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Increasing the Quantity and Quality of GeNose 19 Medical Device Gaskets Using Piercing Tools

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***Abstract*—The Ge Nose C19 medical device gasket is a product from a manufacturing company in Yogya. Gaskets must be of good quality to ensure vacuum or prevent air leakage from entering the test chamber. The core problem in the production process is the quality problem of many rejects and the quantity not yet meeting the production target. The observation results show that the gasket reject problem is found in the four holes that are formed, which do not match the dimensions or are torn. Making four holes in the gasket made from neoprene rubber is done through a drilling process, which can risk tearing or damage. The type of drill bit used can affect the success of drilling gasket holes. The process of making four holes in the gasket using the piercing method is thought to be able to increase the quality and quantity of gasket products. This research aims to increase the quantity and quality of Ge Nose 19 medical device gaskets using a piercing tool. Research methods include problem identification, literature study, design, manufacture, and testing of piercing tools. The test parameters are time and product quality, namely the shape and position of the hole. The results of this research show a reduction in the cycle time of the hole-making process by 53.7%, so production capacity has increased by 51.8%. The quality of gasket production has increased; of the 40 samples tested, 0 gaskets were rejected.**

***Keywords*—The GeNose C19; piercing tool; quantity gasket; quality gasket.**

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I. Introduction

As the COVID-19 pandemic sweeps the world, there is unprecedented demand for rapid and accurate testing methods to identify and track the spread of the virus. Traditional PCR tests, although reliable, often require time-consuming laboratory processes and special equipment, making mass testing and early detection a challenge. Responding to these challenges, scientists and researchers worldwide are working to develop innovative solutions that could revolutionize COVID-19 testing. The Indonesian Ministry of Industry, through one of its work units, namely the Leather, Rubber and Plastics Center, in collaboration with manufacturing companies in Yogyakarta, has contributed to the development of a Covid-19 virus detection tool called Ge Nose C19, as shown in Figure 1. Ge Nose C19 emerged as the answer that promises to address this global health crisis by offering a quicker, more accessible, and non-invasive approach to detecting the presence of the virus. GeNose, as a health screening tool, was already known to the public before the COVID-19 pandemic. Around 2008-2010, this tool was used to detect exhaled breath and whether someone had tuberculosis (TB) or not. Covid-19 is seen as a disease associated with the respiratory tract. Artificial Intelligence (AI) built initially for TB diagnosis, was diverted to COVID-19 [1].

Fig. 1 Ge Nose C19 Covid-19 Virus Detection Tool

This medical device is Indonesia's first innovation to detect COVID-19 through breathing, and the application is connected to a cloud computing system to get real-time diagnosis results [2]. This tool requires large quantities of quality gaskets during its operation, as shown in Figure 2.

The Ge Nose C19 gasket is essential for attaching electronic components to the non-rebreathing mask sample bag sensor module as a test sample air reservoir [3]. The quality of the gasket must be good because it minimizes interference with readings [4]. This gasket serves to ensure a vacuum or unwanted air leaks in the chamber or test room. Gaskets can help ensure that the air being tested is the user's breath so that the test results are more accurate [5]. Gaskets can also help maintain the cleanliness and sterilization of tools by preventing contamination from the surrounding environment [6].

Fig. 2 Ge Nose C19 gaskets

The gasket manufacturing process starts with raw material in the form of a roll of neoprene rubber measuring 10,000 x 1000 x 3, cut into a size of 68 x 1000 x 3 [7]. Then, go to the hydraulic punch machine for the cutting process using die cutting. This process aims to print the gasket so that it is in the shape of a ring with an inner circle diameter of 59 and a circle diameter of 64. The next process is drilling, which is making four holes measuring 3 mm using a drill with a diameter of 3.2 on a conventional drilling machine. This process requires a specially designed jig to grip and position the gaskets during drilling. After the gasket is finished, the drilling process is continued with the washing process using the company's washing machine. This process takes 30 minutes while maintaining a water temperature of 60ºC. The next process is drying and sterilizing the gasket, where the gasket is placed and arranged in an isolated room for 24 hours under the light so that the gasket is completely dry and sterile during the Quality Control (QC) and Assembly processes.

