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JIG PROTOTYPE FOR COMPUTER-ASSISTED TOTAL KNEE REPLACEMENT AND ITS FLOW SIMULATION

Abu Bakar Sulong[1], Amir Arifin[2*], Zambri Harun[1]

[1] *Department of Mechanical and Materials Engineering, Universiti Kebangsaan Malaysia, 43600 Bangi, Selangor, Malaysia*
[2] *Department of Mechanical Engineering, Sriwijaya University, 30662 Indralaya, South Sumatera, Indonesia*

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ABSTRACT

This paper discusses the design and development of a prototype of a knee surgery cutting jig, the jig holder, and the jig injection mold by Rapid Prototyping (RP). The aim of this study is to design a jig and a jig holder that allow surgeons to correctly, precisely, and consistently perform knee replacement surgery. The design concept for the surgery jig and jig holder was selected using the Pugh method with medical-grade 316L stainless steel for material fabrication. A rapid prototype model was built directly from its CAD model in stereo lithography (STL) format by using the Fused Deposition Method (FDM). MasterCAM and Moldflow simulation were performed to generated G-codes and a possibility of jig fabrication using Metal Injection Molding (MIM), respectively. The Moldflow result provided an enhanced interpretation of the injection mold design. A conceptual mold design was again developed by the FDM. The prototype of the cutting jig and its holder underwent a machining process. The prototype was then tested on dummy bones to determine the functional performance and efficiency of the said prototype. Results indicated an increase in cutting accuracy and cutting time compared with computer-assisted total knee surgery without the jig system.

Keywords: Design; Forming process; Knee replacement surgery; Numerical simulation

1. INTRODUCTION

Most people in the Asian region suffer from knee problems requiring knee replacement when these people reach old age. Among various reasons, these knee disorders are attributed to obesity-related problems among the population. Knee replacement or knee *arthroplasty* is a procedure for treating *osteoarthritis* by replacing the worn cartilage between the knee joints with an artificial implant component (Arabelovic & McAlindon, 2005; Harman et al., 2014). This method has been proven to effectively relieve pain and regain normal knee movement in patients suffering from this disorder.

Macdonald et al. (2004) and Kludge (2007) indicate that the success of knee replacement surgery depends on two critical factors: bone cutting alignment and implant position on the cutting plane. Zafiropoulos and Attfield (1995) and Haaker et al. (2005) reported that cutting accuracy can be improved significantly by using a cutting jig rather than solely using bare hands. Researchers have argued that errors can occur despite correct positioning of the jig because of vibration and instability during the cutting procedure or variations in individual

*Corresponding author's email: amir@unsri.ac.id, Tel. +62-711-580272, Fax. +62-711-580272
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anatomy (Macdonald et al., 2004; Kendoff et al., 2009). To ensure successful knee replacement, many factors need to be considered. The factor that exhibits the greatest influence during surgery is cutting accuracy, which is necessary to obtain a good fit of the implant component on the cutting plane (Bardakos, 2014). Failure in this aspect can lead to severe post-surgery problems (Clarius et al., 2009). The use of a jig holder compared with a guidance jig for cutting can more efficiently support and facilitate jig placement in terms of accuracy, consistency, time efficiency, and ergonomics. The conventional design process is time-consuming and laborious as well as risky because of the trial-and-error method involved. Computer-aided design (CAD), computer-aided manufacturing (CAM), and virtual reality have been reported to reduce process time. For instance, RP provides great advantages in reducing the development cycle time, cost, and quantity of parts needed for final assembly while improving the quality of the design (Dieter, 2000; Liou, 2008; Bibb et al., 2009). Metal Injection Molding (MIM) is combination method of powder metallurgy and plastic injection molding. MIM is suitable process to produce small and complex geometry in large quantities (Arifin et al., 2015). Moreover, Metal injection molding has been identified as a potential manufacturing method for improving the production of metal parts (German & Bose, 1997)

The main objective of this work is to design the prototype of a knee surgery jig, including the jig holder. This jig-and-holder assembly is proposed to assist surgeons to increase accuracy and reduce time and labor involved in cutting. This work consists of some various stages, from conceptual design and prototyping to testing, before the final fabrication of the prototype and application. Experiments and numerical simulations were conducted, which successfully generated a complex and intricate design of the prototype by metal injection molding (MIM) (Binet et al., 2005; Barriere et al., 2003; Park et al., 2014). The efficiency of MIM in designing the jig is also investigated in the present study.

