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Analysis Design of 3D Printed Tensioner Ligament Guide in Total Knee Arthroplasty Based on Gap Balancing Technique

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Abstract: Thailand is entering the ageing society hence the number of total knee arthroplasty (TKA) surgeries is increasing every year. Implant alignment and soft-tissue balancing are important success factors in total knee arthroplasty. The goal of the gap balancing technique is to recreate symmetric and rectangular flexion and extension spaces both medial and lateral. This research aims to optimize the design of a cutting tool guide for total knee arthroplasty based on the gap balancing technique. The cutting guide was designed to measure ligament force and the gap distance on the medial and lateral sides. The guide was created using 3-dimension printing (3D printing). The finite element model of the guide under ligament loading was constructed. The finite element method (FEM) was then verified and validated with the experiment and the results agreed well. The influence of the guide parameters was examined using the Taguchi method. Four parameters, namely the width, height, base-knee length, and base-support length were investigated. The Taguchi main effect analysis and ANOVA results show that the height and base-support length are the most important factor. Applying the Taguchi method and using the minimum displacement as the design criteria, the optimum guide design was identified. The verified finite element model and the experimental test of the 3D printed cutting guide using the optimum design were conducted.

Keywords: Total knee arthroplasty; Gap balancing technique; 3D printed; Finite element; Tensioner ligament guide; Design of experiments

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1. Introduction

Osteoarthritis of the knee has increased in recent years approximately 25% of 55 years old or elders had knee pain especially in women, the risk factor for osteoarthritis is weight, knee injury, and activity in daily life [1, 2]. The way to treat or relieve the pain of the knee is through physical therapy, taking medicines, and surgery. The total knee arthroplasty (TKA) operation rate is increasing every year; it was predicted to grow by 673% to 3.48 million procedures per year in 2030 in The United States [3, 4]. The success of TKA depends on the restoration of limb alignment, accurate implant position, and optimal gap balancing. Two balancing techniques are generally used in knee arthroplasty measure resection and the gap balancing technique. The operation of resection in each technique is different but the goal is the same to obtain symmetric and balanced flexion and extension gaps, Measure resection technique requires precise identification of bone landmark, and the gap balancing technique incorporates assessment of ligament tension. Brian and Douglas believed the gap balancing technique provides superior gap balance and function following TKA over measure resection, Measure resection technique often results in flexion gap asymmetry and an increased incidence of femoral condyle lift-off. The surgeon's ability to reproducibly identify the bone landmark accurately is limited but the gap balancing technique is a less dependent bone landmark [5, 6].

3D printing technology is becoming more widespread in medical devices. Many medical fields are using 3D printing to custom medical devices or guides to improve patient outcomes. Nowadays, 3D printing could be used in available material, speed, resolution, accuracy, reliability cost, repeatability of 3D printing technology and be more specific for some patients. Patient-specific guides reduce operating room time. Greater reductions in operation room time were when surgeons have become more used to the guided procedure [7-9]. The feasibility of 3D printing for the medical device has shown in the success some research found the device might resect as good as a normal device. The instrument can be tailor-made to match the size of the knee being operated on Nizam and Batra found that 3D printed patient-specific cutting block for TKA with CT scan had a resection error of less than 1 mm in more than 90% of cases (201 knees) and the mean error of different resections was less than 0.6 mm. Lustig et al., recorded resection of 45 patients with 3D printed patient-specific cutting blocks within ±2 mm for 87.7% [10-12]. The result of studies proved in the future the use of 3D printing technology for a medical device can replace former tools. The design of experiments method (Taguchi method)

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is used to determine important parameters and their levels that using 3 or more levels of the process or design parameters for increasing the result. Taguchi approached one large experiment to study all the main effects and some important interactions [13, 14].

The purpose of this study was to design and optimize the 3D printed cutting guide for TKA based on the gap balancing technique. The guide was able to measure and adjust force including gap distance on the medial and lateral sides during intraoperative. It was created using 3D printed with a finite element model and was then validated with the experiment on displacement using the Taguchi method to reduce experimental runs. The main effect of the most bending displacement of the knee tensioner ligament guide might be the beam guide and it was related to 4 factors width, height, base-knee length, and base-support length.

2. Material and Method

The gap balancer was designed by SOLIDWORK 2016. The majority of the device was printed by fused deposition modeling (FDM) technology in the filament of Acrylonitrile Butadiene Styrene (ABS) material the 3D printed machine is Tiertime Up300 and the program that generate g-code for 3D print was UPStudio However this device was not fully printed, some of the parts were aluminium for reinforcing the rack and pinion gear for adjusting the gap of the joint such as slide way and backet. The application of this device was able to adjust gap of the knee joint in flexion and extension spaces both medial and lateral in the process of automatic and manual by LabVIEW programming and feedback control.

