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Development of the Splint Manufacturing Process Using Indirect Coating and Roll Bonding

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간접 코팅과 롤 접합을 이용한 의료용 스플린트 제작 및 공정기술 개발

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ABSTRACT

With the increase in number of the athletic population and elderly demographic, the demand for orthopedic splints, which are used to support a damaged body, has rapidly increased. Current splints mainly consist of inner and outer parts, which are multiple fabrics covered with polyurethane and nonwoven fabrics, respectively. However, the laminated materials with directly applied pre-polymer coating lead to a high defect rate because of the uneven thickness on the surface. Thus, this study proposes an indirect coating method using a precise clearance controller, which enables the even application of the coating material on multiple inner parts while maintaining a constant thickness. In addition, a roll-to-roll (R2R) technique is applied instead of the sewing mechanism to bond the inner and outer materials together and enhance the productivity in the final stage. In the advanced methods, there is a storage tank that contains polyurethane, a clearance controller, and pairs of rollers in the upper and lower rows. To improve the quality of the products and optimize the equipment, three controllable factors are determined: the viscosity of polyurethane, angle of the gap controller and number of pairs of rollers in the R2R system.

Keywords : Orthopedic Splint(정형외과 부목), Residual NCO(잔류 NCO), Viscosity(점도), Indirect Coating System(간접 코팅 시스템), Roll-to-roll Mechanism(R2R 메커니즘)

1. Introduction

It is reported that medical and scientific advances have changed lifestyle by improving life expectancy over the past decades. As a result, the number of those who enjoy sport activities and order age have increased while musculoskeletal disorders caused by strenuous exercise and osteoporotic fractures in elderly have frequently occurred[1,2]. For treatment of these orthopedic diseases, splints which allow damaged bones and muscles to be fixed with light weight have been widely used. In an existing sewing process, these medical devices were fabricated by a number

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of fabrics spread with polyurethane resin as inner parts and outer nonwoven materials to protect skin. Both substances are normally sewn together to join two pieces and prevent laminated inner polymers from absorbing moisture in the air. However, in the current process, uneven distribution of resin on inner parts by employing a direct dipping system and poor quality of sewing bring disadvantages.

In order to meet increasing demand for medical splints with cost saving and high quality, it needs to derive a new mechanism. Therefore, this study suggests a bonding type splint with an indirect coating system using a gap controller taking into account optimal conditions of adhesive. In addition, the optimal number of paris of rollers in a R2R technique is found to bond two substances together without separation and enhance sealing performance with low production cost.

2. Experimental methods and conditions

2.1 Vital few in pre-polymer process

NCO terminated polyurethane adhesive as pre-polymer used in this study synthesized by reaction between polyisocyanate and polyol. Derived NCO groups which are called as isocyanate are forced to convert carbon dioxide and amine by reaction with water and moisture in the atmosphere. Generated amine reacts with isocyanate and transforms urea groups. After secondary reaction with NCO, crosslinking reaction between reactive oxygen species in urea groups and excessive NCO gives biuret with high thermal stability and adhesive ability as shown in Fig. 1[3]. Thus, it is notable that the amounts of residual NCO are closely related to quality of products and it can be defined as follows.

$$Residual\,NCO(\%) = \frac{V_B\,V_V\,0.042}{W} \bullet 100\% \qquad (1)$$

where V_B is volume of HCl for blank titration in ml, V_V means volume of HCl for specimen titration in ml, N is normality of HCl, 0.042 is milliequivalent weight of NCO and W means specimen weight.

In addition, it is necessary to define an optimal viscosity value of pre-polymer in order to maintain adequate thickness during fabrication. In this study, viscosity of fluid is measured by using a rotational cylinder viscometer(Brookfiled DV-II+). It can be evaluated by measuring torque applied to the cylinder wall as following Eq. (2) when it is rotated at constant angular speed under laminar flow.

$$Viscosity = K_B \frac{M}{w} \qquad (2)$$

where V_B is system constant(rad/cm^3), M is torque on the cylinder wall(10^{-7}N·m), and w means angular speed(rad/s).