2. METHODOLOGY

The overall prototype development cycle is summarized in the flow chart in Figure 1. A final design was selected from two candidate conceptual designs. The comparison was conducted using the Pugh scoring method by referring to a design datum, which is a benchmarked instrument. Scores are evaluated as lower (–), the same as (0), or better (+) according to pre-studied critical criteria, medical codes, and standards needed for this product.

The chosen design was then modeled in 3D for the cutting jig and CAD for the jig holder components. Files were then translated into STL formats to be imported into the machine for RP. The STL format was used because it can efficiently slice the input CAD model automatically, compared with other methods such as B-rep and CSG (Liou, 2008). The RP machine used was the FDM 200mc, which is an FDM type. The model material is an Acrylonitrile Butadiene Styrene (ABS) polymer, which provides good strength for model verification and subsequent evaluation. Machining tool path planning and verification for the jig and the jig holder components were conducted using MasterCAM. The MasterCAM Mill V8 was used for simulating prismatic parts, such as the jig block, whereas cylindrical parts (mainly for the jig holder) were simulated using MasterCAM Lathe V8. Appropriate G-code programs were then generated using the MPFAN.PST post-processor. It was then transferred to a Computer Numerical Control (CNC) machining center for prototype machining.

Moldflow Plastics Insight (MPI) 6.1 was used to simulate the flowability of the MIM feedstock within the mold cavity. The material feedstock used was composed of 64% SS316L stainless steel powder (size 16 µm) and 36% binder (which consisted of 73% weight polyethylene glycol, 25% polymethylmetacrylate, and 2% stearic acid AS). A substitute data model from MIM feedstock properties characterized by Binet et al. (2005) was used as material input for the moldflow simulation, because of lack of data on the properties of the materials. The substituted material consisted of 65% SS316L powder (size 22 μm) and 35% binder. The similarity of the material to our MIM feedstock composition was found to provide a reliable result on the preliminary study of the MIM filling inside the mold cavity. Essential input data for obtaining accurate results included the following: Genetic Algorithm (GA)-fitted coefficients of the pressure–velocity–temperature model, viscosity model, density, and thermal conductivity. The Moldflow result was then used for improving the design of the conceptual injection mold and the subsequent development of its RP model.