This study was focused on the design optimization of the beam by the Taguchi method and ANOVA analysis Through FEM. The main factor was concerned with the width, height, base-knee length, and base-support length of the beam shown in Fig. 1. The other part of the guide was fixed with the bolt. The program of simulation FEM was SIMSOLID2019. The advantage of this program is that eliminates the meshing process and geometry simplification, thereby reducing the time while the processing. The design of experiments using the Taguchi method in 4 factors affecting the beam guide and 3 levels related to the shape of the knee and knee prosthesis.

2.1 Verification of material properties

The material was verified displacement when applying the load for comparing and validating the properties to simulation FEM by SIMSOLID. The weight of 2, 5, 7, and 10 kg were used for verification with repeat 3 times in a row, measuring the bending displacement with a digital vernier caliper after that subtracting the result of the displacement when applying the

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load to the displacement without the load, the result of the subtract was bending of the displacement. Fig. 2 lift the beam up and measure the displacement without the load, setting this gap for the initial displacement the result showed 25.09, 25.05, and 25.00 mm respectively, The average displacement was 25.0467 mm and the standard deviation was 0.0451. At the weight of 2 kg, the measured displacement of the beam when the applied load of 2 kg showed the results of the gap were 24.23, 24.14, and 24.16 mm respectively. The average displacement was 24.1767 mm, and the standard deviation was 0.04726. At the weight of 5 kg, the measured displacements of the beam when the applied load of 5 kg showed the results of the gap were 22.95, 22.90, and 23.08 mm, respectively. The average displacement was 22.9767 mm, and the standard deviation was 0.092916. At the weight of 7 kg, the measured displacement of the beam when the applied load of 7 kg showed the results of the gap were 22.09, 22.11, and 22.01 mm, respectively. The average displacement was 22.07 mm and the standard deviation was 0.0529. At the weight of 10 kg, the measured displacement of the beam when the applied load of 10 kg showed the results of the gap were 20.81, 21.17 and 20.89 mm, respectively. The average displacement was 20.9567 mm and the standard deviation was 0.189. As shown in Table 1, the summary of displacement in all loads applied, without load applied, average (avg) of the subtract of bending result in each load, and standard deviation (SD), the bending displacement was initial bending without load subtract to the weight of each load, the average result of the subtract bending displacement between initial displacement without load to weight 2, 5, 7, and 10 kg was 0.87, 2.070, 2.9767, and 4.090 mm, respectively. The standard deviation was 0.03606, 0.13, 0.03215, and 0.20075. Fig. 3 showed the bending displacement result of FEM simulation at the load of 2, 5, 7, and 10 kg at -0.8023, -1.9697, -2.8081, and -4.0115 mm, respectively.

Material properties for bending simulation related to the average bending result were shown in Table 1. The percent bending displacement error from simulation in Table 1 must not exceed 10% error as shown in Table 2. None of these loads were a percent bending displacement error exceeding 10% which means that could use these material properties to validate the model. Table 3 showed the material properties of ABS for simulation in FEM.

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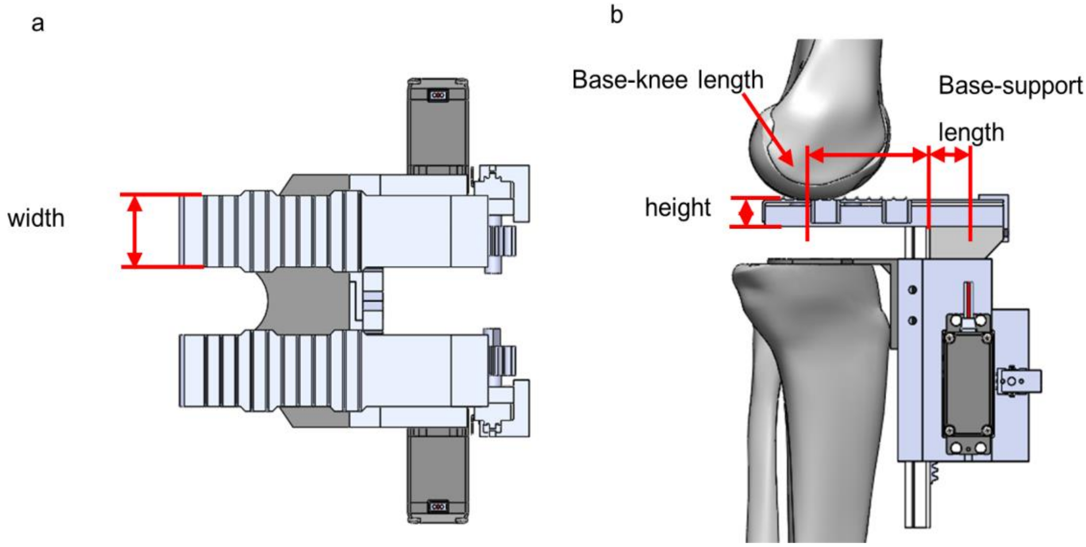

