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Comparison of traditional solvent casting method vs. film applicator casting method for TPU polymer sheets in medical implantable devices

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Abstract
Thermoplastic polyurethane (TPU) is a versatile polymer widely used in implantable medical devices due to its excellent mechanical properties and biocompatibility also shows good resistance to wear, chemicals, and body fluids, It is suitable for devices that stay in the body for years. Solvent casting is commonly used because it is simple, cost-effective, and suitable for producing thin polymer films. This study compares two fabrication methods for TPU sheets (1) the traditional solvent casting technique and (2) solvent casting using a film applicator (doctor-blade method). This article provides a comprehensive overview of solvent casting in biomedical applications and describes the materials and procedures for each method. Process parameters including processing steps, drying time, dry film thickness uniformity, mechanical strength, and surface morphology are evaluated. The film applicator method is found to produce more uniform thickness films with improved consistency in mechanical performance and surface smoothness compared to traditional casting, which is simpler but can yield non-uniform thickness and rough surfaces. The advantages and limitations are explained for each. The framework allows incorporation of user-provided experimental data for direct comparison of film properties. This approach can support the development of more reliable and high-performance implantable medical devices. These insights guide the selection of an appropriate casting technique for high-quality TPU implantable sheet.

Keywords: Thermoplastic polyurethane (TPU), solvent casting, film applicator method, thickness uniformity, implantable medical devices, drying behaviour, mechanical properties, surface roughness

Introduction
Thermoplastic polyurethane, a material that is effective and efficient, has been employed in different applications in the field of medicine and biomedicine due to its superior mechanical properties, elasticity, chemical stability, and biocompatibility. Therefore, based on its superior properties, thermoplastic polyurethane can be employed in different medical device applications, such as cardiovascular devices, catheters, and drug delivery devices. The segmented structure of thermoplastic polyurethane, composed of hard and soft segments, allows for the adjustment of physical properties depending on different biomedical applications. Therefore, thermoplastic polyurethane-based materials are increasingly used in different medical devices, especially when stability, flexibility, and resistance to mechanical fatigue are needed [1, 2]. Different polymers are used in different medical device applications, and sometimes films or sheets are needed for different applications, such as structural, encapsulating, and functional barriers in different medical devices. Therefore, ensuring film thickness, morphology, and mechanical strength are important, especially when they are used in different medical device applications, as they directly influence different medical device applications. Thus, differences in film thickness might influence mechanical strength, drug release, and tissue interactions in different medical device applications [3, 4, 5]. Solvent casting can be carried out through two different methods, namely, traditional casting and doctor blade casting. For traditional casting, a petri plate has to be selected, and the solution has to be poured over it. The petri plate has to be kept at a particular temperature for drying, while in film applicator casting, a blade has to be fixed at a particular gap width and spread over a substrate, and then the solution has to be poured over it and dried at a particular temperature. Therefore, film applicator casting is more efficient than traditional casting, especially when even spreading of the solution over the blade takes place [6, 7, 8]. The aim of this study is to compare traditional casting and film applicator casting techniques for preparing thermoplastic polyurethane sheets for medical device applications.

Literature Review
Solvent casting has been widely used for the fabrication of polymeric films in biomedical and pharmaceutical applications. The technique is particularly useful for producing thin polymer membranes used in wound dressings, drug delivery systems, and implantable medical devices. In this process, a polymer solution is cast into a mold or petri plate, and the solvent is evaporated to form a solid film. Several studies have demonstrated that solvent casting enables the production of flexible polymeric films with controlled composition and functional properties [6, 8].
Thermoplastic polyurethanes [e.g., Carbosil® pellets, Bionate® PCU (DSM Biomedical B.V.), Carbothane™ AC Series, Carbothane™ PC Series (Lubrizol)] are widely recognized as important materials for medical applications due to their excellent mechanical strength, flexibility, abrasion resistance, and biocompatibility. Studies have reported that TPU materials exhibit favourable characteristics for implantable biomedical devices, including cardiovascular implants and polymeric heart valve components. The segmented molecular structure of TPU allows adjustment of mechanical properties, enabling materials with different levels of elasticity and durability suitable for long-term implantation [1, 5].

