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IMPROVING PRODUCTIVITY THROUGH DESIGN AND DEVELOPMENT OF RE-CAPABLE NEEDLE COVER FOR BLOOD BAG NEEDLE ASSEMBLY

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Abstract: Blood bag manufacturers are very keen to maintain high quality of needle assembly but manual needle assembly process tends to compromise the quality of needle to a certain extent which has lead to overall rejection percentage to be around 3.2%. The objective of the project is to increase the productivity of needle assemblies with higher output, lesser rejections and higher product quality. For achieving this emphasis is given on the design and development of re-capable polypropylene outer protective needle cover. The CAD model of the polypropylene cover is completed using Creo 2.0. The breaking torque for inner PVC cover is found to be 58 N-mm. The strength of proposed PP cover to withstand the calculated pinching torque is validated with a factor of safety of 3.72 using ANSYS 14.0. Autodesk Mold flow simulation software is used to optimize the gate location and mold parameters. The effect of varying wall thickness, melt temperature, and injection time are also analyzed in consideration with the gate location and proper processing conditions for quality result. Through analysis results higher melt temperature of 240° C, injection time of 0.25 sec and wall thickness of 1 mm are recommended to achieve successful molding for PP needle cover. It also provides minimum possibility of part warpage and weld lines throughout needle cover.
Keywords: Needle assembly, PP cover, Pinching torque, Injection molding, Mold parameters optimization

INTRODUCTION

Blood bags produced at HLL Life care Limited are sterile, single use PVC Plastic collapsible container system for blood collection. Needle assembly is the most critical part of blood bag system. Quality of needle assembly plays a vital role in blood bag production because it is the only component which comes in direct contact with the human. Painless blood donation is one of the prime aspects to promote blood donation, so as to improve the donor comfort and eliminate the donor complaints. The needle assembly consists of three components; a needle holder (Hub), stainless steel needle (16G / 17G) and a poly vinyl chloride needle cover as shown in Figure 1. The needle is placed inside the needle holder and is bonded using UV curing adhesive. The cover is fixed on the needle holder so as to protect the needle. Hereafter, the assembly becomes tamper evident. At the time of usage, the cover shall be twisted open and perform the veni-puncture (Inserting the needle into the donor's vein) for blood collection.

Figure 1. Needle assembly components

With current annual requirement of 9 million pieces for needle assemblies in the company, the existing method for production is found to be manual assembly, by using some fixtures, jigs and some stand-alone equipment. Since it is fully operator oriented process, there are chances for human errors which has lead to quality issues like wrong bevel orientation, absence of required quantity of adhesive, improper needle siliconization, needle tip damage due to manual handling, improper glue application, improper alignment of needle cover with holder owing to higher rejection rate of up to 3.2 %. Manual needle assembly has also lead to higher manpower requirement as the output per person is on lower side. Rejected components study revealed that about 60% of rejection is resulted due to needle tip damage as shown in Figure 2.

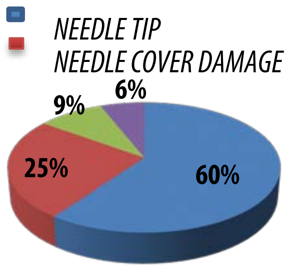

Figure 2. Rejection percentage chart

Since the produced needle is a non re-capable type (without any protective cover) there is rejection while transportation and packaging of blood bag as the needle tip may damage or it may pierce into the PVC cover. Non recap-able needle cover has also lead to safety issues as the contaminated needles, left exposed; present a serious risk to healthcare workers and other personnel in the clinical and hospital setting, including laundry and waste removal staff. Emergency situations and time pressures often result in inadvertent mishandling. Needles used for *repeated injections in the same person are frequently set aside uncapped, also presenting a hazard.*

With the rise in demand for needle assemblies, there is been a concern about the quality issues and resolving these issues is a priority for the company. Through many brainstorming sessions and cause effect analysis it is found that a new recap-able protective cover and cost effective automation is the solution for the current problem. In this project, emphasis is given on the design and development for recap-able protective needle cover. The material used for protective cover is polypropylene which is outside the inner PVC cover. In order to pinch off the inner PVC cover a breaking torque is been applied. Ansys 14.0 finite element tool is used to find the value of torque. Structural analysis for the proposed Polypropylene cover is done in order to validate that the PP cover does not break off when pinching torque is applied. Optimization of gate cover location with respect to various flow parameters for injection molding of PP cover is also analyzed. Effect of variation in melt temperature, injection time, needle cover thickness to injection quality is studied and injection molding parameters are determined.