There are problems in the Ge Nose C19 gasket production process; namely, making four holes with a diameter of 3 mm takes quite a long time, and many gaskets have defective holes during the quality control process. The process of making holes using conventional drill bits and jigs is shown in Figure 3.

Fig. 3 The process of making holes using a drill and jig

The appropriate drill bit material is crucial based on the specific material intended to drill [8]. Using the wrong type of bit for a particular material can damage the bit and result in subpar drilling results. For drilling hard materials like metal or masonry, choosing high-quality HSS or carbide-tipped drill bits is generally advisable, as they are less likely to be easily damaged and perform better [9]. The gasket is inserted into the jig and stacked in four layers. Attach the lid to the jig with four holes as drilling points. Making four holes using a jig and drill bit took 53 seconds and, within 2 hours, produced 533 gaskets, while the target given by the company was 600 gaskets within 2 hours.

The quality of the drilled holes was also inconsistent; out of 40 gasket samples, there were still 11 NG (Not Good). NG products are damaged products that do not pass quality control because the hole's position, size, and shape do not comply with standards, namely oval/ellipse/hole diameter less than 3mm, as shown in Figure 4. The type of drill bit used can affect the success of drilling holes in the gasket. Neoprene rubber gaskets are an elastic material and are resistant to various types of environments. Therefore, choosing the right drill bit is crucial to producing a clean and neat hole. This type of drill bit generally has a blunter cutting angle than drill bits for metal or wood. This type of drill bit minimizes the risk of tearing or damaging the Neoprene rubber gasket. Bits with titanium or carbide coating are resistant to wear and allow for making cleaner holes in Neoprene rubber.

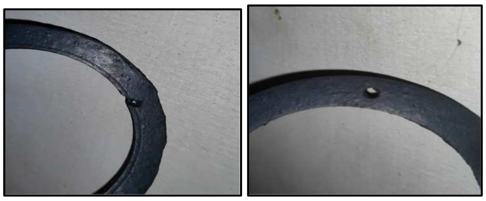


Fig. 4 NG gasket hole oval/elliptical/hole diameter less than 3mm

The process of making holes in gaskets with neoprene rubber material will be more effective using the piercing method [10]. Piercing tools can speed up making several holes in the gasket manufacturing process [11]. The construction of the piercing tool is relatively simple, making it easy to manufacture [12]. The piercing method can maintain the consistent quality of the holes [13], and they are cheap and easy to assemble [14]. The purpose of this study is to design a piercing tool on a dobby-20 type Y0-10020 hyper power press machine to speed up the time for making holes and the quality of holes in the GeNose C19 gasket components, as well as testing the piercing tool to determine the amount of reduction in the cycle time of the 3mm hole making process on the gaskets.

II. Materials and Method

A. *Neoprene Rubber (polychloroprene/CR)*

When a material is to be processed, it is necessary to know the properties of the material. The gasket is made of Neoprene rubber material by taking advantage of the elastic properties and resistance of the material to temperature, deformation, and dust [15]. Neoprene rubber is a synthetic rubber, sometimes referred to as polychloroprene or CR (chloroprene rubber) [16]. Neoprene rubber is moisture and weather-resistant, making it the polymer of choice for heavy industrial applications exposed to elements such as moisture, sunlight, ozone, oxidation, rain, and snow. [17]. Neoprene rubber is abrasion resistant, making it suitable for dealing with sand and dust, making it the right choice [18]. Neoprene rubber exhibits excellent chemical stability and can maintain flexibility over a wide temperature range. [19]. Neoprene rubber specifications based on test results by the Indian Rubber Manufacturers Research Association (IMRA) based on ASTM D395 standards for 35% compression test, ASTM D412 for 17 MPa Tensile test, ASTM D2240 for Durometer 65 ± 5 HA hardness test, and ASTM D297 for composition test Chemical Ash Content 8-12% [20]. The test was carried out with specimens in the form of neoprene rubber sheets with a thickness of 3mm, length of 10m, and width of 1m [21].

The accessibility of specific materials can change over time and is influenced by supply chains, market conditions, and industrial demand. For the most recent information regarding the availability of Neoprene Rubber in Indonesia, it is advised to speak with the industrial zones of nearby suppliers or seek the advice of industry professionals [22]. The availability and sourcing of Neoprene Rubber in the Indonesian market can also be learned about through perusing online markets, going to trade exhibitions, and contacting industry groups [23]. The availability of Neoprene (polychloroprene) rubber gasket materials in Indonesia can vary depending on location and specific needs, including through industrial material suppliers or available at industrial material shopping centers in big cities such as Jakarta, Surabaya, and Medan.

