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Parametric Analysis for the effect of expansion ratio during Co-Cr stent manufacturing using fiber Laser

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Abstract: *This research shows how expansion ratio gets affected by the different input parameters of fiber laser. In this research all input parameters were studied and scrutinize the final parameters which affects or influence the mechanical properties of the stent. In this research the input parameters were selected after performing pilot experiments. ANOVA analysis is used to finding out the percentage contribution of each factors on expansion ratio. Mathematical model has also been derived for prediction of expansion ratio without performing actual experiments. It is observed less effect of gas pressur, contributed 10.36%, Percentage contribution of laser power is 61.88 % and frequency is contributing 26.64%.Software developed featured with which can predict expansion ratio of stent without performing actual performance.*

Keywords*:* *Coronary stent,* Mechanical properties, *Fiber laser machining,* Expansion Ratio, CoCr, *ANOVA etc.*

I. INTRODUCTION

It was in 1994 that The U. S. Food and Drug Administration (FDA) had endorsed the inflatable expandable coronary stent for the anticipation of restenosis in the year 1994[1]. It achieves many changes as the advancement of the stents has resembled the development of endovascular intervention as another claim to fame[2].

Stent is evaluated with numerous mechanical and dimensional measurements, experimental methods vary widely, which makes meaningful comparison between stents difficult. K. P. Schmitz et. al. has been compared five commercially available coronary stents using consistent experimental techniques for each. The results were compared and an attempt was made to link each of the parameters measured to its clinical relevance[3].Also K. P. Schmitz et. al. has been resulting measured values for changes in length due to expansion, recoil, inner diameter after expansion, X-ray contrast, and the flexural and radial strength of the expanded stent are extremely important for handling the stent and for a treatment of stenosis that is aimed at permanent opening of the lumen. The results are discussed with a view toward clinical practice, the desired acute results, and possible long-term results[4]. Flexibility and traceability are two basic features of stents. S. Peter et. al. has been study the four different balloon-expandable coronary stent systems(made from SS316L and CoCr were investigated mechanically in order to compare the unsuitability. The coronary stent frameworks were evaluated by estimations of stent adaptability as well as by examination of powers during recreated stenting in a self-explored coronary vessel model. The one-and four-point bowing tests were done to assess the stent adaptability, under uprooting control in creased and extended configurations. The adaptability of stents would be preferably reliant upon the design than on raw material[5]. W. Schmidt et. al. has been investigated five ballon expandable stents and their going with balloon catheters were contemplated in regards to their geometric and mechanical qualities. The estimations got for profile, versatile backlash, stent foreshortening, detectability, flexural strength creased and extended, as well as X-ray contrast are thought about and examined according to the perspective of conceivable clinical use[6]. “P. Szabaditset. al. has been used complex examination method which allow to determine the basic features of stents on onestent as possible. These tests have three big parts as non destructivetests transforming tests and destructive tests. Then on-destructive contains optical microscope, metallographic microscope and scanning electron microscope (SEM) investigations; while the mechanical part contains tests by tensile machine and hardness measurement on the sample. Based on these procedures the recoil the crossing profile the MSA the foreshortening were measured or calculated and the flexibility the traceability the retention and the hardness were measured and determined”[7]. “P. Szabadits et. al. also has been investigated seven different balloon-expandable coronary stent systems were investigated mechanically in order to compare their suitability. In this, assessed by measurements of stent flexibility as well as by comparison of forces during simulated stenting in a self-investigated coronary vessel model. The stents were cut by laser from a single tube of 316L stainless steel or L-605 (CoCr) cobalt chronium alloy. The one and four point bending tests were carried out to evaluate stent flexibility EI, under displacement control in crimped and expanded configuratios. The L-605 row material stents need lower track force to pass through in the vessel model as the 316L row materials stents. In the curve of the vessel model the sort and long stents passed through in different ways. The long stents nestled to the vessel wall at the outer arc and bent, while the short stents did not bend in the curve, only the delivery systems bent”[8]. “K. Takahataet. al. has been study a new approach that uses planar batch manufacturing technologies is presented for the design and fabrication of coronary artery stents. Stent samples with different wall patterns have been fabricated from 50-m-thick stainless steel foil using micro electro discharge machining. Free-standing stents exhibit diameter variations of 4%, almost zero radial recoil after deflation of the balloon, and longitudinal shrinkage of 3% upon expansion. Loading tests reveal that the radial stiffness of some patterns is comparable to that of commercially available stents with greater wall thickness, while bending compliance, at 0.02 m/N for a 4-mm-longsection of the stent, is also favorably large"[9]. "T.W.Dueriget. al. has been summarizes some of the key differences between self-expanding and balloon-expanding stents, al igning engineering and design differences with clinical performance. While neither type of stent can be considered universally superior, the differences are significant enough to make each type more appropriate in specific circumstances"[10]. "They also study mechanical properties such as strength, stiffness (or compliance), recoil, dynamic scaffolding, vessel conformity and fatigue resistance will be highlighted by studying the mechanics of the stent alone, and then of a stent within a vessel for self expanding and balloon-expandable stents. These differences can be summarized by observing that self expanding stents provide more anatomically-correct scaffolding, while balloon-expandable stents provide rigid and uncompromising reinforcement. Other differences, such as corrosion resistance, placement accuracy and visibility, will also be briefly summarized"[11]. "Dong Bin Kim et. al. has been seeks to improve the mechanical performance of stents by conducting reliability performance testing and finite element method (FEM)-based simulations for coronary stents. And also analysis three commercially available stent designs and own new design were tested to measure the factors affecting performance, specifically foreshortening, recoil, radial force, and flexibility. The new improved design is found to have less foreshortening and recoil than the three designs similar to commercially available ones"[12].