Fig. 1 The knee position with the main parameter consists of 4 factors such as width, height, base-knee length, and base-support length: (a) top view and (b) side view

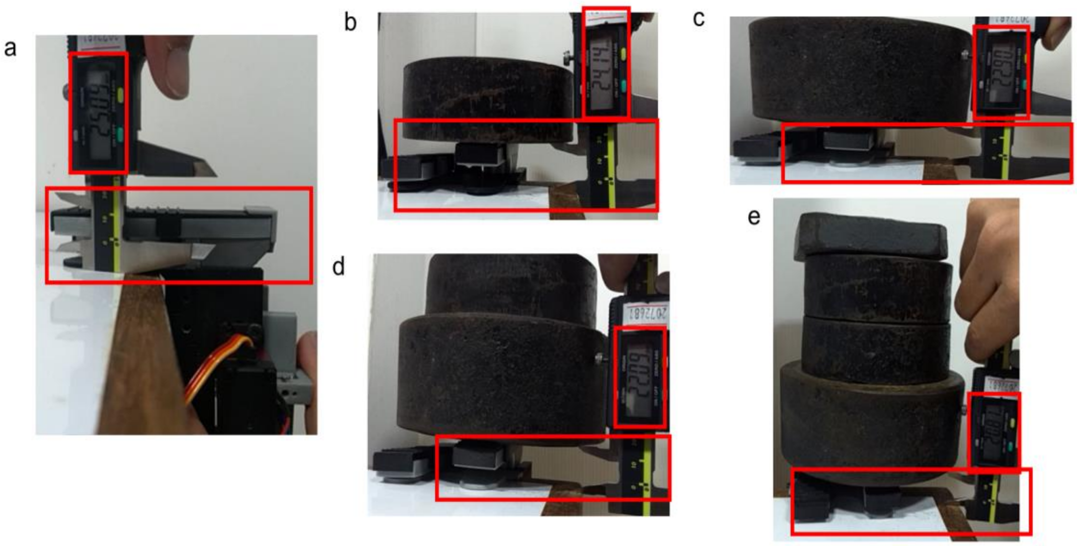

Fig. 2 (a) Initial displacement without load measuring 3 times in a row with a digital vernier caliper and (b) the measuring displacement of the beam with loads at 2 kg and (c) 5 kg

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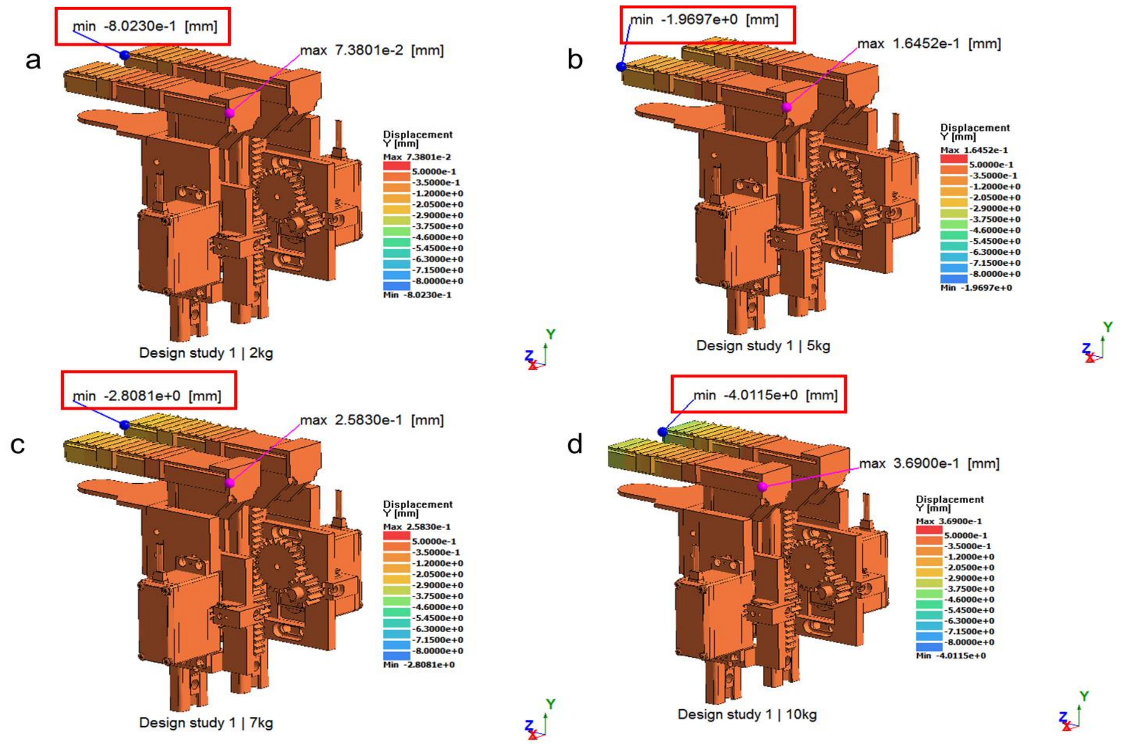