LITERATURE REVIEW

The design process consists of a sequence of process and a set of guidelines that helps define a clear starting point that takes the designer from visualizing a product. Hence;

"... before designers can solve a design problem they need to understand some basics – such as what they are designing, what it should do and who should use it, and under what circumstances" (Randall, Harper and Rouncefield 2007)".

A lot of studies is been carried out on the current product design and development procedure. Ulrich K.T, Eppinger S.D[1] and Kevin Otto[2] briefs about the current product design pattern. Shikawa and Kaoru[3] provides an overview on the root cause analysis using fish bone diagram for quality control. Ola Isakssona, et al.[5] research is based on the implementation of Product service system in various manufacturing firms in order to reduce cost and increase productivity. G.J. Micheal and R.A. Millen[6] justifies the cost effectiveness of automation based on literature review and results of interviews with executives of manufacturing firms. Du Hwan Chun, et al.[8] presented the optimum gate filling location for needle housing with increased wall thickness, lower melt temperature, and longer injection time. The results indicated that higher melt temperatures were recommended to achieve successful molding and injecting the polymer at a longer time (1.2 second) leads to a significant increase in flow stresses. S.R. Pattnaik, et al.[9] and Yathish Kumar K.R, Prof. Nagaraja R[10] also shows the variation of flow parameters on the product quality in plastic injection molding process. Wong C.T, et al.[11] and J. P. Beaumont, et al.[12] presents the design and simulation of plastic product using Pro-E parametric software. The predicted weld lines and air traps were also analyzed.

METHODOLOGY

In order to design and develop a needle cover, a series of product development procedure is been followed starting from the concept generation to prototype fabrication as shown in Figure 3.

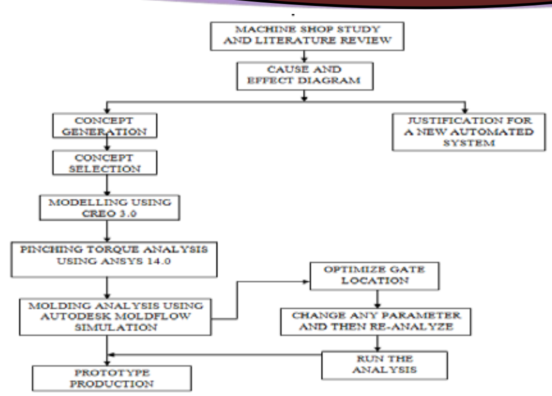

***Figure 3**. Methodology flowchart*

DESIGN OF RECAP-ABLE NEEDLE COVER

In order to find potential root causes for the above mentioned problem several brainstorming sessions were conducted. A well known brainstorming tool used here is "Ishikawa's Fish bone diagram". Because of its function it may be referred to as a cause and-effect diagram. The problem, which is decrease in productivity and increase in rejection rate, is placed at the fish's head and their causes are laid along the fish bone. Figure 4 shows the fish bone diagram.

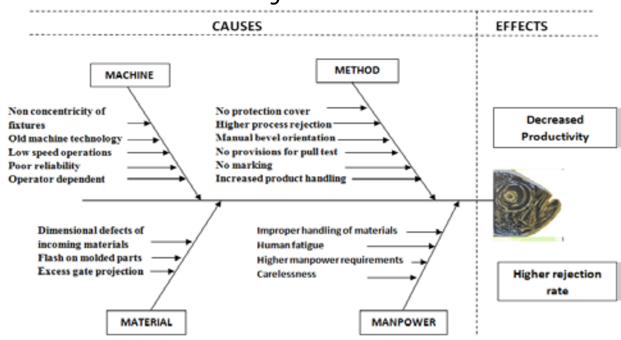

***Figure 4**. Cause and effect diagram*

According to fish bone diagram, cost effective automation and development of recap-able needle cover are the solution for the given problem.

