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Applications of Polyurethanes in Orthopedic Technology

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Based on the material Technogel, Otto Bock has developed a new cold cross-linked elastomer for prosthetic sockets called Polytol®. It was integrated into the product range of Otto Bock HealthCare in 2007. Polytol® is a system consisting of three components (component A: base polyol, component B: aliphatic, monomer-free isocyanate, component C: catalyst). The components are mixed at a fixed ratio of 75 : 15 : 25, and can be processed in the orthopedic workshop using the manual casting process. Polytol® is permanently elastic, offers good skin adhesion and avoids skin irritation. Lamination resin frames are required as a base due to the elasticity of the material. This article describes the application technology and introduces several application examples.

Introduction

The residual limb socket is a key factor for the quality of a prosthesis. Not only are the fit and design of the socket essential for wearer comfort, but also the materials used. Max Näder worked together with Bayer AG back in 1952 in order to lay the foundations for the extensive knowledge now possessed by Otto Bock Kunststoff. Due to the fact that polyurethane resins can be produced with various formulations, the range of applications is extremely varied. Polytol® is a new material in this group. The laminated flexible inner socket made from this PU resin is a new alternative to the flexible inner socket made of thermoplastic resin or silicone, and to laminated sockets made of Orthocryl.

Rigid foam cone for TT sockets

The original development of PU rigid foam is still in use today for the fabrication of prosthesis test sockets using the TF and TT software, followed by subsequent milling of the model in Service Fabrication (Figure 1). During this process, it is important to ensure that the rigid foam



Figure 1 Rigid foam cone for TT socket.

model is not damaged or deformed by the temperature during vacuum forming. A very fine cell structure is also essential in order to achieve a smooth socket finish.

Integral foam for prosthetic feet

Polyurethane integral foams have been used for decades in order to fabricate very durable, lightweight prosthetic feet (Figure 2). The combination of a wear-resistant surface with spring elements results in numerous design options. Improving functionality and optimising



Figure 2 Integral foam for prosthetic feet.

movement patterns are always the main considerations in this process.

Polyurethane components in rehabilitation technology

Soft integral foam is used in wheelchair arm rests, torso and head supports, customised hand grips, seat cushions and back rests (Figure 3). The cohesive membrane is especially important; it needs to be comfortable and prevent the penetration of liquids. Innovative physical foaming agents have created a renaissance for this application. The suitability of viscoelastic integral foams is currently being tested.



Figure 3 Polyurethane components in rehabilitation technology.

Polyurethane ester block foams for prosthesis cosmetics

Special polyurethane ester block foams are suitable for cosmetic covers to conceal the mechanics of a leg prosthesis (Figure 4). This application was a major step towards the humanisation of prostheses with the introduction of the tubular skeletal prosthesis as a cosmetic leg prosthesis in 1969. The material allows the contours to be ground for custom adaptation. A water-repellent coating can be used to seal the fine-pored surface of the cosmetic foam cover.

Polyurethane gels for the fabrication of insoles

Figure 5 shows an insole and Figure 6 a liner made of Technogel. Liners were the first gel application produced by Otto Bock. In addition to being very skin-friendly – as proven by the “Öko-Tex” foundation – the Technogel liner exhibits significant advantages for sensitive residual limbs with bony protrusions in particular. These benefits can be of decisive importance, especially for patients suffering from diabetes mellitus, as skin injuries caused by excessive pressure often lead to wounds that take a very long time to heal. Thanks to the flow characteristic of PU and the resulting even pressure distribution as well as the high damping capacity, it offers maximum reliability and comfort – especially for low to medium activity levels.



Figure 4 Polyurethane ester block foam for prosthesis cosmetics.

Key data for Polytol® development

The material TechnoRIM, which is based on Technogel, was developed by Otto Bock foam systems in 2002-2004. This was immediately followed by the launch of an Otto Bock HealthCare orthopedic project in January 2004 for the development of an aliphatic cold lamination elastomer for prosthesis sockets. From 2005 – 2007, the sys-



Figure 5 Technogel insoles.

tem was developed further in close cooperation between the two Otto Bock business areas and initial field tests were conducted with patients. After the required tests were completed with positive feedback from patients, the product Polytol® was integrated into the product range of Otto Bock HealthCare starting in October 2007.