Thus, this paper analyze effects quantity of free NCO and viscosity on ability of pre-polymer in the polymerization process by adopting a polymerizing furnace with indirect water heating system and a flat

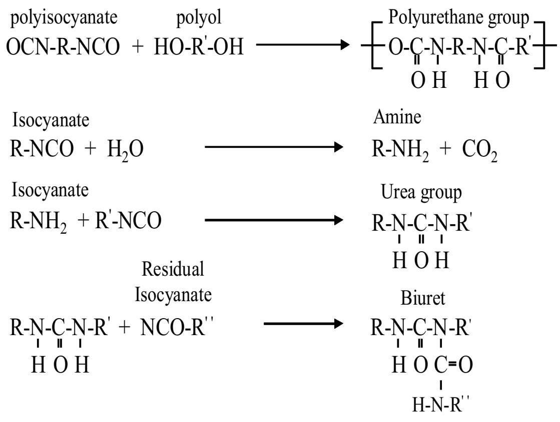


Fig. 1 Chemical reaction formular for polyurethane

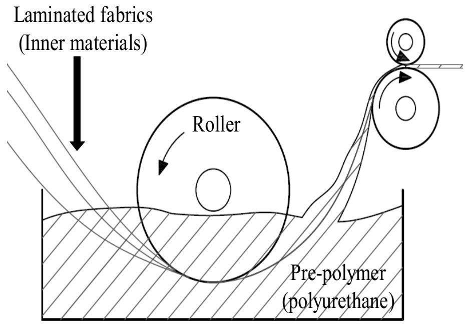
Table 1 Controlled factors of polymerizations

Controlled factors	Levels		
	1	2	3
Water temperature(℃), A	80	90	100
Holding time(hour), B	1	1.5	2
Impeller speed(rpm), C	330	450	590

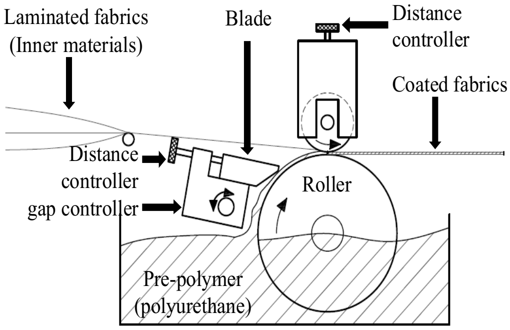
2-blade impeller with an electric motor. Table 1 represents three control variables which include water temperature, holding time at maximum water temperature and rotational speed of impeller. The desired percentage of excessive NCO and viscosity are 14% and 3,950cps respectively taking into account functionality and reliability of renovated splints. In order to figure out optimal parameters, all experiments are conducted based on Taguchi $L_{27}(3^4)$ orthogonal array table with S/N ratio.

2.2 Design an indirect coating system

In a direct dipping process shown in Fig. 2(a), multiple thin fabrics as inner parts of splints are directly put into pre-polymer. However, this simple mechanism causes functional defects due to non-uniform distribution of resin on surface. To avoid drawbacks of a conventional coating system, this study proposes an indirect coating method represented in Fig. 2(b) by adopting a precise gap controller and a pair of different sized rollers. As a boundary layer theory, optimal pre-polymer produced based on section 2.1 is spread on surface of the rotating bigger roller which is sank into the polyurethane storage tank. A role of the gap controller could allow uneven thickness of liquid on surface to have constant thickness by adjusting angle and distance between roller and blade. After these stages, laminated knit tapes pass through a rotating pair of laminated knit tapes pass through a rotating pair of rollers at a certain gap without dipping into the tank directly to



(a) Direct dipping method



(b) Indirect coating method

Fig. 2 Comparison between conventional and new coating system

maintain uniform thickness. The gap between rollers could be controlled manually by a distance controller installed at the top of the smaller roller device. Therefore, it is anticipated that derived new mechanism is superior compared with conventional one in terms of water permeability, elasticity and human plasticity as distributing even adhesive on materials.

2.3 Development of roll-to-roll mechanism

As shown in Fig. 3, an existing final process employs a sewing machine to fix inner and outer materials to prevent moisture in the air from permeating into inner parts. However, this process is not able to completely perform a role due to a structural problem and poor sewing quality. Because of clearance between inner and outer fabrics, it could be separated easily each other. It means that it brings less functionality related to human plasticity, especially in medical operation. In addition, multiple inner parts covered with adhesive are hardened before usage by absorbing moisture in the air.