B. Piercing Tool

Piercing is a cutting process that produces a complete hole in the blank/sheet material/gasket material with a press tool, and all sides are cut [24]. The process of making holes through pressing the punch in the material. Piercing is similar to blanking except that in punching the desired product, materials are removed from the waste. A piercing tool is a tool for cutting products from sheet-based materials that operate using a press machine. The upper plate supports the upper part of the tool as a holding and guide tool for the punch, which functions as a jig, while the lower part consists of a bottom plate and a die set as a support and guide for the workpiece, which functions as a fixture. The working process of this tool is based on the compressive force that is transmitted by the punch to cut the gasket according to the desired geometry and size. Piercing produces residue in the form of thin pieces with a variety of shapes and sizes based on the shape of the punch tip and the hole in the dies [25].

1) Die Set: A Die set is a fundamental part of any die. Figure 5 shows Standard Punching Dies. It consists of a bottom die, or die shoe, and an upper shoe, both aligned for several inches [26]. The standard Die Set construction is shown in Figure 5 [27].

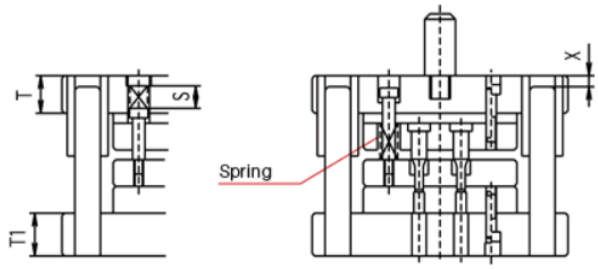


Fig. 5 Standard Punching Dies

2) Shoulder Punch: The shoulder Punch used in the piercing cutting mechanism, shoulder punch from the Misumi company has certain specifications with codes for each type of good [28]. The shoulder punch used in the GeNose C19 piercing tool gasket has the code SPAS 6 50 P3, where SPAS is the code for a circular tip with a short functional part size. Code 6 (six) refers to the diameter of the shank part, which is 6 mm; code 50 means the overall length of the punch is 50 mm, and code P3 refers to the diameter of the functional punch, which is 3 mm. Parts of the Shoulder Punch are seen in Figure 6.

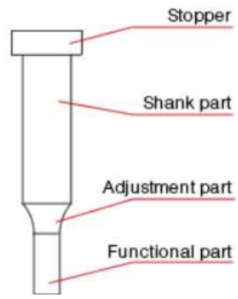
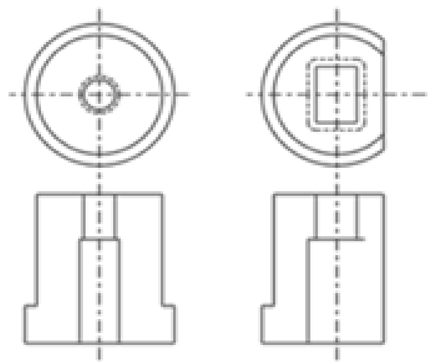


Fig. 6 Sections of the Shoulder Punch

3) Button Dies: Button dies are used in the GeNose C19 gasket piercing tool. Button dies hardened dies where the edge serves as the cutting member as opposed to the punch [28]. The type of Button dies used is MHD 10 20 P3,4, where MHD 10 means the diameter of the Button dies is in the range of 3 mm – 56 mm, namely 10 mm with round shape cutting holes. Code 20 means the overall length of the Button dies is 20 mm. Code P3.4 means that the diameter of the cutting hole (p) is 3.4 mm. Variations in the shape of the cutting hole as shown in Figure 7.



(a) (b)

Fig. 7 Variations in the shape of the cutting hole Button Dies (a) Round Shape, (b) Square Shape.