Concept Generation

For the given needs importance rating were given and remarks for good design were noted. Table 1 shows the concept generation chart. Based on this concept different concept ideas were produced and evaluated.

***Table 1**. Concept generation method*

NEEDS	IMPORTANCE	REMARKS
FUNCTIONALITY		
• Act as a protective cover for the needle. • Provides correct orientation and locking mechanism. • Need to hold cover after pinching.	5 5 5	Flexible – PP cover Stiff locking Extend up to needle hub
OPERATION		
• Easy to hold and assemble. • Adaptable to current manual needle assembly operation.	4 5	Flexible design
SAFETY		
• No sharp edges or corners. • Approved.	3 5	Check for material and safe design.
MANUFACTURABILITY		
• Easy to cast for large assembly. • Low cost.	4 5	Less than Re 1.
ERGONOMICS		
• Pleasant look. • Tight tolerance without any gap.	3 5	No gap between PP and PVC cover.

Concept Selection

Weighted matrix method is used for selection of different concepts. The selection is made in view of product functions needed. Appropriate weightings for each function are given. Out of three different concepts;

PP cover with zip lock, outer PP cover, PP cover with press fit lock Table 2 shows that concept 3 is the most appropriate with highest rating.

***Table 2**. Weighted matrix*

CRITERIA	WEIGHTINGS	CONCEPTS: PVC COVER INSIDE PP COVER FITTED TOGETHER	CONCEPTS: PP COVER WITH ZIP LOCK	CONCEPTS: COVER WITH PRESS FIT LOCK
ADAPTABILITY	0.2	30 / 6.0	100 / 20	100 / 20
MANUFACTURABILITY	0.15	50 / 7.5	40 / 6.0	40 / 6.0
ERGONOMICS	0.1	50 / 5.0	80 / 8.0	70 / 7.0
SAFETY	0.2	70 / 14	30 / 6.0	90 / 18
COMPLEXITY	0.15	30 / 4.5	80 / 12	70 / 10.5
COST	0.2	60 / 12	85 / 17	80 / 16
OVERALL RATING		49	69	77.5

MODELLING AND ANALYSIS

Finite Element Analysis

Cad model, as shown in Figure 5, is been made using Creo 2.0 as per the given dimension.

***Figure 5**. Creo model for PP cover*

In order to remove the inside Polyvinyl chloride cover during usage a breaking torque is applied on the cover so that it pinches off from the needle hub. Since the proposed Polypropylene cover is outside the PVC cover, it will also be subjected to the above mentioned torque. Hence, ANSYS 14.0 is used to determine the value of pinching torque applied on the PVC cover. The hence obtained pinching torque is given as input to determine the stress distribution in the PP cover.

Meshing

Material properties for inner PVC cover are given with density = 1420 kg/m^3 and modulus of elasticity = 3.37 E+09. Fine mesh is done with element size of 2mm as shown in Figure 6. On meshing, the no. of nodes obtained is 3198 and no. of elements used is 1641.

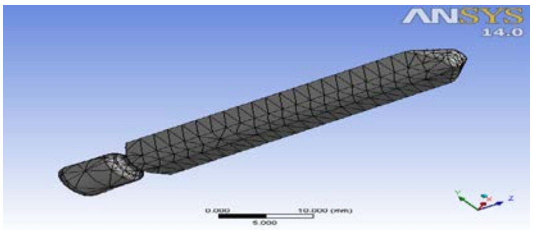

***Figure 6**. Meshed model*

Analysis Result

In order to find the breaking torque Von-mises stress calculation is been done. The tensile yield strength of PVC cover is 19.6 MPa and the corresponding breaking torque required to pinch off the PVC cover from the needle hub is found to be 58 N-mm for a total deformation of 0.089 mm shown in the Figure 7. The value obtained for breaking torque is then applied to the designed PP cover to validate its strength.