Despite the advantages of solvent casting, traditional casting methods can produce films with uneven thickness distribution due to solution pooling, edge effects, or uncontrolled solvent evaporation. These variations may affect mechanical performance and surface quality of the resulting films [9]. Non-uniform drying may also introduce internal stresses, wrinkles, or other surface defects during film formation.

To address these limitations, controlled coating techniques such as doctor blade coating have been developed for producing uniform polymer films. In this technique, a blade with an adjustable gap spreads the polymer solution across a substrate, enabling precise control of the wet film thickness and improving film uniformity. Industrial coating processes such as slot-die coating and blade coating have demonstrated the ability to produce films with minimal thickness variation and consistent material properties [1, 9].

At the laboratory scale, film applicators or doctor blades provide a practical approach to achieving uniform coatings. Previous reports have shown that blade-coated polymer films can exhibit improved thickness control and surface uniformity compared with conventional casting methods [9, 12]. These improvements are particularly important for biomedical applications where dimensional precision and mechanical reliability are critical.

Therefore, evaluating different solvent casting approaches is essential for optimizing the fabrication of TPU films intended for medical implantable devices.

Materials and Methods

Medical-grade TPU pellets or granules (for example, a polyether-based TPU suitable for implantation – Carbothane AC and Carbothane PC Series) were used as the base polymer. Anhydrous tetrahydrofuran (THF) was selected from the group of solvents capable of dissolving TPU [such as tetrahydrofuran (THF), dimethylacetamide (DMAC), and methylene chloride (MC)] due to its relatively low boiling point (66 °C), which facilitates faster solvent evaporation. All preparations were conducted in a laminar air flow given THF's flammability and to ensure safe vapor extraction. The TPU pellets were dehumidified prior to use in a dehumidifier to remove moisture and anhydrous THF was used to prevent any moisture-related effects on casting.

Different concentration of polymer solution was prepared (due to process difference) for both casting methods. This concentration falls in the typical range (7-20% solids by weight) recommended for TPU solution casting. Adjusting the polymer concentration allows control of solution viscosity and final film thickness – higher solid content yields thicker films per given volume but increases viscosity, whereas lower solid content yields thinner films and lower viscosity. In this study, the different concentration of TPU solution was used for both methods.

Traditional Solvent Casting Procedure

In the traditional solvent casting method, the TPU solution is effectively prepared using a magnetic stirrer (Make: REMI) by dissolving TPU pellets in solvent under controlled RPM for continuous stirring. Gradual addition of TPU and maintaining optimal heat ensures complete dissolution and a homogeneous, lump-free and bubble-free solution. Then the prepared TPU solution is cast into a simple molds and allowed to dry under ambient conditions until a solid film forms. A glass petri plate or a stainless steel pan was cleaned using same solvent to avoid any moisture content and levelled. The solution was then poured into the petri plate to form a liquid layer. We used a volume sufficient to cover the petri plate bottom uniformly – for example, 100 ml of 8%w/v TPU solution spread over a 15 × 15 cm petri plate. The natural surface tension of the solution causes it to spread; the petri plate was gently tilted if needed to help the solution cover the entire area evenly.

The solution was left to dry 40 °C in the vacuum oven (Make: HMG) for initial hours (i.e. 2 – 3 hours). During this time, THF evaporates from the exposed top surface of the solution. After 2 hours, increase the temperature gradually up to 70 °C for 7 to 8 hours.

After drying, the solid TPU film was carefully peeled from the petri plate. If the film adhered strongly to the petri plate, a thin edge was gently lifted using a Teflon spatula or the petri plate was briefly dipped in water to assist release (TPU generally peels off easily on clean smooth surfaces like glass or polished metal). The resulting free-standing film was stored in a dry, dust-free container for characterization. The typical thickness of films obtained by this method depends on the solution volume and concentration; in our case, ~100 ml of 8% w/v TPU in a 225 cm^2 area yielded a film about 150–300 µm thick. Any edge irregularities (e.g. a slight raised bubbles at the film walls) were trimmed off before testing. The entire process from solution casting to dry film could take ~10 hours including drying time, though actual drying time varies with film thickness and ambient conditions.