II. MATERIALS AND METHODOLOGY

"The persistence of this examination is to learn about stent fabricating utilizing Fiber laser machining boundaries on Cobalt L-605 material. To accomplish these goals it is vital to design reliable system. Fig. 1. shows the embraced approach stream diagram"[18].

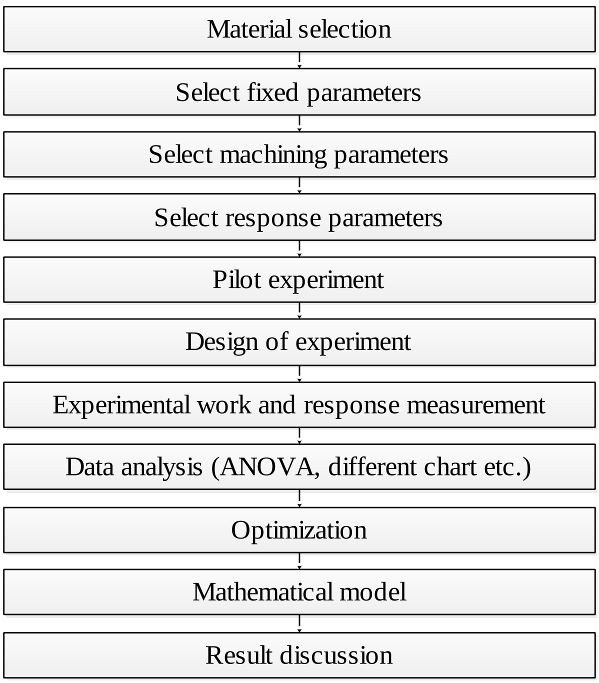


Fig 1. Experimental methodology

With kind permission at Sahajanand laser technology limited, this research could able to work on identified machine model "YLR-1000" which is ytterbium fiber laser cutting machine shown in fig. 2.