Fig. 3 The FEM simulation result of bending displacement in each load of the beam: (a) 2 kg; (b) 5 kg; (c) 7 kg; (d) 10 kg

Table 1 Average of the subtract of bending result

	Initial without load	**2 kg (mm)**	**Bending (mm)**	**5 kg (mm)**	**Bending (mm)**	**7 kg (mm)**	**Bending (mm)**	**10 kg (mm)**	**Bending (mm)**
	25.09	24.23	0.86	22.95	2.14	22.09	3	20.81	4.28
	25.05	24.14	0.91	22.9	2.15	22.11	2.94	21.17	3.88
	25	24.16	0.84	23.08	1.92	22.01	2.99	20.89	4.11
Avg			0.87		2.070		2.9767		4.090
SD			0.03606		0.13		0.03215		0.20075

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Table 2 Average bending displacement difference and simulation displacement

Load	Displacement Y-axis		
	Average bending displacement difference (mm)	**Simulation result (Displacement Y-axis) (mm)**	**% Error**
2 kg	0.87	0.8023	7.7816
5 kg	2.07	1.9697	4.8454
7 kg	2.9767	2.8081	5.6629
10 kg	4.09	4.0115	1.9193

Table 3 ABS material properties for FEM simulation of the bending displacement

Material	Elasticity modulus (Pa)	Poisson's ratio	Ultimate tensile stress (Pa)
ABS	8.5 e+08	0.38	4.00 e+07

2.2 Design of Experiments

The design of experiments to determine the parameter or size of the beam design that optimizes bending displacement while applying load at the beam by Taguchi method at the load of 100 N in the direction of y-. The load position depended on the displacement of the base-knee length, the longer the base-knee length, the closer to the end of the beam. In the Taguchi method, there were 4 concerning factors such as width, height, base-support length, and base-knee length with 3 levels at each factor of the beam as shown in Table 4. The factors and each level or size were limited to the knee shape and knee prosthesis set the data from Table 4 to orthogonal array for determinate experiments condition. In the orthogonal array, 4 factors and 3 levels matched the model experiments of L9 (3^4) which mean there were 9 experiments and none of the experiments had the same level as the other as shown in Table 5. The revising of design files was made using the computer-aided design (CAD) of the model based on each experiment in SOLIDWORK. Simulation of the bending displacement was at the load of 100 N with the beam by SIMSOLID.

Fig. 4 the result of the simulation showed2 values max value was the part that moves the most in the direction of y+, min value was the part that moves the most in the direction of y- and the most bending displacement of the beam was in the direction of y-. This study focused on the most bending displacement which showed in value minus (y-). Fig. 4 (a) to Fig. 4 (i) showed the FEM simulation result of displacement y- direction from experiments in Table 5, Fig. 4 (a) was the most bending displacement in all experiments at 7.8239 mm and Fig. 4 (i) was the fewest bending displacement at 3.5171 mm. The average result in all experiments was 5.422 mm and the standard deviation was 1.412.

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Table 4 Knee factors and 3 levels of the beam for orthogonal array

Factor	Level 1 (mm)	Level 2 (mm)	Level 3 (mm)
Width	20	22	24
Height	9.8	10.3	11.3
Bse-support length	10	14	18
Base-knee length	3	5	7