The chemistry of the Polytol® three-component system

In view of the requirements profile for the Polytol® elastomer, it is easy to see that a simple system solution is not possible. After extensive processing tests, a three-component system turned out to be the best solution. Thanks to corresponding packaging specifications and work instructions, it is relatively easy to process. In principle, the three-component system consists of a component A (base polyol with functional filler), component B (aliphatic, monomer-free isocya-

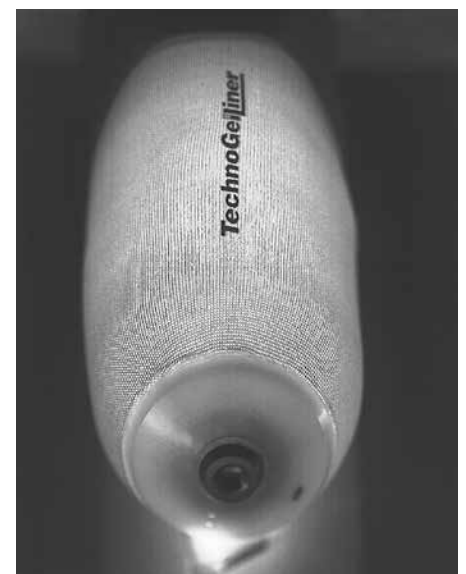


Figure 6 Technogel liner.

anate) and component C (catalyst in co-polyol). All components are processed using an established mixing ratio (75 : 15 : 25) and used for manual casting. Precise compliance with the mixing ratio is of decisive importance. Weighing the highly viscous components to the nearest gram is difficult.

Filling precise amounts of the components into corresponding small containers has made processing in the prosthetist's workshop feasible (Polytol® containers (A-B-C)). This assures reproducible reactivity over a period of six months and minimises handling deviations.

System requirements for the Polytol® material

Since the requirements specification for the Polytol® material is quite elaborate, only the most significant key data are described here. A light and aging-resistant aliphatic material is produced for the final application. The fact that the material is skin-friendly with direct skin contact must be certified by test institutes with corresponding accreditation. For processing by a medical supply company, hand casting with an available processing time of 15 minutes and setting time of no more than three hours must be guaranteed. The components should be easy and straightforward to mix. The resulting pourable elastomer must not exhibit surface porosity after vacuum forming, and has to easily separate from PVA foil. Optimum material bonding to the inlay elements or webbing must be guaranteed. Mechanical processing in the form of grinding is also required. The aliphatic pourable elastomer must have dimensional stability and resistance to swelling, even under the influence of water absorption through body contact. Customer-specific colouring and storage stability of the system after formulation represent additional challenges for the Polytol® elastomer.

Characteristics

Mechanical characteristics of Polytol® C 319-15 colourless RN:

- Raw density (DIN EN ISO 845) 1050 kg/m³
- Tensile strength (ISO 1798, S2) 1200 kPa
- Elongation at rupture (ISO 1798, S2) 80 Prozent
- Tear propagation resistance (DIN 53575) 5,0 N/cm

Polytol® exhibits the characteristics of TechnoRIM, and therefore features good water absorption and release, minor hardness deviations from minus ten to plus 90 degrees Celsius and a pleasantly soft feel with a non-adhesive surface. In particular, the option of mechanical processing by means of grinding, the extremely long start time and

low foaming sensitivity in the presence of moisture are key factors.

Resistance to light and aging are essential for orthopedic technology applications. Light stability has been proven in xenon light tests (10,000 kJ), while the aging test was confirmed with the effects of body fluids in field testing. Compared to other materials, Polytol® is a relatively new material for orthopedic technology, which has not played a major role in the orthopedic workshop to date since it is not quite as easy to process as acrylic resins. Anyone who has already worked with Pedilen soft foams knows this.

The laminated flexible inner socket made of Polytol® is an alternative to the flexible inner socket made of thermoplastic resin. Polytol® is permanently elastic and features good skin adhesion. The PU resin is especially well suited for prosthetic fittings on hip disarticulation patients, knee disarticulation patients, lower leg amputees and patients with short transfemoral residual limbs.

Special tests required by the law for medical products have proven that this material is very skin-friendly.

Testing for biological compatibility according to EN ISO 10993 is relevant for materials with skin contact according to EN ISO 10993 Part 5 (cytotoxicity) and EN ISO 10993 Part 10 (irritation and sensitisation), and also mandatory from a legal point of view, unless other proof of biological compatibility can be provided.