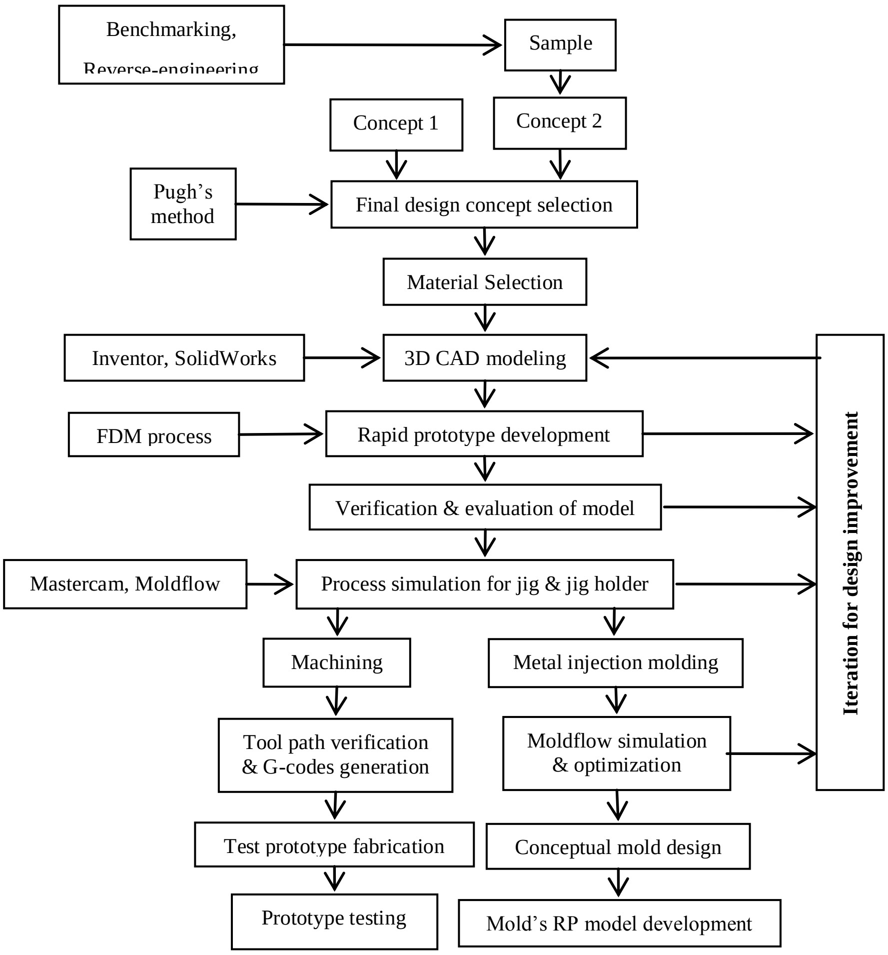
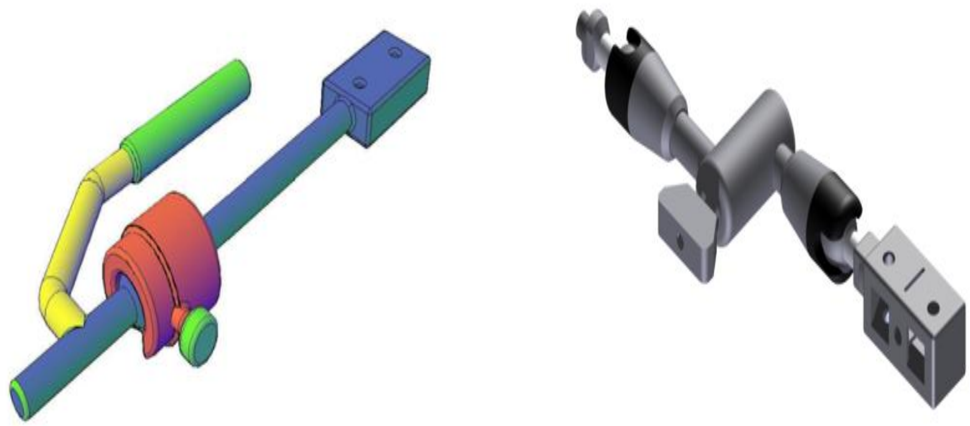


Figure 1 Flow chart of the prototype development process

3. RESULTS AND DISCUSSION

Two concept designs were proposed in Figures 2a and 2b. The first concept in Figure 2a was developed based on the functional mechanism of a camera tripod. The second concept in Figure 2b was generated using a reverse-engineering technique on a benchmarked commercial medical instrument holder. The Pugh method results in Table 1 were obtained after consulting surgeons and considering engineering factors. The first concept obtained a total score of -3, and the second obtained a total score of 1. Thus, the second concept was selected as the prototype design. Meanwhile, the medical-grade 316L stainless steel was chosen because it is low cost, easy to fabricate and possesses high mechanical properties. Properties such as corrosion resistance, biocompatibility, high tensile strength and fatigue resistance make SS 316L suitable as a surgical implant material (Devi et al., 2011).



(a) (b)

Figure 2 Conceptual design candidates for the jig holder: (a) First concept; (b) Second concept

Table 1 Conceptual design candidates for the jig holder

	Reliability	Stability	Installation with other component	Ease of installation	Suitable with orther operation	Practical	Flexible	Sum best	Sum worst	Sum same	Total score
Design 1	0	+1	-1	-1	-1	-1	-1	2	5	6	-3
Design 2	0	0	0	0	0	0	0	1	0	12	1

3.1. Rapid Protyping (RP) Model

The RP models of the jig and the jig holder components required nearly seven hours to be completely developed. Some components of the RP models are shown in Figure 3, with their surface appearance dependent on machine setting factors such as the following: surface resolution, internal solution, supporting model structure, model extrusion path, and orientation of the model relative to the direction of the building table. Despite the similar geometries of the RP and the 3D CAD models, actual measurements indicated that the RP models exhibit a dimension variation of ±0.10 mm from the desired values. This variation is attributed to the smallest extruder diameter setting and the nature of the building material itself. Fitting of mating parts could not be accomplished in the RP model because of dimensional variations; interference occurred particularly in the insert fitting. Failure in assembly could also be attributed to the material properties of the model. Despite the strength of the ABS plastic, the material is brittle and could break if parts are forced to fit. Nevertheless, the RP model clarified and provided a visual aid in progressing to the subsequent design stage.

