised patient-specific implants and surgical guides versus a conventional freehand protocol. Duration of operation was a prespecified outcome measure; other specified outcome measures were accuracy, paresthesia and patient aesthetic satisfaction. The estimated study completion is April 2026.

### 2.2.5 Health technology assessments

The Malaysian Ministry of Health reviewed digital assisted oral and CMF surgery in 2021 (Ros Aziah et al.) and the Belgian Health Care Knowledge Centre (KCE) reviewed 3D printed medical devices in 2018 (Vinck et al.). Both reports included a research question on the cost-effectiveness of these technologies.

In addition to a review of the literature, the Malaysian HTA (Ros Aziah et al. 2021) undertook a cost comparison of digital-assisted compared to conventional oral maxillofacial surgery. Input values in the analysis were not reported but were provided by an oral and maxillofacial surgeon and were compared with values from Xia et al. (2006) and Resnick et al. (2019). The analysis included costs for human resources (surgeon, medical officer, nurses, laboratory assistant), capital equipment and training. Digital-assisted surgery was found to have lower costs compared to conventional surgery (RM 6,420 compared to RM 8,052 respectively) due to reduced surgical time and reduced material requirements to undertake the surgery. The analysis was for the development of in-house digital capacity and has low applicability to the current PLR.

Overall, the Malaysian HTA considered digital CMF surgery to have sufficient evidence supporting its use and to be cost saving when at least 15 surgeries are conducted per month.

The KCE HTA (Vinck et al. 2018) reached different conclusions, stating that evidence was insufficient at the time to support the claims that 3D printed medical devices reduced surgical time and costs. However, the KCE HTA did note that 3D printed medical device costs will decrease over time and that the technology might become increasingly affordable and available. Data from the 2 HTA reports are summarised in Table App. C.9.

### 2.2.6 Clinical practice guidelines

No clinical practice guidelines referring to the cost or cost-effectiveness of surgical guides and biomodels in CMF surgery were identified.

One clinical practice guideline from the Radiological Society of North America considered the appropriateness of anatomical models in a range of clinical scenarios (Chepelev et al. 2018). The guideline was consistent with the Stage 1 PLR findings that anatomical models are appropriate in complex but not simple CMF surgeries.

## 2.3 Outcomes to assess the cost and value of surgical guides and biomodels

The Stage 1 PLR listed the advantages of surgical guides and biomodels as described by stakeholders:

- more efficient and effective surgical procedures:
    - avoid disturbing anatomic structures
    - guide the placement and angles of implants in difficult-to-reach places
    - minimise tissue manipulation or opening flaps (in most procedures)
    - facilitate faster surgery
    - reduce the overall number of surgeries (because of the ability to combine complex surgeries within the one procedure without the need for multiple admissions)
- improved clinical outcomes:
    - reduce incidence of revision surgery
    - optimise aesthetics and functional outcomes (such as chewing)
    - reduce complication rates
- reduced burden on hospitals and the health system:
    - achieve cost savings due to reduced theatre time and bed days saved
    - reduce the time needed for surgeons to develop the required skills and knowledge to perform implant surgeries.

These purported benefits broadly align with the outcomes used in studies assessing the cost-effectiveness of surgical guides and biomodels; however, the clinical outcomes were less commonly used than those related to efficiency.

The comparative cost-effectiveness evidence predominately considered operative time as the main clinical outcome to demonstrate the value of surgical guides and biomodels, with reduced operative time and associated savings offsetting the higher initial cost. However, operative time is not a patient-relevant outcome, and the savings estimated in the analyses may not be realised if that saving does not translate to higher theatre throughput. Furthermore, there was limited consideration given to the pre-operative planning time and whether this off-set the operative time savings.

All 3 modelled economic analyses included reduced operative and/or ischemia time as inputs, but they also included outcomes related to post-procedure complications. These are patient-relevant, and their

treatment is likely to incur a cost to the health system and a reduction in health-related quality of life (HRQoL) to the patient. However, the limited clinical evidence for these outcomes is apparent, given the direction of effect varied across the 3 studies.

In considering the appropriateness of outcomes for assessing the cost-effectiveness and value of surgical guides and biomodels, the clinical heterogeneity of the populations being considered means that different outcomes may be appropriate for different patient populations and surgeries. For example, for patients with malignant pathologies, the most patient-relevant outcome is likely to be survival, but this might not be appropriate in other situations. Similarly, operative time might be more important in longer operations but of limited relevance for short procedures.

Consideration of outcomes specific to the value of surgical guides and biomodels should also be in the context of broader international work to develop core outcome sets to harmonise the conduct and reporting of clinical trials[7] and should use validated measures[8]. In the field of oral and maxillofacial (OMF) surgery, the British Association of Oral and Maxillofacial Surgeons (BAOMS) has a programme called the Quality and Outcomes in Oral and Maxillofacial Surgery (QOMS) that lists outcomes, by condition and procedure, that are being collected in registry data (Ho et al. 2021).

Based on the modelled economic analyses described in Section 2.2.1, the proposed advantages of surgical guides and biomodels described in Stage 1, and the sources noted above, suitable outcomes to assess the cost and value of surgical guides and biomodels are listed in Table 13. Alongside these proposed outcomes, the table indicates which were used in the modelled economic analyses and provides an indication of the available evidence for each outcome.

**Table 13 Suitable outcomes to assess the cost and value of surgical guides and biomodels**

| Outcome | Clinical indications | Used in identified economic analyses | Evidence level availablea |
|---|---|---|---|
| Patient-reported outcome measures (PROMs) | | | |
| **Generic PROMs (e.g EQ-5D)** | All | × | None |
| **Condition specific PROMs (e.g. speech, swallowing, functional, aesthetic etc.)** | All – depending on the specific PROM | Gardiner (2024) – utility values for adjuvant chemotherapy and hardware failure | None |
| Clinical outcomes | | | |
| **Overall survival**<br>**Disease free survival**<br>**Regional or distant recurrence**<br>**Resection margins** | Oral and head and neck cancers | Gardiner (2024) – assumed no difference between arms | None |
| **Visual problems** | Orbital fractures | NA | None |
| Complications | | | |
| **Flap survival**<br>**Donor site complications** | Flap reconstruction | Gardiner (2024), Kurlander (2023), Fatima (2019) | III-2 |

[7] For example, the COMET Initiative.
[8] List of validated Patient-Reported Outcome Measures (PROMs).

| Outcome | Clinical indications | Used in identified economic analyses | Evidence level availablea |
|---|---|---|---|
| **30-day complication rate**<br>**Reoperation**<br>**Readmission**<br>**SSO/infection** | All | Kurlander (2023) | III-2 |
| **Hardware failure** | All | Gardiner (2024) | III-3 (unpublished) |
| Cost related outcomes | | | |
| **Length of operation/ ischemia/ hospital stay** | All | Gardiner (2024), Kurlander (2023), Fatima (2019) | II (Le Fort osteotomy, dental implants)<br>III-2 (FFF) |
| **Length of planning** | All | × | III-2 |
| **Hardware (number/type of guides and biomodels)** | All | × | None |

Abbreviations: EQ-5D, 5-dimension EuroQol Health Survey; FFF, fibular free flap; NA, not applicable; PROM, patient-reported outcome measure; SSO, surgical site occurrence.
**a** National Health and Medical Research Council (NHMRC) level II: a randomised controlled trial; level III-2: a comparative study with concurrent controls; level III-3: a comparative study without concurrent controls.

## 2.4 Pricing in other jurisdictions

Information on public pricing in Australia and international pricing was collated from the systematic review, stakeholder submissions and web searches. This information is often not publicly available and therefore this aspect of the Stage 2 PLR reflects the information that was available rather than a comprehensive analysis.

### 2.4.1 Australia

#### Public prices informed through PL benefit reductions

Benefits for devices listed on the PL are subject to benchmarking against prices paid within the public hospital system. The public benchmark price for each PL price group has been determined through a process of mapping the prices paid in public hospitals (informed by state or territory government agencies or hospital groups and device suppliers) to PL data (IHPA, 2022). Benefit reductions are calculated on the basis of a Weighted Average Price (WAP), which is the average public price for all devices within a Benefit Group weighted by utilisation in the private sector.

As outlined in the Memorandum of Understanding (MOU) between the Minister for Health and Aged Care and the Medical Technology Association of Australia (MTAA),[9] the PL benefits for devices with a benefit level of more than 7 percent above the WAP were to be reduced by:

(a) 40 percent of the difference between the PL benefit and the WAP on 1 July 2022

(b) 20 percent of the difference between the PL benefit and the WAP on 1 July 2023

(c) 20 percent of the difference between the PL benefit and the WAP on 1 July 2024, taking account of the 7 percent 'floor' for all products.

[9] Memorandum of Understanding for the policy parameters of the Prostheses List reforms, published 18 March 2022, updated 27 September 2023.

The MOU effectively provides for the PL benefit to include a 7-20% private adjustment above the public price.

The reductions in PL benefits for surgical guides and biomodels – as a consequence of the MOU and benchmarking – are shown in Table 14, which includes an estimate of the weighted average public price. While biomodels (group 07.02.09) underwent a modest benefit reduction (6.2%), the data reveal a large (>20%) reduction in the benefits for surgical guides in two groups (Cranium and TMJ) and no reduction in a third (Orbit). The PL benefits for surgical guides were initially the same regardless of their anatomical location of use; following the reductions, surgical guides used in the cranium receive a much lower benefit than those for the orbit – a difference of $1,269. This is despite the surgical guides listed in the orbit subgroup also being listed in other anatomical groups.

It is possible that the differential benefit reductions across surgical guide subgroups may reflect a weakness in the benchmarking methodology due to the discontinuous grouping of surgical guides rather than underlying differences in their public prices. For PL groups where public price data were not available (mostly those with no or very low utilisation), benefit reductions were calculated by determining a 'price relativity' based on adjacent price groups. As surgical guide subgroups are not adjacent to each other on the PL, price relativity would be calculated relative to implants at the respective anatomical location. There was no reduction in benefits in the orbit product group, with the exception of the 'wedge for orbit' subgroup where a modest 14% benefit reduction occurred in July 2022 from $448 to $385.

**Table 14 Benefits reductions for surgical guides and biomodels and the inferred public price based on these**

| PL Product Group | Product Sub Group | Suffix | Benefit March 2022 | Adjusted Benefit July 2022 | Difference | Change (%) | Assumed public price 2021 | Current Benefit Nov 2024 |
|---|---|---|---|---|---|---|---|---|
| **07.02.02 - Cranium** | 07.02.02.04 - Surgical Guide | Biomodelled | $2,584 | $1,950 | -$634 | -24.5% | $999 | $1,315 |
| **07.02.05 - Mandible, Maxilla and Temporomandibular Joint (TMJ)** | 07.02.05.07 - Surgical Guide | Biomodelled | $2,584 | $2,011 | -$573 | -22.2% | $1,151 | $1,450 |
| **07.02.07 - Orbit** | 07.02.07.05 - Surgical Guide | Biomodelled | $2,584 | $2,584 | $0 | 0% | $2,584 (or not available) | $2,584 |
| **07.02.09 - Anatomical Biomodel** | - | - | $1,950 | $1,829 | -$121 | -6.2% | $1,647 | $1,762 |

Abbreviations: PL, Prescribed List.

Under the proposed regrouping of the PL as part of PL reform activities, all patient-matched implants were placed within a single group ('Patient Matched Implants') within which a subgroup for surgical guides and another for anatomical biomodels was created.[10] Although some anatomical distinctions were retained for patient-matched implants, it is not clear that such distinctions are required for surgical guides.

[10] Prostheses List Reform overview of restructure of PL, accessed 2 January 2025.

Furthermore, it is not clear whether the differences in benefits as a result of benchmarking to public prices reflects value-based pricing or an anomaly of the methodology used to conduct the benchmarking, given these are infrequently used devices relative to others on the PL.

## Public prices in published studies

One Australian study identified in the literature review (Mazzola et al. 2020) included a cost analysis comparing patients undergoing mandible or maxillary reconstruction with and without VSP technology. The study was conducted at 2 sites in Sydney that treat public and private patients: Royal Prince Alfred Hospital and Chris O'Brien Lifehouse. The publication reported that hardware cost data for the analysis were provided by DePuy Synthes but does not clarify whether each cost is for one or multiple devices; for example, it is not clear whether the cost for modelling and VSP material includes one or multiple surgical guides and/or biomodels. Surgeon time for pre-operative digital planning (approximately 60 minutes) was not included in the analysis as surgeons are not reimbursed for this time.

**Table 15 Prices for medical devices cited in Australian cost analysis (Mazzola 2020)**

| Material | Device costs cited in study |
|---|---|
| **Screw (locking)** | $180 |
| **Screw (non-locking)** | $67 |
| **Pre-formed plate** | $1,600 |
| **Modelling and VSP material[a]** | $3,800 |
| **3D custom made plate** | $2,000 |

Source: Mazzola et al. (2020)
Abbreviations: 3D, 3-dimensional; PL, Prescribed List; VSP, virtual surgical planning.
**a** Includes online planning, virtual design and modelling, and materials for cutting guides. Excludes preoperative imaging and surgeon time for pre-operative digital planning.

The literature search identified 5 additional studies by Australian authors (Ansari et al. 2019; Delpachitra and Bordbar, 2023; D'Urso et al. 1998; Kovacs and Kaing, 2022; Thayaparan et al. 2021). None of these studies included information on pricing in Australia.

Both Mazzola et al. (2020) and Kovacs and Kaing (2022) reported that they use in-house VSP to produce anatomical models and surgical cutting guides.[11] Therefore, such services are available in at least 2 major public hospitals: Royal Prince Alfred in Sydney and Royal Perth Hospital. The cost of in-house planning and printing was not the focus of the literature review; however, there is a consensus across the literature that costs are lower than commercial production (for example Ballard et al. 2020; Smithers et al. 2018). Therefore, costs in public hospitals with in-house facilities are expected to be lower than costs reported for commercial VSP in Mazzola et al. (2020) and costs used for benchmarking by IHPA (now IHACPA).

Three of the Australian studies relate to the Anatomics system (Ansari et al. 2019; Thayaparan et al. 2021; D'Urso et al. 1998).

[11] Mazzola et al. (2020) reported the results from proprietary VSP (provided by DePuy Synthes, Germany) but the authors mentioned 'institutional VSP' developed at Royal Prince Alfred Hospital and consisting of 3D models and cutting guides processed and printed according to a locally developed process.

## 2.4.2 International pricing and reimbursement

### United Kingdom

The UK National Health Service (NHS) Specialised Services Devices Programme (SSDP) is a list of devices that are paid for separately to the procedure in which they are used (i.e. they are excluded from the National Tariff Payment System). The SSDP aims to reduce pricing variation and increase transparency by using centralised purchasing and supply. The 2024-25 NHS payment scheme lists 'Bespoke maxillofacial prostheses' and 'Bespoke orthopaedic prostheses' noting that they are under consideration for inclusion in central procurement for 2025/2612. No details of costs were identified.

The HTA search identified only 2 relevant assessments of customised devices for orofacial reconstruction by the National Institute for Health and Care Excellence (NICE) (IPG449; IPG457). The assessments were published in 2013 and therefore not considered informative.

Two publications reported results of a survey of OMF surgeons in the UK (Goodson et al. 2021a; Goodson et al. 2021b). The rate of utilisation of surgical guides and biomodels was high (88% of respondents); however, costs were considered the greatest barrier to use. The authors noted that funding for patient-specific titanium implants depends on local health authorities and their interpretations of whether the implants are considered standard of care or require individual funding requests (Goodson et al. 2021a).

### Belgium

The HTA search identified a 2018 report from the Belgium KCE (Vinck et al. 2018). In addition to clinical and economic evidence, the HTA considered legal, regulatory, ethical and reimbursement issues. The report noted that custom-made medical devices do not have a CE mark but they can still be reimbursed under the Belgium health insurance system. Custom-made devices reimbursed within this system, and a summary of the conditions of reimbursement are presented in Table 16. Note that dental implants do not fall under this system.

According to the report, there is no separate reimbursement of the pre-operative planning phase, although it is possible to include those costs in the price of the implant as the cost structure is not transparent. However, there is a specific reimbursement code for pre-operative planning in OMF surgery (Nomenclature codes 258790 [ambulant] and 258801 [hospitalised]; Vinck et al. 2018).

**Table 16 Reimbursement of custom-made medical devices under Belgium health insurance**

| Category | Code | Description | Reimbursement | Conditions | Suppliers |
|---|---|---|---|---|---|
| **B.6. Cranioplasty** | 152751-15276 | Custom-made skull bone prosthesis for the replacement of a cranial flap following an accident, tumor, infection, or any other cause responsible for a lack bone, or for the reconstruction of the skull in the context of congenital diseases leading to deformities or cranio-synostoses | €5,943.00 | The service covers the entire implant manufacturing process (scan, etc.) as well as all accessories included.<br>Including fixing accessories (plates, screws, cement, glue, etc.). | JnJ, Rembrandt Medical, Sophysa |

[12] 2023-25 NHS Payment Scheme documentation, accessed January 2025.

| Category | Code | Description | Reimbursement | Conditions | Suppliers |
|---|---|---|---|---|---|
| **L.2.4. Custom-made joint prosthesis** | 167716-167720 | Custom-made prosthesis with the exception of reconstruction cups and temporary prostheses mandibular (individually made according to different dimensions) | - | The service 167716-167720 can be covered by compulsory insurance only after the approval of the College of Medical Directors, which sets the amount of the coverage on the basis of a reasoned request | - |
| **L.2.4. Custom-made joint prosthesis** | 170796-170800 | External part of a custom-made modular reconstruction cup with 3 support points (triflanged), without porous part for filling bone defects | €4,952.50 | The services cover the entire implant manufacturing process (3D model), including all the accessories.<br>Must also meet specific clinical criteria. | ZimmerBiomed |
| **L.2.4. Custom-made joint prosthesis** | 172535-172546 | External part of a custom-made modular reconstruction cup with 3 support points (triflanged), and with one or more fixed parts made of porous metal for filling the bone defects | €8,419.25 | The services cover the entire implant manufacturing process (3D model), including all the accessories.<br>Must also meet specific clinical criteria. | Mobelife (aMace® - custom-made implant + scaffold) |
| **L.10. Guide for osteotomy** | 171172-171183 | Single-use customised instrument for osteotomy during tumour resection | €792.40 | The beneficiary has a primary malignant bone tumour | CenTIS – distributed by other firms , Materialise |
| **L.10. Guide for osteotomy** | 171194-171205 | Single-use customised instrument for cutting massive allografts corresponding to tumour resection | €792.40 | The beneficiary has a primary malignant bone tumour | CenTIS – distributed by other firms , Materialise |

Source: Vinck et al. (2018) and updated from the list of services and nominal lists of individual devices for implants and invasive medical devices, available from the National Institute for Health and Disability Insurance (INAMI), Belgium, accessed 2 January 2025 and translated using Google translate.

The HTA made the following recommendations regarding device reimbursement:

- If an alternative exists, this should be used to establish the price and as a comparator for demonstrating the added value. If the patient's safety is adequately guaranteed, we recommend reimbursing the (3D-printed) medical device at the level of the alternative. In this way the producer is given an incentive to submit a reimbursement file and make evaluation possible if it wishes to receive a surcharge.
- We recommend reimbursing a higher price for a (3D-printed) medical device only if the added value with regard to existing alternatives has, insofar as possible, been demonstrated.
- If no (suitable) alternative exists, a unique solution for the patient is involved and reimbursement should be assessed case by case (individually or by indication).
- For the preoperative phase too, we recommend that reimbursement only be considered if sufficient added value can be demonstrated.

## USA

In July 2019 the American Medical Association (AMA) defined 4 new Current Procedural Terminology (CPT) codes relating to 3D printed anatomical models and surgical tools.