Film Applicator (Doctor Blade) Casting Procedure

For the film applicator method, the more concentrate and viscous TPU solution was prepared as per the same method mentioned above. Thereafter it is casted using a doctor blade film applicator to achieve controlled thickness using micrometer adjustable film applicator. (Refer figure no.: 1). A micrometer adjustable film applicator is a tool with an adjustable gap that spreads the polymer solution in a uniform layer. (Refer figure no.: 2). In this work, a stainless steel blade applicator was used, with the gap set (wet film thickness) to a desired dry film thickness according to below mentioned table:

Table 1: DFT at different WFT

Wet Film Thickness - WFT (microns)	Dry Film Thickness - DFT (microns)
1700	160 - 200
1600	140 - 180
1500	130 - 170
1300	110 - 150
1000	80 - 110

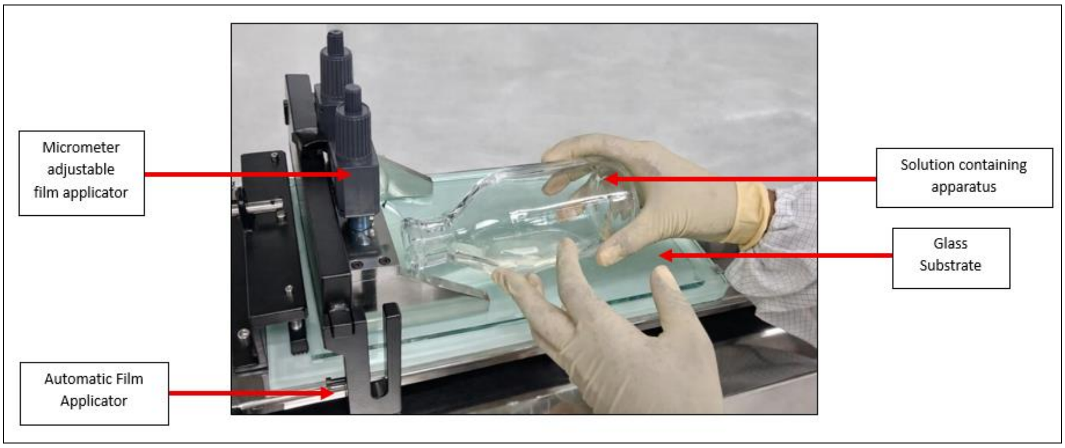


Fig 1: Solution Puring

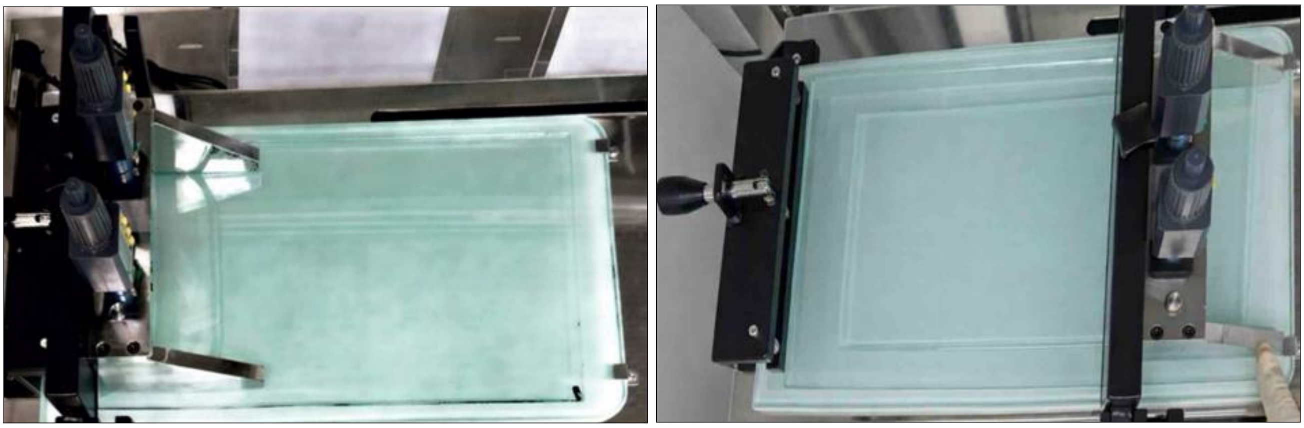


Fig 2: Film Casting

The substrate for coating was a flat glass plate (cleaned with solvent to reduce moisture content). A measured volume of the TPU solution was poured or placed in front of the micrometer adjustable film applicator (Make: STECH) at one end of the substrate. The blade was then drawn across the substrate at a set speed, spreading the solution into a thin film of uniform thickness defined by the gap. This automatic coating process was performed in one smooth motion to avoid streaks. In our example, a 1700 µm wet film thickness setting produced a uniform dry film of about 160–200 µm thick after solvent evaporation. The applied wet film thickness is larger than the final dry thickness because the polymer only constitutes a fraction of the solution.

After coating, the wet film on the substrate was allowed to dry in the vacuum oven. The plates were initially placed in the vacuum oven at ambient temperature for initial hours (i.e. 2 hours). After that the temperature was increased up to 50°C for next one to two hours. The film typically became dry to touch within a few hours. Once dried, the TPU film was peeled off the glass substrate. The uniformity of thickness made peeling straightforward, and the resulting film had a consistent appearance.

For both methods, the film thickness was measured at multiple points using a thickness gauge (Make: Mitutoyo) to assess uniformity. Mechanical testing samples were then cut from the films (e.g. dog bone strips for tensile testing or rectangular samples for other tests), and surfaces were examined using roughness tester. In all cases, films were handled with gloves to maintain cleanliness suitable for biomedical use.

Film Characterization Methods