Processing in orthopedic technology

The procedure for processing is adapted to the conditions in an orthopaedic workshop, and largely corresponds to lamination with acrylic resins. PVA foils are normally used. Residual moisture must be carefully removed prior to lamination, since polyurethane resins are very moisture-sensitive during processing. A Technical Information publication describes the details of processing*. First a PVA foil tube is applied over the model and tied off; negative pres-

sure is created on the inside. The reinforcement consists of flexible tricot tubing and Dacron felt; it serves to evenly absorb the PU resin. Since the mechanical properties of the material are very good, no additional reinforcement is required. Figure 7 illustrates the applied foil under a vacuum.

Polyurethanes have the tendency for individual components to settle on the bottom of the container. Therefore, start by carefully stirring components A and C without creating air bubbles. Then combine components A and C, and weigh lamination resin colour paste into



Figure 7 Foil under negative pressure.

the mixture. Mix thoroughly for at least one minute. Finally open the isocyanate container (component B) and pour the contents into the Polytol® container. Allow exactly one minute for draining and stir the reactant mixture for at least two minutes. The reactant mixture can be processed for approximately 15 minutes. Now the Polytol® is quickly poured into the foil and immediately laminated between the two foils with controlled negative pressure (Figure 8). The thickness of the inner socket is established by purposefully massaging the resin as it quickly thickens. The reactant mixture hardens in approximately three hours and can then be pulled off the model. The edge of the socket is trimmed with scissors and then ground down.

* "Fabrication of Polytol® Prosthetic Sockets" (646T7=4.1GB)

Indications for Poytol®

The positive characteristics of very high surface adhesion exhibited by the Poytol® material are especially well suited for short residual limbs. Some examples of short transfemoral residual limbs



Figure 8 Lamination

illustrate that patients have much more freedom of movement and improved prosthesis control (Figure 9). The socket no longer slips off the residual limb, so that no additional support guides are required. High surface adhesion also reduces twisting of the prosthesis, so that the socket is firmly seated on the residual limb. Figure 10 illustrates an example of a patient on an ergometer. This material allows patients to resume sports activities. Sweating in the prosthesis during sports is significantly reduced and the flexible edges allow gymnastic exercises to be executed.

Since this material does not have load-bearing characteristics, lamination resin frames continue to be used. These are laminated into the



Figure 9 Patient with short transfemoral residual limb.

Poytol® in a subsequent processing step. Using a special primer is essential in order to create a secure connection between the lamina-

tion resin frame and polyurethane. This sandwich structure facilitates precise separation of soft and hard zones. Especially when sitting down, the patient is once again able to feel his or her residual limb musculature; this results in significant advantages, e.g. when cycling.

Figure 11 shows a knee disarticulation patient with a Poytol® socket. Comparative measurements between hard carbon frame sockets and soft polyurethane sockets with lamination resin frame taken using the "Dartfish" video analysis tool illustrate the advantages for prosthesis control. When the images are superimposed on each other, the faster movements – especially on the stairs – and improved prosthesis control are clearly visible.



Figure 10 Patient on ergometer.

Special technology is used for the application area of transtibial fittings. Load-bearing and non-load-bearing zones can be customised to patient requirements using an especially fabricated frame structure made of acrylic resin combined with polyurethane resin.

Figure 12 illustrates an example of a flexible socket for a pelvic socket prosthesis. The construction of a pelvic socket after hip disarticulation using the Poytol® material significantly improves patient comfort. The socket fits the body closely and the edges do not cut in as the result of flexibility. Since the processing time of just fifteen minutes is

challenging even for transfemoral sockets, a Poytol® pelvic socket can only be laminated by experienced technicians. As a result, this



Figure 11 Knee disarticulation patient with Poytol® socket.

sophisticated technology is offered by Service Fabrication. In order to offer patients the maximum benefit of this new socket material, load-bearing and soft zones have to be precisely defined. Active people who need to use a hip disarticulation prosthesis on an everyday basis should have as much mobility as possible. These persons require a lot of concentration in order to properly control their prosthesis. For everyday activities in particular, the combination of very firm zones and soft polyurethane zones has to be precisely defined in order to achieve maximum flexibility for the patient.



Figure 12 Flexible socket for pelvic socket prosthesis.

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