- 0559T Anatomic model 3D-printed from image data set(s); first individually prepared and processed component of an anatomic structure
- 0560T Anatomic model 3D-printed from image data set(s); each additional individually prepared and processed component of an anatomic structure (List separately in addition to code for primary procedure)
- 0561T Anatomic guide 3D-printed and designed from image data set(s); first anatomic guide
- 0562T Anatomic guide 3D-printed and designed from image data set(s); each additional anatomic guide (List separately in addition to code for primary procedure)

CPT codes are unform coding for medical services and procedures and are used for claims processing. The codes for 3D printed models and guides are category III temporary codes that allow data collection for emerging technologies; health insurers are not obliged to reimburse them.

A recent review on regulation and reimbursement of personalised anatomical models (Paxton, 2023) reported that:

- a survey of over 300 health insurers' reimbursement schedules in the USA suggests that only 15 health insurers currently choose to reimburse for these specific CPT codes, to an average value of US$91.78 per model (n = 15)
- the Veterans Health Administration reimburses the highest amount of the surveyed insurers, to a maximum of US$372.78.

# 3 Findings from the review of evidence

## 3.1 Summary of the evidence

Summarise the knowledge/evidence to address the following questions:

- Are surgical guides and biomodels cost-effective compared to standard care or other therapeutic approaches when used to implant a device in CMF procedures?
- Is the current PL benefit for surgical guides and/or biomodels relative to the clinical effectiveness?

Can any conclusions/recommendations be made from the evidence?

### 3.1.1 Methodological considerations

Consistent with the findings of Stage 1, the clinical evidence base was limited by a lack of randomised or appropriately adjusted studies, small sample sizes, retrospective designs and the presence of confounding factors.

With respect to confounding, in the non-randomised studies patients selected for VSP had different characteristics compared to those selected for conventional surgery, tending to be more complex and/or less urgent. For example:

- >5 fibular segments in 6 patients (40%) selected for VSP and none undergoing conventional surgery in Bolzoni et al. (2020)
- malignant pathology in 19 patients (43%) selected for VSP and 40 (77%) undergoing conventional surgery (p=0.001) in Speed et al. (2024).

Without statistical adjustment, these baseline differences between study groups introduce clear selection bias and reduced confidence in the study findings. The potential for selection bias is minimised in randomised trials and can also be minimised in observational studies by accounting for potential confounding variables through statistical methods (such as regression analysis) or the use of propensity score matching to create comparable groups.

Although RCTs are the highest level of evidence, the RCTs that were identified in the literature searches were small and poorly reported. They had limited statistical power, and their risk of bias was difficult to assess because key aspects of the trials were not available in the publications. Likewise, the one relevant matched cohort study that was identified in the search was also small and the matching process excluded the most complex cases and did not account for all potential confounding variables.

Operative time was the most consistently reported outcome of potential use for the purposes of comparative costing. Although reduced anaesthesia time might be beneficial for patients and could have flow on effects in reducing costs due to higher surgical throughput and lower staff costs, whether these efficiencies translate in real-world settings is uncertain.

The ability to make definitive conclusions from the evidence for surgical guides and biomodels is complicated by the complexity of the intervention (which often included any/all of VSP, use of 3D printed surgical guides and/or biomodels, other 3D printed tools and patient-specific implants) and the interaction of the physical guides and models with the VSP procedure itself and changes that may entail to the surgical procedure. The aspect of the intervention leading to a clinical effect is difficult to disentangle and as such, outcomes cannot be solely attributed to the physical surgical guides and biomodels. Furthermore, most studies did not clearly specify which surgical guides and biomodels were used or how many, therefore linking the evidence directly to PL listed devices is challenging.

A further methodological difficulty is the range of indications within CMF surgery for surgical guides and biomodels. The evidence was predominately for orthognathic (jaw) osteotomies and maxilla and mandibular reconstructions, for both benign and malignant pathologies. These are likely to be considered complex CMF procedures and therefore within scope, although the Stage 1 PLR noted that simple single jaw surgery is not considered complex. The next most common indication in the literature was dental implants, which are generally considered simple procedures and would therefore not be within scope. However, the included studies tended to be of more complex implant surgery; for example, Ravida et al. (2018) included edentulous patients.

For the remaining indications listed in the Stage 1 PLR as appropriate surgeries for the use of surgical guides,[13] there was a lack of evidence on cost-effectiveness. This is not unexpected given many of these indications are uncommon or rare and therefore present greater challenges for undertaking clinical research, particularly prospective comparative studies. However, these indications are likely to be the more complex and individualised surgeries where the use of surgical guides and biomodels is of greatest value, but evidence from RCTs is unlikely to ever be available.

> "The heterogeneous nature of patient-matched medical devices and the wide range of indications within complex CMF procedures, makes this type of review difficult and prone to oversimplification and inaccuracy. The [Stage 1 PLR] report lists 7 'typical' CMF procedures where surgical guides and biomodels are used, however these can be divided much further. For example, orthognathic surgery is further classified as Le Fort I osteotomy, bilateral sagittal split osteotomy, genioplasty, bimaxillary osteotomy, segmental osteotomy, and these procedures, or combination of procedures, have unique requirements and cost inputs in terms of planning, material selection, size and design complexity." (Sponsor)

### 3.1.2 Comparative cost-effectiveness

The findings from the targeted systematic review relating to the comparative cost-effectiveness of surgical guides and biomodels are based on 3 modelled economic evaluations, 3 RCTs reporting cost outcomes, and 6 non-randomised comparative studies reporting cost outcomes.

[13] The Stage 1 report lists the following as complex CMF procedures that would necessitate use of surgical guides: orthognathic surgery (double jaw and complex single jaw, e.g. with segmentation); facial trauma surgery; temporomandibular joint (TMJ) disorder surgery; cancer resection and reconstruction; correction of cleft and craniofacial deformities (e.g. craniosynostosis conditions);cranial vault reconstruction and cranioplasties; surgery for rare conditions (e.g. fibrous dysplasia, anodontia); dental surgery where it is part of a CMF procedure (for example, where multiple teeth are replaced as a result of trauma, cancer resection, cleft and palate procedures).

The clinical inputs to the 3 modelled economic analyses were derived from small, non-randomised and largely retrospective studies that – similar to the comparative observational studies identified – were at risk of selection bias. The economic analyses are summarised in Table 9. Overall, although 2 analyses concluded that VSP was cost-effective,[14] the findings should be interpreted in the context of the uncertain clinical impact of VSP due to the low-level evidence from which the model inputs were derived.

Given that the non-randomised comparative studies have demonstrable selection bias, the clinical evidence reporting cost outcomes are summarised in Table 17, based solely on the 3 RCTs and one matched observational study. Two RCTs in patients undergoing Le Fort osteotomy demonstrated a statistically significant reduction in operative time, favouring the use of patient-specific surgical guides and biomodels. The third RCT was conducted in partially edentulous patients undergoing prosthetic restoration and found no statistically significant differences in operative time between groups. None of the RCTs used surgical guides or biomodels that are listed on the PL.

The observational study by Mazzola et al. (2020) found a statistically significant reduction in operative time and hospital length of stay for the unmatched cohort (N=138), favouring VSP, but no statistically significant differences in these outcomes in the matched subset (N=32). The most complex cases, who might be expected to benefit most from VSP, could not be matched.

In the 3 RCTs, the cost of surgery using surgical guides and biomodels was consistently higher than usual care, although statistical significance was not reported. In the Australian matched observational study (Mazzola et al. 2020), the total cost was not significantly different between groups.

**Table 17 Summary of findings from RCTs and matched observational study reporting cost outcomes**

| Study ID N | Indication | Quality of the evidence | Planning time | Operative time | Health outcomes | Cost |
|---|---|---|---|---|---|---|
| RCTs | | | | | | |
| **Omara (2021) N=20** | Orthognathic surgery – Le Fort II osteotomy | Low | NR | **Favours SG&BM 2.23 h less, p <0.001** | NR | Favours UC ≈A$530, statistical significance NR |
| **Schneider (2019a) N=21** | Orthognathic surgery – Le Fort I osteotomy & bilateral split osteotomy of the mandible | Low | NR | **Favours SG&BM 40 min less, p =0.041** | NR | Favours UC ≈A$670, statistical significance NR |
| **Schneider (2019c) N=73** | Dental – partially edentulous | Low | **Favours UC +7.2 mins, p <0.05** | No significant difference | No significant difference in QoL at 7 days | Favours UC ≈A$670, statistical significance NR |
| Matched observational cohort | | | | | | |
| **Mazzola (2020) N=32** | Reconstructive orthognathic – osseous free flap | Low | NR | No significant difference | No significant difference in surgical complications | No significant difference |

[14] Based on willingness-to-pay thresholds of US$100,000 (Gardiner et al. 2024) and US$50,000 (Kurlander et al. 2023).

Abbreviations: A$, Australian dollars; h, hours; min, minutes; NR, not reported; QoL, quality of life; SG&BM, surgical guides and biomodels; UC, usual care. **Bold** indicates statistical significance.

# 3.2 Conclusions based on the evidence

## 3.2.1 Are surgical guides and biomodels cost-effective compared to standard care or other therapeutic approaches when used to implant a device in CMF procedures?

The review of stakeholder submissions, the targeted systematic literature review and searches of HTA agencies and clinical trial registries identified very limited evidence to support the cost-effectiveness of patient-specific surgical guides and biomodels when used to implant devices in CMF procedures. The findings are consistent with Stage 1 where evidence limitations were noted. No additional pivotal clinical evidence was identified, and modelled cost-effectiveness analyses were limited by the inadequate evidence available on the comparative clinical effectiveness of surgical guides and biomodels.

The heterogeneity of surgical guides and biomodels, and the wide range of clinical applications within CMF surgery, further complicate the ability to make conclusions based on the evidence.

Overall, the use of surgical guides and biomodels in CMF surgery tended to cost more than usual care; however, the actual costs were poorly reported, and the costs of the devices were infrequently separated from that of the virtual planning system. The applicability of cost studies from other jurisdictions is usually low, and this is particularly the case for the studies identified, given the limited details provided in the study publications. The exception is the observational study by Mazzola et al. (2020), which was conducted in an Australian setting.

In the matched analysis, Mazzola et al. (2020) found surgery using surgical guides and biomodels for osseous free flap mandibular reconstruction to be $3,113 more expensive than usual care, though this difference was not statistically significant. The material costs for surgical guides and biomodels was $8,123.50 compared to $3,648.50 for usual care ($p < 0.001$); however, shorter operative time and intensive care unit stay in the VSP group reduced the cost difference overall. The authors stated that although the median cost per case was higher, the overall cost for the 16 matched cases was $29,632 lower in the surgical guides and biomodels group. They further noted that the more complex cases could not be matched and this eliminated patients likely to benefit most from the intervention.

Planning time was infrequently considered, though expected to be higher for virtual planning. Mazzola et al. (2020) noted that surgeons in Australia are not reimbursed for digital planning time, therefore this aspect of the cost-effectiveness remains poorly explored. However, an MBS item was introduced in July 2023 for bony free flap reconstruction of the maxilla or mandible that specifies in the descriptor ‘including all necessary 3-dimensional planning’ (MBS item 45609). Therefore, for this surgery the MBS does appear to reimburse planning time within the surgical item. No other similar item descriptors were identified on the MBS.

### 3.2.2 Is the current PL benefit for surgical guides and/or biomodels relative to the clinical effectiveness?

There is insufficient clinical evidence to determine whether the current PL benefit for surgical guides and biomodels is relative to the clinical effectiveness.

No convincing data were identified to support that the use of patient-matched surgical guides and/or biomodels is more effective or safer than conventional procedures without the use of such devices. Although the identified cost-effectiveness studies included revision and complication rates in their analyses, the added value of surgical guides and biomodels for the patient in terms of decreased risk of complications or reoperation, or improvement in functional outcomes or quality of life, has not been demonstrated. The available RCTs were too small and too few to address all complex CMF procedures that could potentially benefit from the use of patient-relevant surgical guides and biomodels. Furthermore, the duration of patient follow up was often short (usually limited to the perioperative phase) and few relevant endpoints were measured. Therefore, based on the current evidence, the value of surgical guides and biomodels is limited to a potential reduction in operative time and associated cost-savings, particularly for complex CMF procedures.

Although accuracy is often reported as an outcome in studies of VSP and/or surgical guides and biomodels, the lack of uniformity in the measurement of accuracy makes it difficult to draw definitive conclusions. More importantly, there is no reliable evidence that improved accuracy from the use of surgical guides and biomodels translates to improved patient-relevant outcomes.

A multicentre, open label RCT with target enrolment of 132 patients with oral or oropharyngeal cancer undergoing fibula free-flap mandibular reconstruction is underway in France with completion estimated in September 2025 (CURVE; NCT04725396). This trial has the potential to provide more robust evidence than is currently available in relation to the comparative effectiveness (assessed using patient-relevant functional outcomes and quality of life at one year) and resource implications (operative time and postoperative surgical complication rate) of VSP versus conventional care. However, similar to other studies of VSP, the trial is not designed to assess the impacts of surgical guides and biomodels specifically, and the findings may not be generalisable across all CMF indications.

Notwithstanding the limitations in the clinical evidence for surgical guides and biomodels, a search was conducted to try to identify information on pricing in the Australian public health system and internationally. Prices paid for surgical guides and biomodels in the Australian public system were not readily available and had to be inferred. Benefits for some, but not all, surgical guides on the PL have undergone considerable reductions based on benchmarking to public prices, while anatomical biomodels have undergone more modest reductions. It is not clear whether the discrepant benefit reductions (for surgical guides compared with biomodels, and between surgical guides in different anatomical subgroups) reflect true differences in public prices or challenges in the benchmarking methodology and anomalies of the PL grouping.

In terms of international pricing, the only country where a reimbursed price was identified was Belgium where a surgical guide for osteotomy is reimbursed at €792.40 (≈A$1,313), specifically for primary malignant bone tumours. Patient-matched implants on the Belgium list of implants and invasive medical

devices included the 'entire implant manufacturing process (3D model), including all the accessories'. Reimbursement for anatomical models in the USA was reported to average US$91.78 (≈A$150). There is a broad consensus that in-house surgical planning is cheaper than commercial planning; however, not all in-house facilities can produce high quality patient-matched implants. In-house facilities are available in at least 2 major public hospitals in Australia.

### 3.2.3 Can any conclusions/recommendations be made from the evidence?

Consistent with comments in the Stage 1 PLR, this Stage 2 PLR – with a focus on cost-effectiveness – highlights the need for more and/or higher quality evidence for both the clinical effectiveness and relative costs of surgical guides and biomodels to inform PL benefits.

Although there is no convincing evidence that the use of surgical guides and biomodels is more effective or safer than conventional procedures without the use of such devices, RCTs have shown that surgical guides and biomodels provide added value in complex CMF surgeries by reducing operative time. Based on the available evidence, this does not appear to be the case for less complex procedures, such as dental implant surgery. This brings into question the value of surgical guides and biomodels for dental implants that are not part of a complex CMF procedure involving facial reconstruction or correction of significant jaw deformities.

# 4 Options to ensure benefits represent value for money on the PL

Present options, for the department to consider, to ensure the benefit for surgical guides and biomodels represents value for money on the PL when used to implant a device in CMF procedures.

A range of options are presented in Table 18 for consideration by the department. These options build on those presented in Stage 1 and are not mutually exclusive. The options are described in more detail in the following sections.

**Table 18 Overview of potential options to ensure benefits for surgical guides and biomodels represent value for money on the PL**

| | |
|---|---|
| | **Options for deriving appropriate benefits** |
| **A1** | Establish benefits relative to the clinical effectiveness of surgical guides and biomodels |
| **A2** | Align PL benefits for surgical guides and biomodels with the public sector or with internationally reimbursed prices |
| **A3** | Establish benefits that reflect the cost of production of surgical guides and biomodels |
| **A4** | Establish benefits for surgical guides and biomodels that are proportionate to other costs associated with the implantation procedure |
| | Conditions on benefits payable |
| **B1** | Retain conditions on the maximum number of surgical guides and biomodels that can be used per procedure |
| **B2** | Create a new condition allowing a single benefit for surgical guides or biomodels per procedure rather than per item |
| **B3** | Implement a stratified approach, where benefits payable for surgical guides and biomodels are reduced for each additional product used |
| **B4** | Implement a tiered approach, where benefits payable for surgical guides and biomodels are higher for more complex surgeries |
| **B5** | Create a condition that surgical guides or biomodels only attract a benefit when used without a patient-matched implant |

Abbreviations: PL, Prescribed List.

In describing the options, consideration is given to whether some are likely to present greater implementation challenges than others. For example, conditions that link PL benefits with MBS item numbers (option B4) or other costs (option A4) have few precedents and therefore might not be possible. There are risks of unintended consequences when changes are made; such risks are noted where they could reasonably be foreseen.

Further options for the department to consider are presented in Table 19. Some of these are included as a mechanism to facilitate the benefit setting options (C1-C3) and would have no impact on benefits in isolation. These options could be combined (i.e. C1, C2 and C3 all implemented) and could be implemented alongside any of the other options.

A second group (options D1-D3) considers the benefit for surgical guides and biomodels as a 'package' that includes patient-matched implants. Benefit setting therefore considers how the 'package' of devices is listed and reimbursed and takes into consideration the uncertainty of their clinical and cost effectiveness and the impact of this on their eligibility for PL listing.[15] It is acknowledged that this approach draws in devices that were out of scope of the PLR and that further stakeholder consultation would be necessary for their implementation. Option B5 also uses the 'package' of devices in setting a condition for benefits payable.

A final option, E3, is proposed based on the findings of both the Stage 1 and 2 PLR and could be considered a version of option A1; an approach to align benefits to clinical effectiveness.

**Table 19 Other options for the department to consider**

| | |
|---|---|
| | Changes to PL grouping structure to facilitate benefit setting |
| **C1** | Implement changes to surgical guides, biomodels and patient-matched implants as proposed under PL reform activity |
| **C2** | Group dental surgical guides and biomodels with dental implants |
| **C3** | Separate splint guides from cutting and drilling guides |
| | **Changes that affect the 'package' of benefits for VSP** |
| **D1** | Remove biomodels from the PL |
| **D2** | Remove surgical guides and biomodels from the PL |
| **D3** | Lower the benefit of patient-matched implants to be the same as standard implants |
| | **Changes to reduce use in 'simple' procedures** |
| **E3** | Remove surgical guides and biomodels for dental implant surgery from the PL |

Abbreviations: PL, Prescribed List.

### 4.1.1 Options for deriving appropriate benefits for surgical guides and biomodels on the PL

Options for deriving appropriate benefits for surgical guides and biomodels are presented in Table 20.

**Table 20 Summary of potential options for deriving appropriate benefits for surgical guides and biomodels on the PL**

| # | Option | Rationale |
|---|---|---|
| **A1** | Establish benefits relative to the clinical effectiveness of surgical guides and biomodels | PL listing criteria specify that 'the benefit amount for the medical device must be proportionate to the clinical effectiveness of the device'. This approach to benefit setting is hampered by the limited and confounded evidence base for surgical guides and biomodels. |
| **A2** | Align PL benefits for surgical guides and biomodels with the public sector or with internationally reimbursed prices | Although this option aligns with the benchmarking of all devices in Part A of the PL to public prices, it is unable to be implemented beyond the benefit reductions that have already occurred due to a lack of publicly available price data. |

[15] Criterion 5 for listing in Part A of the PL: The product has been compared to alternative products on the PL or alternative treatments and (i) assessed as being, at least, non-inferior in terms of clinical effectiveness; and (ii) the cost of the product is relative to its clinical effectiveness.

| # | Option | Rationale |
|---|---|---|
| **A3** | Establish benefits that reflect the cost of production of surgical guides and biomodels | The cost of materials and 3D printing of surgical guides and biomodels is modest relative to the PL benefits. Furthermore, these devices are made-to-order and have reduced costs in terms of inventory, warehousing and waste compared with off-the-shelf devices. A benefit that is established on the basis of published costs for in-house facilities – with an additional commercial profit margin – would be substantially lower than the current benefit. |
| **A4** | Establish benefits for surgical guides and biomodels that are proportionate to other costs associated with the implantation procedure | Deriving a benefit for surgical guides and biomodels that is proportional to the total episode benefit (either restricted to prostheses or including medical services) provides a transparent mechanism to set a benefit that reflects the added value attributable to the addition of surgical guides and biomodels to the overall procedure. Using mean values, taken from all episodes where surgical guides and biomodels were used, could be easily implemented but might not accurately reflect the heterogeneity of use. A more complex mechanism that allows for differences in benefits according to surgical complexity would be more difficult to implement. |

Abbreviations: 3-dimensional; CMF, craniomaxillofacial; PL, Prescribed List; VSP, virtual surgical planning.

