REVIEW ARTICLE

A Comprehensive Review of 3D Printed Moulds for Temporary Knee Arthroplasty Spacers

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ABSTRACT

The increasing demand for total knee arthroplasty (TKA) is accompanied by a rise in subsequent revision total knee arthroplasty (rTKA) procedures, necessitating immediate, cost-effective, and personalized temporary knee spacers made from moulded bone cement. Although temporary knee spacer moulds are widely available, the potential of 3D printed moulds remains underexplored. 3D printing offers precise fabrication of custom anatomical spacers, ensuring better fit, stability, and reduced risk of failure compared to conventional methods. Polylactic Acid (PLA) polymer, chosen for its biocompatibility and low melting temperature, facilitates easy printing. This review synthesizes literature on knee anatomy, TKA, rTKA components, and the application of 3D printing for mould production, highlighting its potential in enhancing surgical outcomes through personalized spacer solutions. The integration of SolidWorks-based modelling, FEA simulations, and FDM-based production optimises the creation of knee spacers and moulds.
Malaysian Journal of Medicine and Health Sciences (2025) 21(SUPP11):224-232. doi:10.47836/mjmhs.21.s11.30

Keywords: 3D-Printing, Knee Arthroplasty, Mould, Temporary Knee Spacers, Biomechanics, Finite Element Analysis

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INTRODUCTION

Total knee arthroplasty (TKA) is a common and effective treatment for severe knee osteoarthritis, reducing pain and enhancing function (1, 2). The highest number of knee of patients are found in India and the United States of America (USA) (2, 3). Knee joint replacement surgeries are highly reliable and effective in treating severe osteoarthritis that effectively reduces pain experienced by patients, enhances their ability to walk, and enhances their overall quality-of-life (4). With an increasing demand for primary TKA, there is also a rise in the number of revision procedures, particularly due to periprosthetic joint infections (PJI) and other complications such as instability and wear (1, 5, 6). It is estimated that the number of revision TKA (rTKA) cases on the USA will increase to 268,200 annually by 2030, with similar trends expected in countries such as Australia, the United Kingdom (UK), South Korea, and Germany (2, 7, 8). Therefore, two-stage rTKA with antibiotic-loaded spacers is the gold standard for treating chronic PJI, achieving infection control rates of 80% to 90% while reducing morbidity, complications, and cost (4, 9). However, improper design and non-optimal surface quality of the temporary spacers may be affected by their mechanical stability, and frictional properties (10). Recently, 3D printing technology has been utilized in orthopaedic surgery to create customized implants and devices,with polylactic acid (PLA) being popular material for 3D printed moulds sue to its biodegradability and ease of use (10–12). Although various studies have investigated how printing factors affect the performance of FDM components, optimal design and layer thickness for several applications in manufacturing high-quality knee spacers's mould for rTKA is yet unclear (13). Additionally, increased surface roughness in TKA components can accelerate wear, increase friction, and heighten the chance of implant failure, severely compromising long-term surgical success (14). Therefore, surface quality analysis was conducted following 3D printing and post-processing.

THE KNEE JOINT ANATOMY

The knee joint, which is a adapted hinge construction and the largest synovial joint, guarantees stability and control when subjected to different loads. The knee joint enables movement in three planes (frontal, transverse, and sagittal) and has six degrees of freedom such as, flexion, extension, internal and external rotation, and varus and valgus stress (5). Although the knee plays a crucial function in supporting weight and facilitating movement, it is susceptible to both sudden and long-term injuries because of its limited protection and its location between the femur and tibia (6). Although the native knee and artificial knee have different origins and functions, both total knee arthroplasty (TKA) and revision total knee arthroplasty (rTKA) are performed with the goal of alleviating pain, improving mobility, and enhancing overall knee function (5, 6).

Native Knee

The main joints of the knee, including the femorotibial and patellofemoral joints, consist of connections between the femur, tibia, and patella. The femorotibial joint, which is the largest joint in the body, plays a vital role in bearing weight and transmitting stress throughout the body (7, 8). The patellofemoral joint is a saddle joint located between the patella and the femoral trochlea. Its primary function is to facilitate smooth movement and provide stability (7). The patella, which is the largest sesamoid bone in the body, transfers stresses from the extensor mechanism (11). The anterior cruciate ligament (ACL) and posterior cruciate ligament (PCL) are responsible for regulating knee flexion, rotation, and restraining excessive motions (7, 11).