To reduce burdens of cost and time, in this study, a bonding type splint as a new process is proposed by adopting roll-to-roll(R2R) mechanism as represented in Fig. 3. Unlike the previous process, derived new method could be able to bond both parts completely by using another indirect coating system and multiple paris of rollers which have same diameter. The principle of indirect coating system is identical as stated in section 2.2, but it needs to apply adhesive on a side of outer part. After this process, multi-layered inner fabrics and coated outer parts are pressurized and transferred with even force by passing a series of upper and lower rollers in a row. However, it is difficult to reach desired thickness of products at once through a pair of rollers. Therefore, it is important to determine the number of pairs of rollers, which could be attributed to longevity of rollers and quality of products with cost effectiveness. For optimization of the number of pairs, it is assumed that the amount of pairs are from 1 to 5 and desired height of splint is about 5mm from initial thickness, about 10mm. Moreover, diameter of roller, D, force per roller, P, and roller speed, N, are 60mm, 18kg, and 1,500rpm respectively. Based on these parameters, required power, H, is calculated as follows.

$$H = \frac{P\mu\pi DN}{6{,}120{,}000} \tag{3}$$

where μ is coefficient of friction.

μ is dependent upon contact angle, α, between rollers and the orthopedic product, and it could figure out as follows.

$$\mu = \tan\alpha \tag{4}$$

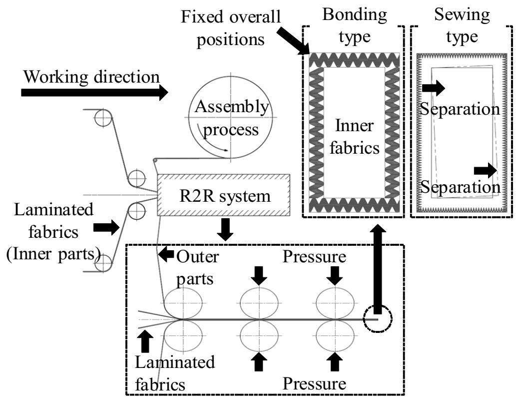


Fig. 3 Roll-to-roll mechanism for a bonding splint

Table 2 Results of viscosity and NCO quantity

Vital few	Optimum values			Results
	A	B	C	
Viscosity	80	1	330	3,939cps
NCO	100	1.5	330	13.7%
Viscosity + NCO	100	2	330	3,827cps 13.7%

3. Experimental results

3.1 Optimization of NCO and viscosity

In order to provide optimal adhesive, target values of viscosity and the percentage of free NCO is 3,950cps and 14% respectively. Based on considering factors represented in Table. 1, all simulations were conducted by Taguchi $L_{27}(3^4)$ orthogonal array table with the-nominal-the-best characteristic[4,5]. As a result, it was clear that a significant parameter affecting viscosity was holding time at maximum water temperature, followed by impeller speed and water temperature. In case of the amount of residual NCO, a critical factor was water temperature for heating polymerization furnace, followed by impeller speed and holding time. Table 2 showed optimal parameters which represented the highest values of S/N ratio among the each controlled factor. In accordance with Table 2, optimal parameter related to viscosity was 3,939cps at A1B1C1 corresponding to A, 80℃, B, 1hour, and C, 330rpm. In addition, optimal NCO quantity, about 13.7%, was obtained when A, B, and C were 100℃, 1.5hour, and 330rpm respectively. According to the results, it needed to find the most effective parameters to satisfy both target values of vital few except for same impeller speed. With regard to water temperature, 100℃ was designated as the maximum value of NCO because it was not the primary factor influencing viscosity among controlled parameters. Holding time was considered about 2hours to meet both optimal results. Consequently, viscosity and the amount of free NCO were measured about 3,827cps and 13.7% respectively.