## Option A1: Establish benefits relative to the clinical effectiveness of surgical guides and biomodels

PL listing criteria specify that 'the benefit amount for the medical device must be proportionate to the clinical effectiveness of the device.' The Stage 1 PLR reviewed the clinical evidence and concluded that the findings indicated improved or comparable outcomes for the use of surgical guides and biomodels but that there were limitations in the evidence. The review of the economic evidence in the Stage 2 PLR (the current report) similarly concluded that a lack of high-quality evidence hinders the ability to draw conclusions regarding the cost-effectiveness of surgical guides and biomodels.

Given the clinical conclusion that surgical guides and biomodels are comparable to usual care – with improved outcomes remaining uncertain – a PL benefit relative to clinical effectiveness might align with that for surgery without the use of surgical guides and biomodels. Given that surgical guides and biomodels are additional devices when compared to usual surgery, this is equivalent to them attracting no PL benefit (or options D1 and D2). In particular, the evidence relating to dental surgery did not demonstrate added value above usual care (option E1).

For more complex surgery, there was limited evidence demonstrating that the additional cost of surgical guides and biomodels could be recouped in reduced operative time and/or length of stay, including in an Australian setting (Mazzola et al. 2020). However, the evidence is low level, confounded with the use of patient-matched implants, and the cost inputs reported in clinical and economic studies are not able to be directly linked to the surgical guides and biomodel components. Establishing a PL benefit on the basis of this, and other identified studies, is not feasible and would need to also incorporate the added value associated with patient-matched implants.

One limited option for benefit setting relative to clinical effectiveness is to set a single benefit for surgical guides within the Plastics and Reconstructive category. Currently, surgical guides listed in the subgroup 07.02.07.05 attract a benefit $1,000 higher than those listed in 07.02.05.07 (Table 14). Those listed in the former are in the anatomical product group 'orbit' whereas the latter are in the group 'mandible, maxilla and temporomandibular joint.' This discrepancy arose following benchmarking to public prices (discussed in 'Public prices informed through PL benefit reductions'). No evidence specifically relating to the orbit was identified in the Stage 1 or Stage 2 literature reviews and therefore there is no basis for a higher benefit for surgical guides used at this location compared to other CMF locations. All identified evidence was in jaw or

dental procedures, therefore if benefits are relative to clinical effectiveness, then the PL benefits for surgical guides used in the cranial and orbital locations are difficult to justify and the department might consider aligning them with the group 'mandible, maxilla and temporomandibular joint' or to the lower benefit associated with the group 'cranium.'

## Option A2: Align PL benefits for surgical guides and biomodels with the public sector or with internationally reimbursed prices

As part of the cost-effectiveness evidence review in this Stage 2 PLR, public and international prices for surgical guides and biomodels were sought; however, few were identified. The benefits for surgical guides and biomodels currently on the PL have been reduced following benchmarking to public prices, so this option has been implemented to some extent. However, the PL benefits retain a premium above public prices of at least 7% and up to 20%. Different reductions were applied to surgical guides in different subgroups (Table 14) but it is unclear whether this is a reflection of their actual public sector price.

Therefore, due to the lack of publicly available information, this option is not feasible to implement beyond the reductions that have already occurred.

## Option A3: Establish benefits that reflect the cost of production of surgical guides and biomodels

The cost of production of surgical guides and biomodels was widely reported in studies of in-house 3D printing but is not reported for commercial production. However, consideration of the cost of production for in-house situations could provide guidance for setting an appropriate benefit.

The most applicable estimate identified is from a study reporting on the use of in-house maxillofacial reconstruction at RPA (Smithers et al. 2018). The study stated that the aim was 'to determine whether an 'in-house', institution-specific VSP process could be developed that would provide the additional advantages of VSP without the inflated costs.' They state that the costs were for materials only and were approximately A$200 whereas costs for commercial products would have been in excess of A$6,000. The cost only involved materials as the service had been set up at their institutions; however, estimated set up costs were:

- A$4,000 for the 3D printer
- A$60 per 0.5 kg for materials
- A$6,195 for software subscription (Autodesk 3ds Max) with other software open source.

The study did not consider staff costs, and off-the-shelf plates were used for the surgeries.

The costs are similar to those reported in 2 studies from the USA:

- Ballard et al. (2020) reported the cost of a simple surgical guide or model at US$119 and a complex surgical guide or model at US$320 including the costs of materials and allocation of time for segmenting and printing. Fixed costs were the software (US$20,000 per year) and salary (US$120,000 per year). The upfront cost of the printer was reported as US$12,000.
- Sinha et al. (2018) reported the cost of pre-operative planning with use of a 3D mandible model for mandibular fracture. The study reported the total cost of in-house printing of a mandible was approximately US$200, taking into consideration the cost of consultation (US$30), modelling using

open-source software (US$120), materials and 3D printing (less than US$20). They compared this to the commercial price of approximately US$2,200.

Although in-house printing of surgical guides and biomodels is significantly cheaper than commercial production, not all in-house facilities will have the capability to produce patient-matched implants as these require more advanced materials and higher-cost printers.

The costs reported are for plastic surgical guides. Titanium surgical guides have become available, particularly for orthognathic surgery, as they are thinner and therefore can make surgery less invasive (Gigliotti et al. 2020); however, they are also higher cost and cannot be printed in-house.

Establishing a benefit for surgical guides and biomodels based on reported production costs, with the addition of an appropriate commercial profit margin that recognises that these devices are made to order and that there are no excess freight costs or need for warehousing, is an option for benefit setting. Such an approach could be combined with option B2 – a condition allowing a single benefit per procedure rather than per device, given that the major cost is the planning time rather than the material costs for the physical guide or model (assuming plastic surgical guides are used).

This option may require establishing a different benefit for higher cost titanium surgical guides compared to plastic surgical guides; however, these distinctions are not currently explicit on the PL and would need to be established. Furthermore, the comparative clinical and cost-effectiveness of surgical guides made from different materials has not been reviewed and was rarely detailed in the included studies.

### Option A4: Establish benefits for surgical guides and biomodels that are proportionate to other costs associated with the implantation procedure

The Stage 1 PLR suggested that the department considers whether the benefits paid for surgical guides and biomodels are proportionate to other costs associated with implantation of prostheses. The advantage of this option is that it provides a transparent mechanism to set a benefit that reflects the added value estimated to be attributable to the addition of surgical guides and biomodels to the overall procedure. This option could be implemented in a complex or a simple manner.

To implement this option such that it is a dynamic proportion that reflects the complexity of each specific procedure presents several challenges. Firstly, it would likely require the implementation of a condition that specifies that only a single benefit per episode is payable for surgical guides and biomodels (option B2). Secondly, the heterogeneity in procedures and use of surgical guides and biomodels within those procedures means that currently the proportion of the total episode benefit (either restricted to prostheses or including medical services) that is attributable to surgical guides and biomodels is highly variable. This means that the appropriate proportion for the benefit might differ according to surgical complexity. Finally, this heterogeneity also means that the total episode cost and/or total prostheses cost per episode is highly variable; therefore, the benefit for the surgical guides and biomodels would need to be calculated following the procedure when all other costs have been calculated. This would place a burden on hospitals and uncertainty for patients. Alternatively, this option might overlap with option B3, where a tiered benefit is introduced to reflect the complexity of the procedure.

However, a reduction in PL benefits based on the mean proportion of total prostheses costs or total episode costs per procedure might provide a simple, justified approach to reducing the benefit without the need for making broader changes. For example, if the current mean proportion of total protheses benefits per episode that is attributable to surgical guides and biomodels is around 50%, this would be considered too high based on the evidence review. New benefits could be calculated that would reduce this proportion to an agreed value acknowledging the impact might differ for different clinical indications and levels of complexity. Further data analysis and modelling would be required to establish such benefits, but they could be set to a level that balances the clinical support for surgical guides and biomodels with the uncertain evidence base.

### 4.1.2 Options for conditions on benefits payable for surgical guides and biomodels

Following the Stage 1 PLR, conditions were implemented on the PL for listed surgical guides and biomodels. These were intended to restrict their use to:

- CMF procedures using implantable medical devices
- intraoperative use to aid in the implantation of those devices
- 3 surgical guides and/or 3 biomodels per episode.

The department has committed to monitoring the impact of these conditions. Retaining, refining or altering these conditions could have an impact on the overall cost of benefits paid for surgical guides and biomodels.

**Table 21 Summary of potential options for conditions on benefits payable for surgical guides and biomodels on the PL**

| # | Option | Rationale |
|---|---|---|
| **B1** | Retain conditions on the maximum number of surgical guides and biomodels that can be used per procedure | Implementation of this condition caps the number of surgical guides and biomodels that are payable per episode but may have inadvertently set an effective floor volume, encouraging greater use of these devices than is required for simpler procedures. This approach also impacts complex surgeries more than simpler procedures, despite evidence of greater value of surgical guides and biomodels in complex procedures. |
| **B2** | Create a new condition allowing a single benefit for surgical guides or biomodels per procedure rather than per item | Planning is the major cost input in the development of surgical guides and biomodels and occurs at the procedure level rather than the device level. Restricting to a single benefit payable per procedure would reflect the additional value of using VSP to produce all surgical guides and biomodels required for that procedure. |
| **B3** | Implement a stratified approach, where benefits payable for surgical guides and biomodels are reduced for each additional product used | A stratified approach, similar to that in place for pathology services on the MBS, would contain costs for surgical guides and biomodels and could be implemented alone or in addition to the current cap on the number of devices payable per episode, or in combination with other options. |
| **B4** | Implement a tiered approach, where benefits payable for surgical guides and biomodels are higher for more complex surgeries | A tiered approach could be based on MBS fees for the procedure in which the surgical guides or biomodels are used, with the aim of establishing benefits that increase with increasing surgical complexity. |
| **B5** | Create a condition that surgical guides or biomodels only attract a benefit when used without a patient-matched implant | This restriction is proposed as a mechanism to remove the 'double dip' benefit premiums associated with claiming both patient-matched implants and surgical guides and biomodels. It risks favouring simpler procedures. |

Abbreviations: MBS, Medicare benefits schedule; PL, Prescribed List; VSP, virtual surgical planning.

## Option B1: Retain conditions on the maximum number of surgical guides and biomodels that can be used per procedure

The first option is to retain the current conditions that limit the maximum number of surgical guides and biomodels used per procedure to 3 of each. Stakeholders have expressed concern that this inadvertently sets a 'floor volume' for surgical guides and biomodels and that some procedures may be split out into multiple procedures to enable greater numbers to be claimed.

## Option B2: Create a new condition allowing a single benefit for surgical guides or biomodels per procedure rather than per item

Given the major cost input into the development of surgical guides and biomodels is the planning rather than the printing of the devices (excepting titanium guides), and that planning occurs at the procedure level rather than the device level, a single claim for 'surgical guides and biomodels' per episode might be an appropriate condition to place on the devices. This might require implementation of option D1 (remove biomodels from the PL), or a variation of that option, such that for each sponsor, their surgical guides and corresponding biomodel (where applicable) are listed as a single item rather than two separate items. This benefit would then reflect the additional value of using VSP to produce all surgical guides and biomodels required for that procedure. The current benefit that surgical guides attract could be used, or alternatively, a new benefit could be established using one of the options described.

This option could be partially disaggregated to specify a single claim for one surgical guide and one biomodel per episode if no changes to the listing were undertaken. This has the advantage of simpler implementation, but the disadvantage is that it aligns less closely with the justification for the option (i.e. a single benefit for the VSP outputs as a whole), and it is probable that for most procedures both items would be claimed regardless.

## Option B3: Implement a stratified approach, where benefits payable for surgical guides and biomodels are reduced for each additional product used

The Stage 1 PLR found that on average, 2.1 surgical guides and 1.8 biomodels were used per separation in financial year 2020-21 but variability was noted, with higher numbers used in a small but growing number of separations. Rather than the current condition where there is a restriction on the total number of surgical guides and biomodels that can be claimed per procedure, a stratified approach would lower the benefit that can be claimed for each additional device that is used in a single procedure. This could be implemented in addition to the current condition, or instead of the current condition.

For example, if the current condition were retained, the first surgical guide might attract 100% of the benefit, the second 75%, the third 50% and the fourth and any further surgical guides would not attract any benefit. Alternatively, removing the current condition, the benefit might reduce by 20% for each additional surgical guide, effectively limiting the total to 5 surgical guides per procedure.

Although a similar approach is in place for pathology services on the MBS, no conditions specifying stratified benefits are currently in place on the PL and further consideration may need to be given to the feasibility of this approach. This option could be implemented alone, or combined with other options, for example D1 (removal of biomodels from the PL) or D3 (removal of dental surgical guides and biomodels).

The risk with a stratified approach, as for the current limit on maximum benefits, is that complex surgeries are impacted more than simpler surgeries, despite evidence that use of surgical guides and biomodels is of greater value in more complex surgeries.

## Option B4: Implement a tiered approach, where benefits payable for surgical guides and biomodels are higher for more complex surgeries

A tiered approach – such that more complex procedures receive a higher benefit for surgical guides and biomodels than simpler procedures – is consistent with stakeholder feedback and the clinical evidence, both of which point to the greater value of surgical guides and biomodels in more complex procedures. However, implementation of a tiered approach might be challenging. As the Stage 1 PLR noted, classifying complex procedures is not clear cut and there is no precedent for such an approach on the PL.

The simplest approach is expected to be linking the PL benefit to the associated MBS item number. Common MBS items that are co-claimed with surgical guides and biomodels in the CMF subcategory are listed in Table 22. The higher complexity procedures have both higher MBS fees and higher rates of utilisation of surgical guides and biomodels. In its simplest form, this option could entail setting the PL benefit for surgical guides and biomodels at a proportion of the associated MBS fee. For example, if the proportion were set at 10% then the benefit for alveolar ridge augmentation would be $54 and that for complex bilateral osteotomy of the jaw would be $247. This could be undertaken in conjunction with other options, such as option B2, such that the benefit is applied only once per procedure, or it could be that if 3 biomodels are used in the complex jaw osteotomy then the $247 benefit can be claimed 3 times.

This approach might pose challenges where multiple MBS procedure items are claimed, allowing for multiple claims for surgical guides and biomodels. An alternative approach would be to allow the highest cost MBS item to set the benefit for that episode. Two devices on the PL currently have conditions that link to MBS item numbers (Cerclage System [Billing Code HU267] and Navitor™ Transcatheter Aortic Valve [Billing Code SJ482]); however, adjustment of benefits based on the MBS item used has no precedent and implementation of such an option might be challenging.

**Table 22 MBS items commonly used with surgical guides and biomodels**

| MBS Item | MBS item description | MBS fee | Utilisation ratea |
|---|---|---|---|
| **45841** | Alveolar ridge augmentation | $539.65 | 0.07 |
| **45849** | Sinus lift procedure | $661.80 | 0.10 |
| **45857** | TMJ arthroscopy | $744.85 | 0.30 |
| **52357** | Osteotomies or ostectomies of the mandible or maxilla | $1,799.05 | 0.60 |
| **52363** | Complex bilateral osteotomies or ostectomies of mandible or maxilla | $2,064.60 | 3.90 |
| **52375** | Complex bilateral osteotomies or ostectomies of mandible or maxilla | $2,467.25 | 6.40 |

Source: Adapted from Table 11 of Stage 1 PLR.

Abbreviations: MBS, Medicare Benefits Schedule; PLR, post-listing review; TMJ, temporomandibular joint.

**a** Utilisation rate is from the Stage 1 PLR and is the number of surgical guides and biomodels used per MBS item reported admissions for financial year 2020-21.

### Option B5: Create a condition that surgical guides or biomodels only attract a benefit when used without a patient-matched implant

This option assumes that the benefit premium associated with patient-matched implants already reimburses the associated planning process, including the production of surgical guides and biomodels. It could be implemented without making any other changes. Benefits would be restricted to episodes where no patient-matched implant is used. Therefore, this condition would be simple to implement and would be a refinement of the current condition. That is, currently a benefit for surgical guides and biomodels is only payable when claimed with a CMF implant; the proposed condition would drill this down further such that the CMF implant could not be patient-matched. The risk of implementing this option is that procedures that do not use patient-matched implants are more likely to be simple procedures, in particular dental implant. Therefore, this approach might have the unintended effect of retaining the current benefit for surgeries with evidence that they are no more effective than usual care but reducing the benefit for surgeries where the clinical value of surgical guides and biomodels is higher.

This approach may, however, lead to reduced utilisation of high-cost patient-matched implants where off-the-shelf implants are suitable. An Australian study of bimaxillary orthognathic surgery concluded that using in-house VSP to manufacture splints was reliable and reproducible and avoided the additional cost of patient-matched implants (Delpachitra and Borbar, 2023). Such approaches might be encouraged by option B5.

## 4.1.3 Other options for the department to consider

### Changes to PL grouping structure to facilitate benefit setting

At present, surgical guides are located in different subcategories on the PL with different benefits and limited clinical rationale for this grouping.

The Stage 1 PLR provided the following options with respect to the grouping of surgical guides and biomodels:

- Separating dental implant guides from CMF surgical guides and re-categorising the former to the subcategory 07.03 Dental Implants and 07.03.03 Endosseous Implants product group.
- Redefining subgroups for surgical guides to separate out splint guides, which could be more suitably reimbursed at a lower benefit than other surgical guides, because they are less costly to produce.
- Considering whether surgical guides and biomodels should be moved to Part C of the PL or be required to be packaged with biomodelled implants.

As Part C of the PL is for devices that do not meet the criteria for listing in Part A and, furthermore, requires ministerial approval, this option with respect to grouping of surgical guides and biomodels is not considered further.

**Table 23 Summary of other options for the department to consider – grouping options**

| No. | Option | Rationale |
|---|---|---|
| C1 | Implement changes to surgical guides, biomodels and patient-matched implants as proposed under PL reform activity | Creation of a new product group for patient-matched devices for craniofacial reconstruction that brings together all patient-matched implants, surgical guides and biomodels would ensure that components of kits are co-located and facilitate greater consistency in benefit setting across these products. |
| C2 | Group dental surgical guides and biomodels with dental implants | Relocation of dental surgical guides and biomodels to the endosseous implants group would enable a different benefit to be set for dental compared to CMF surgical guides and biomodels, in recognition that the clinical evidence relating to dental implants suggests no advantage over standard surgery. |
| C3 | Separate splint guides from cutting and drilling guides | Creation of a separate subgroup for splints would recognise the notable differences between surgical splints (which are not readily identifiable on the PL) and surgical cutting and drilling guides. |

Abbreviations: CMF, craniomaxillofacial; PL, Prescribed List.

### Option C1: Implement changes to surgical guides, biomodels and patient-matched implants as proposed under PL reform activity

As part of the PL reform activities, a revised structure for the Plastic and Reconstructive Category of the list was proposed16. This structure was developed in collaboration with clinical experts and a clinical working group, and subject to review by industry and sponsors.

In the current grouping of the PL, patient-matched implants for CMF surgery are indicated with a suffix designated 'biomodelled' (in the subgroups marked with a star in Figure 2). Surgical guides are separated across the list anatomically while anatomical models are in their own group (surgical guides and biomodels are indicated with red boxes in Figure 2).

It was noted in the Stage 1 PLR that 3 surgical guides are listed in multiple anatomical groups. One of these anatomical groups has been removed (07.02.06.06 – Nose and Zygoma Surgical Guide); however, there appears to remain duplication of products listed multiple times in different anatomical groups but with identical ARTG numbers (e.g. ProPlan ARTG ID 276733 is listed in 3 product groups with 3 different benefits).[17] Based on the clinical evidence, there does not appear to be any reason for surgical guides for different anatomical locations (within the craniofacial structures) to receive different benefits (excluding consideration of dental indications).