Total Knee Arthroplasty (TKA) Surgery

Total knee arthroplasty (TKA) is a surgical procedure that involves replacing the damaged bone and cartilage in the knee joint with artificial components. The goal of this procedure is to achieve accurate alignment, balance, and correction of deformities to improve stability and mimic the natural movement of the knee (8). The components of a set of TKA prostheses generally comprised of the femoral component, articulating surface of tibial spacers, stemmed tibial plate components, and patellar components (12). TKA prostheses commonly consist of a cobalt-chromium femoral component, a metal tibial component with a polymer articulating surface, and a polyethylene patellar component (15, 16). Bone cement, composed of calcium phosphate, poly(methyl methacrylate) (PMMA), and acrylate materials, is utilised to attach these components to the bone, hence enhancing implant attachment and osseointegration (17–20).

Revision Total Knee Arthroplasty Surgery

Periprosthetic joint infection (PJI) is a common and costly complication occurring in 1%-2% of cases following TKA and often requires rTKA (3, 4, 9, 21). PJI, along with complications like implant loosening, joint instability, polyethylene wear, and osteolysis, often necessitates spacer-only modifications (1, 22). The preferred treatment for persistent PJI is a two-stage rTKA with antibiotic-loaded spacers, which achieves an infection eradication rate and reduces complications, morbidity, mortality, and the need for further procedures (4, 9, 23). This approach involves replacing contaminated implants with temporary antibiotic spacers, followed by a second surgery once the infection is cleared (23). Recovery from bone infection varies by the Anderson Orthopedic Research Institute (AORI) classification of bone defects in the femur and tibia, such as F1/T1 defects stabilized with PMMA bone cement and screws, F2/T2 defects needing modular augmentation with morselized allografts or metal augments, and F3/T3 defects requiring extensive replacement with large allografts (23, 24). As depicted in Table I, based on the AORI, necessitates multiple stages of recovery following a bone infection.

Table I Classification and description of femur and tibia bone defects based on the AORI classification (24).

F1	F2A (one condyle)	F2B (both condyles)	F3
- No sign of femoral osteolysis - No significant component malalignment - Intact metaphyseal bone	- The defect can be seen in either condyle - Damaged unicondylar bone - The bone of the opposite femoral condyle is normal, - Metaphyseal segment might be damaged by osteolysis	- Involves both femoral condyles - Metaphyseal bone is damaged - Osteolysis is observable between the component and the metaphyseal edge of the femoral bone - Lack of cancellous bone for supporting the component	- The defect is more than 20 mm - Loss of collateral ligament attachment (one or both condyles) - Significant condyle bone loss due to osteolysis, fracture, etc. - Deficient metaphyseal segment
T1	**T2A (one plateau)**	**T2B (both plateaus)**	**T3**
- No sign of tibial osteolysis - No significant component malalignment - Intact metaphyseal bone	- The defect can be seen in one tibial plateau - A broad radiolucency can be observed - Intact joint line for the opposite part of the tibial plateau - Damaged unilateral metaphyseal bone	- Involves both plateaus - Damage to the metaphyseal segment of the tibia - Lack of cancellous bone to support the component - Bone loss might be seen in fibular head	- Severe loss of cancellous bone in the proximal tibia (more than 20 mm) - Component instability - The metaphyseal segment of the tibia might be damaged

In the first stage of surgery for periprosthetic joint infection (PJI), infected synovial fluid and synovium samples are collected for bacteriological culture (23). The patellar, tibial, and femoral components, along with infected soft tissues including the synovium and cement, are meticulously debrided (16, 23). The entire knee is flushed with at least 6 litres of normal saline and immersed in 0.35% povidone-iodine solution for 3 minutes (23). Antibiotic-loaded cement spacers, created using a manually crafted silicone mould, are then surgically implanted (23). To minimize infection risk, the procedure should be completed within 60 minutes for component removal, 60 minutes for joint repair, and 30 minutes for wound closure (25). Figure 1A and 1B illustrates the first-stage surgery, which involves the placement of antibiotic-loaded articulating cement spacers for treating PJI.

The second stage operation was scheduled after confirming successful infection treatment, indicated by normal local examination findings, laboratory tests, and a negative culture of the joint fluid, following at least 2 weeks of antibiotic cessation (23). During the second stage rTKA, the antibiotic-loaded cement spacers were removed out and a re-debridement procedure was carried out (26). Additionally, the synovium was collected while the operation was ongoing. If the intraoperative cell count indicated fewer than five leukocytes per high-power field, a revision surgery was performed (23). This included utilizing a newly implanted metallic femoral component, a new all-polyethylene articulating surface, and a new stemmed tibial component (16, 23). Figure 1C and 1D shows that second-stage surgery of rTKA.

