3D-printed surgical guides

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Abstract: Conventional bone replacement surgeries have always been associated with different critical drawbacks. Deviation of the implant from its original position is one of the most important problems associated with surgery. The emergence of computer-aided design/computer-aided manufacturing technology opened a new opportunity for the solution of this problem by the use of patient-specific surgical guides. These 3D-printed surgical guides provide a specific cut and therefore reduces the drawbacks associated with surgical techniques including the fixation difficulties. In this review, 3D-printed guides for knee arthroplasty, pedicle screw placement and mandibular reconstruction will be discussed covering both the progress and the drawbacks.

Keywords: 3D printing; surgical guides; total knee arthroplasty (TKA); spine, mandible

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Introduction

In 2008, a survey by National Health Interview Survey stated that approximately half of American adults have a disabling musculoskeletal condition (1). In most bone or joint cases, implants are used to restore the normal functionality of the affected part. Failure is one of the most critical problems associated with the use of orthopedic implants. A revision surgery is required in such cases, which itself is generally more complicated and time consuming than the primary surgery. Moreover, numerous risk factors accompany such revision surgeries include increased risk of infection, fractures and or perforation of the bone during removal of old prosthesis. To avoid revision surgeries, better fixation processes are needed. Moving from standard off-the-shelf implants to more patient-specific implants is a means of addressing this need. Such designs would provide accuracy and stabilization.

In general, fixation procedure consists of two main steps: (I) drilling the screw trajectory; (I) fixing the screw in the drilled position. Unfortunately, this procedure is usually linked with a number of drawbacks including (2,3):

(I) Deviation in the drilling trajectory of the screw hole: in which a deviation from the originally intended screw trajectory and that being drilled by the surgeon, free-hand, with limited sightlines through the incision;
(II) Screw fixation deviation: in which the use of implant curvature to fix the screw would cause a deviation in the screw fixation from the intended place due to the nature of the implant itself;
(III) Implanted screw deviation: in which the implanted screw would deviate from its planned positioning, leading to damage to the soft tissues.

Such deviations could affect the accuracy of fixation in a number of ways. For example, when screw fixation is directed towards low quality bone, or when insertion of one screw would intersect and block the insertion of another

Table 1 Drawbacks associated with current implant fixation techniques.

Technique	Definition	Disadvantages
Navigation technology	Infrared sensors for accurate alignment	Expensive and time consuming
Attached guide device is attached to a bone plate	Guide device is attached to a bone plate (4)	Limited use
Standard-size drill guiding cylinders	Standard-sized drill guiding cylinders are fixed in the implant screw holes allowing more control over the screwing procedure (3)	Production process and costs are not practical except for limited types of implants
Patient-specific bone guides	CAD software/3D printed (3)	Not practical in complicated revision surgeries

CAD, computer-assisted design.

screw (2,3).

For these reasons, research has been pursued during the last few years to overcome the fixation problem. Navigation technology, guide device attached to a bone plate, standard-size drill guiding cylinders and patient-specific bone guides are among the techniques that were developed towards this aim. The drawbacks associated with each of these techniques are summarized in (*Table 1*). Due to such difficulties an accurate fixation is not always obtained, especially in complicated revision surgeries. The state-of-the-art for optimized implant fixation is the 3D-printed, patient-specific bone guide technology, which will be reviewed thoroughly below for three different applications: knee arthroplasty, pedicle screw replacement and mandible reconstruction.

3D-printed guides for total knee arthroplasty (TKA)

TKA is a common treatment option mostly for patients with osteoarthritis. It is a surgery in which an artificial joint replaces a damaged knee joint. This treatment option is preferred in cases where the other treatment options have failed. It relieves the pain due to osteoarthritis and help patients to become physically more active. In 2017, it is estimated that 700,000 people underwent this procedure in the US (5).

There are several methods used to perform total knee replacements (TKR). These methods include the conventional surgical method, computer-assisted surgery (CAS), and surgery using patient-specific guides. Although the patients benefit greatly from these surgery (in terms of pain relief and ease of movement), there are still problems to be solved including a high frequency of blood loss and fat embolism. For those reasons, a need for more reliable tools were investigated.