The proposal presented as part of the reform activities was to bring all customised[18] devices for craniofacial reconstruction together into a single group and within this create a single subgroup for surgical guides and another for anatomical biomodels (Figure 2). This would enable a single benefit to be set for surgical guides. Grouping of all customised implants together into a single group would also facilitate other options with respect to benefit as all components of the kits would be co-located.

The regrouping proposal as part of the PL reforms did not consider surgical guides and biomodels in detail and noted they were subject to a PLR to advise on eligibility. Therefore, further distinctions within the proposed subgroups were not considered. The Stage 1 PLR advised that further distinction may be

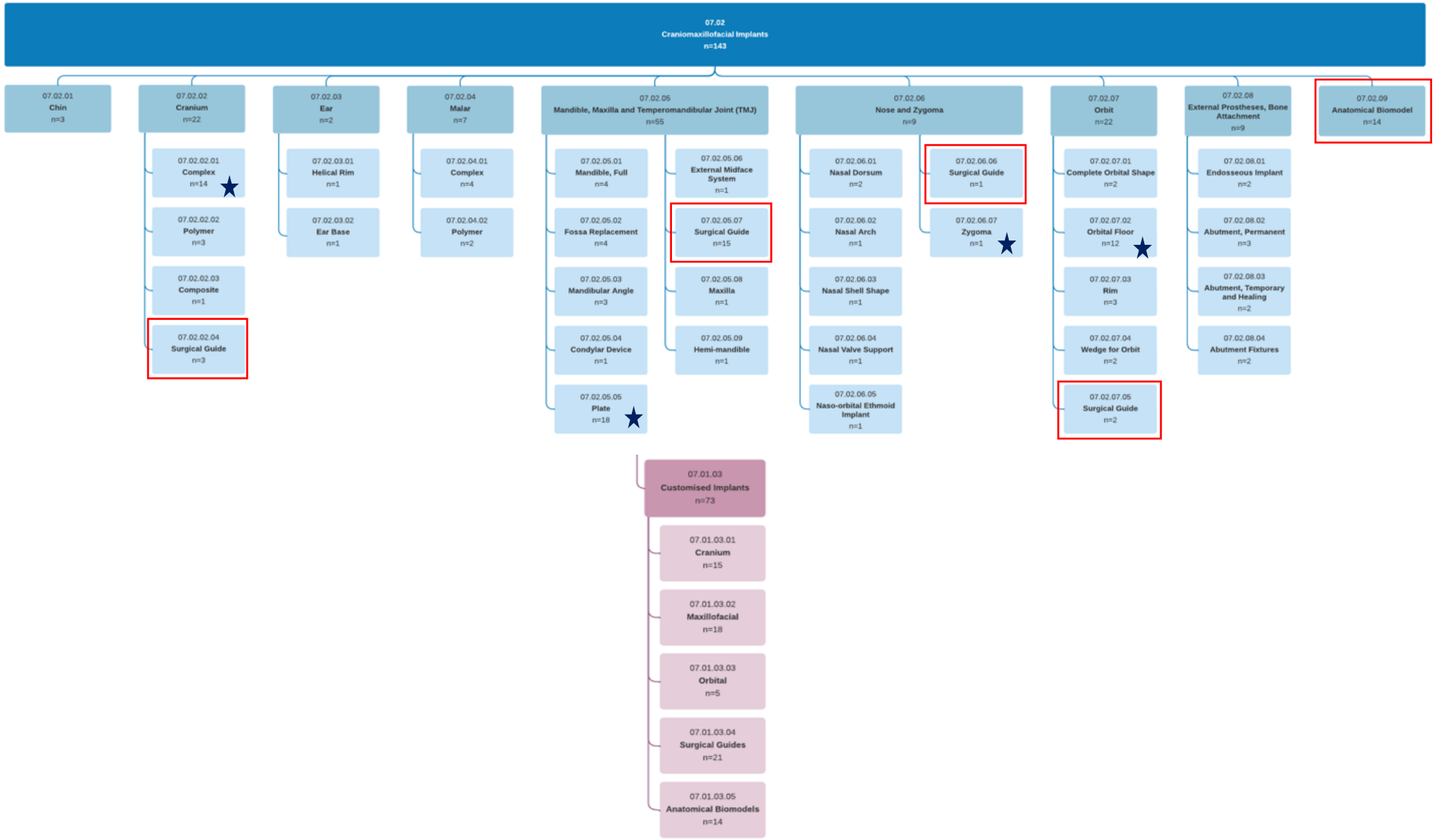
[16] https://consultations.health.gov.au/technology-assessment-access-division/prostheses-list-reforms-mixed-benefit-groups/, accessed 2 January 2025.

[17] Note that the ARTG number includes all components of a kit and therefore the patient-specific implants and anatomical biomodels also have the same ARTG number.

[18] The name of this group might be better labelled 'Patient-matched Implants' to align with TGA terminology as described at https://www.tga.gov.au/resources/guidance/understanding-personalised-medical-devices-rules-including-3d-printed-devices

necessary, although the suggestions were based on clinical indication and not anatomical location. Consideration could be given to creating a separate group, with a higher benefit, for titanium surgical guides.

**Figure 2** Structure of the subcategory 07.02 Craniomaxillofacial Implants to the subgroup level on the PL (November 2023) [blue] and proposed group for customised implants developed as part of the PL reform activities [pink]




Note: Patient-matched implants for CMF surgery are in the subgroups marked with a star. Surgical guides and biomodels are indicated with red boxes.

### Option C2: Group dental surgical guides and biomodels with dental implants

Surgical guides and biomodels associated with dental implants are listed in Table 27. If dental-associated surgical guides and biomodels continue to be listed on the PL, then the proposal from the Stage 1 PLR to move dental guides and biomodels to the group 07.03.03 Endosseous Implants in subcategory 07.03 Dental Implants is clinically logical and recommended. It enables a different benefit to be set for dental compared to CMF surgical guides and biomodels. However, the eligibility for listing of these products remains in question unless it can be demonstrated that they are being used appropriately in complex procedures and/or further conditions are imposed on them (for example, a condition that no benefit is payable for dental surgical guides and biomodels when used for alveolar ridge augmentation and other procedures that are not part of a complex CMF procedure involving facial reconstruction or correction of significant jaw deformities).

### Option C3: Separate surgical splints from cutting and drilling guides

The definition of surgical splints from the Stage 1 PLR is reproduced in Box 3 and representative images are shown in Figure 3.

**Box 3 Definitions of surgical splints from the Stage 1 PLR**

> **Orthognathic surgical splints** are surgical guides used in single or double jaw surgery to guide the mobile jaw segments into their virtually planned dental occlusion. They may be used to implant patient-matched implants or standard plates (definition supplied by the MTAA).

Abbreviations: MTAA, Medical Technology Association of Australia.

Although the definitions include splints within the broader category of surgical guides, there are notable differences between a surgical cutting and drilling guide and a surgical splint. Splints are generated pre-operatively to model the post-operative position of the jaw, whereas surgical cutting and drilling guides model the pre-operative anatomy (Jacobs and Lin, 2017). In orthognathic surgery, splints are used to position the jaw during surgery but can also be used post-surgery to maintain that position. Splints have been traditionally generated by prosthetists using plaster casts (described in Bachelet et al. 2016) but can now be digitally designed and printed. Alternatively, surgery can be digitally planned, and splints replaced with surgical cutting guides (Chen et al. 2021).

**Figure 3 Example of surgical cutting and drilling guide (left) and a splint guide (right) both supplied by KLS Martin for orthognathic surgery**

Source: Product brochure 'KLS Martin IPS Implants Orthognathic', accessed 2 January 2025.

The option to separate splint guides from surgical cutting and drilling guides could be justified based on their different characteristics. However, at present there are no PL items that are specific to splint guides

and therefore this does not appear to be a practical option unless sponsors were requested to resubmit applications for all surgical guides currently listed in group 07.02.05 Mandible, Maxilla and Temporomandibular Joint. The 2 products illustrated in Figure 3 are likely to both be available under Billing Code KT005.

Splint guides have been used in orthognathic surgery before the routine use of VSP and 3D printing, but not listed on the PL. They are, however, reimbursed on the MBS (Table 24) and this could provide a suitable basis for benefit setting if splints were able to be identified and separately categorised on the PL.

**Table 24 MBS items for the fabrication and fitting of dental splints**

| **Category 7 – Cleft and craniofacial services** |
|---|
| **75618**<br>**Fabrication and fitting of a bite rising appliance or dental splint for the management of temporomandibular joint dysfunction syndrome**<br>**Fee: $263.80 Benefit: 75% = $197.85 85% = $224.25** |
| **75621**<br>**The fabrication and fitting of surgical splint or guide in conjunction with orthognathic surgical procedures and implant treatment, if provided in association with a service to which:**<br>**(a) any item in the following series applies:**<br>**(i) any of items 46150 to 46161 apply; or**<br>**(ii) any of items 52342 to 52375 apply; or**<br>**(b) item 52380 or 52382 applies;**<br>**(c) item 75610 applies**<br>**Fee: $263.80 Benefit: 75% = $197.85 85% = $224.25** |

Abbreviations: MBS, Medical Benefits Schedule

## Options that change the benefits associated with a VSP 'package'

Options D1 to D3 use changes to listings or associated implants as a mechanism to set benefits for VSP as a whole. As noted in Stage 1, 'many of the listed products cannot be categorised as only a surgical guide or biomodel, as they form part of a kit that includes biomodels, surgical guides, and other items such as fixation plates, screws and implants'. Furthermore, the kit generally includes the VSP process and software. Options D1 to D3 consider this 'package' and propose mechanisms to set an appropriate benefit across for a VSP episode. They reflect the limited evidence to support comparative clinical and cost effectiveness; however, as they also affect the benefits of implants that are used with VSP, further stakeholder consultation would be required.

**Table 25 Summary of other options for the department to consider – VSP 'package' options**

| No. | Option | Rationale |
|---|---|---|
| **D1** | Remove biomodels from the PL | Reduces overall benefit for procedures involving surgical guides and biomodels. Biomodels do not strictly meet PL eligibility requirements and their value-add has not been definitively demonstrated. These devices can be considered part of the manufacturing process for patient-matched implants rather than essential to implanting a device. |
| **D2** | Remove surgical guides and biomodels from the PL | Reduces overall benefit for procedures involving surgical guides and biomodels. This approach aligns with other implants on the PL, such as knee, hip and spine, which do not provide PL benefits for surgical guides and biomodels. Patient-matched implants in the Plastic and Reconstructive category on the PL already attract a higher benefit than off-the-shelf implants and therefore any added value of surgical guides and biomodels is already accounted for in the benefit for the patient-matched implant. Most surgical guides and biomodels on the PL are packaged as part of a kit with the patient-matched implant. |
| **D3** | Lower the benefit of patient-matched implants to be the same as standard implants | Lowering the benefit for CMF patient-specific implants would align with other patient-matched implants on the PL, which do not attract a premium over off-the-shelf implants. This approach also recognises that surgical guides and biomodels are often provided as parts of kits, and it would prevent the VSP process, which is currently 'absorbed' in the benefit for patient-matched implants as well as for surgical guides and biomodels, from being funded multiple times in a single procedure. |

Abbreviations: PL, Prescribed List; PLR, post-listing review.

### Option D1: Remove biomodels from the PL

Although both surgical guides and biomodels are considered in this Stage 2 PLR, these devices have different clinical roles. The necessity of considering surgical guides and biomodels as two distinct devices rather than a single device class was raised in stakeholder feedback.

> *It is vital in my opinion that surgical guides be treated separately from biomodels. Biomodels are helpful adjuncts for confirming positioning of bone fragments, and allowing a visual reference for faster and more accurate bone manipulation and reduction. However, it would be a rare case where more than one biomodel would be of great help.*

> *The use of biomodels and guides in dental implant surgery has also been promoted. Whilst there are clear benefits in complex cases such as full arch reconstructions, zygomatic implants or reconstructions after tumour resections, the benefit is questionable for routine implant cases. There is almost no need for biomodelling in these cases other than as a handy, albeit expensive, storage device for the guide. (OMF surgeon)*

Biomodels are rarely used in isolation of a surgical guide. Their role in surgery, if any, is limited to providing an intra-operative anatomical reference; they are more frequently part of the design and fabrication process. Anatomical biomodels might reasonably be considered part of the VSP workflow and not listed on the PL. Meanwhile, surgical guides, as patient-matched tools for surgery, might be retained. If no other changes were made to benefits, the removal of anatomical biomodels would reduce overall expenditure on 'surgical guides and biomodels' by approximately a quarter, based on the analysis of utilisation patterns in the Stage 1 PLR.

### Option D2: Remove surgical guides and biomodels from the PL

The option to remove surgical guides and biomodels from the PL is considered a mechanism for benefit setting and does not necessarily mean that they are not reimbursed on the PL. Surgical guides and biomodels are most frequently used with patient-matched implants, and frequently come as a kit with all these devices having the same ARTG number. One stakeholder stated that 'biomodels and guides are iterative steps in making the final [patient-matched] implant.'

Patient-matched implants are identified in the Plastic and Reconstructive Surgery category of the PL by the suffix 'biomodelled' and attract a higher benefit than off-the-shelf products in the same category[19]. This higher benefit is considered by some stakeholders to represent sufficient margin to cover the entire process of planning and manufacture of associated surgical guides and biomodels.

Surgical guides and biomodels are used more broadly than CMF surgery and are frequently used in orthopaedic procedures (11.4% of primary total knee replacement procedures in 2023[20]). However, elsewhere on the PL surgical guides and biomodels are not eligible for listing. Examples of patient-matched devices listed for orthopaedic procedures were provided by stakeholders:

- Sybios Origin Patient Specific total knee replacement (WQ005, WQ006, WQ007, WQ008)
- Bespoke iTotal cruciate-retaining total knee replacement system (FL007, FL008, FL009, FL010, FL012)
- 3DMorphic 3D fusion cages (GK001, GK002, GK005, GK007, GK008, GK009) and vertebral body replacement (QQ302)

None of these devices attract a benefit higher than the off-the-shelf equivalent and none of them attract an additional benefit for associated surgical guides and/or biomodels. Therefore, if surgical guides and biomodels were removed from the Plastic and Reconstructive category of the PL, it would bring this category partially in-line with the remainder of the PL. The higher benefit associated with patient-matched implants has not been replicated elsewhere on the PL. It would be reasonable for this benefit premium to cover all planning and manufacture of associated surgical tools. Alternatively, this benefit premium could be reviewed in light of the limited clinical evidence to support improved patient outcomes and the inconsistency with other categories on the PL.

[19] Not all patient matched implants in the Plastics and Reconstructive category of the PL have a 'biomodelled' suffix and attract a higher benefit (e.g. Zimmer TMJ system, billing codes XU017 and BI569). Therefore, this option may also require changes to the grouping and/or benefits of some patient-matched implants.

[20] Australian Orthopaedic Association National Joint Replacement Registry Annual Report 2024.

A risk of removing surgical guides and biomodels from the Plastic and Reconstructive category of the PL is that not all are supplied as part of a kit, and some may be used in surgeries that use off-the-shelf implants rather than patient-matched implants. Of 32 surgical guides and biomodels on the PL, the Stage 1 PLR identified 12 as not belonging to a kit and 2 were listed as 'not known'.

Four of these are surgical guides and biomodels sponsored by SPECIFICA (Billing Codes UI001, UI002, UI003, UI004). This sponsor has no other products on the PL and therefore removal of surgical guides and biomodels would remove all SPECIFICA listings. The PLR submission from SPECIFICA during Stage 1 only referred to orthopaedic applications and therefore their eligibility for listing following the implementation of conditions is unclear.

Appendix B of the Stage 1 PLR listed some Stryker surgical guides and biomodels as belonging to a kit and others as being stand-alone devices, but elsewhere stated the Stryker surgical guides and biomodels are part of a kit. Given at least some Stryker surgical guides and biomodels are part of a kit, it is anticipated they would continue to be available if benefits were associated with the patient-matched implant rather than continuing to list surgical guides and biomodels separate to the implant. Similarly, Maxoniq and KLS Martin have a listed biomodels and/or surgical guides that are not part of a kit; however, these sponsors also have patient-matched implants on the PL and the biomodels and guides would be expected to be claimed with the patient-matched implants in most cases.

The other group of surgical guides and biomodels that are not part of a kit are those associated with dental implants. These are considered separately below (option E1).

As acknowledged by stakeholders in the Stage 1 PLR, an unintended consequence of removing surgical guides or biomodels from the PL is that the funding burden could potentially shift, for example, to the public sector or to patients. Consideration of an alternative funding mechanism for VSP (and virtual biomodels) is not within scope of this PLR but was suggested in the Stage 1 PLR. The MBS provides reimbursement for 'all necessary 3-dimensional planning' when performed with bony free flap reconstruction of the maxilla, mandible or skull base (MBS item 45609) but not for other CMF procedures.

### Option D3: Lower the benefit of patient-matched implants to be the same as standard implants

Concerns were raised by a stakeholder that the benefit premium for patient-matched implants over off-the-shelf implants, in addition to the separate benefits for surgical guides and biomodels, was a form of 'double dipping' with the additional costs of developing the 'kit' being claimed multiple times for a single procedure. The VSP process produces all 3 patient-matched components – model(s), guide(s) and implant(s) – rather than them being produced as separate individual devices. Therefore, any benefit above 'usual care' should only be for a single component of that kit.

If surgical guides and biomodels are retained on the PL, option D3 is to reduce the benefit of patient-matched implants in line with off-the-shelf implants. This would lower the overall benefit claimed for procedures where all components of a 3D patient-matched kit are claimed.

This is the reverse approach to that of option D2 where the cost of VSP is considered already reimbursed within the benefit for patient-matched implants. The concern with option D2 is that some surgical guides and biomodels are used without a patient-matched implant or are not part of a kit. Option D3 addresses this concern but, if it is predominately dental implants that are utilising surgical guides and biomodels

without a patient-matched implant, this option might have the unintended consequence of retaining a high total benefit for simple surgery and reducing the overall benefit for complex surgery. This would be contrary to the intent of the option, which is designed to reflect the limitations in the clinical and economic evidence.

Further benefit reductions would result if option D3 and D2 were combined. This would be consistent with the approach taken for orthopaedic patient-matched implants (e.g. Sybios Origin Patient Specific total knee replacement [Billing Codes WQ005, WQ006, WQ007, WQ008]), where patient-matched devices do not attract a higher benefit for any aspect of the device above a standard implant. It is anticipated that the cost of production of 3D printed patient-matched devices will continue to reduce and it is likely they will become standard of care. Where new devices are listed with higher benefits than currently listed devices and older devices become redundant, the costs continue to increase despite cost of production decreasing. In the absence of strong evidence to demonstrate patient-relevant improvement in clinical outcomes, combining options D3 and D2 could be justified; however, there may be a risk that costs shift to patients in the public system.

## Option to remove benefits for simpler procedures

Option E1 makes the distinction between dental-specific surgical guides and biomodels and those more likely to be used in complex CMF procedures. Other options may be able to be tailored to set a differential benefit for dental-specific surgical guides and biomodels (e.g. option A3) or attempt to set a differential benefit based on surgical complexity (e.g. options A4 and B4) however option E1 proposes to remove benefits for simple surgeries entirely.

**Table 26 Option for the department to consider – dental implant surgery**

| No. | Option | Rationale |
|---|---|---|
| **E1** | Remove surgical guides and biomodels for dental implant surgery from the PL | Removes benefits associated with procedures where clinical effectiveness is not demonstrated. PL eligibility criteria are not met for surgical guides or biomodels that are used for '*simpler procedures*'. Surgeons consulted during the Stage 1 PLR considered dental implant surgery and alveolar ridge augmentation as 'simpler'. |

Abbreviations: PL, Prescribed List; PLR, post-listing review.