C. Piercing Tool Design

Piercing tool design starts with determining the power requirements for the piercing process. Next, the die set design, which consists of punches, Button dies, and plates, is carried out. Contact pressure analysis is used to determine the maximum pressure that can be applied without causing damage to the Finite Element Area structure. This information can be used to help decide whether or not to apply higher pressures in planned operations. Contact pressure is a measure of how much force is required to cause two or more parts to contact each other. This pressure is caused by the forces exerted between the parts. The equation for the contact pressure that occurs between an elastic spherical surface and an elastic flat surface [29]is:

$$Po = \frac{3F}{2\pi a^2} = \frac{1}{\pi}\left(\frac{6FE^2}{R^2}\right)\frac{1}{3} \qquad (1)$$

Where: Po = maximum contact pressure (MPa), F force (N), a = width of the surface of the ball in contact (mm), E Young's modulus (Pa), R = radius of the ball (mm). Design analysis is used on die elements that experience contact pressure, namely modification of the tip profile of the shoulder punch and bottom dies is carried out using the Finite Element Method. Its function is to determine the effective geometry that can be used to carry out the piercing process [30]. The finite element method is a computer-based numerical method for solving engineering problems in user-defined planes or volume geometries [31].

D. *Quantity testing*

Process time testing is carried out by observing, recording, and calculating the time taken to make four holes in the gasket. The time calculation starts from the first step, where the gasket is placed according to the position; the second step continues with the stamping process, and the third step removes the gasket from the tool. The three steps of the piercing gasket were repeated four times to take one experimental data, and ten trials were carried out. This was done because the previous work, when using a jig required four gaskets in one drill.

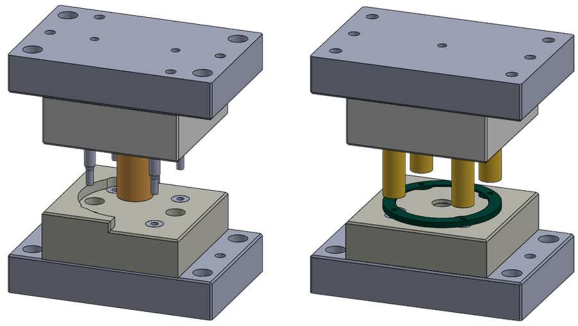
E. *Quality Testing*

Quality testing is carried out using a circular positioner with a diameter of 64 mm with four M3 bolts spaced 28.3 mm from the center at degrees 45.44º, 132.65º, 225.44º and 312.65º counterclockwise as a reference for the position of the four holes on the gaskets. The four holes in the pre-treated gasket are threaded into the positioned M3 bolts. It is necessary to pay attention to the angle reference of the gasket hole so that measurement errors do not occur. These criteria include the difference between the outer and inner rings having the same size on the gasket circumference with a tolerance of < 1mm, the distance between the small holes for the bolt input, and the inner and outer circles being right in the middle or with a tolerance < 0.5 mm, the size of 4 small holes on the gasket should fit M3 bolts.

III. Results and Discussion

A. *GeNose-19 Gasket Piercing Tool Design*

The GeNose-19 Gasket piercing tool design process is carried out by considering various factors, namely the machining process, aesthetics, the installation and/or removal process, the shape and dimensions of the gasket material, the availability of materials and components, and designed according to field conditions. In contrast, the supporting components follow the standard [32]. There are two design alternatives in the following, as shown in Figure 8. Alternative design (a) on the stripper (urethane) section has a diameter of 6 mm and is located in the middle. This is due to the previous piercing concept of making four holes first and then cutting the center of the gasket with a diameter of 59 mm using a die cut. Alternative design (b) drastically changes the die plate and stripper. Fundamental changes also occur in the material (gasket) where in alternative design (a) the gasket is still a circle-shaped material without a hole in the middle so that the stripper can lock the gasket position; in alternative design, the two gaskets are already in the form of a ring so that the stripper is placed on each punch.



(a) (b)

Fig. 8 Alternative Piercing Tool Designs

Design (b) is the final design concept of the piercing tool, which will be taken with the addition of a dowel pin as a position between the die plate, lower support plate, punch plate, and upper support plate.

1) Press Machine Capacity. The capacity of the press machine is calculated based on how thick the product is to be cut, the tensile strain used, and the cross-sectional area of the product feed. Use the equation below.

$$\text{Tonnage} = \text{Ts.Sf}\left(\frac{\text{kg}}{\text{mm}}\right) \text{ x A } (\text{mm}^2) \qquad (2)$$

where Ts is the tensile strength of the Neoprene rubber gasket material = 17 N/mm2, A is the cutting area = 28.28 mm2, and Sf is the power correction factor, which can be taken as 1.5. So, the gasket piercing process requires 0.7 tons of power or 5kN per part. The available press machine capacity is 20 tons or 200 kN so a press machine can be used (200 kN>7 kN).