CAS has been developed to facilitate surgeon's hand motions in limited operating spaces. These devices offer advantages such as improved access, magnified vision, and stabilized instrument implementation (6). It was introduced in 1990s to achieve a neutral mechanical alignment in the frontal plane which is proven to be associated with prolonged implant survival (7). Since then, CAS has gained a large acceptance even to the point of becoming the gold standard technique for lower limb alignment due to the proven efficiency (7). Still the cost, increased operating room time, learning curve, and complications constitute the reasons for the hold-back on the widespread use of CAS. The advantages and disadvantages associated with CAS technique is summarized in (*Table 2*).

To overcome the previously mentioned limitations of fixation procedures, patient-specific surgical guides were developed. The emergence of 3D printing technology played a critical role in the development of patient-specific surgical guides (*Figure 1*) starting from the beginning of 1990s (9-13).

There are many commercially available surgical guides systems in use (*Table 3*). These systems require either preoperative MRI or CT scans. With the help of these scans, the mechanical and anatomical axes across the knee are defined. Using the data acquired from the scans, a 3D model of the femur and tibia are generated. The software also enables the surgeon to make plans about the size and positioning of the components. This plan is taken into consideration while the tibial and femoral virtual templates are used for manufacturing the cutting jigs for bone preparation. According to the anatomy of the patient, the location landmarks are created on the contact surface of the jigs, making sure that the jigs match perfectly with the

Table 2 The advantages and disadvantages of computer-assisted surgery

Advantages
Uses extramedullary instrumentation
Blood loss and the incidence of embolic fat are decreased (8,9)
The calculation of the soft tissue tension provides the surgeon with the ability to achieve a well-balanced knee
Disadvantages
Requires the surgeon to identify the anatomical landmarks intraoperatively
The OR time increases
Additional instrumentation and issues around the insertion of tracking pins
Cost
Not enough evidence to prove long-term benefits
Unavoidable learning curve (7)

OR, operating room.

Figure 1 ConforMIS' iTotal joint replacement kit includes a set of various surgical tools required for the knee replacement surgery mainly. Most of them are printed using 3D SLS printer. Source: https://3dprint.com/78272/conformis-3d-printed-knee/. SLS, selective laser sintering.

surface of several locations of the bone. These jigs are then manufactured using rapid prototyping and sterilized for the operating room (14).

Patient-specific surgical guides have been used either for fixing pins in certain places allowing the usage of conventional guides or as a totally new guide with a specific cut for the surgical saw (14). The use of these guides provides some advantages over the conventional techniques which are discussed below and summarized in (*Table 4*).

Alignment improvement

The use of surgical guides has been shown to increase the alignment compared to the other techniques. A less mechanical axis misalignment in the favor of patient specific surgical guides were shown in various studies in comparison

Table 3 Some of the characteristics of several different surgical guide systems

Trade name	Manufacturer	Type of guide	Imaging type
Signature-Vanguard	Biomet	Pinning	MRI
Visionaire	Smith & Nephew	Cutting	MRI and full-length AP X-ray
Trumatch	DePuy	Cutting	CT
PSI Knee	Zimmer	Pinning	MRI
Prophecy	Wright Medical	Pinning	CT or MRI
ConforMIS	ConforMIS	–	CT
My Knee	Medacta	Cutting	CT or MRI
Otis Knee	OtisMed Corporation	Cutting	MRI

AP, anterior-posterior.

Table 4 Advantages of the use of patient-specific surgical guides in knee arthroplasty

Advantages
Alignment improvement
Reduction of operating time and hospital stay
Less of learning curve
Technique simplicity
Reduced blood loss and risk of fat embolism

to conventional surgery and CAS (9,13,15,16).

However, there are contradictory reports in the literature showing that the use of patient specific surgical guides does not improve accuracy in knee arthroplasty (17,18). Moreover, these studies also report that the use of surgical guides are impractical since they require modifications or was abandoned in half of the patients in the study groups.

These contradicting reports reveal that more detailed systematic investigations are required to fully demonstrate the contribution of patient-specific surgical guides to knee arthroplasty.

Reduction of operating time and hospital stay

One of the other aims of the surgical guides that had been brought into question is the reduction of operating time. Different reports have shown a clear reduction in the operating time and hospital stay of patient specific instrumentation (PSI) over conventional and CAS (15,19). However, Hamilton *et al.* acquired different results. They found that the surgical guides did not reduce the operating time. In fact, the conventional method group's operating time was over 4 minutes less compared to the group in which guides were used during surgery (20).