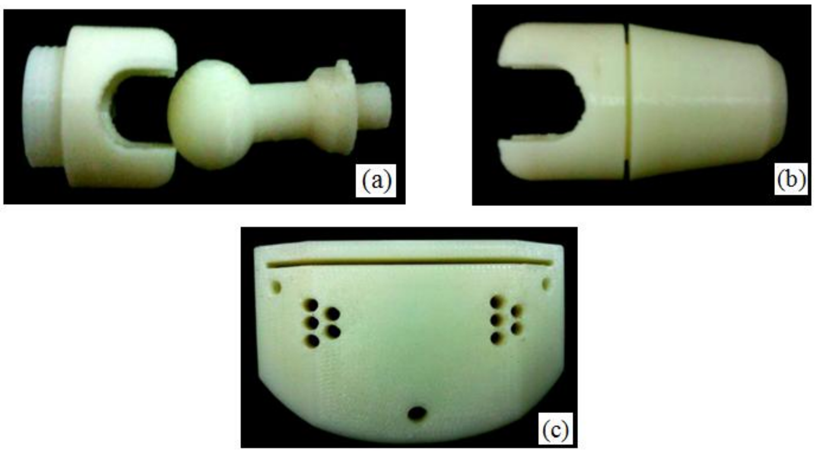


Figure 3. Components of jig holders (a) and (b) as well as (c) the jig

3.2. Prototype from Machining

After the tool path planning and verification, the G-code programs were then sent to the CNC machine for prototype machining. Representations of simulation machining form a block presented in Figure 4 for the (a) upper and (b) bottom parts of the jig. The CNC machine was used because it allowed a greater degree of freedom in controlling the direction of machining in producing the test prototype, which consisted of different complex geometry parts. Figure 5 shows all components of the jig and the jig holder after they had been machined.

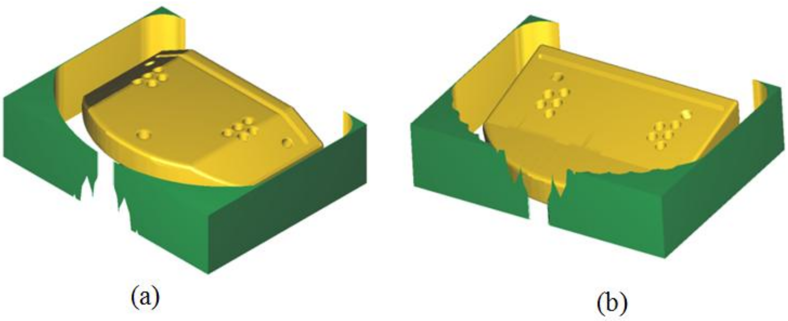


Figure 4 Representation of the MasterCAM simulation of machined parts (a) upper, and (b) bottom

Figure 5 Jig and jig holder components

3.3. Prototype Jig and Jig Holder Evaluation by using Sawbones

The machined prototype of the jig system was tested with sawbones to evaluate for performance and effectiveness, as shown in Figure 6. The evaluation was conducted by experienced knee surgeons. Data pertaining to bone cutting alignment, deviation, and cutting accuracy were collected and evaluated. If the results did not meet the requirements, iteration of surgery steps had to be implemented. On the basis of the results, the prototype was tested on a human knee after approval by the Ethics Committee of the Malaysian Medical Association (MMA) was obtained. By using this prototype, the collection of sawbone cut data indicated that the level of bone cuts were verified using computer software and then compared with the planned cuts. Distal femoral cuts were made first, which reflected the varus–valgus values of the bone cuts (coronal plane alignment). Considering that this jig assembly is mainly intended for distal femoral and proximal tibial cuts, the anterior–posterior cuts and chamfer cuts were not performed during this trial. After the completion of the femoral cut, the proximal tibial cut followed. As indicated in Table 2, a distal femoral cut measured 10 mm, although the planned cut was 9 mm. This slight difference is acceptable and it can be accommodated by a tibial insert. The coronal alignment was 0.5 degree varus. For the distal femoral bone cuts, it was able to measure the sagittal plane (flexion–extension) alignment as well. The cut is only 1.0 degree extended, which is also acceptable.