2) Die set design. Piercing tool design requires calculations regarding clearance, the force that occurs on the punch during the piercing process, the force on the stripper, and determining the size of each plate, including the top plate, punch plate, bottom plate, and die plate. These calculations aim to create a piercing tool design that can produce the desired product.

Clearance. A diagram of the relationship between clearance and the depth of the punch basin was taken [33]. Based on the punch modification design carried out with a punch basin depth of 2.5mm, the clearance was found to be 0.1mm. This is based on the work material, namely neoprene rubber, with a material tensile stress of 17 MPa.

Upper Plate. The upper plate is a unit with the punch where the plate will move down. The Upper Plate design must adapt to each position and size of the Base Plate. This Upper Plate will pair with the Upper Support Plate. The upper plate will be the highest part of the die, holding the punch plate and shoulder punch. From the results of designing the top plate,

Punch Plate. The Punch Plate is a positioning shoulder punch and a support for urethane. The size and shape must match the punch within the press fit tolerance. From the design results of the Punch Plate, we get the dimensions: length x width x height = 80 x 78 x 25. So, the total weight of the punch plate is 12.043 x 103 N

Base Plate. The Base Plate is located at the very bottom, where it will be paired with the Support Plate and bottom Guide House, functioning as a support for the Dies. From the Base Plate design results, the dimensions are length x width x height = 200 x 200 x 35. So, the total weight of the Base Plate is 10.808 x 103 N.

Button Dies Plate. The Button Dies Plate functions as a place where the Piercing process takes place and for positioning the Button Dies, which will be inserted into the available holes. From the results of designing the Button Dies Plate, we get the dimensions: length x width x height = 80 x 78 x 20. So, the total weight of the Button Dies Plate is 9.635 x 10^3 N

Piercing Forces. The cutting force on the flat punch required for piercing can be calculated with the equation Fs=0.6. σB (Punch circumference rubber thickness) =1153.6 (N). Because the punch chosen was a punch with a PDDS profile, there was a reduction of 31.04% in the cutting force of the flat punch. So, the force required for the 4-hole piercing process is 795.5 N.

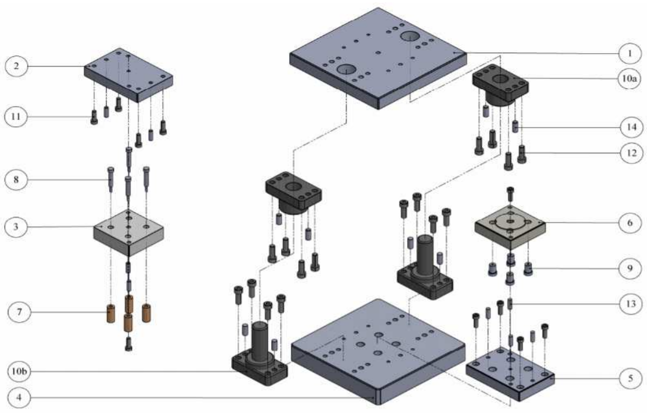


Fig. 9 Explode Piercing Tool

Where:
1. Upper Plate
2. Upper Support Plate
3. Punch Plate
4. Base Plate
5. Support Plate
6. Button Dies Plate
7. Urethan
8. Shoulder Punch
9. Button Dies

10\. a Plain Guidepost Sets
10\. b Plain Guidepost Sets

11. Hexagon Socket Head Cap Screws M6
12. Hexagon Socket Head Cap Screws M8
13. Dowel Pin 1
14. Dowel Pin 2

B. *Desain Punch*

In the design of the piercing tool, several design alternatives for the punch tip profile are selected to produce the most optimal piercing holes and machining process availability in modifying the punch profile. The most effective shape of the piercing punch tip for piercing on polymer materials is a Double sheared (inverted chamfered) punch (PDDS)[30], [34].