Less of learning curve

Less of a learning curve has also been put forward as a superior aspect of surgical guides over CAS and the conventional method. Chinnappa *et al.* conducted a study that was participated by 86 patients undergoing the TKA using patient-specific guides with the same surgeon. According to the author there was a significant difference in the learning curve in favor of PSI with no significant difference postoperative TKA alignment between different groups (21). However, in a different study, the authors noted that the patient-specific positioning guides should not be seen as a tool that can reliably provide the less experienced knee surgeons with optimal alignment results, considering the mixed results related to alignment with this method in the literature, and given the number of precision steps required to achieve accurate outcomes (22).

Technique simplicity

It has been hypothesized that using surgical guides are simpler to use than other techniques and that it requires less inventory in the operating room compared to other techniques. Renson *et al.* found that, with the use of PSI, there was a significant reduction in the number of trays used compared to the conventional method (55%) (15). Several other teams also acquired data supporting this result (23,24). Renson *et al.* also noted that the reduction in the number of trays required during surgery is cost effective not only as a result of reduced inventory but also due to decreased costs associated with handling, sterilization and stock keeping (15).

There are contradictory research results regarding the use of patient-specific guides in knee arthroplasty. Some reports claim that these guides improve alignment, reduce blood loss and operative time while simplifying procedures, especially in cases that require a surgeon to have significant experience. Patient-specific guides are claimed to eliminate the learning curve associated with the conventional method and computer navigation system, making it more accessible to less experienced knee surgeons. However, it is obvious that the literature also includes many studies that disagree with the claimed benefits of using surgical guides in TKA. Therefore, more research is warranted to prove their efficacy.

3D-printed surgical guides for the spine

Pedicle screw placement is one of the most common procedures in spinal surgery. This procedure takes place for spinal fusion in patients with conditions that include scoliosis, hyperkyphosis, fractures and tumors. Despite its common use, pedicle screw placement remains questionable in terms of safety while using the conventional techniques. There have been studies that looked at the rates of pedicle violation rates and complication rates due to screw misplacement. While they found that pedicle violation rate ranges from 3% to 54.7% (25-27) they found the complication rate as 0–7% (25).

Screw placement can not only cause nerve damage, but it can also cause damage to proximal blood vessels and nearby organs. Additionally, they can cause weakening in reduction and fixation, and may make it necessary to undergo revision surgery (25,26).

There are different approaches to achieve accuracy in screw placement. These approaches include free-hand technique, image-guided (navigation) techniques which takes advantage of CT and fluoroscopy, drill template techniques (surgical guides) and robot-assisted technology.

A recently developed technique is robot-assisted technology. While some studies found that there is an increased accuracy of pedicle screw placement with the use of robot-assisted technology compared to free-hand technique, computer-assisted pedicle screw navigation and drill guide template technique (28) a recent review reported that there isn't much difference in terms of overall accuracy compared to free-hand technique.

There are several disadvantages associated with this technique. Fan *et al.* reported that they had difficulties with this technique regarding matching the preoperative CT images and intraoperative fluoroscopy images and this caused the surgeon to switch to free-hand technique in eight cases during their study (28).

It has also been reported that, even with a good image registration, there is still a risk of the cannula sliding off an angled bone surface and resulting in lateral screw inaccuracies. Another disadvantage is the costs associated with the robot's supplies and maintenance (28). The same review by Shin *et al.* also added that operating time was longer with the use of robot-assisted technology compared to free-hand technique while there was less radiation exposure (29).

While it has been shown that computer-assisted pedicle screw navigation reduces the incidence of misplaced screws, it has also been pointed out that there are several disadvantages regarding the use of image-guided techniques. The main reasons for the no utilization are that it is:

(I) Fault-prone and time consuming, chiefly during the long learning curve (30);
(II) Additionally, this technique also has high initial and continuing costs;
(III) One of the reasons that has been put forward also was the lack of trained support personnel (31).

In fact, a recent worldwide survey showed that, although the use of image-guided technique is mostly accepted to be beneficial, only 11% of surgeons reported the routine use of this technique (32).