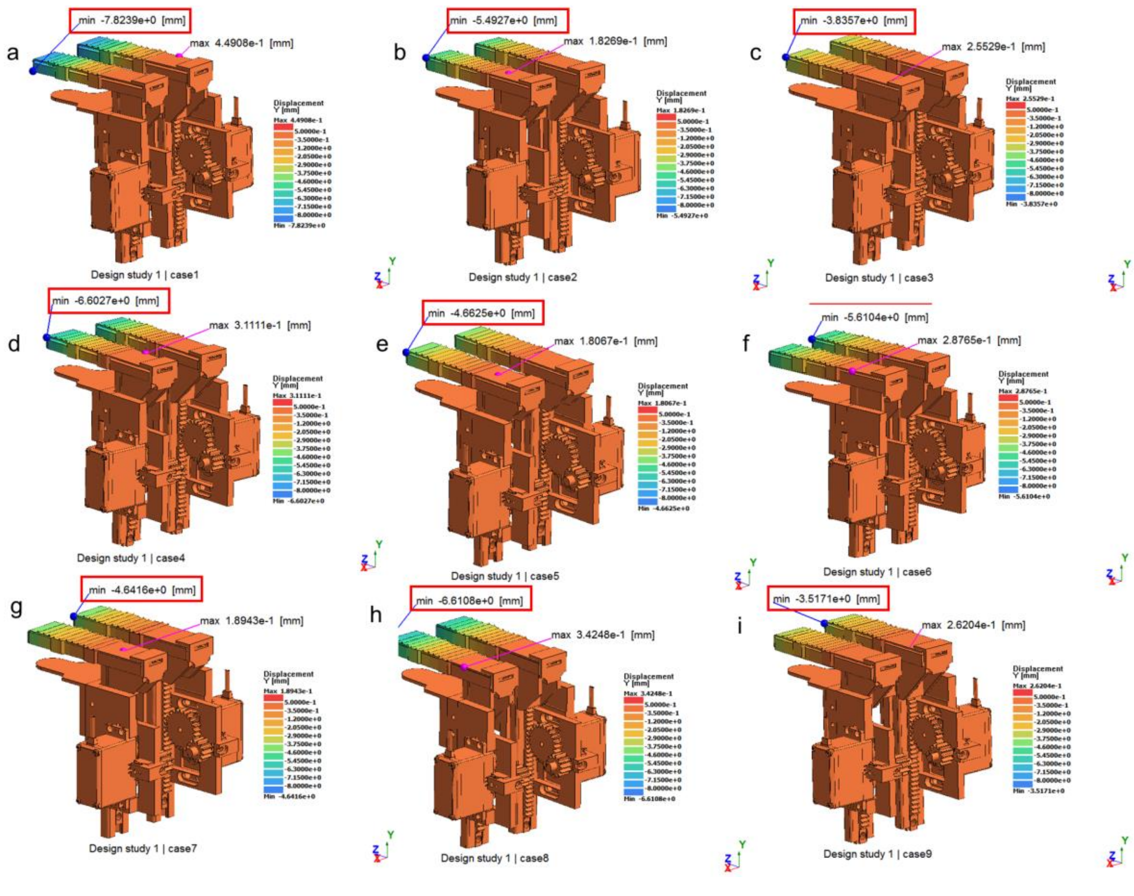

Fig. 4 The FEM simulation in the y direction of the model beam from Table 4: (a) experiment 1, (b) experiment 2, (c) experiment 3, (d) experiment 4, (e) experiment 5, (f) experiment 6, (g) experiment 7, (h) experiment 8 and (i) experiment 9

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Moreover, Table 5 included the summary of all experimental data and FEM simulation bending displacement results of all experiments including the sum and average of the result. Table 6 showed the average result in each level of factor and the result of subtracting max to min in each factor. By using the Taguchi method and the ANOVA the result was calculated from the data and the result in Table 7 which was calculated from Table 5 to Table 6 showed the percent error of experiments was 0.67%. the most effective factor to the beam was the base-support length, height, width, and base-knee length of the percent contribution at 51.06%, 39.60%, 6.89%, and 1.78%, respectively.

In the Taguchi analysis, there were 3 types of analysis to optimize the design “small is better”, “nominal is best”, and “large is better” in this study we used “small is better” to determine the parameter of the beam design to find the fewest bending displacement by plotting the data from Table 6 as shown in Fig. 5. The factor and the points in Fig. 5 were the levels of the parameters. The lowest point of the line has selected and found that the size of the width, height, base-support length, and base-knee length was 24, 11.3, 18 and 3 mm, respectively.

Table 5 Orthogonal array with L9 (3^4) and FEM simulation result of the bending displacement in Y-axis

Experiment	Width	Height	Base-support length	Base-knee length	Bending displacement Y-axis (mm)
1	20	9.8	10	3	7.8239
2	20	10.3	14	5	5.4927
3	20	11.3	18	7	3.8357
4	22	9.8	14	7	6.6027
5	22	10.3	18	3	4.6625
6	22	11.3	10	5	5.6104
7	24	9.8	18	5	4.6416
8	24	10.3	10	7	6.6108
9	24	11.3	14	3	3.5171
sum					48.7974
sumSQ					280.524
aver					5.422
CF					264.5762

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Table 6 The result of average bending displacement in the Y-axis on each level of factors

No.	Width	Height	Base-support length	Base-knee length
1	14.78	15.87	16.42	14.05
2	14.92	14.86	14.04	14.37
3	13.55	12.53	12.79	14.83
max-min	1.36	3.34	3.62	0.77

Table 7 The result obtained from ANOVA

Factor	SS	DOF	Variance	F-ratio	Pure S	% Contribution
Width	1.132	2	0.566	32.04	1.097	6.89
Height	6.337	2	3.169	179.34	6.302	39.60
Base-support length	8.161	2	4.080	230.95	8.125	51.06
Base-knee length	0.318	2	0.159	9.00	0.283	1.78
Error	0.318	18	0.018		0.106	0.67
Total	15.948	26			15.912	100.00