C. *Finite Element Analysis Punch and Button Dies*

In the analysis of yield strength with Neoprene rubber material using a punch with a profile in the form of a double-sheared (inverted chamfered) punch (PDDS) [35], as shown in Figure 10, the results obtained were 282.7 MPa. The stress distribution on the surface attached to the punch ranges from 155.4 MPa to 361.7 Mpa.

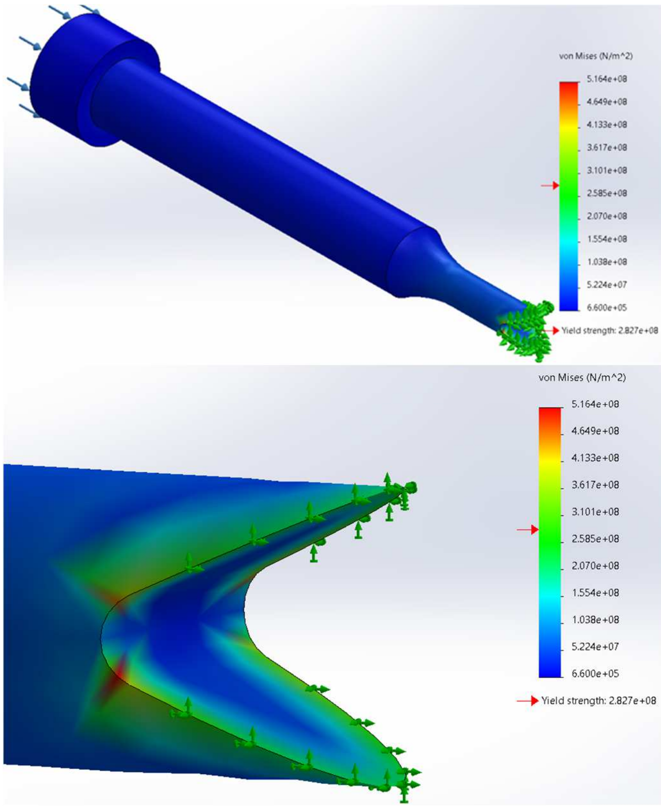


Fig. 10 Stress Simulation Results on Shoulder Punch

Analysis of Button dies obtains stress distribution results at the end of the dies hole, as shown in Figure 11. Button dies have a minimum stress value of 11.52 MPa and a maximum value of 188.2 MPa, while the yield point is 282.7 MPa. This means that the yield strength value is higher than the maximum value, so it can be concluded that the construction is safe.

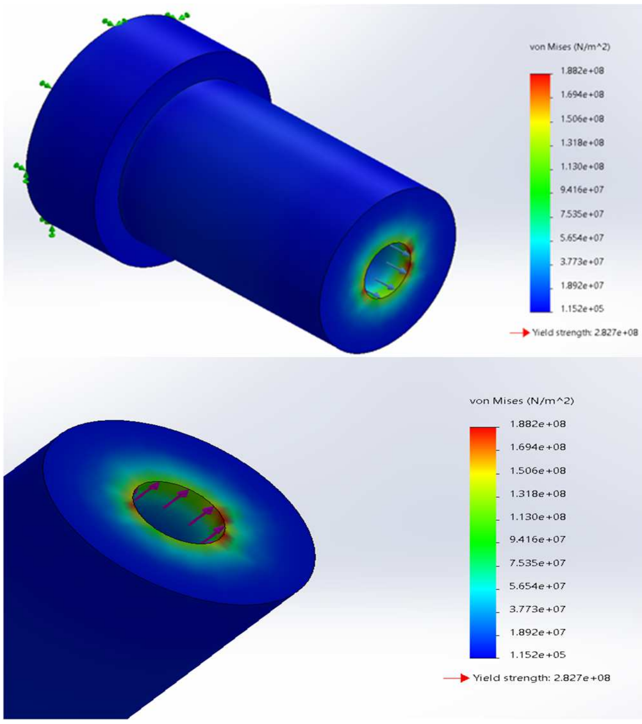


Fig. 11 Stress Simulation Results on Button Dies

D. Results and Specifications of the GeNose C19 Piercing Tool Gasket

The piercing tool uses four shoulder punches, and four Button dies as cutters. The piercing tool is mounted on a mechanical press machine with pneumatic power as a balancer and die cushion. The gasket is mounted on the positioner with a capacity of one gasket per piercing process. When the switch button on the press machine is pressed, the upper die set will perform the punching process at 1-second intervals.