In comparison to the other techniques like free-hand technique, image-guided (navigation) techniques, 3D-printed surgical guide techniques showed a high level of accuracy (*Figure 2*).

In different studies for thoracic or cervicothoracic pathologies, pedicle screws for different positions like [cervical (34,35), thoracic (31,36,37) and lumbar (31)] showed a significant improvement in the mean deviation between the fixed screw and the preplanned trajectory. At the same time a significant improvement in neurovascular complications have been reported (*Table 5*).

More examples of increased accuracy compared to free-hand technique can be found in the literature (39,41). It has been demonstrated in multiple studies that patient-specific drilling guide templates have been useful for pedicle screw insertion.

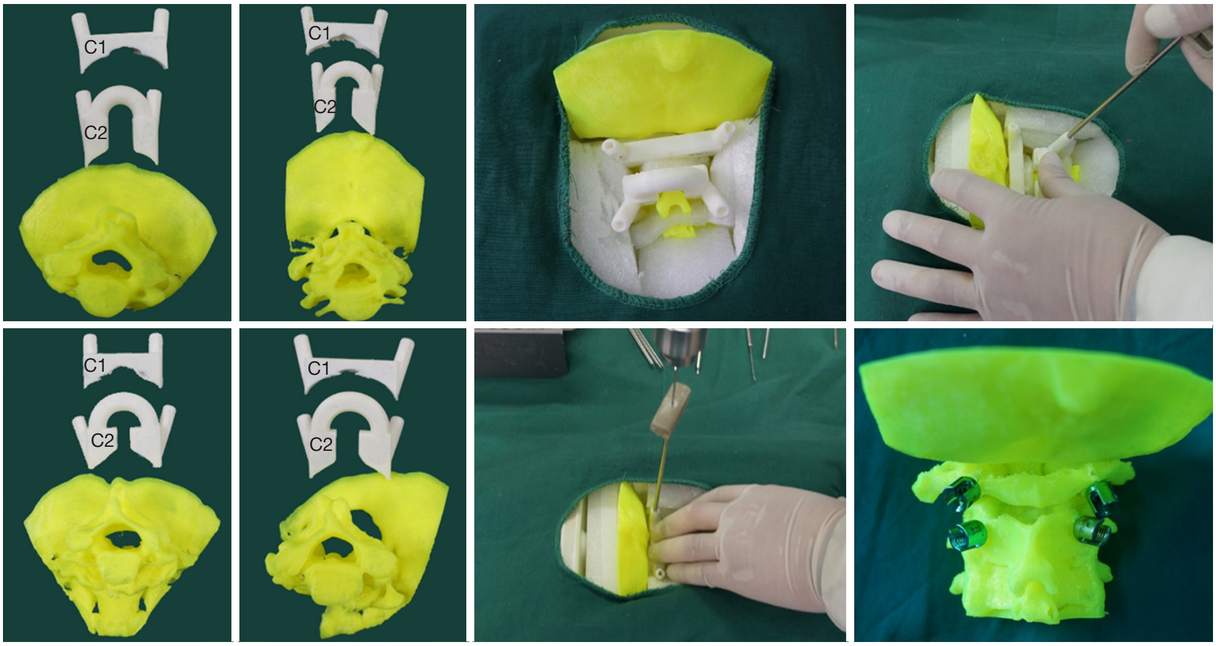

Figure 2 On the left side, different 3D-printed cervical spine guides for pedicle screw placement surgeries. On the right side, steps for fixation pedicle screws using 3D printing guide in the upper cervical spine. Source: Guo *et al.* (33).

Table 5 Studies in the literature for different 3D pedicle guide surgeries

Screw type	#patients	#screws	The mean deviation from the preplanned trajectory	Ref.
Midcervical (C)	20	80	0.29±0.31 mm	(34)
Thoracic (T)	10	58	0.87±0.34 mm	(38)
Cervical (C2)	–	19	–	(35)
Thoracic (T2 to T12)	16	168	0	(36)
Cervical (C2 to C7)	25	88	71 screws had no deviation and 14 screws had deviation less than 2 mm, and 1 screw had deviation between 2 to 4 mm while there was no misplacement	(37)
56 thoracic (T) and 20 lumbar (L)	4	76	Only 2 screws (2.6%) were misplaced intraoperatively	(31)
Thoracic (T)	10	48	Only 3 screws (6.2%) were misplaced intraoperatively	(39)
Lumbar (L1–L5)	6	60	91.7% accuracy	(40)
Thoracic (T)	20	396	96.7% accuracy	(41)

The simplicity of the handling

While the use of these templates resulted in lower risk of perforation, it has also been portrayed to be easier to use due to the simplicity of the handling. The drill guides can be fitted on the posterior surface lamina manually (28,36-38).