### Option E1: Remove surgical guides and biomodels for dental implant surgery from the PL

There are 4 dental-specific surgical guides and 2 dental-specific biomodels currently listed on the PL (Table 27). Although surgical guides and biomodels do not meet PL eligibility criteria when used in 'simpler procedures', (and dental implant surgery is listed as a simpler procedure in the Stage 1 PLR), these items remain on the PL. This is presumably because – as acknowledged in the Stage 1 PLR – when a dental implant procedure is undertaken as part of CMF reconstructive surgery or correction of significant jaw deformities, the procedure would be considered complex. The department undertook a consultation specific to dental implants in March 2024 but did not change the conditions of listing.

**Table 27 Dental surgical guides and biomodels on the PL**

| Product Group | Product Sub Group | Suffix | Billing Code | Benefit | Sponsor | Product Name | ARTG |
|---|---|---|---|---|---|---|---|
| **07.02.05 – Mandible, Maxilla and Temporomandibular Joint (TMJ)** | 07.02.05.07 – Surgical Guide | Biomodelled | QQ312 | $1,450 | DENTAL DEVICES PTY LTD | AI Guide | 443915 |

| Product Group | Product Sub Group | Suffix | Billing Code | Benefit | Sponsor | Product Name | ARTG |
|---|---|---|---|---|---|---|---|
| **07.02.05 – Mandible, Maxilla and Temporomandibular Joint (TMJ)** | 07.02.05.07 – Surgical Guide | Biomodelled | HI001 | $1,495[a] | DIGITAL DENTAL NETWORK PTY LTD | DDN Guide | 336209 |
| **07.02.05 – Mandible, Maxilla and Temporomandibular Joint (TMJ)** | 07.02.05.07 – Surgical Guide | Biomodelled | HI006 | $1,450 | DIGITAL DENTAL NETWORK PTY LTD | DDN Guide | 336209 |
| **07.02.05 – Mandible, Maxilla and Temporomandibular Joint (TMJ)** | 07.02.05.07 – Surgical Guide | Biomodelled | MV007 | $1,450 | MORE GROUP PTY LTD | Mguide | 348196 |
| **07.02.09 – Anatomical Biomodel** | | | HI002 | $1,762 | DIGITAL DENTAL NETWORK PTY LTD | DDN Biomodel | 336209 |
| **07.02.09 – Anatomical Biomodel** | | | HI005 | $1,762 | DIGITAL DENTAL NETWORK PTY LTD | DDN Biomodel | 336209 |

**a** Unclear why HI001 attracts a higher benefit than other surgical guides listed in the same group.

Although the Stage 2 PLR systematic review included 2 comparative studies of dental implant procedures that reported costs (Schneider et al. 2019c; Ravida et al. 2018), it is possible that the procedures investigated were 'simpler' as they did not include patients requiring implants following trauma, cancer or cleft palate procedures. In both studies, VSP-guided dental implant placement cost more than usual care, and no statistically significant differences were found in complication rates on a per patient basis (Ravida et al. 2018) or in patient quality of life (Sancho-Puchades et al. 2019). Implant survival was statistically better on a per implant basis (Ravida et al. 2018). Operative time was not significantly different between groups in the RCT (Schneider et al. 2019c), although planning time was longer for patients who received VSP. Therefore, the evidence for surgical guides and biomodels for dental implant placement is suggestive of no advantage over standard surgery and this is consistent with stakeholder feedback. No cost studies on the use of dental-specific surgical guides in complex craniofacial surgery were identified. Furthermore, it is unclear whether the surgical guides and biomodels that are used for simple dental implant surgery would also be used where dental implants are required as part of complex CMF surgery.

An example of a complex CMF procedure that involves dental rehabilitation – the Sydney Modified Alberta Reconstruction Technique (SM-ART) – was described by a group of surgeons from Sydney for dental rehabilitation following mandibulectomy or maxillectomy (Johal et al. 2021). The surgical technique is described in detail in the study publication and includes 'custom cutting and implant guides for the mandible/maxilla and fibular bone' and patient-matched plates. The surgery is substantially different to implant placement due to edentulism and is unlikely to be affected by the removal of the surgical guides and biomodels listed in Table 27.

Given the lack of evidence and their overwhelming association with simple procedures, the removal of surgical guides and biomodels that are specifically for dental implant surgery is an option, even where surgical guides or biomodels remain listed for use during complex CMF procedures.

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# Appendix A Sponsors and stakeholders that provided Stage 2 submissions

**Table App. A.1 Sponsors and stakeholder providing submission for the Stage 2 PLR**

| Name | Stage 1 involvement | Stage 1 submission provided to Hereco | Stage 2 submission provided to Hereco |
|---|---|---|---|
| Sponsors | | | |
| **Digital Dental Network Pty Ltd** | ✓ (submission & interview) | ✓ | ✓ |
| **Johnson & Johnson Medical Pty Ltd** | ✓ (submission & interview) | ✓ | ✓ |
| **KLS Martin Australia Pty Ltd** | ✓ (submission & interview) | ✓ | ✓ |
| **MAXONIQ Pty Ltd** | ✓ (submission) | ✓ | ✓ |
| **More Group Pty Ltd** | ✓ (submission) | × | ✓ (More Dent) |
| **Specifica Pty Ltd** | ✓ (submission) | ✓ | × |
| **Stryker Australia Pty Ltd** | ✓ (submission) | ✓ | × |
| **AnatomicsRx Pty Ltd** | ✓ (submission) | × | × |
| **AA-Med Pty Ltd** | ✓ (report feedback only) | × | × |
| **Dental Devices Pty Ltd** | × | NA | × |
| Peak Body | | | |
| **Neurosurgical Society of Australasia** | ✓ (interview) | NA | × |
| **Day Hospitals Australia** | ✓ (interview) | NA | × |
| **Medical Technology Association of Australia** | ✓ (interview) | NA | × |
| **The Australasian and New Zealand Association of Oral and Maxillofacial Surgeons** | ✓ (interview) | NA | × |
| **Royal Australasian College of Surgeons** | ✓ (interview) | NA | × |
| **Australian Health Services Alliance** | ✓ (interview) | NA | × |
| **Members Health Fund Alliance** | ✓ (interview) | NA | × |
| **Private Healthcare Australia** | ✓ (interview) | NA | ✓ |
| **Catholic Health Australia (CHA)** | × | NA | ✓ |
| Other stakeholder | | | |
| **Lyka Smith (used with AA-Med products)** | | | ✓ |
| **Medibank Private Ltd** | | | ✓ |
| **BUPA** | | | ✓ |
| Public | | | |
| **Surgeon 1** | | | ✓ |
| **Surgeon 2** | | | ✓ |
| **Surgeon 3** | | | ✓ |

**Prescribed List Post-listing Review – Surgical guides and biomodels – Stage 2**

| Name | Stage 1 involvement | Stage 1 submission provided to Hereco | Stage 2 submission provided to Hereco |
|---|---|---|---|
| **Surgeon 4** | | | ✓ |

Abbreviations: NA, not applicable; PLR, post-listing review.

# Appendix B Surgical guides and biomodels listed on the PL

Since 1 November 2024, all surgical guides and biomodels remaining on the PL are in the Craniomaxillofacial Implants Subcategory of the Plastic and Reconstructive Category (07.02).

**Table App. B.1 Surgical guides listed on the PL (November 2024)**

| Product Group | Product Sub Group | Suffix | Billing Code | Benefit | Sponsor | Product Name | ARTG |
|---|---|---|---|---|---|---|---|
| **07.02.02 – Cranium** | 07.02.02.04 – Surgical Guide | Biomodelled | QQ014 | $1,315 | ANATOMICSRX PTY LTD | Anatomics Surgical Guide | 288564 |
| **07.02.02 – Cranium** | 07.02.02.04 – Surgical Guide | Biomodelled | SY777 | $1,315 | JOHNSON & JOHNSON MEDICAL PTY LTD | ProPlan | 276733 |
| **07.02.05 – Mandible, Maxilla and Temporomandibular Joint (TMJ)** | 07.02.05.07 – Surgical Guide | Biomodelled | ZZ047 | $1,450 | AA-Med Pty Ltd | OrthoTin Surgical Guide | 293845 |
| **07.02.05 – Mandible, Maxilla and Temporomandibular Joint (TMJ)** | 07.02.05.07 – Surgical Guide | Biomodelled | ZZ049 | $1,450 | AA-Med Pty Ltd | Lyka Smith Patient Specific Guides | 293845 |
| **07.02.05 – Mandible, Maxilla and Temporomandibular Joint (TMJ)** | 07.02.05.07 – Surgical Guide | Biomodelled | QQ008 | $1,450 | ANATOMICSRX PTY LTD | Anatomics Patient Specific Surgical Guide | 288564 |
| **07.02.05 – Mandible, Maxilla and Temporomandibular Joint (TMJ)** | 07.02.05.07 – Surgical Guide | Biomodelled | QQ312 | $1,450 | DENTAL DEVICES PTY LTD | AI Guide | 443915 |
| **07.02.05 – Mandible, Maxilla and Temporomandibular Joint (TMJ)** | 07.02.05.07 – Surgical Guide | Biomodelled | HI001 | $1,495 | DIGITAL DENTAL NETWORK PTY LTD | DDN Guide | 336209 |
| **07.02.05 – Mandible, Maxilla and Temporomandibular Joint (TMJ)** | 07.02.05.07 – Surgical Guide | Biomodelled | HI006 | $1,450 | DIGITAL DENTAL NETWORK PTY LTD | DDN Guide | 336209 |
| **07.02.05 – Mandible, Maxilla and Temporomandibular Joint (TMJ)** | 07.02.05.07 – Surgical Guide | Biomodelled | SY778 | $1,450 | JOHNSON & JOHNSON MEDICAL PTY LTD | ProPlan | 276733 |
| **07.02.05 – Mandible, Maxilla and Temporomandibular Joint (TMJ)** | 07.02.05.07 – Surgical Guide | Biomodelled | SY829 | $1,450 | JOHNSON & JOHNSON MEDICAL PTY LTD | Custom made plates (including Megaplates) – Surgical Guides | 276733 |

| Product Group | Product Sub Group | Suffix | Billing Code | Benefit | Sponsor | Product Name | ARTG |
|---|---|---|---|---|---|---|---|
| **07.02.05 – Mandible, Maxilla and Temporomandibular Joint (TMJ)** | 07.02.05.07 – Surgical Guide | Biomodelled | KT005 | $1,450 | KLS MARTIN AUSTRALIA PTY LIMITED | UNIQOS Patient Specific Surgical guides | |
| **07.02.05 – Mandible, Maxilla and Temporomandibular Joint (TMJ)** | 07.02.05.07 – Surgical Guide | Biomodelled | OG001 | $1,450 | MAXONIQ PTY LTD | OMX Solutions patient Optimized Guide system | 276176 |
| **07.02.05 – Mandible, Maxilla and Temporomandibular Joint (TMJ)** | 07.02.05.07 – Surgical Guide | Biomodelled | MV007 | $1,450 | MORE GROUP PTY LTD | Mguide | 348196 |
| **07.02.05 – Mandible, Maxilla and Temporomandibular Joint (TMJ)** | 07.02.05.07 – Surgical Guide | Biomodelled | UI001 | $1,450 | SPECIFICA PTY LTD | OsGuide | 292759 |
| **07.02.05 – Mandible, Maxilla and Temporomandibular Joint (TMJ)** | 07.02.05.07 – Surgical Guide | Biomodelled | UI003 | $1,450 | SPECIFICA PTY LTD | DGUIDE | 322576 |
| **07.02.05 – Mandible, Maxilla and Temporomandibular Joint (TMJ)** | 07.02.05.07 – Surgical Guide | Biomodelled | HW650 | $1,450 | STRYKER AUSTRALIA PTY LTD | VSP Orthognathics Bundle (Surgical Guide and Implants) | 200615 |
| **07.02.05 – Mandible, Maxilla and Temporomandibular Joint (TMJ)** | 07.02.05.07 – Surgical Guide | Biomodelled | HW653 | $1,450 | STRYKER AUSTRALIA PTY LTD | VSP Reconstruction Mandibular/Maxillary Case Bundle | 200615 |
| **07.02.07 – Orbit** | 07.02.07.05 – Surgical Guide | Biomodelled | QQ013 | $2,584 | ANATOMICSRX PTY LTD | Anatomics Patient Specific Surgical Guide | 288564 |
| **07.02.07 – Orbit** | 07.02.07.05 – Surgical Guide | Biomodelled | SY830 | $2,584 | JOHNSON & JOHNSON MEDICAL PTY LTD | Surgical Guide for OBL PorousiTi® PSI System – Orbital Floor | 276733 |

Abbreviations: ARTG, Australian Register of Therapeutic Goods; PL, Prescribed List of Medical Devices and Human Tissue Products.

**Table App. B.2 Biomodels listed on the PL (November 2024)**

| Product Group | Product Sub Group | Suffix | Billing Code | Benefit | Sponsor | Product Name | ARTG |
|---|---|---|---|---|---|---|---|
| **07.02.09 – Anatomical Biomodel** | – | | ZZ046 | $1,762 | AA-Med Pty Ltd | OrthoTin Anatomic Biomodel | 293845 |
| **07.02.09 – Anatomical Biomodel** | – | | ZZ050 | $1,762 | AA-Med Pty Ltd | Lyka-Smith Anatomical Biomodel | 293845 |

| Product Group | Product Sub Group | Suffix | Billing Code | Benefit | Sponsor | Product Name | ARTG |
|---|---|---|---|---|---|---|---|
| **07.02.09 – Anatomical Biomodel** | – | | QQ001 | $1,762 | ANATOMICSRX PTY LTD | Anatomics Biomodel | 288564 |
| **07.02.09 – Anatomical Biomodel** | – | | HI002 | $1,762 | DIGITAL DENTAL NETWORK PTY LTD | DDN Biomodel | 336209 |
| **07.02.09 – Anatomical Biomodel** | – | | HI005 | $1,762 | DIGITAL DENTAL NETWORK PTY LTD | DDN Biomodel | 336209 |
| **07.02.09 – Anatomical Biomodel** | – | | SY779 | $1,762 | JOHNSON & JOHNSON MEDICAL PTY LTD | ProPlan | 276733 |
| **07.02.09 – Anatomical Biomodel** | – | | KT004 | $1,762 | KLS MARTIN AUSTRALIA PTY LIMITED | UNIQOS Patient Specific Anatomical Biomodel | |
| **07.02.09 – Anatomical Biomodel** | – | | OG004 | $1,762 | MAXONIQ PTY LTD | The OMX Solutions Biomodel | 276753 |
| **07.02.09 – Anatomical Biomodel** | – | | UI002 | $1,762 | SPECIFICA PTY LTD | BIOMODEL | 292561 |
| **07.02.09 – Anatomical Biomodel** | – | | UI004 | $1,762 | SPECIFICA PTY LTD | OMF Model | 322576 |
| **07.02.09 – Anatomical Biomodel** | – | | HW544 | $1,762 | STRYKER AUSTRALIA PTY LTD | Stryker Anatomical Biomodel for Mandible | 218563 |
| **07.02.09 – Anatomical Biomodel** | – | | HW546 | $1,762 | STRYKER AUSTRALIA PTY LTD | Stryker Anatomical Biomodel for PEEK | 218563 |
| **07.02.09 – Anatomical Biomodel** | – | | HW651 | $1,762 | STRYKER AUSTRALIA PTY LTD | VSP Orthognathics Bundle (Custom Biomodel and Implants) | 200615 |
| **07.02.09 – Anatomical Biomodel** | – | | HW652 | $1,762 | STRYKER AUSTRALIA PTY LTD | VSP Reconstruction Maxillofacial Case Bundle | 200615 |
| **07.02.09 – Anatomical Biomodel** | – | | QQ311 | $1,762 | STRYKER AUSTRALIA PTY LTD | Stryker Patient-Matched TMJ – Anatomic Biomodel | 427023 |

Abbreviations: ARTG, Australian Register of Therapeutic Goods; PL, Prescribed List of Medical Devices and Human Tissue Products.

# Appendix C Methodology

## C.1 Systematic review

### C.1.1 PICO

A systematic literature review was conducted to address the following question:

> *Are surgical guides and biomodels cost-effective compared to standard care or other therapeutic approaches when used to implant a device in CMF procedures?*

The systematic review was guided by PICO criteria:

- **Population** – patients who have undergone CMF implant placement procedures
- **Intervention** – implant or prosthesis placement utilising patient-specific surgical guides and/or biomodels listed on the PL
- **Comparator** – implant or prosthesis placement that is performed with usual care (i.e. without patient-specific surgical guides and/or biomodels or VSP)
- **Outcomes** – comparative cost effectiveness or comparative costs.

The restriction of the intervention to studies of PL-listed devices excluded many otherwise-eligible records, so the PICO were adapted during the execution of the systematic review to include studies of any commercially supplied patient-specific surgical guides or biomodels (i.e. not produced in house or at point of care).

### C.1.2 Bibliographic database searches

To identify relevant evidence for the cost effectiveness of surgical guides and biomodels, 2 systematic literature searches were conducted in the PubMed bibliographic database on 07 January 2025:

**Search strategy 1** (search strategy shown in Table App. C.1)**:**

- used generic search terms for surgical guides and biomodels
- limited to CMJ procedures
- limited to reporting of cost or economic outcomes
- limited to publication from 2013 onwards
    - aligning with PubMed search undertaken for the Stage 1 PLR.

Search strategy 2 identified 870 records for screening.

**Search strategy 2** (search strategy shown in Table App. C.2):

- used device-specific search terms for surgical guides and biomodels
- limited to devices listed on the PL.

Search strategy 2 identified 190 records for screening. As this second strategy identified relatively few records, it was decided not to limit records to CMJ procedures, cost or economic outcomes, or by publication date, as this may have excluded records of relevance. Instead, these limits were applied as eligibility criteria during screening.

Together, these searches identified a total of 1,055 unique records (i.e. only 5 records were identified by both search strategies).

**Table App. C.1 Search strategy 1 – using generic search terms for surgical guides or biomodels**

| No. | PubMed Query 07 January 2025 | Results |
|---|---|---|
| **1** | "surgical guide" OR "surgical guides" OR "surgical template*" OR "surgical splint*" OR "patient-specific guide" OR "patient-specific guides" | 2,525 |
| **2** | (("3D print*" OR "three dimensional print*" OR "additive manufacturing" OR "rapid prototyping") AND (implant* or prosth*)) | 9,469 |
| **3** | biomodel* OR "anatomical model*" OR "patient-specific model*" | 5,716 |
| **4** | ("virtual surgical planning" or ("surgical planning" AND "patient-specific")) AND ("virtual surgical planning" or ("surgical planning" AND "patient-specific")) | 1,768 |
| **5** | #1 OR #2 OR #3 OR #4 | 18,229 |
| **6** | #5 AND ("2013"[Date - Publication] : "3000"[Date - Publication]) | 16,420 |
| **7** | (maxillofacial or maxilla* or mandib* OR craniomaxillofacial or craniofacial or cranial OR oral OR jaw or TMJ or temporomandibular OR dental) | 2,092,490 |
| **8** | #6 AND #7 | 6,175 |
| **9** | (efficienc* or cost* or saving* or economic*) | 2,479,179 |
| **10** | #8 and #9 | **870** |

**Table App. C.2 Search strategy 2 – using device-specific search terms for devices listed on the PL**

| No | PubMed Query | Results |
|---|---|---|
| **1** | Anatomics | 22 |
| **2** | ProPlan | 99 |
| **3** | OrthoTin - Schema: all | 0 |
| **4** | OrthoTin | 0 |
| **5** | "Lyka Smith" | 8 |
| **6** | "Dental devices" AND "AI Guide" - Schema: all | 0 |
| **7** | "AI Guide" | 5 |
| **8** | "DDN Guide" | 17 |
| **9** | "Custom made plates" | 17 |
| **10** | "KLS Martin" AND (biomodel or "surgical guide") | 1 |
| **11** | "OMX solutions" | 2 |
| **12** | MGuide | 3 |
| **13** | OsGuide - Schema: all | 0 |
| **14** | DGUIDE | 1 |
| **15** | Stryker virtual surgical planning | 15 |
| **16** | BIOMODEL AND SPECIFICA - Schema: all | 0 |
| **17** | BIOMODEL AND SPECIFICA | 0 |
| **18** | OMF AND SPECIFICA - Schema: all | 0 |
| **19** | Stryker AND "Anatomical Biomodel" - Schema: all | 0 |
| **20** | Stryker AND "Anatomical Biomodel" | 0 |
| **21** | Stryker AND "Anatomic Biomodel" - Schema: all | 0 |

| No | PubMed Query | Results |
|---|---|---|
| **22** | Stryker AND "Anatomic Biomodel" | 0 |
| **23** | #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 | **190** |

Abbreviations: PL, Prescribed List of Medical Devices and Human Tissue Products.