Based on the results of the analysis of the design and manufacturing processes that have been carried out, a press tool was produced using the piercing cutting method to make four holes with a diameter of 3 mm on the GeNose C19 gasket. The following is the documentation for the GeNose C19 gasket piercing tool, as shown in Figure 12, and complete specifications are shown in Table 1

Fig. 12 Piercing Tool Gasket GeNose C19

TABLE I
GENOSE-19 GASKET PIERCING TOOL SPECIFICATIONS

No	Nama Part	Material	Dimension	Qty
1	Upper Plate	SUS 304	200x200x20	1
2	Upper Support Plate	ASTM A29 1045	120x80x20	1
3	Punch Plate	ASTM A29 1045	80 x78 x25	1
4	Base Plate	SUS 304	200x200x35	1
5	Support Plate	ASTM A29 1045	120x80x20	1
6	Button Dies Plate	ASTM A29 1045	80x78x20	1
7	Urethane	Urethane	Ø12x30	4
8	Shoulder Punch	SKD 11	Ø9x50	4
9	Button Dies	SKD 11	MHD 10 20 P3.4	4
10	Plain Guide Post Sets	Misumi MYP25 – 100		2
11	Hexagon Socket	HCBMTB6 - 20		8
12	Hexagon Socket	HCBMTB8 – 25		8
13	Dowel Pin 1	Misumi MS 6-20	Ø6 x 20	8
14	Dowel Pin 2	Misumi MS 8-20	Ø8x 20	8
Main Dimensions:				
- Upper Dead Point			200x200x210	
- Lower Dead Point			200x200x165	

E. Genose C19 Gasket Quantity

Piercing tool gasket GeNose C19 is said to be successful if it can produce holes in positions according to company standards, namely at 45.44º, 132.65º, 225.44º and 312.65º anticlockwise with a tolerance of ±2º, the shape of the hole is a circle, and hole size 3mm.

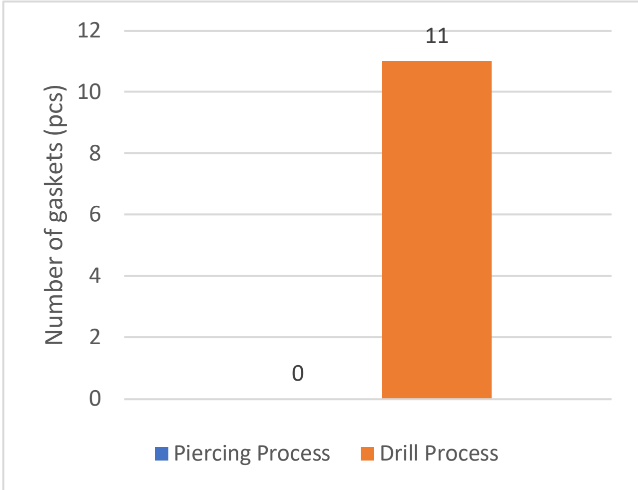


Fig. 13 Comparison of "Not Good" Gaskets on Piercing Tools and Drilling Machines

From the sample data of 40 gaskets above, the number of gaskets with good quality, namely 29 gaskets, and the number of gaskets with Not Good quality, namely 11 gaskets, is presented in Figure 13. It can be concluded that in collecting sample data, it was found that 27.5% of the total 40 samples did not pass QC with Not Good gasket quality. Of the 40 gasket samples that were worked on using a piercing tool, all of the samples taken had good hole quality results and were still within the standard tolerances set by the company. A comparison of the total Not Good gasket between the process of making holes using a piercing tool and the process of making holes using a drilling machine and jig is presented in Figure 13.

F. GeNose C19 Gasket Quality

The results of making a press tool can be examined and compared with the cycle time before and after the press tool was available is presented in Figure 14.