Surgeon's safety consideration

Another advantage has been put forward regarding the radiation exposure of the members of the surgical team. In comparison with the other methods, it was suggested that there was less use of radiation compared to image-guided

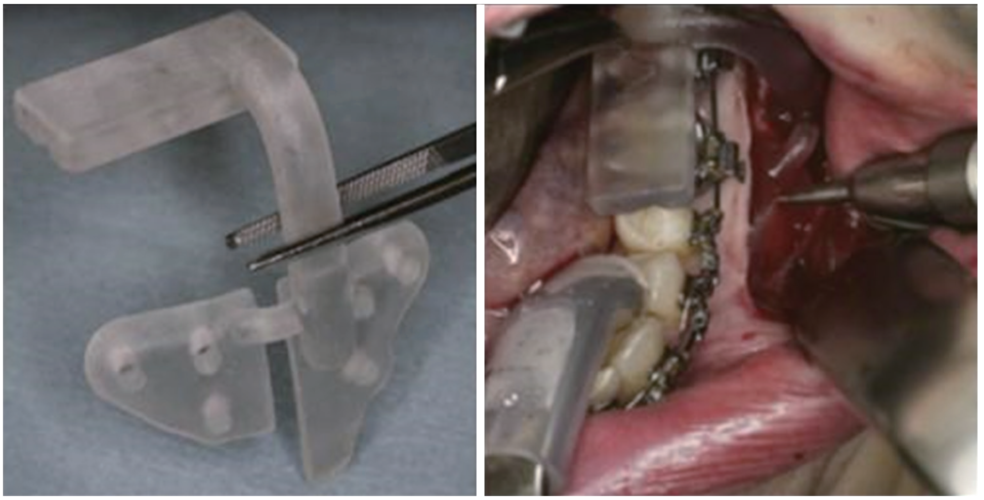

Figure 3 3D surgical guides for mandible surgery. Source: Suojanen *et al.* (22).

technique (28,36-38).

Operative time

It was also claimed that the use of patient-specific drill guides resulted in improved operative time compared to the free-hand technique and computer assisted surgery, and robot-assisted technology (41).

However, there are several disadvantages with the use of these guides. Due to the pure geometric approach of this method, soft tissue is not taken into account (41). This is problematic because the guide must fit and lock onto the surface. If the soft tissue is not stripped thoroughly, there may be issues with the fitting and, thus, issues with accuracy. The other disadvantage is the time required to produce the templates. Due to the manufacturing process, this method cannot be used for emergency surgeries (38).

Mandible surgeries with 3D surgical guides

Mandibular surgery is generally not included in the scope of orthopedic surgery. However, there is a comprehensive literature on the use of 3D-printed surgical guides for the mandible. Therefore, here we briefly review these experiences which may be important in designing better strategies for orthopedic applications.

Mandibular reconstruction is a procedure that takes place after oncological resection, segmental loss due to benign cystic of fibrotic bone diseases or trauma. There are several treatment options for the reconstruction. These include microvascular free flaps, non-vascularized bone grafts, and alloplastic implants which include titanium reconstruction plates (42). Surgical cutting guides (*Figure 3*) have been used for mandibular segmental osteotomies and reconstruction using a fibula.

However, the gold standard with this procedure is the use of free fibular flaps. The use of free fibular flaps possesses a high success rate and a low donor site morbidity (43). There are several challenges associated with the use of free fibular free flaps. These involve an increased ischemia time, the high level of dependence on the surgeon's experience and the increased level of difficulty that comes along with a more extensive bone defect (41).