Fig. 2. Ytterbium fiber laser machine for stent cutting

Conventional coronary stent made with various metals like tempered steel (316L), cobalt-chromium alloys, nickel-titanium alloys (Nitinol), platinum, and tantalum composites.Cobalt L-605 (otherwise called alloy 25) is a cobalt-based superalloy with significant degrees of chromium and tungsten. It is described by extraordinary high-temperature strength up to 1500 °F (815 °C), superb oxidation obstruction at high temperatures up to 2000 °F (1093 °C) in destructive conditions, and better opposition than sulfidation wear and irritating. Cobalt L-605 has other less-realized characteristics like high flexibility and biocompatibility. Cobalt L-605 is non-attractive. On account of its biocompatibility, Cobalt L-605 can likewise be utilized in the clinical business, chiefly for assembling of heart valves. Along these lines, here choose Cobal L-605 Material for stent Manufacturing.

The experiments" have doing on hollow tube having internal diameter 1.5 mm and thickness and having length of 300mm with 130 micron thickness of Cobalt L605. Machined specimen is shown in Fig 3.

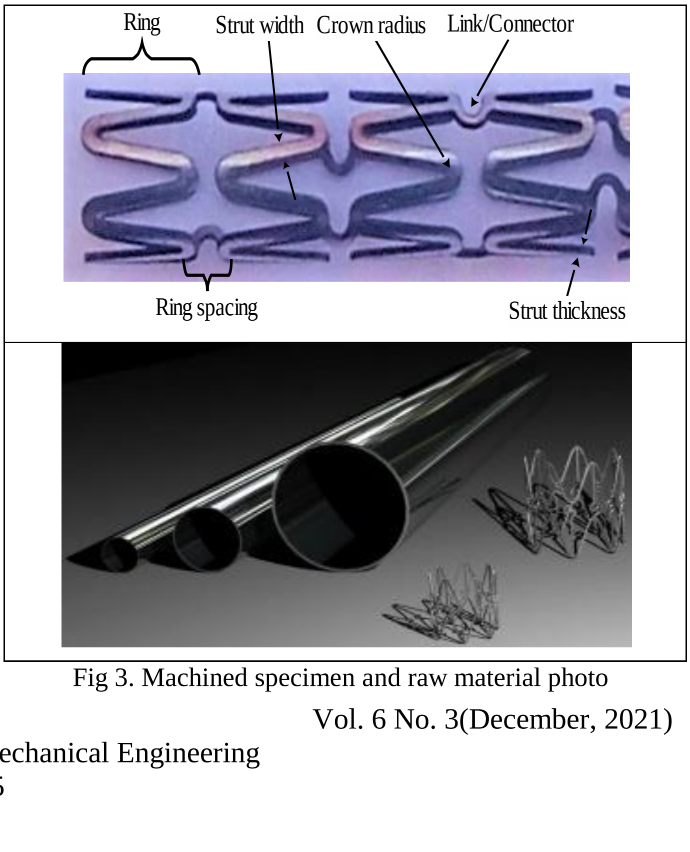


Fig 3. Machined specimen and raw material photo

The stent manufacturing by fiber laser process parameters and their ranges after pilot experimentation as shown in Table 1. So, here select the following ranges for final experiments.

Table 1. Fiber Laser parameters/ranges after pilot experimentation

Parameters	Range in machine	Used range in stent manufacturing	Selected range after pilot experimentation
Gas Pressure (GP)	1-10 bar	1-10 bar	4-8
Laser power (LP)	1-1000 W	1-150 W	60-100
Frequency (FQ)	0-50 kHz	1-10 kHz	1-5

In industry, product quality would maintained by designed experiments which, used to systematically investigate the process or the product variables. In plan of trials, the experimenter is regularly inspired by the impact of some cycle or examination. Expanding usefulness and further developing quality are significant objective in any business. Thus, here utilized Full factorial Method to test experimental run generation.

In design of experiments, the experimenter is often interested in the effect of some process or investigation. Increasing productivity and improving quality are important goal in any business. So, here used Full factorial Method to experimental run generation.

It is generally acknowledged that the most ordinarily involved exploratory designs in manufacturing are full and partial factorial design at two levels and three-levels. Factorial designs would empower an experimenter to concentrate on the cooperative impact of the parameters. A factorial design can be either full or partial factorial[13].