Figure 6 Locating the prototype jig on sawbone cutting

Table 2 Verification of the distal femoral cut

	Varus	Resection	Extension	Verified Anterior
Reference	Mechanical Axis	Distal Condyle	Mechanical Axis	Mechanical Axis
Planned	0.0°	9.0 mm	0.0°	-
Verified	0.5°	10.0 mm	1.0°	-
Deviation	0.5°	1.0 mm	1.0°	-

Table 3 Verification of proximal tibia cut

	Varus	Resection	Resection	Slope
Reference	Verification of Tibial Cut	High Plateau	Low Plateau	Anteroposterior Direction
Planned	0.0°	10.0 mm	7.5 mm	7.0° Posterior
Verified	1.5°	8.0 mm	6.5 mm	5.5° Post
Deviation	1.5°	-2.0 mm	-1.0 mm	1.5° Ant

Proximal tibial surfaces are not congruent, thereby preventing the alignment of the extramedullary cutting block to obtain the desired cut during actual knee surgery. However, the desired position of the cutting jig was easier to obtain using this prototype. The accuracy of the tibial cut is shown in Table 3. The deviation was narrow despite the 1.5-degrees varus cut. The 5.5-degree posterior slope was also acceptable. Slight deviations in cut parameters are insignificant relative to other important aspects of knee surgery, such as the soft tissue procedure and ligament balancing.

3.4. Moldflow Simulation and Conceptual Mold Design

The volume of the 3D jig model was initially scaled up by 14.5% because of the nominal shrinkage value from the green compact to the finished sintered part (Quinard et al., 2009). The mesh model was built from 67472 3D tetrahedral elements and had 12,586 nodes. The global edge length was 2.63 mm, and the chord height control was 0.1 mm. 3D meshing was used because it represents a true entity model that provides an insight into the simulated process. Figure 7 shows the Moldflow processing windows with the heating channel.