In more recent studies, surgical cutting guides have been used for mandibular segmental osteotomies and reconstruction using a fibula (43). While the superiority of the use of the surgical guides is yet to be proven, there is an obvious theoretical advantage due to the computer involvement in calculating lengths and cutting angles of bones (42). These cutting guides also simplify the making of the osteotomies (44,45).

High accuracy

It has been claimed that the use of surgical guides has a high level of accuracy. Different mandible surgeries as mandibular osteotomy, fibular osteotomy and reconstructions of mandible those underwent the reconstruction with the aid of computer-assisted design (CAD) and rapid prototype modeling (RPM) showed less deviation (compared to the planned position) in comparison to conventional surgical techniques (44).

On the other hand, different reports using mandible surgical guides showed no significant differences between surgical guides and conventional technique (46) or even the opposite (conventional techniques showed a better result) (43). The authors claim that this was due to limitations created by the compression of the vascular peduncle and the learning curves of the surgeons which required repositioning of the screw holes (43). Moreover, some authors claim that this was not observed intraoperatively and happened during the recovery process specifically after the radiotherapy (46).

Reduced operating and ischemia time

Another aim with the use of surgical guides, CAD and RPM in mandibular reconstruction is the reduced operating time. Hanasono *et al.* compared the operating times between the group of patients who underwent the reconstruction with the help of CAD and RPM and the group of patients who underwent the procedure without the help of these technologies. The results showed that the mean operating time was significantly lower in the group of patients with the procedure undertaken with the help of CAD and RPM than in the defect-matched control group patients (8.8±1.0 *vs.* 10.5±1.4 hours) (P=0.0006) (44).

Bao *et al.* found similar results which showed that the groups that used surgical guide system had a significantly reduced operating time compared to the group that used the conventional techniques. The operation times for groups A, B and C were 439.42±36.18, 466.29±35.30 and 620.56±59.83 min, respectively. Additionally, they found that ischemia time was significantly greater in the conventional techniques group than in the surgical guide system groups. While the mean ischemia time for group C (conventional techniques group) was 159.44±12.71 min, the authors found that this was 70.75±6.93 and 101.64±9.83 min for groups A and B (surgical guides system groups), respectively (42).

Although they didn't find a significant reduction in the operating time, Culié *et al.* also found that the ischemia time was significantly reduced with the CAD and RPM aided group (47).

Overall, surgical cutting guides bring simplicity, accuracy and reduced operating time on the table for mandible reconstruction. Besides the general benefits of having reduced the operating time, lowered ischemia time with the use of CAD and RPM is also proven to be a positive influence on the survival of the fibula flap. However, the use of CAD and RPM also involves extra costs compared to the traditional methods (42). Although it is also important to note that these extra costs may be balanced or mitigated due to the reduced operating time, if not justified by the benefits of reduced operating time (43-45).

Conclusions

Anatomical variances are a common occurrence among patients. While not all of variances pose difficulties for surgeons to undertake the operation, in different procedures, it may not be the case.

With the arrival of the CAD and RPM technologies, taking these differences into account, surgical guides provide the surgeons with help they need in determining exactly where and how to cut. This not only helps with giving the patients the personalized treatment that is the best for them specifically, but also simplify the procedure for the surgeons. There are several advantages of using surgical guides that had been put forward for the procedures we discussed in this review. These include accuracy, the simplicity we mentioned, benefit of preplanning the surgery, reduced blood loss, reduced risk of fat embolism, reduced risk of infection, less equipment necessary compared to other techniques, less of a learning curve, reduced operating time and reduced radiation exposure (9,15,18,19,21,28,34,44).

The literature also reported a number of disadvantages. These involve the extra costs and time being put into the manufacturing process associated with the CAD and RPM, the manufacturing steps of these guides being outsourced (46), pure geometric approach it possesses which causes difficulties due to the soft tissues present (36).

While it is true that there are extra costs associated with the use of surgical guides, it has been suggested that the clinical benefits and the financial benefits that come along with reduced operating time causes balances or at least mitigate these extra costs (44,45). Additionally, the manufacturing steps being outsourced can be problematic.

Despite the fact that there are still some controversies (11, 12,17,20,48) ongoing regarding some of the claimed aspects, it is believed that, with its promising results and decreasing costs of the use of CAD and RPM in the coming years as they gain wider use, the surgical guide techniques will gain more popularity in the future.

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