Various boundaries are considered as predictable boundaries. The machining system boundaries and its level are portrayed in Table 2.

Table 2. Control parameter

Machining process parameter		Indicated name	Level		
			1	2	3
A	Gas Pressure (bar)	GP	4	6	8
B	Laser power (W)	LP	60	80	100
C	Frequency (kHz)	FQ	1	3	5

The stents were extended utilizing an inflatable catheter (Clear Line-CL1515R) and a manual expansion gadget (New Tech Medical, 20cc30, Gun type Premium (JR)). Fig. 4 shows a schematic drawing of the arrangement for the tests. To ensure equivalent circumstances along all the stent outside surfaces, a home-made development stage was utilized to keep the stent mounted on the inflatable catheter liberated from outer limitations and it is displayed in Fig. 4. Pictures during stent extension were taken utilizing a Profile projector (RPP-3000) with a 0.5X amplification. To improve the difference of the pictures, blue food colorant was added to water and infused inside the catheter. Every one of the stents were extended with an expansion of the inflatable strain from 0 to16 bar and recordings were obtained. At each strain step of 1 bar, the stent outer width was estimated in the focal part of the gadget.

Three estimations were taken at each situation for each tension worth. Development proportion was additionally determined from the estimations with the accompanying condition

$$ER = d_i/d_o$$

Where di is the diameter measured at a RBP pressure (p), and d0 is the initial diameter of stent.RPP-3000 profile projector photo shown in Fig. 4.

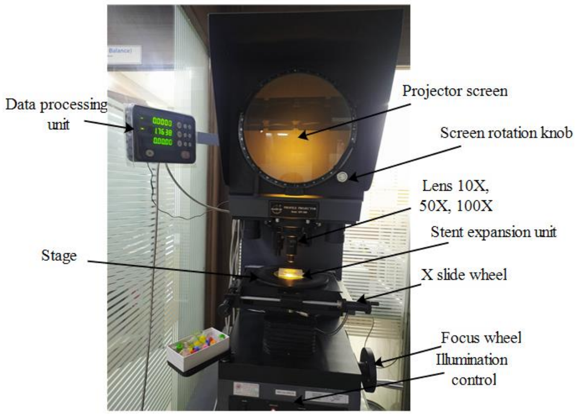


Fig. 4.RPP-3000 profile projector with annotation

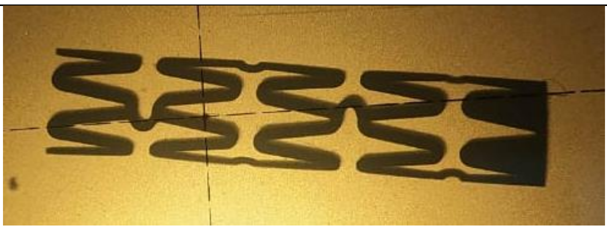
RPP-3000 profile projector detail specifications are shown in Table 3.

Standard of procedures to measurement

Stent is placed on the working table (stage), and the objective lens with high magnification (50X/100X) is used to adjust the focus. The projector screen rotation zero alignment, namely short white screen frame of zero mark. To adjust the direction of the worktable to be measured in parallel with the measuring axis with parallel to the stent surface axis. Step-4 We need to move or fall worktable, the measured length of one end on the screen, X and Y coordinates to zero. Move the X or Y axis, the other end you want to measure. Repeat same for three times at three different place for accuracy of measurement.

This procedures used for measurement of link/Connector width, Strut width, Stent diameter after machined, Inflected stent diameter at RBP, Expansion ratio at RBP, Final diameter of stent and Recoil.

Three different magnificent X zooming are shown in Fig.5.