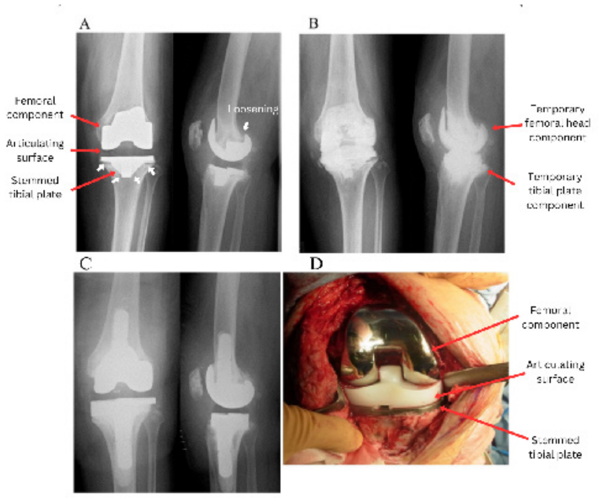

Figure 1: Two-stage revision total knee arthroplasty (rTKA) for the treatment of periprosthetic joint infection. (A) Pre-operative radiograph as evident implant loosening was found, (B) pre-operative radiograph before to the second surgical procedure shown that implantation of articulating cement spacers containing antibiotics was performed, (C) The radiograph at the final follow-up showed that the rTKA was completed without implant loosening, and (D) The macroscopic image depicts the TKA prosthesis (23).

TEMPORARY SPACERS

Temporary spacer is one of the components used for revision knee surgery. The spacer is implanted temporarily with the specific retention time range can vary from several weeks to a few months. Depending on the degree of bone defect, internal fixation and two-stage bone transplantation were carried out three to six months after the osteomyelitis was under control (27). Temporary spacers become crucial in two-stage rTKA surgeries due to their important role in aiding the recovery process.

The primary factors contributing to prosthesis failure are infection, osteolysis resulting from polyethylene wear, loosening, stiffness, and instability (25). The spacers have a crucial role in keeping joint space and maintaining tension in soft tissues, which helps prevent contracture and preserves the range of motion during the treatment of the infection (28–30). They improve in the process of functional recovery by offering temporary stability and weight bearing support, allowing patients to participate in physical therapy and get prepared to undergo the following stage of the rTKA operation (31, 32). Furthermore, spacers enhance the healing of bones and soft tissues by serving as a scaffold for tissue growth and ensuring correct alignment during the period of transition (33, 34).

Existing Type of Temporary Spacers

In two-stage revision surgery, the two commonly types of spacers used are static non-articulating spacers and dynamic articulating spacers. Static non-articulating bone cement spacers consist of a single piece of bone cement that is infused with antibiotics and placed in the joint space (24). While they are cost-effective and easier to implant, these spacers may restrict knee joint mobility and potentially lead to complications reducing patient quality-of-life, including bone loss and soft tissue damage (35, 36). The objective of these spacers is to release antibiotic medication into the surrounding environment (24). However, the knee joint is limited to either complete extension or little flexion, and may contribute to an increase in bone loss because of the patient's limited ability to move the knee (24).

In contrast, dynamic articulating spacers improve knee function recovery and reduce complications, offering good flexion and extension post-prosthesis implantation, although with greater manufacturing expenses (35). It enable the utilization of type F1/T1 to F3/T3 bone defects (24). Dynamic articulating spacers have demonstrated comparable rates of eradication to static spacers in the treatment of chronic PJI in RTKA, while also promoting joint mobility throughout the recovery process (24, 37). Multiple studies have proven it enhances the range of motion and reduces bone loss. Study conducted by Tao et al. (35) proved that patients with dynamic spacers had significantly better functional scores, knee mobility, and significantly less bone loss ($p < 0.05$) than static spacers in meta-analysis. Additionally, similar results to the static spacer in terms of infection control of the prosthesis (35). An overview of and the current manufacture of temporary spacers is provided in Table II.

Table II Current temporary spacer fabrication commercially available.