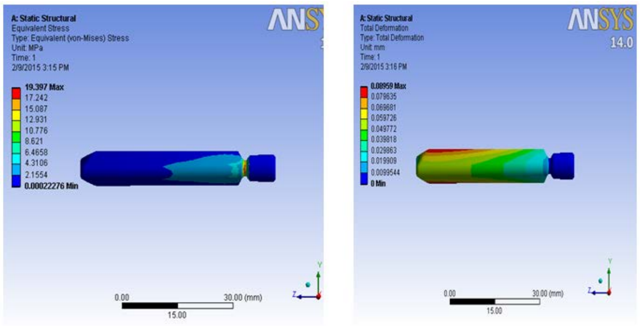

***Figure 7**. Von misses stress and total deformation*

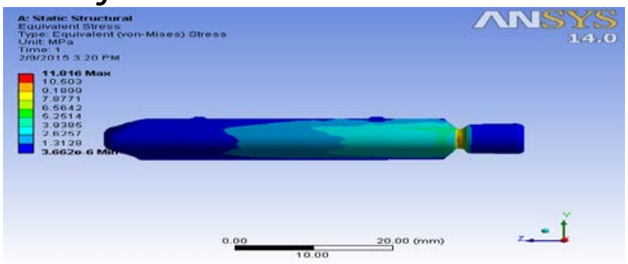

***Figure 8.** Stress distribution of needle cover*

Figure 8 shows the stress distribution for the given PP cover. For an input breaking torque of 58 N-mm, the maximum von-mises stress acting on the PP cover is found to be 11.816 MPa. The tensile yield strength of Poly propylene is 41MPa which is well above the obtained breaking torque with a factor of safety of 3.72. Hence, the proposed PP cover is safe.

MOLD FLOW SIMULATION

Injection molding is one of the most popular manufacturing methods for the cost-effective mass production of the plastic parts. In order to investigate the process conditions of molten polymer, filling analysis is done. Autodesk mold flow simulation is a powerful simulation tool to optimize the gate location and to predict the production time required at the lowest possible cost. Verification using simulation requires achieves quality results within minimum time, and with no material costs, as compared with the conventional trial and-error methods on the production floor. In order to validate appropriate gate location for a POLYPROPYLENE NEEDLE COVER, mold quality and defects are analyzed for different gating options and operating parameters are compared. Figure 9 shows the suitable location for the gating system from best to worst scale. Based on this result optimum number of gates to be used are analyzed.

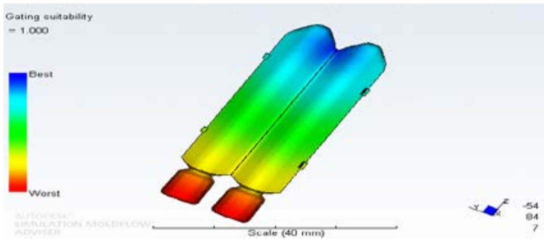

***Figure 9**. Suitable gate location*

For an injection pressure of 38.67 MPa, melt temperature of 220°C and injection time of 0.232 sec quality prediction for one gating system and two gating system is been done as shown in Figure 10.

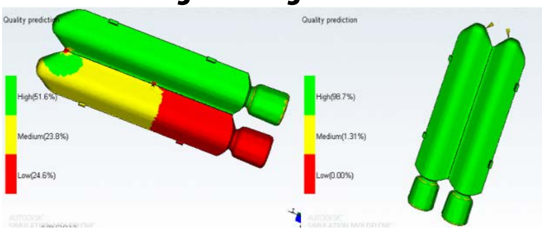

***Figure 10**. Mold quality prediction for one gate system and two gate system*

Analysis result shows an increase in mold quality to 98.7% with two gating system. Based on the results, the optimum gate location for the minimum flow stresses and uniform fill patterns is selected. The effect of increasing injection time and varying melt temperature for a given injection pressure of 38.67 MPa is also analyzed. Lowering injection time to less than 0.2 sec is not practically possible as there will not be proper filling in the mould. In Figure 11 quality of the PP cover is checked for longer injection time of 0.4 sec. Change in mold flow quality is also analyzed for lower melt temperature of 200°C and higher melt temperature of 240°C as shown in Figure 12.