10X

50X

100X

Fig. 5. Stent view on 10X, 50X and 100X lens in profile projector

Balloon catheter photos and specification shows in Fig. 6

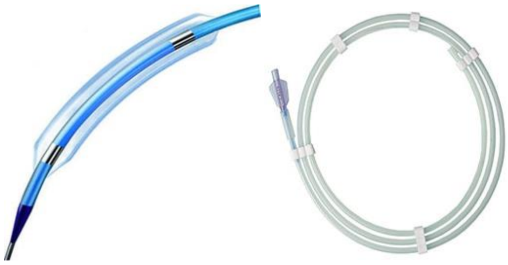


Fig. 6. Balloon catheter photos

Fig. 7. Inflation device photos

III. Design of experiment with result table

The investigation involves full factorial DOE with L27 symmetrical cluster for trial and error. The exploratory outcomes are displayed in Table 3.

Table 3. Experiment result table for ER

Run	Gas Pressure (GP)	Laser Power (GP)	Frequency (Fq)	Inflected stent diameter at RBP in mm				Expansion ratio at RBP (ER)
				S1	S2	S3	Average	
1	6	60	5	2.0481	2.0511	2.0961	2.0651	1.17
2	6	100	3	2.2429	2.2439	2.2349	2.2406	1.27
3	4	60	5	1.9675	1.9975	1.9185	1.9612	1.11
4	6	60	3	2.0280	1.9820	2.0420	2.0173	1.15
5	8	100	1	2.0535	2.0385	2.0375	2.0432	1.16
6	4	100	5	2.1825	2.2005	2.2215	2.2015	1.25
7	8	60	5	1.9796	1.9666	1.9346	1.9602	1.11
8	6	60	1	1.9070	1.9190	1.8780	1.9014	1.08
9	6	80	3	2.1354	2.1784	2.0974	2.1371	1.21
10	6	100	1	2.1220	2.1650	2.1130	2.1333	1.21
11	4	100	1	2.0414	2.0784	2.0884	2.0694	1.18
12	6	100	5	2.2631	2.2631	2.2811	2.2691	1.29
13	6	80	1	2.0145	2.0305	2.0345	2.0265	1.15
14	4	80	5	2.0750	2.0290	2.0630	2.0556	1.17
15	8	100	3	2.1744	2.1924	2.1764	2.1811	1.24
16	8	100	5	2.1946	2.1776	2.2266	2.1996	1.25

17	4	80	3	2.0548	2.0568	2.0778	2.0632	1.17
18	8	80	1	1.9460	1.9220	1.9400	1.9360	1.10
19	8	60	3	1.9594	1.9874	1.9294	1.9588	1.11
20	4	60	3	1.9473	1.9543	1.9523	1.9513	1.11
21	4	100	3	2.1623	2.1183	2.1873	2.1560	1.22
22	6	80	5	2.1556	2.1276	2.1706	2.1513	1.22
23	8	80	5	2.0871	2.0501	2.0471	2.0614	1.17
24	8	80	3	2.0669	2.0789	2.0439	2.0633	1.17
25	4	60	1	1.8264	1.7824	1.7834	1.7974	1.02
26	4	80	1	1.9339	1.8839	1.9459	1.9212	1.09
27	8	60	1	1.8385	1.8285	1.8885	1.8518	1.05

III. DATAANALYSIS AND INTERPRETATION

The ideal still up in the air by concentrating on the primary impacts of every one of the elements. The interaction comprise of minor math control of the mathematical outcomes. The primary impact shows the overall patterns of the impact of the variables. Thinking about the attributes, i.e., regardless of whether a sequential worth delivers the longing results, the level of the elements which are relied upon to create all that outcomes can be anticipated. The information on the commitment or job of individual elements is a key to choose the idea of the control to be laid out on a creation interaction [14]–[17].

Above research shows the rate commitment of individual boundaries on ER. The rate commitment of gas power is 7.83%, laser power is 53.83% and frequency is 37.88%. Parametric analysis is carried out for the quality of the sample. i.e. ER. This ANOVA shows the rate commitment of parameters separately as mentioned in below table:

Table 4. Percentage contribution of each input parameters for ER

Sources of Alternation	D.O.F	Sum of squares S	Variance (Mean square)	Variance ratio F	Percentage contribution P
Factor A	2	0.0125	0.0063	92.5137	10.36
Factor B	2	0.0749	0.0374	552.3497	61.88
Factor C	2	0.0322	0.0161	237.7596	26.64
Error (O)	20	0.00135	0.0001	1	1.12
Total	26	0.121			100

The calculated value in table is also found out with the use of our developed software ANOVA analyzer, so by using this software; the value is as same as calculated value as shown in below Fig. 8.