Spacer Type	Result	Advantages	Disadvantages	References
Static non-articulating (surgeon fabricated)	– Indications for this procedure encompass significant bone loss, insufficient collateral ligament function, fractures near the joint, and the lack of a properly functioning extensor mechanism. – The reported infection-free rate was 94% after an average follow-up period of 3.7 years, ranging from 2 to 10 years. – The average knee flexion ranged from 60° to 139°, with a mean of 100°.	Stability issues can arise with bone loss, periarticular fracture, collateral ligament insufficiency, or absence of the extensor mechanism.	There may be no range of motion during the interval, and reimplantation could prove more challenging compared to using a mobile spacer.	(31, 37, 38)
Handmade dynamic articulating	– Articulating spacers typically exhibit lower rates of reinfection, improved range of motion, less bone loss, and enhanced re-implantation capabilities when compared to static spacers. – The average range of motion was 100° in articulating spacers, whereas it was 92° in static spacers. However, there were no significant variations in Knee Society scores between the two groups.	Commercially available, possibility of adding higher doses of antibiotic in the bone cement	No standardization because everything depends on the surgeons, has no reproducible mechanical characteristics, rough, improperly shaped, and fails to integrate properly with the surrounding tissue.	(39, 40)
InterSpace prefabricated (Exactech)	– There are four distinct sizes of femoral and tibial components available, each carrying a different amount of gentamicin ranging from 0.9 to 2.7 grams. – 30 out of 33 cases showed complete elimination of the infection, with an average follow-up period of 3.5 years (ranging from 2 to 5 years), and no instances of spacer fracture or dislocation were reported.	Multiple sizes are available, eliminating the need for intraoperative fabrication.	There is no tibial stem, and the sizes of intraarticular posts are not interchangeable. A single antibiotic was used.	(31)
Remedy prefabricated (Osteoremedies)	– Offered in various dimensions, the components of this product comprise a range of 0.9 to 3.2 grams of gentamicin. – Consists of tibial components that have a stem and other structures to compensate for the loss of tibial bone. – There are no existing studies that have been published regarding the outcomes of this particular prefabricated knee spacer.	Multiple sizes are available, eliminating the need for intraoperative fabrication. Femoral and tibial sizing is interchangeable, and options include a tibial stem and tibial augment.	Single antibiotic.	(31)
Stage One Knee Spacers by Using Moulds (Zimmer BioMet)	– Cement-on-cement spacers are introduced into moulds, undergo polymerization outside the knee, and subsequently implanted. – At a mean follow-up of 35 months, there was a reported reinfection rate of 12% and one case of femoral spacer fracture.	Allows for the use of multiple antibiotics at higher doses as needed.	There is an increased intraoperative time required for fabrication and a possibility of fracture.	(31)
Metal-on-polyethylene, or known as PROSTALAC™ knee spacer moulds (DePuy Synthes)	– The femoral mould has moulded spacers with metal runners, while the tibial mould contains moulded spacers with polyethylene runners. – The initial success rate was 87%, with reinfection occurring in 14 out of 110 knees during a mean follow-up period of 5.8 years (ranging from 1 to 11 years).	Allows for the use of multiple antibiotics at varying higher doses.	This approach may lead to increased intraoperative time for fabrication and a risk of fracture.	(24, 31, 41)
New metal femoral and polyethylene tibial components with antibiotic cement	– The knee replacements consist of metal femoral and all-polyethylene tibial components, which are placed using antimicrobial cement in a temporary manner. – Reinfection was observed in 6 out of 50 patients after a mean follow-up period of 73 months, ranging from 24 to 150 months. – A subset of patients attained favorable functional outcomes without necessitating a subsequent intervention.	The second stage may not be necessary if the patient has successfully eradicated the infection and achieved good functional outcomes.	There is no antibiotic elution from the metal and polyethylene, and there may be a higher cost associated with new components.	(28, 31)
3D printed knee spacers	– Notably less bone loss at the tibial and femur sites than with static spacers. – Improved knee function and range of motion in the interim. – Absence of long-term clinical data demonstrating the robustness and security of spacers made via 3D printing. – Potential for wearing particles throughout the body, even though no obvious particles or symptoms of osteolysis were noted during the research period. – Self-made surgical instruments must comply with local medical rules and regulations or have authorization from the appropriate authorities (such as the FDA).	Better precision in design, highly customizable, biocompatible, affordable material.	Limited publication exhibits antibiotics usage, safety, and sterilization-compatible 3D printed spacer material.	(10,42–44)

Existing Type of Moulds of the Spacers

There are three main types of existing knee spacers moulds. This includes the hand moulded silicone mould, prefabricated standardized mould and 3D-printed mould. The hand moulded knee spacers comprise two silicone mould components, namely the femoral and tibial articulating surface moulds (26). This mould will require the surgeons to physically shape the silicone moulds before the operation with a high dose of combination antibiotics (26). Once the dough-like consistency was achieved, the cement containing antibiotics was tightly packed and compressed into moulds for the femoral and tibial components (26). Once the femoral and tibial cement components had solidified, they were extracted from the moulds, then placed in distal femur and proximal tibia (26). The silicone moulds are less expensive to fabricate than commercially available moulds or spacers, yet still have a restricted sample size and lack of control (4). Figure 2A and 2B shows the silicone mould and spacers fabrication.