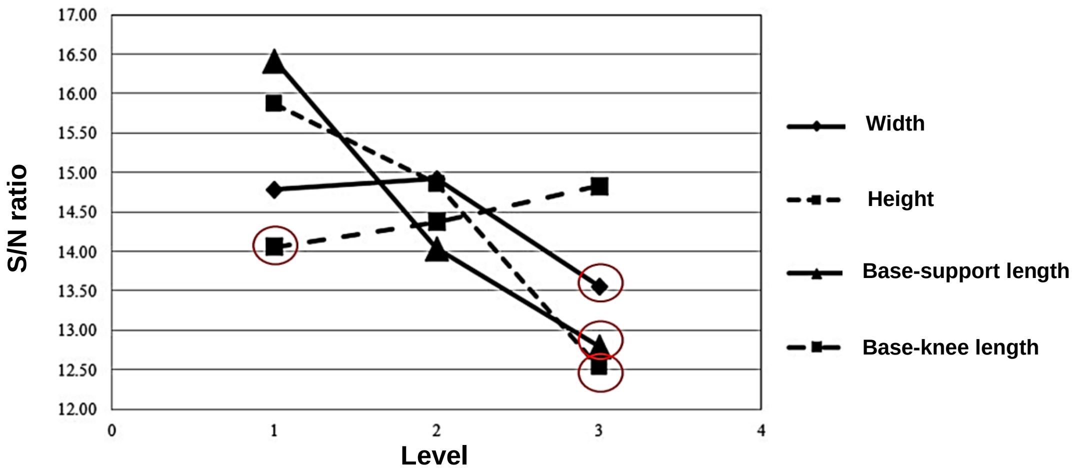

Fig. 5 The result of average bending displacement

2.3 Validation of the result of Taguchi

The result of the Taguchi analysis was validated by simulating the bending motion of the following to the lowest point of the line in Fig.5 at a load of 100 N. The result of FEM was 3.4253 mm as shown in Fig. 6. It was the fewest of all experiments compared to Table 5 which means the design parameter of height, base-support length, width, and base-knee length was 11.3, 18, 24, and 3 mm, respectively must be used.

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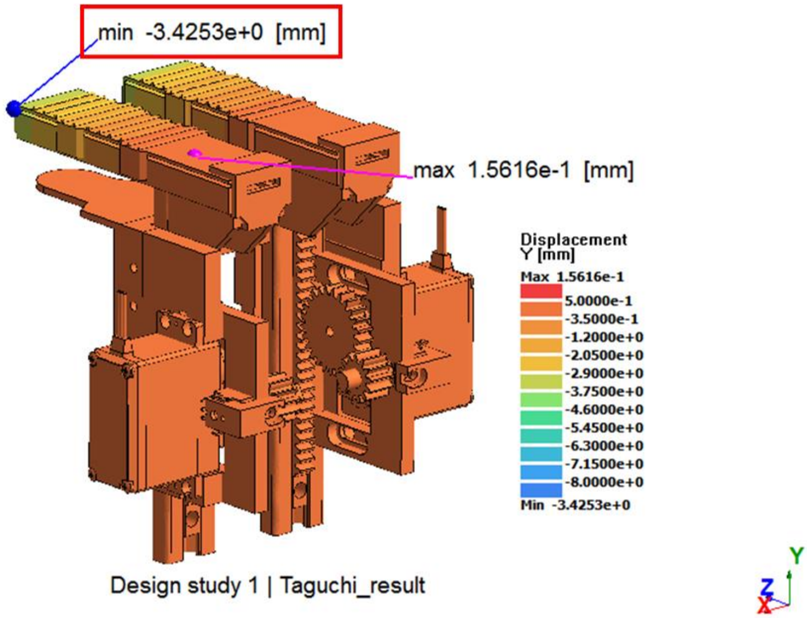

Fig. 6 The FEM result of bending displacement of the parameter from Table 8

3. Result and Discussion

Determining the size of the beam by the Taguchi method with small is better, the bending displacement has been the fewest via FEM simulation. To ensure the bending displacement from FEM simulation and 3D printed beam had no difference we verified the beam with FEM simulation compared to the load of 2, 5, 7 and 10 kg to the 3D printed beam size followed by the lowest point of the line in Fig. 5 the percent error of the beam must not exceed 10%. The experiments of the test were 4 factors and 3 levels which there were 3^4 or 81 experiments; however, we used the Taguchi method to reduce the experiment to 9 cases because the Taguchi method suit for the experiment contains more than 3 factors.