### C.1.3 Eligibility criteria

In addition to the PICO criteria, the following eligibility criteria guided the screening of records identified in the systematic bibliographic literature search:

**Included:**

- quantitative, comparative clinical studies
- published in English between 01 January 2013 and 07 January 2025 with full text available

**Excluded:**

- systematic reviews and non-clinical studies
- conference abstract, book chapters, letters to the editor etc
- studies that describe software development or manufacturing processes.

### C.1.4 Studies screened at full text

The following tables list the studies from the PubMed literature searches described above that were screened at full text: included studies (Table App. C.3); and excluded studies (Table App. C.4).

**Table App. C.3 Studies from the bibliographic database searches eligible for inclusion**

| Citation | Study type |
|---|---|
| **Fatima, A., Hackman, T.G. and Wood, J.S. (2019). Cost-Effectiveness Analysis of Virtual Surgical Planning in Mandibular Reconstruction. Plast Reconstr Surg. 143(4):1185-1194.** | Economic study |
| **Gardiner, L., Smith, B., Kubik, M., Solari, M., Smith, K., de Almeida, J.R. and Sridharan, S. (2024). Long-term outcomes in virtual surgical planning for mandibular reconstruction: A cost-effectiveness analysis. Microsurgery. 44(5):e31206.** | Economic study |
| **Kurlander, D.E., Garvey, P.B., Largo, R.D., Yu, P., Chang, E.I., Hanasono, M.M. and Mericli, A.F. (2023). The Cost Utility of Virtual Surgical Planning and Computer-Assisted Design/Computer-Assisted Manufacturing in Mandible Reconstruction Using the Free Fibula Osteocutaneous Flap. J Reconstr Microsurg. 39(3):221-230.** | Economic study |
| **Omara, M., Ali, S. and Ahmed, M. (2021). Accuracy of midface advancement using patient-specific surgical guides and pre-bent plates versus conventional interocclusal wafers and conventional plate fixation in quadrangular Le Forte II osteotomy. A randomised controlled trial. Br J Oral Maxillofac Surg. 59(10):1253-1258.** | RCT |
| **Schneider, D., Kämmerer, P.W., Hennig, M., Schön, G., Thiem, D.G.E. and Bschorer, R. (2019). Customized virtual surgical planning in bimaxillary orthognathic surgery: a prospective randomized trial. Clin Oral Investig. 23(7):3115-3122.** | RCT |
| **Schneider, D., Sancho-Puchades, M., Schober, F., Thoma, D., Hämmerle, C. and Jung, R. (2019). A Randomized Controlled Clinical Trial Comparing Conventional and Computer-Assisted Implant Planning and Placement in Partially Edentulous Patients. Part 3: Time and Cost Analyses. Int J Periodontics Restorative Dent. 39(3):e71-e82.** | RCT |
| **Garza-Cisneros, A.N., García-Pérez, M.M., Rodriguez-Guajardo, W.J., Elizondo-Riojas, G. and Negreros-Osuna, A.A. (2024). Cost-effective Solution for Maxillofacial Reconstruction Surgery with Virtual Surgical Planning and 3D Printed Cutting Guides Reduces Operative Time. Plast Surg (Oakv). 32(1):70-77.** | Non-randomised comparative study |

| Citation | Study type |
|---|---|
| King, B.J., Park, E.P., Christensen, B.J. and Danrad, R. (2018). On-Site 3-Dimensional Printing and Preoperative Adaptation Decrease Operative Time for Mandibular Fracture Repair. J Oral Maxillofac Surg. 76(9):1950.e1-1950.e8. | Non-randomised comparative study |
| Lignon, J., Guerlain, J., Bozec, A., Gorphe, P., Lauwers, F., Vergez, S., Jalbert, F., Chabrillac, E., de Bonnecaze, G., Chaltiel, L. and Dupret-Bories, A. (2021). Multicentre evaluation of the interest in planned surgery for mandibular reconstruction with fibula free flap: a retrospective cohort study. Eur Arch Otorhinolaryngol. 278(9):3451-3457. | Non-randomised comparative study |
| Mazzola, F., Smithers, F., Cheng, K., Mukherjee, P., Hubert Low, T.H., Ch'ng, S., Palme, C.E. and Clark, J.R. (2020). Time and cost-analysis of virtual surgical planning for head and neck reconstruction: A matched pair analysis. Oral Oncol. 100:104491.<br>[Included in Stage 1 PLR] | Non-randomised comparative study |
| Park, S.Y., Hwang, D.S., Song, J.M. and Kim, U.K. (2019). Comparison of time and cost between conventional surgical planning and virtual surgical planning in orthognathic surgery in Korea. Maxillofac Plast Reconstr Surg. 41(1):35. | Non-randomised comparative study |
| Resnick, C.M., Inverso, G., Wrzosek, M., Padwa, B.L., Kaban, L.B. and Peacock, Z.S. (2016). Is There a Difference in Cost Between Standard and Virtual Surgical Planning for Orthognathic Surgery? J Oral Maxillofac Surg. 74(9):1827-33.<br>[Included in Stage 1 PLR] | Non-randomised comparative study |
| Rodríguez-Arias, J.P., Tapia, B., Pampín, M.M., Morán, M.J., Gonzalez, J., Barajas, M., Del Castillo, J.L., Navarro Cuéllar, C. and Cebrian, J.L. (2022). Clinical Outcomes and Cost Analysis of Fibula Free Flaps: A Retrospective Comparison of CAD/CAM versus Conventional Technique. J Pers Med. 12(6). | Non-randomised comparative study |
| Rogers-Vizena, C.R., Sporn, S.F., Daniels, K.M., Padwa, B.L. and Weinstock, P. (2017). Cost-Benefit Analysis of Three-Dimensional Craniofacial Models for Midfacial Distraction: A Pilot Study. Cleft Palate Craniofac J. 54(5):612-617. | Non-randomised comparative study |
| Speed, O.E., Rickels, K.L., Farsi, S., Merrill, T., Gardner, J.R., King, D., Sunde, J., Vural, E. and Moreno, M.A. (2024). Virtual surgical planning for mandibular reconstruction in an abbreviated admission pathway. Am J Otolaryngol. 45(3):104141. | Non-randomised comparative study |
| Steinhuber, T., Brunold, S., Gärtner, C., Offermanns, V., Ulmer, H. and Ploder, O. (2018). Is Virtual Surgical Planning in Orthognathic Surgery Faster Than Conventional Planning? A Time and Workflow Analysis of an Office-Based Workflow for Single- and Double-Jaw Surgery. J Oral Maxillofac Surg. 76(2):397-407. | Non-randomised comparative study |

Abbreviations: RCT, randomised controlled trial; PLR, post-listing review.

**Table App. C.4 Records from the bibliographic database searches excluded at full text review**

| Citation | Reason for exclusion |
|---|---|
| Abo Sharkh, H. and Makhoul, N. (2020). In-House Surgeon-Led Virtual Surgical Planning for Maxillofacial Reconstruction. J Oral Maxillofac Surg. 78(4):651-660. | Wrong study type |
| Alkaabi, S., Maningky, M., Helder, M.N. and Alsabri, G. (2022). Virtual and traditional surgical planning in orthognathic surgery - systematic review and meta-analysis. Br J Oral Maxillofac Surg. 60(9):1184-1191. | Wrong study type |
| Almahrous, G., David-Tchouda, S., Sissoko, A., Rancon, N., Bosson, J.L. and Fortin, T. (2020). Patient-Reported Outcome Measures (PROMs) for Two Implant Placement Techniques in Sinus Region (Bone Graft versus Computer-Aided Implant Surgery): A Randomized Prospective Trial. Int J Environ Res Public Health. 17(9). | Wrong outcomes |
| Antúnez-Conde Hidalgo, R., Silva Canal, J.L., Navarro Cuéllar, C., Sánchez Gallego-Albertos, C., Arias Gallo, J., Navarro Cuéllar, I., López Davis, A., Demaria Martínez, G., Naranjo Aspas, N., Zamorano León, J. and Chamorro Pons, M. (2023). Guided Genioplasty: Comparison between Conventional Technique and Customized Guided Surgery. J Pers Med. 13(12). | Wrong outcomes |

| Citation | Reason for exclusion |
|---|---|
| **Ballard, D.H., Mills, P., Duszak, R., Jr., Weisman, J.A., Rybicki, F.J. and Woodard, P.K. (2020). Medical 3D Printing Cost-Savings in Orthopedic and Maxillofacial Surgery: Cost Analysis of Operating Room Time Saved with 3D Printed Anatomic Models and Surgical Guides. Acad Radiol. 27(8):1103-1113.**<br>**[While not eligible for inclusion in the Stage 2 PLR, this was used to inform Benefit options deliberations]** | Wrong study type |
| **Barr, M.L., Haveles, C.S., Rezzadeh, K.S., Nolan, I.T., Castro, R., Lee, J.C., Steinbacher, D. and Pfaff, M.J. (2020). Virtual Surgical Planning for Mandibular Reconstruction With the Fibula Free Flap: A Systematic Review and Meta-analysis. Ann Plast Surg. 84(1):117-122.** | Wrong study type |
| **Bergeron, L., Bonapace-Potvin, M. and Bergeron, F. (2023). Printing in Time for Cranio-Maxillo-Facial Trauma Surgery: Key Parameters to Factor in. Craniomaxillofac Trauma Reconstr. 16(2):121-129.** | Wrong study type |
| **Block, O.M., Khromov, T., Hoene, G., Schliephake, H. and Brockmeyer, P. (2024). In-house virtual surgical planning and guided mandibular reconstruction is less precise, but more economical and time-efficient than commercial procedures. Head Neck. 46(4):871-883.** | Wrong comparator |
| **Chan, T.J., Long, C., Wang, E. and Prisman, E. (2022). The state of virtual surgical planning in maxillary Reconstruction: A systematic review. Oral Oncol. 133:106058.** | Wrong study type |
| **Chen, Z., Mo, S., Fan, X., You, Y., Ye, G. and Zhou, N. (2021). A Meta-analysis and Systematic Review Comparing the Effectiveness of Traditional and Virtual Surgical Planning for Orthognathic Surgery: Based on Randomized Clinical Trials. J Oral Maxillofac Surg. 79(2):471.e1-471.e19.** | Wrong study type |
| **Cho, K.H., Papay, F.A., Yanof, J., West, K., Bassiri Gharb, B., Rampazzo, A., Gastman, B. and Schwarz, G.S. (2021). Mixed Reality and 3D Printed Models for Planning and Execution of Face Transplantation. Ann Surg. 274(6):e1238-e1246.** | Wrong study type |
| **Delpachitra, S.N. and Bordbar, P. (2023). Surgical accuracy of CAD/CAM splints using virtual surgical planning in orthognathic surgery: policy implications for healthcare in Australia. ANZ J Surg. 93(11):2742-2747.** | Wrong study type |
| **Dubron, K., Van Camp, P., Jacobs, R., Politis, C. and Shaheen, E. (2022). Accuracy of virtual planning and intraoperative navigation in zygomaticomaxillary complex fractures: A systematic review. J Stomatol Oral Maxillofac Surg. 123(6):e841-e848.** | Wrong study type |
| **Gleissner, H., Castrillon-Oberndorfer, G. and Gehrlich, S. (2022). Introduction of 3D Printing in a German Municipal Hospital-Practice Guide for CMF Surgery. Craniomaxillofac Trauma Reconstr. 15(4):369-378.** | Wrong study type |
| **Hammoudeh, J.A., Howell, L.K., Boutros, S., Scott, M.A. and Urata, M.M. (2015). Current Status of Surgical Planning for Orthognathic Surgery: Traditional Methods versus 3D Surgical Planning. Plast Reconstr Surg Glob Open. 3(2):e307.** | Wrong study type |
| **Johal, M., Ma, J.N.B., Parthasarathi, K., Dunn, M., Howes, D., Wallace, C., Palme, C.E., Leinkram, D., Cheng, K. and Clark, J.R. (2022). Institutional-based and commercial virtual surgical planning in maxillomandibular reconstruction - Comparing the digital plan and postoperative scan. J Plast Reconstr Aesthet Surg. 75(4):1399-1407.** | Wrong outcomes |
| **Kumar, S., Khanna, V., Singh, B.P., Mehrotra, D. and Patil, R.K. (2021). Impact of technology in temporomandibular joint reconstruction surgeries: A systematic review. J Plast Reconstr Aesthet Surg. 74(6):1331-1345.** | Wrong outcomes |
| **Lannon, M., Algird, A., Alsunbul, W. and Wang, B.H. (2022). Cost-Effective Cranioplasty Utilizing 3D Printed Molds: A Canadian Single-Center Experience. Can J Neurol Sci. 49(2):196-202.** | Wrong study type |
| **Low, P.H., Abdullah, J.Y., Abdullah, A.M., Yahya, S., Idris, Z. and Mohamad, D. (2019). Patient-Specific Reconstruction Utilizing Computer Assisted Three-Dimensional Modelling for Partial Bone Flap Defect in Hybrid Cranioplasty. J Craniofac Surg. 30(8):e720-e723.** | Wrong study type |
| **Matsui, C., Tokuyama, E., Senoo, T., Yamada, K., Kameda, M., Takeuchi, T. and Kimata, Y. (2020). Utilization of a Simple Surgical Guide for Multidirectional Cranial Distraction Osteogenesis in Craniosynostosis. Plast Reconstr Surg Glob Open. 8(4):e2797.** | Wrong outcomes |
| **Moe, J., Foss, J., Herster, R., Powell, C., Helman, J., Ward, B.B. and VanKoevering, K. (2021). An In-House Computer-Aided Design and Computer-Aided Manufacturing Workflow for Maxillofacial Free Flap Reconstruction is Associated With a Low Cost and High Accuracy. J Oral Maxillofac Surg. 79(1):227-236.** | Wrong study type |

| Citation | Reason for exclusion |
|---|---|
| **Narita, M., Takaki, T., Shibahara, T., Iwamoto, M., Yakushiji, T. and Kamio, T. (2020). Utilization of desktop 3D printer-fabricated "Cost-Effective" 3D models in orthognathic surgery. Maxillofac Plast Reconstr Surg. 42(1):24.** | Wrong study type |
| **Nobis, C.P., Kesting, M.R., Wolff, K.D., Frohwitter, G., Rau, A. and Weitz, J. (2020). Development of a template tool for facilitating fibula osteotomy in reconstruction of mandibular defects by digital analysis of the human mandible. Clin Oral Investig. 24(9):3077-3083.** | Wrong outcomes |
| **Oley, M.H., Oley, M.C., Sukarno, V. and Faruk, M. (2024). Advances in Three-Dimensional Printing for Craniomaxillofacial Trauma Reconstruction: A Systematic Review. J Craniofac Surg. 35(7):1926-1933.** | Wrong study type |
| **On, S.W., Cho, S.W., Park, S.Y., Yi, S.M., Park, I.Y., Byun, S.H., Kim, J.C. and Yang, B.E. (2024). Advancements in computer-assisted orthognathic surgery: A comprehensive review and clinical application in South Korea. J Dent. 146:105061.** | Wrong study type |
| **Ostaș, D., Almășan, O., Ileșan, R.R., Andrei, V., Thieringer, F.M., Hedeșiu, M. and Rotar, H. (2022). Point-of-Care Virtual Surgical Planning and 3D Printing in Oral and Cranio-Maxillofacial Surgery: A Narrative Review. J Clin Med. 11(22).** | Wrong study type |
| **Rommel, N., Kesting, M.R., Rohleder, N.H., Bauer, F.M.J., Wolff, K.D. and Weitz, J. (2017). Mandible reconstruction with free fibula flaps: Outcome of a cost-effective individual planning concept compared with virtual surgical planning. J Craniomaxillofac Surg. 45(8):1246-1250.**<br>**[Included in Stage 1 PLR]** | Wrong comparator |
| **Sinha, P., Skolnick, G., Patel, K.B., Branham, G.H. and Chi, J.J. (2018). A 3-Dimensional-Printed Short-Segment Template Prototype for Mandibular Fracture Repair. JAMA Facial Plast Surg. 20(5):373-380.** | Wrong study type |
| **Spaas, C. and Lenssen, O. (2019). Economic analysis of a low-cost virtual surgical planning protocol for mandibular reconstruction: a case series. Br J Oral Maxillofac Surg. 57(8):743-748.** | Wrong study type |
| **Tanveer, W., Ridwan-Pramana, A., Molinero-Mourelle, P., Koolstra, J.H. and Forouzanfar, T. (2021). Systematic Review of Clinical Applications of CAD/CAM Technology for Craniofacial Implants Placement and Manufacturing of Nasal Prostheses. Int J Environ Res Public Health. 18(7).** | Wrong outcomes |
| **Tanveer, W., Ridwan-Pramana, A., Molinero-Mourelle, P. and Forouzanfar, T. (2021). Systematic Review of Clinical Applications of CAD/CAM Technology for Craniofacial Implants Placement and Manufacturing of Orbital Prostheses. Int J Environ Res Public Health. 18(21).** | Wrong outcomes |
| **Tanveer, W., Ridwan-Pramana, A., Molinero-Mourelle, P. and Forouzanfar, T. (2023). Applications of CAD/CAM Technology for Craniofacial Implants Placement and Manufacturing of Auricular Prostheses-Systematic Review. J Clin Med. 12(18).** | Wrong population |
| **Tel, A., Tuniz, F., Fabbro, S., Sembronio, S., Costa, F. and Robiony, M. (2020). Computer-Guided In-House Cranioplasty: Establishing a Novel Standard for Cranial Reconstruction and Proposal of an Updated Protocol. J Oral Maxillofac Surg. 78(12):2297.e1-2297.e16.** | Wrong study type |
| **Virani, F.R., Chua, E.C., Timbang, M.R., Hsieh, T.Y. and Senders, C.W. (2022). Three-Dimensional Printing in Cleft Care: A Systematic Review. Cleft Palate Craniofac J. 59(4):484-496.** | Wrong study type |
| **Williams, A., Walker, K., Hughes, D., Goodson, A.M.C. and Mustafa, S.F. (2022). Accuracy and cost effectiveness of a waferless osteotomy approach, using patient specific guides and plates in orthognathic surgery: a systematic review. Br J Oral Maxillofac Surg. 60(5):537-546.** | Wrong study type |
| **Willinger, K., Guevara-Rojas, G., Cede, J., Schicho, K., Stamm, T. and Klug, C. (2021). Comparison of feasibility, time consumption and costs of three virtual planning systems for surgical correction of midfacial deficiency. Maxillofac Plast Reconstr Surg. 43(1):2.** | Wrong comparator |
| **Xiao JB, Banyi N, Tran KL, and Prisman E (2024) 'Cost Outcomes of Virtual Surgical Planning in Head and Neck Reconstruction: A Systematic Review', *Head Neck*, doi:https://doi.org/10.1002/hed.28035.**<br>**[Selected for sourcing primary studies]** | Wrong study type |

Abbreviations: PLR, post-listing review.