Commercially prefabricated standardized mould, COPAL® knee moulds (Heraeus Medical GmbH, Wehrheim, Germany) maintains a consistent and unchanging form while the bone cement is being filled and hardened. An advantage of this technique is that allows for the simultaneous assembly of the proximal and distal portions of the femoral component, hence reducing the amount of time required for the operation (45). The proximal section of the femoral stem was covered with PMMA cement, while the distal section of the stem was left uncovered to allow for adjustments in length and rotation (45). On the other hand, prefabricated standardized spacer using COPAL® mould are quite expensive (39). Figure 2C shows prefabricated standardized mould.

Figure 2: Existing moulds and prefabricated cement spacers used in two-stage revision TKA. (A) Antibiotic-impregnated articulating silicone moulds (71), (B) Zimmer BioMet company silicone mould (72), and (C) COPAL® prefabricated standardized mould (73).

ADDITIVE MANUFACTURING TECHNIQUE

Additive manufacturing is an advanced method employed to fabricate intricate geometries and structures by incrementally depositing material in layers, utilising 3D model data. There are several additive manufacturing processes, including Stereolithography (SLA), Selective Laser Sintering (SLS), and Fused Deposition Modelling (FDM) (46). These processes utilise many materials, including ceramics, plastics, metals, liquids, powders, or even live cells. These innovations make it feasible to use 3D model data to create sophisticated, shaped 3D components that would be difficult to create using conventional manufacturing methods (46). It uses a layer-by-layer construction method to create three-dimensional physical models directly from a computer-aided design (CAD) model. In additive manufacturing, the machine interprets data from a CAD model and deposits successive layers of various materials, constructing the physical model through a succession of layers (47).

3D Printing

Fused Deposition Manufacturing (FDM) is a manufacturing technology that creates three-dimensional objects by sequentially depositing and melting materials to form layers. It is the most versatile, cost-effective, and widely used technique for 3D printing, compared to SLAand SLS (48–50). FDM enables the construction of 3D objects with intricate geometries by utilizing heated thermoplastic filaments extruded from a nozzle in a partially melted condition, which then solidifies at the chamber temperature (48,50). The filament is unwound from a reel to provide material to the extrusion nozzle head, which applies heat and controls the flow (48). Stepper motors control the extrusion head's movement along the horizontal x-axis and y-axis, while the build platform moves vertically along the z-axis, all operated by computer-aided design (CAD) or computer-aided manufacturing (CAM) software through a microcontroller (48, 50). A high-temperature nozzle releases liquefied polymer onto a solid structure, cooling and hardening to form a strong structure (50). FDM’s compatibility with a wide range of biocompatible materials makes it ideal for biomedical applications (48). It is also suitable for fabricating moulds used in implant casting and medical equipment (49).

3D Printing Parameter

The effectiveness, accuracy, and characteristics of the manufactured additive products are greatly influenced by the printing parameters. The nozzle size, responsible for extruding the filament, typically ranges from 0.1 mm to 1 mm, with 0.4 mm being commonly used for a balance between print speed and precision (51). Filaments come in two standard diameters: 1.75 mm and 2.85 mm, with the latter often referred to as "3 mm" filament (51). Process-based parameters like melting temperature, bed heat, and printing speed also significantly affect print quality. The optimal bed temperature for PLA is 55°C to 70°C, while extruder temperatures range from 210°C for PLA to 240°C for ABS (51–53). Print speed, which measures how quickly the printer's motors can move, should range between 40 and 70 mm/s (52,53). Layer height, crucial for surface texture and print duration, is typically recommended between 0.10 mm and 0.20 mm (51,54), with 0.10 mm optimizing accuracy (55). A lower printing temperature improves surface quality (56). Infill geometry, with patterns like honeycomb or concentric lines, should be 50% to 100% for best surface quality and wear resistance, though 10% can withstand a 500 kg force (52, 53, 57). Infill density affects load distribution, influenced by the raster angle, which should be between 0° and 90° (51, 58, 59). The raster width depends on the nozzle size, while the air gap refers to the space between adjacent filaments in the same layer (51, 59).