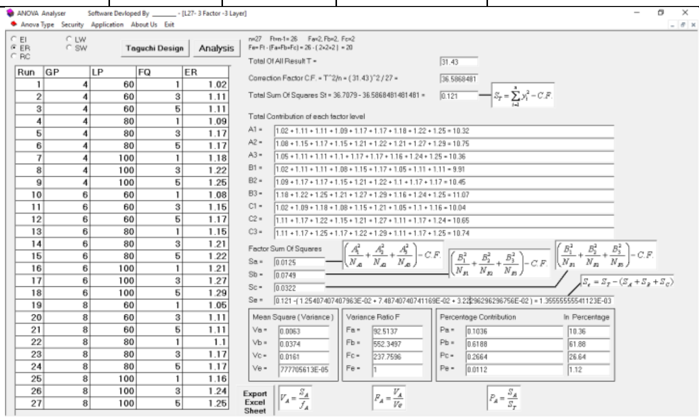
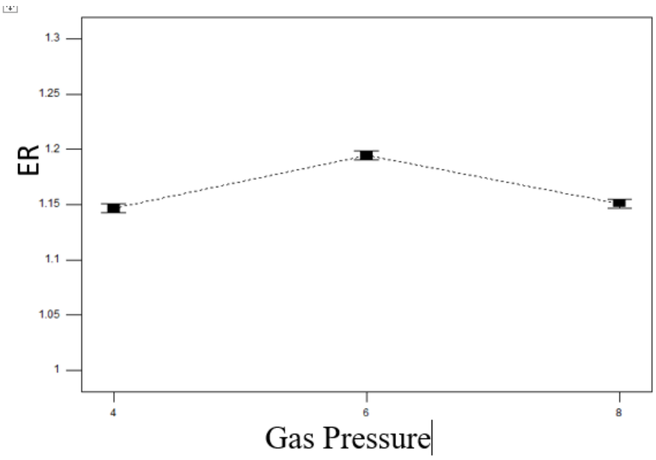


Fig. 8. GUI of ANOVA analyzer with EI results

III. Linear representation of response parameter.

Fig. 9 represents the point of graphical valuation and illustrates the plots of mean effects as changes arise in expansion ratio.