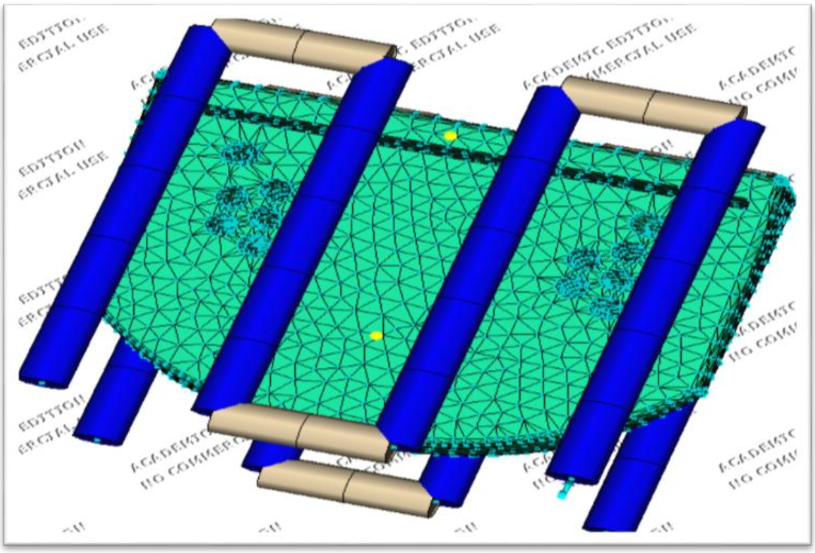
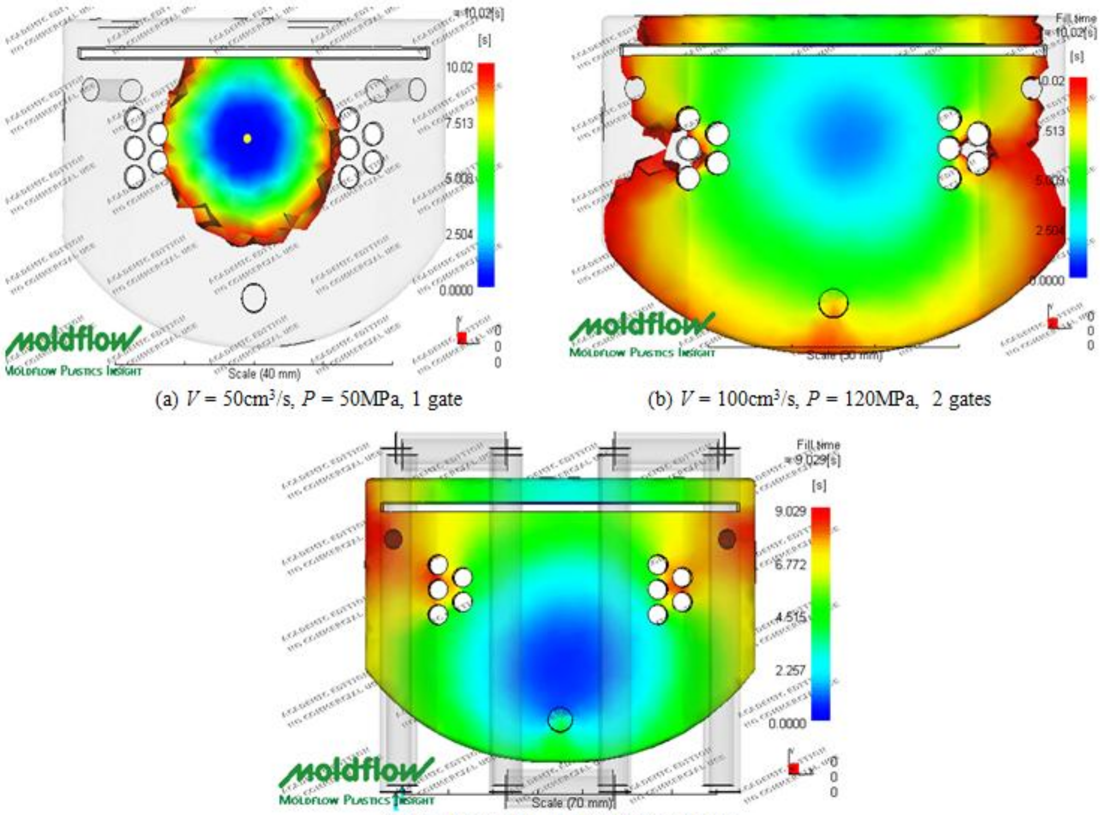


Figure 7 Moldflow processing windows of jig

Table 4 Suggested parameter ranges for MIM

Parameter	Value
Injection Temperature	130 – 160 °C
Mold Temperature	55 – 65 °C
Ejection Temperature	60 – 65 °C
Flow Rate	>100 cm^3/s
Injection Pressure	>200 MPa

Preliminary simulation was examined during the filling phase to identify the correct process parameter range. As illustrated in Figure 8, the MIM feedstock exhibits high viscosity and hardly flows through the narrow area (indicated by red circles in Figure 8a) of high-flow resistance. Therefore, at least two locations are needed; the high flow rate (*V*) and the injection pressure (*P*) are identified in Table 5. Factors such as distribution of bulk temperature distribution, shrinkage, frozen layer fraction, sink index; air trap, and weld lines areas also need to be considered. This characterization can only be obtained from the MPI/Fusion model. A study of the variation of these factors across the molds provides a better idea for optimizing the mold design, including the feed system and the cooling circuit, among others. An RP model of the conceptual mold design built from the 3D CAD model is shown in Figure 9.



(a) V = 50cm³/s, P = 50MPa, 1 gate (b) V = 100cm³/s, P = 120MPa, 2 gates

(c) V = 100cm³/s, P = 200MPa, 2 gates

Figure 8 Simulated filling of the jig pattern under various conditions

Figure 9 RP model of the conceptual mold design

4. CONCLUSION

In this work, Design prototypes for a knee surgery jig, jig holder, and jig injection mold were developed by rapid prototyping (RP). Based on the results and analysis, initial performance testing for the jig-and-holder assembly showed acceptable results with respect to the following objectives: accuracy, consistency, cost, and ergonomics. Further experimentation is required to verify the simulation results, the model can be compared with the experimental results to verify its reliability. An improved jig design should also consider manufacturing, as well as eliminating narrow and thick sections.

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