Layer Height

The accuracy and specificity of the knee spacer quality are determined by the layer height, which is a critical parameter in the process of 3D printing. Precision is essential in moulds for knee spacers to prevent excessive wear. This is consistent with the research conducted by Prajapati (60), which showed that the improper selection of layer height can lead to an inordinate amount of wear in patients by increasing the hardness and roughness. The optimal layer height in 3D printing is 0.10 mm, which is recommended to minimise wear and friction, and it is contingent upon the material and application improves the quality of the surface, the level of detail, and the strength of the object by enhancing the bonding between layers (61). These characteristics are especially important in prototype applications requiring accuracy, quality and reliability, such as knee spacers (62). Higher layer heights, such as 0.2 or 0.3 mm, significantly minimises the amount of duration of printing and the amount of material that is consumed, while still guaranteeing that acceptable precision is achieved for a broad variety of medical applications which is beneficial for large-scale manufacturing and rapid prototyping (63,64). Mould production with 0.1, 0.2, and 0.3 mm layer heights are highly suggested for health-related prototypes using desktop 3D printers as it provides a balance between cost-efficiency, accuracy, and surface quality (63). This will result in smoother surfaces and a decrease in "stair stepping effects," which are necessary for the fabrication of high-quality moulds with minimal post-processing (55,63,64). While, decreasing the height of each layer. Therefore, choosing the optimal layer height involves finding a compromise between enhancing production efficiency and fulfilling the stringent standards of the medical device manufacturing industry.

Polylactic Acid (PLA) for 3D Printing Material

Polylactic acid (PLA) is the most widely used material in FDM printing, favoured for its biocompatibility and status as a bioplastic derived from renewable resources like corn or sugarcane (50). It is non-toxic, biodegradable, and typically regarded as safe for purposes involving indirect human contact (50). PLA is more cost-effective than thermoplastic polyurethane (TPU) and acrylonitrile butadiene styrene (ABS), and it degrades into environmentally friendly substances under natural conditions (50, 65). It has a glass transition temperature of 50 to 70°C and a melting point of 180 to 220°C, making it compatible with most 3D printers (50). Despite its advantages, PLA can be more brittle and challenging to handle, with a higher susceptibility to extrusion blockages compared to polymers ABS. Consequently, it is strongly advised that PLA material be employed in this investigation during the 3D printing procedure.

SURFACE ROUGHNESS ANALYSIS

Surface roughness is a crucial determinant of bacterial adhesion to bone cement. Roughness plays a crucial function in the initial development of plaque and provides a larger surface area for bacteria to grow (24). To quantify these surface characteristics, specialized instruments such as a surface roughness tester (66) or a profilometer (67) are employed. In order to examine the effects of printing layer height on surface roughness, the study may entail measuring variables like average roughness (Ra), and mean peak-to-valley height (Rz) (67). It is efficient in identifying scratches on an otherwise smooth surface. The surface roughness is at its lowest at a layer height of 0.1 mm, the roughness values (Ra) ranging from 3-8 μm and Rz reaching 18–22 μm, indicating more obvious layer lines (67, 68). The surface roughness continues to increase at 0.2 mm, with Ra values ranging from 8 to 15 μm and Rz values ranging from 22 to 27 μm (67, 69). The fewer number of deposited layers results in a rougher texture. The roughness peaks at 0.3 mm, with Ra values exceed 12 μm and Rz values of 25-30 μm (67, 70).

CONCLUSION

The study concludes by demonstrating that it is conceivable to generate moulds for temporary knee spacers through 3D printing, thereby offering a plausible solution for revision total knee arthroplasty (rTKA). By employing PLA as the primary 3D printing material, the research not only highlights the material's suitability for biomedical applications but also emphasizes the potential of additive manufacturing techniques to enhance the precision and quality of the moulds. The potential for future research to investigate larger moulds for revision spacers and implants, such as femoral stem and head spacers, is supported by the success of this experiment, thereby improving the quality and performance of rTKA procedures. This chapter describes the limits discovered in this investigation, including constraints relating to the experimental set-up, software capabilities, manufacturing issues, and measurement approaches. These limitations emphasise areas that might be improved in future study to enhance the accuracy, reliability, and application of the findings.

ACKNOWLEDGEMENT

This work was supported by the Universiti Teknologi Malaysia under the BioInspired Device and Tissue Engineering Research Group (BioInspira) is acknowledged.

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