3.1 Verification of the bending displacement

Verification of the bending displacement of the optimum size of the beam from the Taguchi method by comparing the bending displacement result to the FEM simulation displacement result. Using the weight of 2, 5, 7, and 10 kg and did the same method as 2.1 Fig. 7 lift the beam up and measure the displacement without the load, setting this gap for the initial displacement the result showed 25.03, 25.07, and 25.02 mm respectively the average displacement was 25.04 mm, and the standard deviation was 0.0265. Displacement the load of 2 kg was 24.39, 24.42, and 24.41 mm respectively the average displacement was 24.4067 mm, and the standard deviation was 0.0153. Displacement the load of

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5 kg was 23.46, 23.38, and 23.40 mm, respectively. The average displacement was 23.4133 mm, and the standard deviation was 0.0416. Displacement the load of 7 kg was 22.57, 22.63, and 22.60 mm, respectively. The average displacement was 22.60 mm, and the standard deviation was 0.03. Displacement the load of 10 kg was 21.70, 21.74, and 21.87 mm, respectively. The average displacement was 21.77 mm, and the standard deviation was 0.0889. The summary of displacement in all loads applied was shown in Table 8. The average result of the subtract bending displacement between initial displacement without load to weight 2, 5, 7, and 10 kg was 0.6333, 1.627, 2.44, and 3.27 mm, respectively and the standard deviation was 0.0208, 0.0586, 0.02, and 0.1039. Fig. 8 showed the most bending displacement in the y-direction result (min values in the simulation was the maximum bending displacement) of simulation at the load of 2, 5, 7, 10 kg was 0.67364, 1.6841, 2.3577, and 3.3682 mm respectively. Table 9 showed the percent bending displacement error of the new beam from avg of Table 8 compared to the FEM simulation the error must not exceed 10 % the percent bending displacement error at the load of 2, 5, 7, and 10 kg was 6.364%, 3.531%, 3.373%, and 3.003%, respectively. None of these loads there were the percent bending displacement error exceed 10% and percent bending displacement error at the load of 5, 7, and 10 kg were not exceeded 5 %. It was showed that we could use the bending displacement of FEM result as a bending replacement of a 3D printed model with an error of 10%.

3.2 Bending displacement percentage

Validation of material properties with the 3D printed device compared to the finite element program the displacement value must not exceed 10% in varied load. This study aimed to design optimization the beam size of the device by determining the factors and levels that affect the displacement of the beam with the Taguchi method. The optimization of the beam as shown in the lowest point of the line in Fig.5 had the minimum bending displacement from FEM at 3.4253 mm. In Table 5 the most bending displacement was 7.8239 mm in the first experiment and the fewest was 3.5171 mm in the ninth experiment. The optimum case of the beam could be reduced to 56.22% compared to the most bending displacement (first experiment) as showed the percent of reduced bending displacement in Table 10. The 56.22% reduction was the optimum result from the Taguchi method. There was no other case that was lower than this case.

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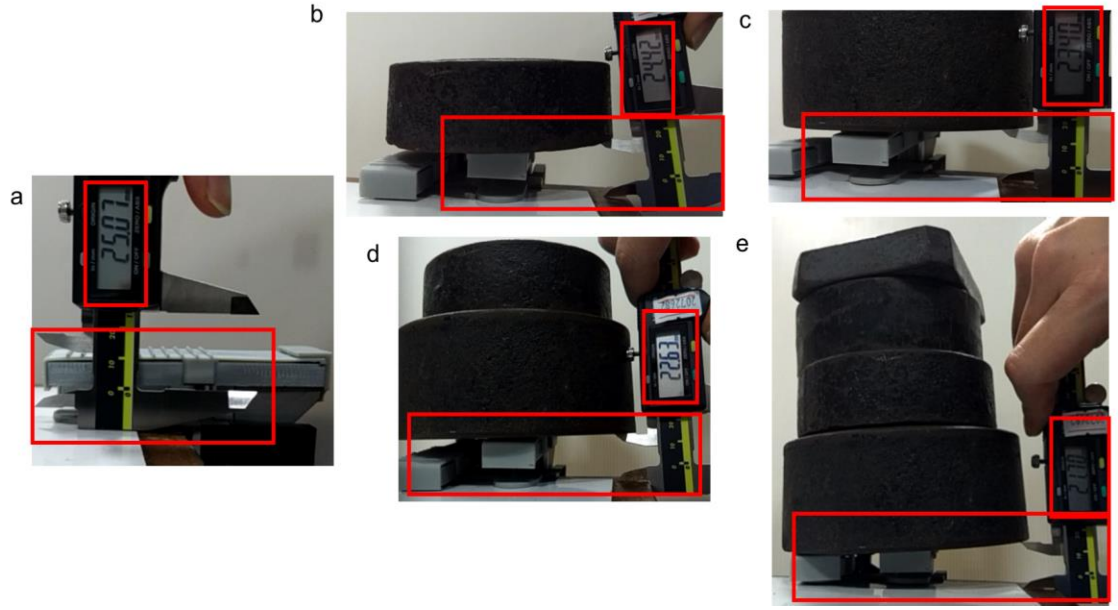

Fig. 7 (a) The initial displacement without load measuring 3 times in a row with a digital vernier caliper and the (b) measuring bending displacement with loads of 2 kg, (c) 5 kg, (d) 7 kg, and (e) 10 kg