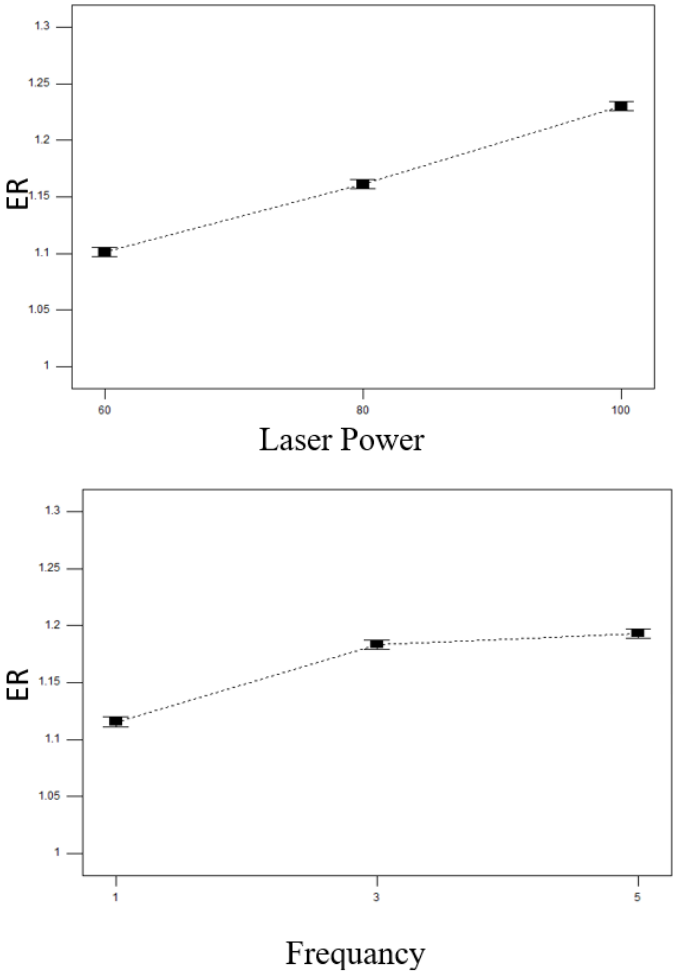


Fig.9. Graph of median outcome of input parameters on ER

Figure 9 show that the effect of input parameter on expansion ratio. In above figure first graph shows the relation of expansion ratio in connection with gas pressure. Graphs shows that when gas pressure increases Expansion ratio will increase initially, but when gradually increasing gas pressure the phenomena of expansion ratio is firstly increasing and than in decreasing in nature. It shows the gas pressure is not that much affected the expansion ratio. But in case of laser power and frequency it shows while increasing both input parameters individually the expansion ratio is increasingly in manner.

R-Square value of Expansion Ratio:

R-Square for ER $=1-\left[\frac{0.001407}{0.12+0.001407}\right]$

=0.9884

Value of R^2 regard show that the pointers close to 98.84% of the variance in ER. The value of modified R^2 is 98.49% which records for the quantity of indicators in the model. The two qualities described the model is correct and given instruction well. Original and assumed result's graph as shown in Fig. 10.

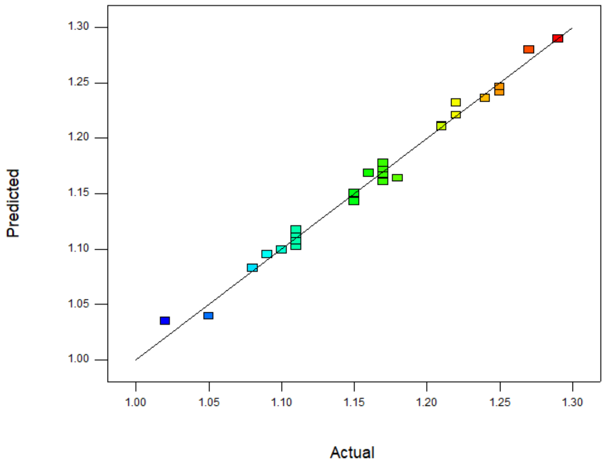


Fig.10. Graphical comparison of original and assumed values

The relapse recipe was observed utilizing the Design Expert programming and the relapse condition is referenced as beneath:

Derived regression equations for actual factor:

$$ER = +1.16 - 0.017 * A[1] + 0.030 * A[2] - 0.063 * B[1] - 2.963E - 003 * B[2] - 0.049 * C[1] + 0.019 * C[2]$$

(Eq.no.2)

IV. CONCLUSION

Looking to the deliberate result boundary that is development proportion, in worry with separate in put boundaries. It is observed that there is less impact of gas pressure contributed just 10.36% the explanation is gas sis used for smoother execution of activity as well as defensive cutting from natural impact which won't make a lot of impact on cutting rapidly.

It is likewise seen that development proportion increments as laser power expanding. Rate commitment of laser power is 61.88 %. Material expulsion increments ultimately swagger width will decreases which will increments extension proportion as displayed in diagram fig. 10,6

In the event of recurrence conduct of recurrence is likewise like laser power contributing 26.64% , explanation for this as recurrence increments heat dissemination time will increments, accordingly material expulsion rate increments as a rest swagger width diminishing thus development proportion increments as displayed in fig. 9

Along these lines, it is presumed that one can foresee twisting solidness without performing real operation utilizing inferred numerical condition no. 2 by placing worth of info boundary in to the range determined.

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