### C.1.5 Economic studies from the Stage 1 PLR

The Stage 1 PLR included 4 economic studies. Three were found in the literature search conducted for the current report and one (Zweifel 2015) was provided by Stage 2 submissions. All are non-randomised comparative studies and 3 were eligible for inclusion in the Stage 2 PLR:

- **Mazzola (2020)** – included
- **Resnick (2016)** – included but not taken further (within-patient comparisons)
- **Rommel (2017)** – excluded due to wrong comparator (commercially supplied versus in-house-manufactured surgical guides and/or biomodels)
- **Zweifel 2015** – included but not taken further (<10 patients in VSP group).

**Table App. C.5 Systematic reviews of costs identified in the literature review and used to identify primary studies**

| Study ID<br><br>Title | Research Question | Inclusion/ exclusion criteria | Search Dates<br>Databases<br><br>Included studies | Results | Authors' conclusion |
|---|---|---|---|---|---|
| **Xiao (2024)**<br><br>**Cost Outcomes of Virtual Surgical Planning in Head and Neck Reconstruction: A Systematic Review** | to perform the first comprehensive examination of all peer-reviewed evidence in the literature pertaining to the economic evaluation of virtual surgical planning (VSP) in head and neck reconstruction | Inclusion – (1) described pediatric or adult patient populations who underwent VSP prior to any type of head and neck reconstruction procedure and (2) performed an economic evaluation of any sort including but not limited to cost description, cost-outcome, cost analysis, cost–benefit analysis, and cost-effectiveness analysis. | Inception to July 5, 2024<br><br>Medline (Ovid), Embase, Scopus, CINAHL, and Cochrane CENTRAL<br><br>18 studies included (5 commercial suppliers, 8 in-house, 2 compared commercial with in-house, 2 NR) | In the studies where VSP was found to generate cost savings compared to FHS, VSP was performed in-house using open-source software. By contrast, in studies where the cost of VSP was found to be similar to FHS, with no net economic gain, VSP was outsourced to a third-party. | The results of this review support the economic benefit of VSP for head and neck reconstruction in many institutions across the world. Specifically, VSP-associated reductions in OR time and LOS/LOH and the employment of in-house VSP workflows were key in generating cost savings. However, while VSP has the potential to generate cost savings and give rise to high quality care, more studies are needed, particularly randomized controlled trials, to tackle the limitations of the existing evidence base and generalize the economic feasibility of VSP in a plethora of healthcare contexts. |

| Study ID<br><br>Title | Research Question | Inclusion/ exclusion criteria | Search Dates<br>Databases<br><br>Included studies | Results | Authors' conclusion |
|---|---|---|---|---|---|
| **Serrano (2020)**<br><br>**Evaluation of 3D printing costs in surgery: a systematic review** | To identify the costs associated with the use of 3D printing in surgery and highlight the first quantitative data available | No inclusion limits were set on the printing technology used or on the place of production (hospital, third-party provider). All printed medical devices were considered (anatomical models, surgical guides, or implants) intended for use in any surgical domain. All items with a cost calculation related to 3D printing were included. Only articles published in English and French between 2009 and 2019 were considered. Exclusion criteria: studies in dental surgery or for the production of external prostheses, studies related to fundamental research or without hospital application or not applied in humans, literature reviews and studies presented at conferences | 2009-2019<br><br>PubMed, Embase, National Health Service Economic Evaluation Database<br><br>9 studies included (6 anatomical models, 2 surgical instruments, 1 stimulator, 1 surgical template; 6/9 produced in-house) | According to the CHEERS checklist, the quality of the studies included was poor. Nine types of costs were identified, the 3 main ones being printing material costs (n = 6), staff costs (n = 3), and operating room costs (n = 3). The printing cost ranged from less US$1 to US$146 (2019 values) depending on the criteria used to calculate this cost. Three studies evaluated the potential savings generated by the use of 3D printing technology in surgery, based on operating time reduction. | This literature review highlights the lack of reliable economic data on 3D printing technology. In addition, no studies involving implants were found in the literature, although they are widely used, particularly in maxillofacial surgery. Nevertheless, this review makes it possible to identify expenditures or items that will have to be taken into account in order to carry out more robust studies, such as cost-effectiveness analyses, and to collect information that is useful for decision-makers in a hospital setting. Further economic and organizational studies will be essential to determine the future of this technology in surgery, which is competing with other innovative technologies such as virtual reality. |

Abbreviations: CHEERS, Consolidated Health Economic Evaluation Reporting Standards; FHS, freehand surgery; LOH, length of hospitalisation; LOS, length of stay; NR, not reported; OR, operating room; VSP, virtual surgical planning.

## C.2 Clinical trial registry search

A search of clinical trial registries was conducted on 29 January 2025 to identify ongoing or unpublished comparative studies reporting on costs or cost-effectiveness of surgical guides or biomodels in CMF procedures. The search terms and the number of records retrieved are shown in the table below.

**Table App. C.6 Searches of clinical trial registries to identify unpublished or ongoing studies**

| No. | Search terms | Records retrieved |
|---|---|---|
| | **ClinicalTrials.gov** | |
| **1** | Condition/disease terms: "Maxillofacial Abnormalities" OR "Maxillofacial Injuries" OR "Temporomandibular Disorder" OR "Temporomandibular Joint Dysfunction" OR "Temporomandibular Joint Disorders" OR "TMJ Disorders" OR "Craniofacial Abnormalities" OR "Craniofacial Injuries" OR "Orthognathic Surgery" OR "Orthognathic Surgical Procedures" OR "Dental Implant" OR "Dental Implants" OR "Dental Implantation"<br>AND<br>Intervention/treatment terms: "Surgical Guide" OR biomodel OR "Patient Specific Guide" OR "Surgical Template" OR "surgical splint" OR "virtual surgical planning" OR VSP | 51 |
| **2** | Intervention/treatment terms: "virtual surgical planning"<br>AND<br>Other terms: maxillofacial | 29 |
| **3** | Other terms: "maxillary osteotomy" OR "mandibular osteotomy" OR "corrective jaw surgery" OR "sagittal split osteotomy" OR "le fort I osteotomy" OR "le fort II osteotomy" | 58 |
| **4** | Other terms: anatomics OR ProPlan OR OrthoTin OR "Lyka Smith" or "AI Guide" OR "DDN Guide" OR "KLS Martin" OR "OMX solutions" OR MGuide OR OsGuide OR DGUIDE | 16 |
| **5** | Other terms: OMF OR Specifica | 10 |
| **6** | Condition/disease terms: "Maxillofacial Abnormalities" OR "Maxillofacial Injuries" OR "Temporomandibular Disorder" OR "Temporomandibular Joint Dysfunction" OR "Temporomandibular Joint Disorders" OR "Craniofacial Abnormalities" OR "Craniofacial Injuries" OR "Orthognathic Surgery" OR "Orthognathic Surgical Procedures" OR "Dental Implant" + synonyms<br>AND<br>Other terms: Stryker | 4 |
| **7** | Intervention/treatment terms: "Surgical Guide" OR biomodel OR "Patient Specific Guide" OR "Surgical Template" OR "surgical splint" OR "virtual surgical planning" OR VSP<br>AND<br>Other terms: Stryker | 2 |
| | **TOTAL** | **170** |
| | **TOTAL WITH DUPLICATES REMOVED** | **149** |
| | **ANZCTR[a]** | |
| **1** | "Surgical Guide" OR biomodel OR "Patient Specific Guide" OR "Surgical Template" OR "surgical splint" | 2 |
| **2** | "virtual surgical planning" OR VSP | 9 |
| **3** | biomodel OR "anatomical model" | 1 |
| **4** | (maxillofacial OR temporomandibular OR craniofacial OR orthognathic) AND reconstruction | 6 |
| **5** | (maxillofacial OR temporomandibular OR craniofa*cial OR orthognathic) AND (surgery OR surgical) | 43 |

| No. | Search terms | Records retrieved |
|---|---|---|
| 6 | "maxillary osteotomy" OR "mandibular osteotomy" OR "corrective jaw surgery" | 1 |
| 7 | "sagittal split osteotomy" OR "le fort I osteotomy" OR "le fort II osteotomy" | 0 |
| 8 | anatomics OR ProPlan OR OrthoTin OR "Lyka Smith" or "AI Guide" OR "DDN Guide" OR "KLS Martin" | 1 |
| 9 | "OMX solutions" OR MGuide OR OsGuide OR DGUIDE | 0 |
| 10 | Stryker AND (maxillofacial OR temporomandibular OR craniofacial OR orthognathic) | 1 |
| | **TOTAL** | **64** |
| | **TOTAL WITH DUPLICATES REMOVED** | **53** |

Abbreviations: ANZCTR, Australian New Zealand Clinical Trials Registry (anzctr.org.au).
**a** Each search in ANZCTR is limited to 100 characters. Excludes trials where the original record is in ClinicalTrials.gov.

The search of ClinicalTrials.gov identified 149 unique records, of which 17 were comparative studies of potential relevance to the Stage 2 PLR (CMF or complex dental procedures, often assessing VSP or patient-matched implants or guides).

Six of the potentially relevant studies were reported as completed: 3 RCTs (NCT03869021; NCT04283981; NCT06188403) and 3 non-randomised comparative cohort studies (NCT03869723; NCT03986723; NCT04965441). None of the completed studies specified cost or cost-effectiveness as an outcome. Two RCTs (with a total of 16 patients each) and 2 comparative cohort studies (one with a total of 36 matched patients) specified operation time as an outcome but did not specify any other outcome measures that are suitable for use in an economic analysis.

Four small RCTs had a study status of 'unknown' in ClinicalTrials.gov. One was found to have published results for patient satisfaction and operation time (NCT04836130); the others did not specify any outcome measures that are suitable as inputs in an economic analysis (NCT05340036; NCT03277443; NCT03530891).

Of the 7 potentially relevant studies with a status of 'active' or 'recruiting' at the time of the search (NCT03986164; NCT04725396; NCT06174532; NCT06297109; NCT06442787; NCT06588075; NCT06737289), none specified cost or cost-effectiveness as an outcome measure. Two active RCTs, one with a total of 28 patients (NCT06588075) and the other with a target enrolment of 132 patients (NCT04725396), specified duration of operation as an outcome. The larger RCT (recruiting at multiple sites in France) will also assess quality of life and functional outcomes. Study completion is estimated in September 2025. None of the other active studies specified outcome measures that are suitable for use in an economic analysis.

The search of the Australian New Zealand Clinical Trials Registry (ANZCTR) identified 53 unique records, none of which were comparative studies of relevance to the Stage 2 PLR.

## C.3 HTA agency and clinical practice guideline search

A targeted search of HTA agencies and the key clinical guideline repository was performed on 3 January 2025 for evidence on the cost-effectiveness of surgical guides and biomodels in CMF surgery. The same search terms as used for the systematic review were applied. The sites searched and the number of relevant results are detailed in Table App. C.7.

One guideline reporting on appropriate clinical scenarios for anatomical models was identified (Chepelev et al. 2018). The guideline was developed by the Radiological Society of North America and did not discuss cost nor cost-effectiveness. No other clinical practice guidelines referring to the cost or cost-effectiveness of surgical guides and biomodels in CMF surgery were identified.

Of the 10 relevant HTA reports identified, 8 were excluded from further analysis (Table App. C.8). Two HTAs (Ros Aziah et al. 2021; Vinck et al. 2018) included economic analyses and their findings are summarised in Table App. C.9.

**Table App. C.7 Sites searched to identify HTAs and clinical practice guidelines**

| Agency | Website | Relevant results |
|---|---|---|
| **Agency for Clinical Effectiveness (ACE, Singapore)** | https://www.ace-hta.gov.sg/ | 0 |
| **Agency for Healthcare Research and Quality (AHRQ, USA)** | https://www.ahrq.gov/ | 0 |
| **Belgian Health Care Knowledge Centre (KCE)** | https://kce.fgov.be/en/about-us/what-is-kce/our-activity-domains/health-technology-assessment | 1 |
| **Canadian Agency for Drugs and Technologies in Health (CADTH)** | https://www.cda-amc.ca/search?s=&f%5B0%5D=result_type%3Aproject | 0 |
| **Finnish Institute for Health and Welfare** | https://thl.fi/en/main-page | 0 |
| **Google search engine** | | 5 |
| **Guidelines International Network (GIN)** | https://g-i-n.net/ | 0 |
| **Health Council of the Netherlands** | https://www.healthcouncil.nl/ | 0 |
| **Institute of Health Economics (IHE, Canada)** | https://www.ihe.ca/advanced-search | 0 |
| **Institut national d'excellence en santé et en services sociaux (INESSS, Canada)** | https://www.inesss.qc.ca/en/home.html | 0 |
| **International Network of Agencies for Health Technology Assessment (INAHTA)** | https://database.inahta.org/ | 2 |
| **Medical Services Advisory Committee (MSAC)** | https://www.msac.gov.au/applications | 0 |
| **National Institute for Health and Care Excellence (NICE, UK)** | https://www.nice.org.uk/ | 2 |
| **Norwegian Institute of Public Health, Norwegian Knowledge Centre for the Health Services** | https://www.fhi.no/en/ | 0 |

Abbreviations: HTA, health technology assessment.

**Table App. C.8 HTAs identified and excluded with reasons**

| Reference | Reason |
|---|---|
| **DEFACTUM, Osteba. Custom-made or customisable 3D printed implants and cutting guides versus non-3D printed standard implants and cutting guides for improving outcome in patients undergoing knee, maxillofacial, or cranial surgery. EUnetHTA Project ID: OTCA11. 2019** | No economic analysis |
| **NICE, Insertion of customised exposed titanium implants, without soft tissue cover, for complex orofacial reconstruction. Interventional procedures guidance, 23 July 2013** | Out of date |

| Reference | Reason |
|---|---|
| **NICE, Insertion of customised titanium implants, with soft tissue cover, for complex orofacial reconstruction. Interventional procedures guidance, 27 March 2013 (update 1 July 2013)** | Out of date |
| **AHRQ Horizon Scan of 3D printed biomodels (2015)** | Out of date |
| **An Overview of Clinical Applications of 3-D Printing and Bioprinting. Ottawa: CADTH; 2019 Mar. (CADTH Issues in Emerging Health Technologies; Issue 175).** | Overview – no additional information or analyses (reference list checked) |
| **Department of Health Abu Dhabi - 3D printing of anatomic biomodels** | Brief, no useful information |
| **Agency for Care Effectiveness (ACE) Overview for New and Emerging Health Technologies. 3D Printing and Its Clinical Applications. Document Number HSO-M 02/2020 Date: September 2020** | Overview – no additional information or analyses (reference list checked) |
| **Health Technology Wales. 3D printed patient-specific implants in cranial neurosurgical and craniomaxillofacial (CMF) surgery. 2021** | Overview – no additional information or analyses (reference list checked) |

Abbreviations: AHRQ, Agency for Healthcare Research and Quality; DEFACTUM, Danish Social & Health Services and Labour Market; HTA, health technology assessment; NICE, National Institute for Health and Care Excellence.

**Table App. C.9 Data extraction for identified HTAs of surgical guides and models reporting economic outcomes**

| Study ID<br>Title<br>Agency | Research Question | Search Dates<br>Databases<br>Inclusion/ exclusion criteria | Included studies | Results | Authors' conclusion |
|---|---|---|---|---|---|
| **Ros Aziah (2021)**<br>**Digital Assisted oral & cranio-maxillofacial surgery**<br>**Ministry of Health Malaysia: Malaysian Health Technology Assessment Section** | To assess the effectiveness, **cost-implication**, safety and organisational issues related to the application of digital assisted technology for oral and cranio-maxillofacial surgery. | 1946 - 12 June 2021<br>Ovid MEDLINE, INAHTA, PubMed, US FDA, Google<br>P: oral & CMF patients<br>I: digital or computer-assisted surgery<br>C: conventional surgery<br>O: effectiveness, economics, safety, organisational and social issues<br>EXCLUDED: case series, case reports, narrative reviews, non-English language | 12 studies included:<br>2 CEA (Xia 2006; Bengtsson 2019)<br>1 CBA (Resnick 2019) | Two studies show costs savings (Xia 2006, Resnick 2019) and one showed no significant difference (Bengtsson 2019). Resnick and Xia were used to populate a cost comparison analysis (Excel). Digital assisted cranio-OMFS has lower costs in terms of human resource and material costs compared with conventional surgery. The estimated total cost of one conventional and digital assisted cranio-OMFS was approximately RM 8,052.00 and RM 6,420.00 respectively, reflective of 20% savings from conventional surgery. The savings were directly related to the time spent for each surgery and reduction in the amount of materials used to construct the model. | There was fair to good level of evidence retrieved to suggest that digital/ computer-assisted oral & CMF surgery has better soft tissue prediction and CMF skeletal harmony for both maxillary and mandibular site. As for the navigation, the accuracy and ZMC eminence were better compared to surgery without navigation. However, the asymmetry index and orbital volume ZMC width was comparable between both groups. For safety, there was similar adverse event rate in both groups. In terms of organisational issues, digital/ computer-assisted oral & CMF surgery has shorter operative/surgery time, reconstructive, ischaemic time and length of stay. **Digital/ computer-assisted oral & CMF surgery was also found to have lower cost compared to conventional method with a cost saving of approximately RM 1,632.00/surgery. However, a minimum number of 15 surgeries per month in a hospital is suggested to achieve a minimum savings.** |

| Study ID<br>Title<br>Agency | Research Question | Search Dates<br>Databases<br>Inclusion/ exclusion criteria | Included studies | Results | Authors' conclusion |
|---|---|---|---|---|---|
| **Vinck (2018)**<br><br>**Responsible use of high-risk medical devices: the example of 3D printed medical devices**<br><br>**KCE (Belgium)** | 1. What is the effectiveness and safety for the patient of 3D printing technology for medical indications?<br>**2. What is the available evidence on cost-effectiveness of 3D printing technology for medical indications?**<br>3. What are the legal issues related to 3D printing/3D printed medical devices?<br>*Discussion of reimbursement options for 3D printed devices.* | January 2017<br>Medline (Ovid), CRD, grey literature<br><br>Eligibility not reported in detail | 8 economic evaluations:<br><br>4 CMF surgery (Rogers-Vizena 2016; Resnick, 2016; Baj 2016; Prisman 2014)<br><br>1 dental (Romero, 2015) | Three studies on maxillofacial and dental surgery indicate on the basis of prospective and retrospective study that 3D models for operation planning and 3D implants shorten the (pre)operative time (and length of stay in Baj et al.) and consequently are less expensive than the standard techniques. However, 2 other studies, also on maxillofacial surgery, report no significant reduction in the operating time, and also no difference on costs, with sometimes even an increase.<br><br>In 2 studies on back and cranial surgery the costs also increased, without a significant difference in (pre)operation time or length of hospital stay, or even a significant drop in operating time or length of hospital stay.<br><br>In general there are presently no convincing data demonstrating that the use of 3D printing is more cost-effective or even cost-saving than the current treatment. This is, given the observations in the medical section, not surprising.<br><br>Some assert that 3D printing is especially time-saving in highly labour-intensive, specialised surgery. Yet the results from 4 studies of highly labour-intensive maxillofacial surgery are also not convincing.<br><br>In no study are the results expressed in QALY, which hinders assessment of the cost-effectiveness of 3D printing. | It is likely that the cost of the 3D printing technology will decrease over time, as the technology improves (e.g. the software) and the material costs might decline. The technology would then become increasingly affordable and available. But this still needs to be confirmed by quantitative, prospective studies with larger sample sizes and longer follow-up times.<br><br>In conclusion, based on the results of this review, the frequently reported claim that 3D printed applications will reduce surgical time and cost and improve patient safety cannot be backed so far.<br><br>Reimbursement:<br><br>If an alternative exists, this should be used to establish the price and as a comparator for demonstrating the added value. If the patient's safety is adequately guaranteed, we recommend reimbursing the (3D-printed) medical device at the level of the alternative. In this way the producer is given an incentive to submit a reimbursement file and make evaluation possible if it wishes to receive a surcharge.<br><br>We recommend reimbursing a higher price for a (3D-printed) medical device only if the added value with regard to existing alternatives has, insofar as possible, been demonstrated.<br><br>If no (suitable) alternative exists, a unique solution for the patient is involved and reimbursement should be assessed case by case (individually or by indication).<br><br>For the preoperative phase too we recommend that reimbursement only be considered if sufficient added value can be demonstrated. |

Abbreviations: CBA, cost-benefit analysis; CEA, cost-effectiveness analysis; CMF, craniomaxillofacial; CRD, Centre for Reviews and Dissemination; FDA, Food and Drug Administration; INAHTA, International Network of Agencies for Health Technology Assessment; KCE, Belgian Health Care Knowledge Centre; OMFS, Oral and Maxillofacial Surgery; QALY, quality-adjusted life year; RM, Malaysian Ringgit; ZMC, zygomaticomaxillary complex.