Table 8 Average of the subtract of new beam bending displacement result

	Initial without load	**2 kg (mm)**	**Bending (mm)**	**5 kg (mm)**	**Bending (mm)**	**7 kg (mm)**	**Bending (mm)**	**10 kg (mm)**	**Bending (mm)**
	25.03	24.39	0.64	23.46	1.57	22.57	2.46	21.70	3.33
	25.07	24.42	0.65	23.38	1.69	22.63	2.44	21.74	3.33
	25.02	24.41	0.61	23.40	1.62	22.6	2.42	21.87	3.15
avg			0.6333		1.627		2.44		3.27
SD			0.0208		0.0586		0.02		0.1039

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Table 9 Average Bending displacement difference and simulation displacement

Load	Displacement Y axis		
	Average Bending displacement difference (mm)	**Simulation result (displacement Y-axis) (mm)**	**% Error**
2 kg	0.6333	0.67364	6.364
5 kg	1.627	1.6841	3.531
7 kg	2.44	2.3577	3.373
10 kg	3.27	3.3682	3.003

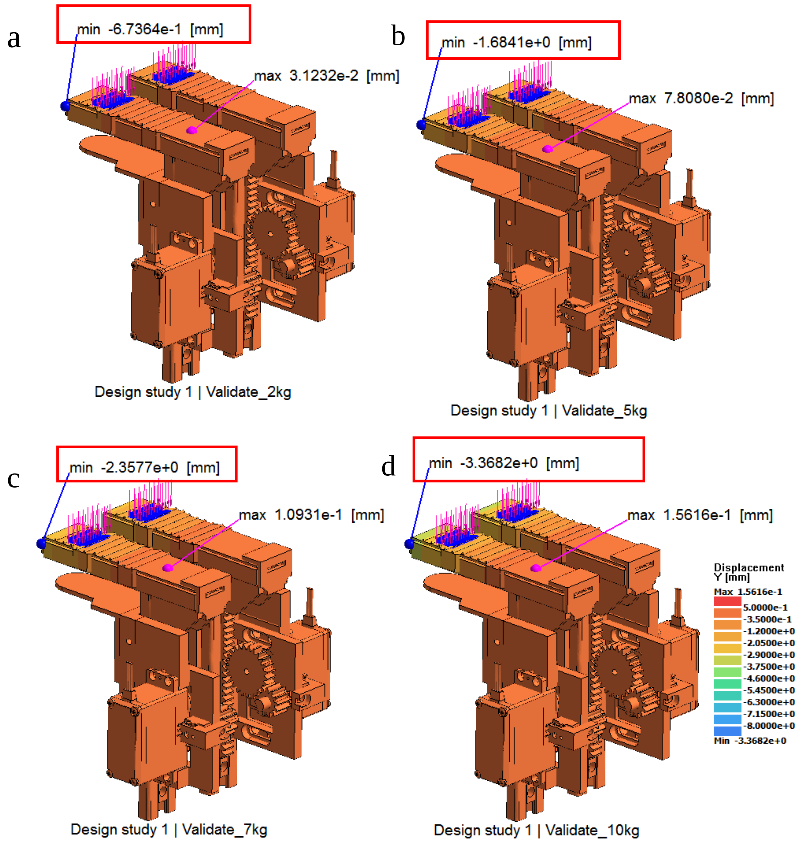

Fig. 8 The FEM simulation result of the new beam bending displacement in each load of the beam: (a) 2 kg, (b) 5 kg, (c) 7 kg, (d) 10 kg

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Table 10 Percent of reduced bending displacement compared to the most bending displacement

Experiment	Width	Height	Base-support length	Base-knee length	Bending displacement Y- axis (mm)	Percent of reduced bending displacement (%)
1	20	9.8	10	3	7.8239	The most bending displacement
2	20	10.3	14	5	5.4927	29.7959
3	20	11.3	18	7	3.8357	50.9746
4	22	9.8	14	7	6.6027	15.6086
5	22	10.3	18	3	4.6625	40.4069
6	22	11.3	10	5	5.6104	28.2915
7	24	9.8	18	5	4.6416	40.6741
8	24	10.3	10	7	6.6108	15.5050
9	24	11.3	14	3	3.5171	55.0467
optimum case	24	11.3	18	3	3.4253	56.2200

4. Conclusion

The design optimization of the beam for the total knee balancing device could use FEM analysis. The FEM used the material properties for calculating and simulating the displacement of the device. In this study, the optimum of the beam to create the knee tensioner ligament guide was 24, 11.3, 18, and 3 mm in width, height, base-support length, and base-knee length respectively. It could use this result as a new shape guide for the knee tensioner ligament guide design. The bending displacement of the beam in each printing depends on a lot of conditions such as material filament, infill while printing, printing setup, and etc.

The total knee arthroplasty rate has been increasing every year not only surgical technology has been improved for convenience and precision in arthroplasty but also the device as well. In the medical field, 3D printing applications are still in research and development.

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