3.2 Optimization of paris of rollers

This study proposed the R2R process with the bonding apparatus to prevent separation between two components of the orthopedic splint and eliminate additional sewing process. Table 3 showed reduction height, contact angle, and required power at the number of pairs. Required power was an essential factor to determine productivity with cost efficiency. As can be seen, it was inversely proportional to a series of rollers in a row, which obtained that maximum and minimum values were 3.60kW at the first pair and 1.53kW at the fifth paris of rollers. Although minimum required power was calculated at the fifth paris, this paper selected fourth pairs of rollers compared to effects of reduction power between H_{34} and H_{45} represented in Fig. 4.

Fig. 5 represented the overall process for bonding type splint derived in this study based on optimizing results. Fabrication of this advanced medical supports were mainly divided into 3 steps. Multi-layered inner fabrics were bonded with pre-polymer which had adequate viscosity and the quantity of remaining NCO by the indirect coating system. To avoid hardening inner parts, outer materials were supplied in the

Table 3 Conditions and required power of rollers

Pairs	Reduction height(mm)	Contact angle(°)	Required power(kW)
1	5.00	23.6	3.60
2	2.50	16.6	2.47
3	1.65	13.5	1.99
4	1.25	11.7	1.72
5	1.00	10.5	1.53

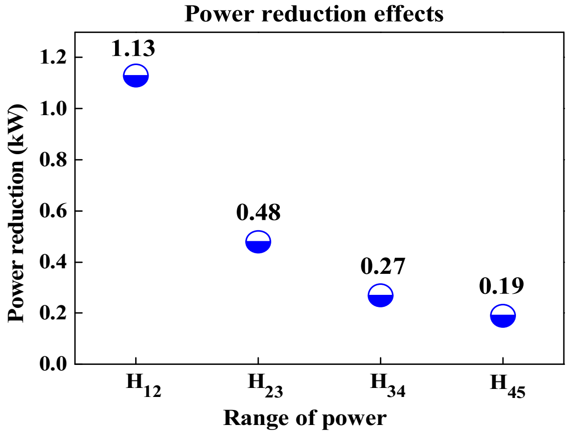


Fig. 4 Power reduction effects of pairs of rollers

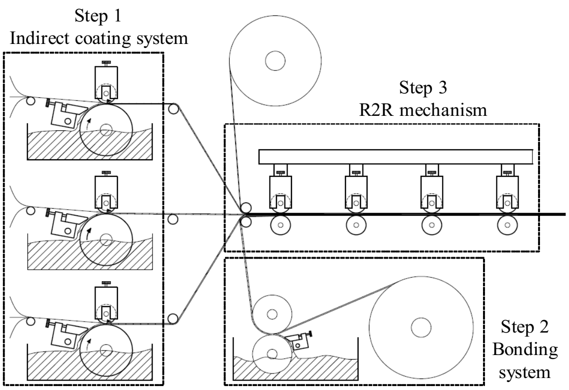


Fig. 5 Overall process for bonding type splint

second stage and one of the parts were applied to the bonding material by the same coating system as previous stage. In the last step, combining parts were passed through the R2R system to evenly join them together without the additional sewing process.

4. Conclusion

This paper aimed to provide a renovated process for a medical splint to improve productivity and functionality as a cost effective way. The following results can be drawn.

1. It was noted that viscosity and quantity of residual NCO played a vital role in quality of inner parts and it was led to enhance ability of pre-polymer in the polymerization process.
2. Based on the Taguchi method, viscosity and the percent of free NCO were 3,827cps and 13.7% respectively at optimal conditions for water temperature, 100℃, holding time 2hours, and impeller speed 330rpm. It was clear that values were closely reached at target values about 3,950cps and 14% respectively.
3. It was expected that indirect coating system could be able to reduce defect rate compared with direct dipping system by applying adhesive evenly on inner fabrics by a precise gap and distance controllers.
4. In order to improve productivity and functionality in the final stage, R2R mechanism having multiple rollers with adhesive were applied. All the rollers have same diameter, about 60mm and pressurized products by identical force and speed about 18kg with 1,500rpm respectively. It can be seen that the fifth paris of rollers required minimum power about 1.5kW in the range of from the fist pair to fifth paris. However, this study selected fourth pairs of rollers as optimum bonding system considering initial and maintenance cost.

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