## C.4 Studies from stakeholder submissions

Table App. C.10 lists 52 studies reporting economic or cost outcomes sourced from stakeholder submissions for Stage 2 (k=24), stakeholder submissions for Stage 1 (k=9), studies included in the Stage 1 PLR (k=9) and primary studies identified from the HTAs and 2 systematic reviews identified in the literature search for the Stage 2 PLR (k=11). Eight of these studies were eligible for inclusion in the Stage 2 PLR (bold and highlighted text). Five of these were non-randomised comparative studies that were not selected for presentation (not taken further); for low-level evidence, the Stage 2 PLR focused on studies using commercially supplied patient-matched surgical guides and/or biomodels with at least 10 patients per group.

Additional studies provided by stakeholders in feedback to the Stage 2 PLR draft report were also screened against the inclusion criteria and none were eligible for inclusion.

**Table App. C.10 Studies from Stage 1 PLR, stakeholder submissions for Stage 1 and Stage 2, plus primary studies identified from HTAs and SRs**

| Study ID | Studies from stakeholder submissions for Stage 2 | Studies from stakeholder submissions for Stage 1 | Studies included in Stage 1 PLR | Primary studies from HTAs and SRs | Source ID | Included in Stage 2 PLR |
|---|---|---|---|---|---|---|
| **Abdelhay et al. (2021)** | ✓ | | | ✓ | Ros Aziah (2021) – HTA | |
| **Amorfini et al. (2017)** | ✓ | | | | | |
| **Arisan et al. (2010)** | ✓ | | | | | |
| **Arisan et al. (2013)** | ✓ | | | | | |
| **Arnal-Burró et al. (2017)** | | ✓ | | | | |
| **Baj et al. (2016)** | | | | ✓ | Vinck (2018) – HTA | |
| **Ballard et al. (2020)** | | ✓ | | | | |
| **Bengtsson et al. (2019)** | ✓ | ✓ | | | | |
| **Bolzoni et al. (2020)** | | | | ✓ | **Xiao (2025) – SR** | ✓ |
| **Carvalho et al. (2022)** | | ✓ | | | | |
| **De Maesschalck et al. (2017)** | | | ✓ | | | |

| Study ID | Studies from stakeholder submissions for Stage 2 | Studies from stakeholder submissions for Stage 1 | Studies included in Stage 1 PLR | Primary studies from HTAs and SRs | Source ID | Included in Stage 2 PLR |
|---|---|---|---|---|---|---|
| **D'Urso et al. (1998)** | | ✓ | | | | |
| **Frizzera et al. (2021)** | ✓ | | | | | |
| **Gargallo-Albiol et al. (2020)** | ✓ | | | | | |
| **Gleissner et al. (2022)** | ✓ | | | | | |
| **Graf et al. (2021)** | | ✓ | | | | |
| **Johal et al. (2022)** | | | ✓ | | | |
| **Legocki et al. (2017)** | | | | ✓ | Serrano (2020) – SR | |
| **Li et al. (2018)** | | | | ✓ | Serrano (2020) – SR | |
| **Mahardawi et al. (2025)** | ✓ | | | | | |
| **Mazzola et al. (2020)** | | | ✓ | | | ✓ |
| **McAllister et al. (2018)** | | ✓ | | | | |
| **Modabber et al. (2012)** | ✓ | | | | | |
| **Murtezani et al. (2022)** | ✓ | | | | | |
| **Pérez-Mañanes et al. (2016)** | | ✓ | | | | |
| **Prisman et al. (2014)** | | | | ✓ | **Vinck (2018) – HTA** | ✓ **[NTF]** |
| **Ravidà et al. (2018)** | ✓ | | | | | ✓ |
| **Resnick et al. (2016)** | | ✓ | ✓ | ✓ | **Vinck (2018) – HTA** | ✓ **[NTF]** |
| **Rogers-Vizena et al. (2017)** | | | | ✓ | **Vinck (2018) – HTA** | ✓ **[NTF]** |
| **Romandini et al. (2023)** | ✓ | | | | | |
| **Romero et al. (2015)** | | | | ✓ | Vinck (2018) – HTA | |

| Study ID | Studies from stakeholder submissions for Stage 2 | Studies from stakeholder submissions for Stage 1 | Studies included in Stage 1 PLR | Primary studies from HTAs and SRs | Source ID | Included in Stage 2 PLR |
|---|---|---|---|---|---|---|
| Rommel et al. (2017) | | | ✓ | | | |
| Seikaly et al. (2019) | | | | ✓ | Xiao (2025) – SR | ✓ [NTF] |
| Seruya et al. (2013) | | | ✓ | | | |
| Si et al. (2023) | ✓ | | | | | |
| Silva et al. (2020) | | | ✓ | | | |
| Smitkarn et al. (2019) | ✓ | | | | | |
| Succo et al. (2015) | ✓ | | | | | |
| Tan et al. (2018) | ✓ | | | | | |
| Varga et al. (2020) | ✓ | | | | | |
| Vercruyssen et al. (2015) | ✓ | | | | | |
| Wang, Fan et al. (2016) | | | ✓ | | | |
| Wang, Zhang et al. (2016) | | | ✓ | | | |
| Weitz et al. (2016) | | | ✓ | | | |
| Wilde et al. (2015) | ✓ | | | | | |
| Xia et al. (2006) | | | | ✓ | Ros Aziah (2021) – HTA | |
| Xiang et al. (2023) | ✓ | | | | | |
| Younes et al. (2019) | ✓ | | | | | |
| Zhang et al. (2020) | ✓ | | | | | |
| Zhang et al. (2015) | | | ✓ | | | |
| Zhang et al. (2016) | | | ✓ | | | |

| Study ID | Studies from stakeholder submissions for Stage 2 | Studies from stakeholder submissions for Stage 1 | Studies included in Stage 1 PLR | Primary studies from HTAs and SRs | Source ID | Included in Stage 2 PLR |
|---|---|---|---|---|---|---|
| **Zweifel et al. (2015)** | ✓ | | ✓ | | | ✓ **[NTF]** |

Abbreviations: HTA, health technology assessment; NTF, not taken further (i.e. non-randomised comparative study eligible for inclusion but not presented in the Stage 2 PLR); PLR, post-listing review; SR, systematic review.
Note: studies eligible for inclusion in the Stage 2 PLR shown in bold and highlighted text.

**Table App. C.11 Citations for studies from Stage 1 PLR, stakeholder submissions for Stage 1 and Stage 2, plus primary studies identified from HTAs and SRs (above table)**

| Citation |
|---|
| **Abdelhay N, Prasad S, and Gibson MP (2021) 'Failure rates associated with guided versus non-guided dental implant placement: a systematic review and meta-analysis', BDJ Open, 7(1): 31, doi:https://doi.org/10.1038/s41405-021-00086-1.** |
| **Amorfini L, Migliorati M, Drago S, and Silvestrini-Biavati A (2017) 'Immediately Loaded Implants in Rehabilitation of the Maxilla: A Two-Year Randomized Clinical Trial of Guided Surgery versus Standard Procedure', Clin Implant Dent Relat Res, 19(2): 280-295, doi:https://doi.org/10.1111/cid.12459.** |
| **Arisan V, Karabuda CZ, Mumcu E, and Özdemir T (2013) 'Implant positioning errors in freehand and computer-aided placement methods: a single-blind clinical comparative study', Int J Oral Maxillofac Implants, 28(1): 190-204, doi:https://doi.org/10.11607/jomi.2691.** |
| **Arisan V, Karabuda CZ, and Ozdemir T (2010) 'Implant surgery using bone- and mucosa-supported stereolithographic guides in totally edentulous jaws: surgical and post-operative outcomes of computer-aided vs. standard techniques', Clin Oral Implants Res, 21(9): 980-988, doi:https://doi.org/10.1111/j.1600-0501.2010.01957.x.** |
| **Arnal-Burró J, Pérez-Mañanes R, Gallo-Del-Valle E, Igualada-Blazquez C, Cuervas-Mons M, and Vaquero-Martín J (2017) 'Three dimensional-printed patient-specific cutting guides for femoral varization osteotomy: Do it yourself', Knee, 24(6): 1359-1368, doi:https://doi.org/10.1016/j.knee.2017.04.016.** |
| **Ballard DH, Mills P, Duszak R, Jr., Weisman JA, Rybicki FJ, and Woodard PK (2020) 'Medical 3D Printing Cost-Savings in Orthopedic and Maxillofacial Surgery: Cost Analysis of Operating Room Time Saved with 3D Printed Anatomic Models and Surgical Guides', Acad Radiol, 27(8): 1103-1113, doi:https://doi.org/10.1016/j.acra.2019.08.011.** |
| **Bengtsson M, Wall G, Becktor JP, and Rasmusson L (2019) 'A comparison of cost-effectiveness of computer-assisted 2-and 3-dimensional planning techniques in orthognathic surgery', Br J Oral Maxillofac Surg, 57(4): 352-358, doi:https://doi.org/10.1016/j.bjoms.2019.03.012.** |
| **Bolzoni AR, Segna E, Beltramini GA, Sweed AH, Giannì AB, and Baj A (2020) 'Computer-Aided Design and Computer-Aided Manufacturing Versus Conventional Free Fibula Flap Reconstruction in Benign Mandibular Lesions: An Italian Cost Analysis', J Oral Maxillofac Surg, 78(6): 1035.e1031-1035.e1036, doi:https://doi.org/10.1016/j.joms.2019.03.003.** |
| **Carvalho FSR, de Oliveira Barbosa DI, Torquato IF, Britto de Souza AM, Dalcico R, Chaves FN, and Costa FWG (2022) 'The Use of Surgical Splints in Orthognathic Surgery: A Bibliometric Study', Indian J Plast Surg, 55(1): 26-30, doi:https://doi.org/10.1055/s-0041-1734570.** |
| **De Maesschalck T, Courvoisier DS, and Scolozzi P (2017) 'Computer-assisted versus traditional freehand technique in fibular free flap mandibular reconstruction: a morphological comparative study', Eur Arch Otorhinolaryngol, 274(1): 517-526, doi:https://doi.org/10.1007/s00405-016-4246-4.** |

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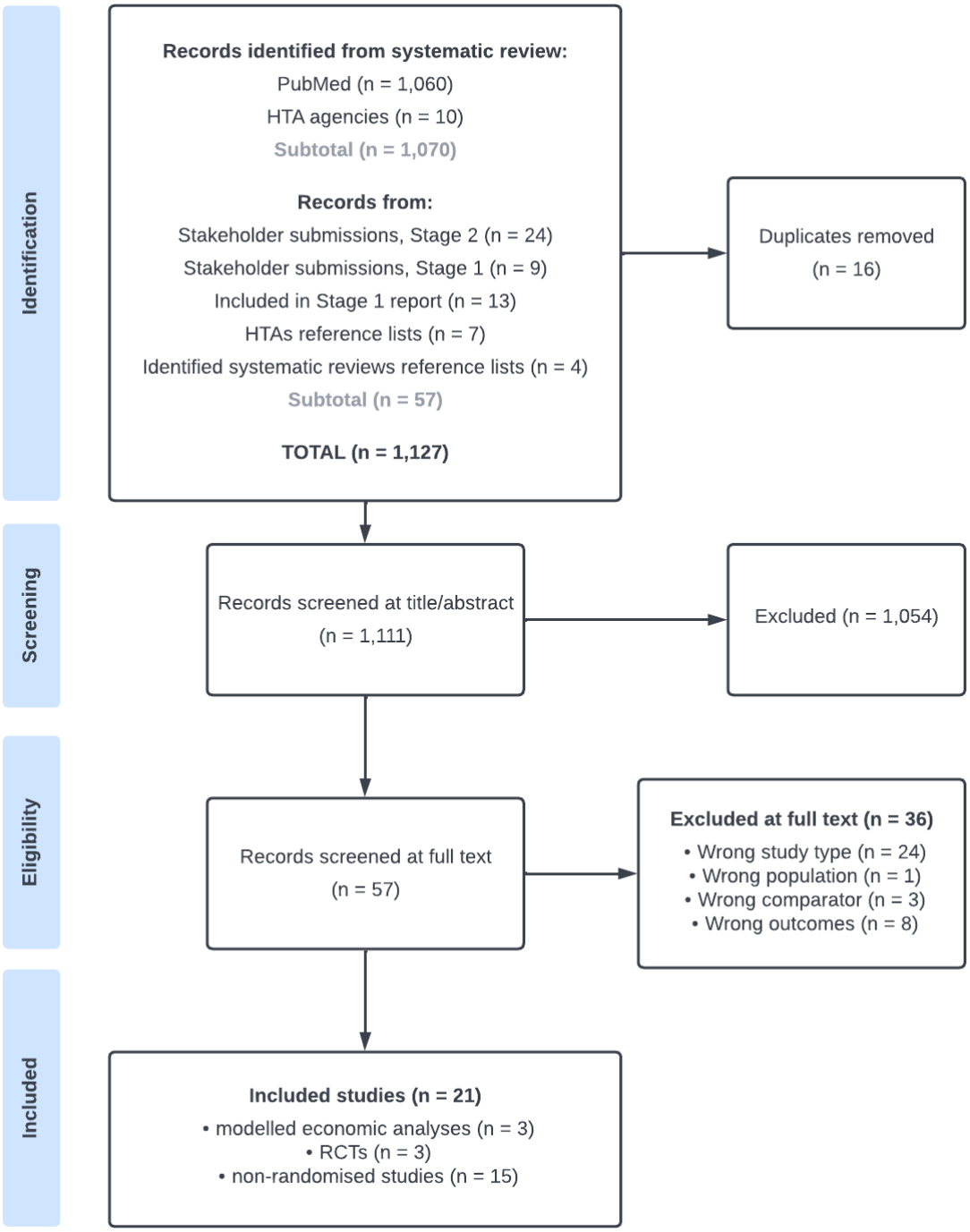
Abbreviations: PLR, post-listing review.

# C.5 PRISMA

**Figure App. C.1 PRISMA diagram for literature review – all sources**




Abbreviations: HTA, health technology assessment; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

# C.6 Included studies from all sources

All studies included in the Stage 2 PLR, from all sources, are listed in Table App. C.12. This includes 2 HTAs, 3 modelled economic analyses, 3 RCTs, and 15 non-randomised comparative studies (of these 15, 9 were not taken further in the current report as, for low-level evidence, this Stage 2 PLR focused on studies using

commercially supplied patient-matched surgical guides and/or biomodels with at least 10 patients per group). Two systematic reviews were also selected for sourcing primary studies.

**Table App. C.12 All studies eligible for inclusion in the Stage 2 PLR, and systematic reviews used to identify primary studies**

| Study ID | Title | Source |
|---|---|---|
| HTAs | | |
| **Vinck et al. (2018)** | Responsible use of high-risk medical devices: the example of 3D printed medical devices. | HTA search |
| **Ros Aziah et al. (2021)** | Digital assisted oral & cranio-maxillofacial surgery. | HTA search |
| Modelled economic analyses | | |
| **Fatima et al. (2019)** | Cost-Effectiveness Analysis of Virtual Surgical Planning in Mandibular Reconstruction | PubMed search |
| **Gardiner et al. (2024)** | Long-term outcomes in virtual surgical planning for mandibular reconstruction: A cost-effectiveness analysis | PubMed search |
| **Kurlander et al. (2023)** | The Cost Utility of Virtual Surgical Planning and Computer-Assisted Design/Computer-Assisted Manufacturing in Mandible Reconstruction Using the Free Fibula Osteocutaneous Flap | PubMed search |
| RCTs | | |
| **Omara et al. (2021)** | Accuracy of midface advancement using patient-specific surgical guides and pre-bent plates versus conventional interocclusal wafers and conventional plate fixation in quadrangular Le Forte II osteotomy. A randomised controlled trial | PubMed search |
| **Schneider et al. (2019a)** | Customized virtual surgical planning in bimaxillary orthognathic surgery: a prospective randomized trial | PubMed search |
| **Schneider et al. (2019b)** | A Randomized Controlled Clinical Trial Comparing Conventional and Computer-Assisted Implant Planning and Placement in Partially Edentulous Patients. Part 3: Time and Cost Analyses | PubMed search |
| Non-randomised comparative studies | | |
| **Bolzoni et al. (2020)** | Computer-Aided Design and Computer-Aided Manufacturing Versus Conventional Free Fibula Flap Reconstruction in Benign Mandibular Lesions: An Italian Cost Analysis | Identified in Xiao (2025) |
| **Lignon et al. (2021)** | Multicentre evaluation of the interest in planned surgery for mandibular reconstruction with fibula free flap: a retrospective cohort study | PubMed search |
| **Mazzola et al. (2020)** | Time and cost-analysis of virtual surgical planning for head and neck reconstruction: A matched pair analysis | PubMed search |
| **Ravida et al. 2018** | Clinical outcomes and cost effectiveness of computer-guided versus conventional implant-retained hybrid prostheses: A long-term retrospective analysis of treatment protocols | Stage 2 submissions |
| **Rodríguez-Arias et al. (2022)** | Clinical Outcomes and Cost Analysis of Fibula Free Flaps: A Retrospective Comparison of CAD/CAM versus Conventional Technique | PubMed search |
| **Speed et al. (2024)** | Virtual surgical planning for mandibular reconstruction in an abbreviated admission pathway | PubMed search |

| Study ID | Title | Source |
|---|---|---|
| Non-randomised comparative studies not taken further | | |
| **Garza-Cisneros et al. (2024)** | Cost-effective Solution for Maxillofacial Reconstruction Surgery with Virtual Surgical Planning and 3D Printed Cutting Guides Reduces Operative Time | PubMed search |
| **King et al. (2018)** | On-Site 3-Dimensional Printing and Preoperative Adaptation Decrease Operative Time for Mandibular Fracture Repair | PubMed search |
| **Park et al. (2019)** | Comparison of time and cost between conventional surgical planning and virtual surgical planning in orthognathic surgery in Korea | PubMed search |
| **Prisman et al. 2014** | Value of preoperative mandibular plating in reconstruction of the mandible | Identified in Vinck (2018) |
| **Resnick et al. (2016)** | Is There a Difference in Cost Between Standard and Virtual Surgical Planning for Orthognathic Surgery? | PubMed search |
| **Rogers-Vizena et al. (2017)** | Cost-Benefit Analysis of Three-Dimensional Craniofacial Models for Midfacial Distraction: A Pilot Study | PubMed search |
| **Seikaly et al. (2019)** | The Alberta Reconstructive Technique: An Occlusion-Driven and Digitally Based Jaw Reconstruction | Identified in Xiao (2025) |
| **Steinhuber et al. (2018)** | Is Virtual Surgical Planning in Orthognathic Surgery Faster Than Conventional Planning? A Time and Workflow Analysis of an Office-Based Workflow for Single- and Double-Jaw Surgery | PubMed search |
| **Zweifel 2015** | Are virtual planning and guided surgery for head and neck reconstruction economically viable? | Stage 2 submissions |
| SRs for sourcing primary studies | | |
| **Xiao et al. (2024)** | Cost Outcomes of Virtual Surgical Planning in Head and Neck Reconstruction: A Systematic Review | PubMed search |
| **Serrano et al. (2020)** | Evaluation of 3D printing costs in surgery: a systematic review | Grey literature search |

Abbreviations: HTA, health technology assessment; PLR, post-listing review; RCT, randomised controlled trial; SR, systematic review.
See Reference list for full citations.