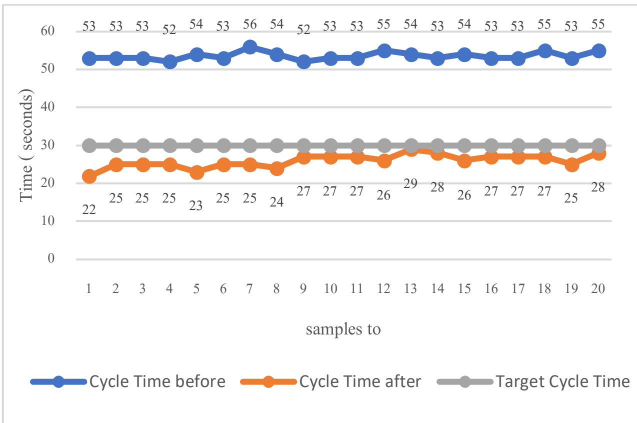


Fig. 14 Comparison of Cycle Time Before and After improvement

The Cycle Time test was carried out 20 times before the improvement, namely with a drill machine and jig tools, and after the improvement was carried out with a piercing tool. Based on cycle time data collection before improvement and test data after 20 times improvement, it was found that the average cycle time on the drilling machine was 54 seconds/4 gaskets, and the average cycle time on the piercing tool was 26 seconds/4 gaskets is presented in Figure 15. The target time for making four holes using a piercing tool is 30 seconds.

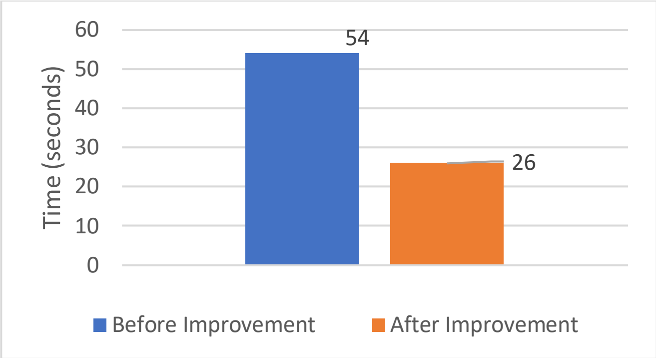


Fig. 15 Decreasing Cycle Time After Improvement

The percentage decrease in cycle time can be seen in the following calculation:

$$\text{Cycle time reduction} = \frac{\boldsymbol{CTai-CTbi}}{\boldsymbol{CTbi}} \boldsymbol{x\ 100\%} \quad (3)$$

CTai is the Cycle Time before Improvement of 26 seconds, CTbi is the Cycle Time after Improvement of 54 seconds, and the cycle time reduction = - 53.7%. From the calculations that have been made, the cycle time of the process of making four holes with a diameter of 3 mm can be reduced by 53.7% from the original time.

The decrease in the cycle time of the process of making four holes on the GeNose C19 gasket also affects the resulting production capacity. Production capacity with the improvement of the piercing tool design can be seen in the following calculation.

$$\text{production capacity} = \frac{\text{actual runtime}}{\text{total production time}} \quad (4)$$

where the actual runtime is 2 hours per day and the total production time is 26 seconds per 4 gasket or 1107 gasket per day. In 54 seconds, it can produce four gaskets, then in 1-minute production using a drilling machine, it can produce four gaskets (4 gaskets/minute). Using a piercing tool in 26 seconds can produce four gaskets, and then the Production capacity in 1 minute is nine gaskets. Then, the percentage increase in part production capacity per day is 51,8 %

IV. Conclusion

In this study, an improvement was made to solve the problem, namely in the form of a press tool design with the piercing cutting method to increase production capacity and quality of perforation results in the Ge Nose C19 air tank gasket. The piercing tool uses four shoulder punches with a diameter of 3 mm and four Button dies with a hole diameter of 3.2 mm as cutting media to make four holes in the gasket and produce the shape and size of the holes according to company standards.

The test was carried out by taking 20 samples of the method of making holes before improvement, namely with a drilling machine and jig tools, and compared with 20 samples of the method of making holes after improvement, namely piercing. The results of the comparison are a decrease in the cycle time of 53.7% from 54 seconds/4 gaskets to 26 seconds/4 gaskets or 13.5 seconds/gasket to 6.5 seconds/gasket and meeting production targets that were not previously achieved with an increase in production capacity of 51.8%. NG product testing was carried out using a quality test tool by taking 40 gasket samples, which were processed using a drill machine and jig tool to produce 11 NG gaskets, while the quality test results on 40 gasket samples, which were processed using a press tool produced 0 NG gaskets.

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