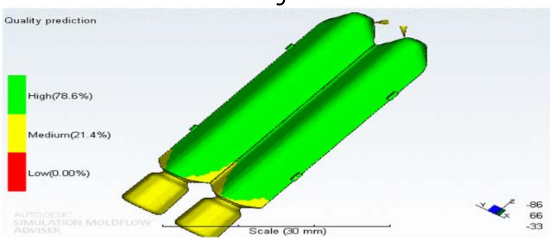

***Figure 11**. Quality prediction (0.4 sec injection time)*

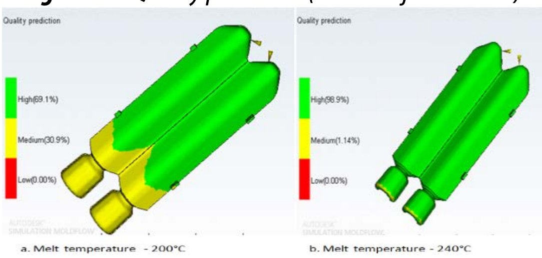

***Figure 12**. Quality predictions for varying melt temperature*

***Figure 13**. Weld line defect*

The recommended wall thickness for polypropylene material is 0.635 to 3.032 mm. The selected wall thickness is 1mm. Analysis result shows that with increase in wall thickness mold quality reduces. Since two gate system are prone to mold defects such as weld lines. Figure 13 shows the weld defects. Higher melt temperature of 240°C, injection time of 0.25 sec and wall thickness of 1 mm is selected as the optimum mold flow parameters for needle cover.

CONCLUSION

Improving overall productivity is the main objective for all manufacturing sector. With increasing competitiveness increase in quality has become the measuring parameter for company's success. Increase in rejection rate to 3.2% had an alarming effect on the profit. The cause-effect diagram highlights all the relevant solution for the mentioned problem. Design of recap-able outer polypropylene needle cover is done in reference to the product development methods starting from concept design to prototype fabrication. Cad model is generated using Creo 2.0. Static structural analysis is done using ANSYS 14.0 and the strength of the proposed PP cover is validated for the calculated pinching torque with a factor of safety of 3.72. Autodesk Moldflow simulation is done to optimize the mold parameters. Through analysis it is found that higher injection times leads to decrease in quality. The results of analysis on varying melt temperature, and longer injection time indicated that higher melt temperatures and normal injection time are recommended to achieve successful molding. Thus it also provides minimum possibility of part warpage and weld lines throughout needle cover.

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REFERENCES

[1] Ulrich K.T. and Eppinger S.D, 2007, "Product design and development"; CITY: McGraw-Hill.
[2] Kevin Otto, Kristin Wood ; "Product Design: Techniques in Reverse Engineering and New Product Development" December 8, 2000;
[3] Shikawa, Kaoru, "Guide to Quality Control"; Tokyo, Japan: Asian Productivity Organization (1986).
[4] American Society for Quality, Fishbone diagram; http://www.asq.org/learn-about quality/cause-analysistools/overview/fishbone.html.
[5] Ola Isakssona, Tobias C. Larsson and Anna Ronnback, "Development of Product-Service Systems: Challenges and Opportunities for the Manufacturing Firm"; Journal of engineering design, Vol- X.
[6] G.J. Micheal and R.A. Millen; "Economic justification of modern computer based factory automation: A status report"; Annals of operation research 3(1985), pp- 25 to 34.
[7] Ullman. D. G., 2003. "The Mechanical design process"; 3rd ed. New York: McGraw-Hill.
[8] Du Hwan Chun, Byoung Hee You1, and Dong Joo Song, "Injection Molding Analysis of a Needle Cover – Optimum Filling for Gate Location Design"; Fibers and Polymers 2012, Vol.13, No.9, 1185-1189.
[9] S.R. Pattnaik, D.B. Karunakar, P.K. Jha," Application of computer simulation for finding optimum gate location in plastic injection moulding process", International Journal of Advanced Engineering Research and Studies, Vol-1, 159-161.