Thickness and Uniformity: Thickness measurements were taken with a digital thickness gauge at various locations across each film (e.g. Center and four corners of a 10×10 cm sample) to quantify uniformity. The average thickness was recorded for films from each method. For a more detailed thickness map, one could use a thickness profilometer or optical measurement, but thickness gauge readings suffice for uniformity assessment in this study.

Tensile Mechanical Tests: Tensile properties of the TPU films were evaluated using a uniaxial tensile test (as per ASTM D882 for thin films). Strips of film (e.g. 5 mm wide, gauge length 20 mm) were clamped in a mechanical tester and pulled at a constant rate (e.g. 50 mm/min) until failure. From stress–strain data, the ultimate tensile strength, elongation at break, and Young's modulus were obtained. At least 3 specimens from each film were tested to ensure reproducibility.

Suture Retention Tests: The suture retention strength was evaluated in accordance with ISO 7198:2017 using a straight-pull test method. Rectangular test sample were prepared from the test material. A polypropylene (Prolene) suture was inserted from the test sample and passed through the material. The free ends of the suture were tied to form a loop, which was secured in the upper grip of a universal testing machine, while the test sample was clamped in the lower grip. Tensile force was applied at a crosshead speed of 50 mm/min until failure occurred by suture pull-out or material tearing. The maximum force (N) recorded at the point of failure was reported as the suture retention strength.

All experimental data collected were analysed comparatively between the two casting methods. The following section presents the results and discussion of these comparisons.

Results and Discussion

Film Thickness and Uniformity

Thickness Outcomes: Both methods produced TPU films in the tens or hundreds of micrometers thickness range (precise values depending on the casting parameters). However, there was a clear difference in thickness uniformity. Films produced via the traditional solvent casting showed noticeable thickness variation across the sample. For example, a representative traditionally cast film had an average thickness of ~200 µm, but varied by ±80 µm in different areas (thicker toward the center where the solution pooled slightly, and thinner toward the edges). In contrast, the film applicator method yielded a much more uniform thickness; a film cast with a 1700 µm wet gap had a dry thickness around 180 µm with variation of only a 20 microns across the entire area. The use of the doctor blade ensured that the polymeric solution was evenly distributed initially, so the solvent evaporation shrinkage occurred uniformly.

Our measurements confirmed that the standard deviation of thickness in films from the applicator method was significantly smaller than that of the traditional cast films (Refer Table -2)

Table 2: Thickness Outcomes

Sample No.	Thickness Range of Solvent Casted Film (micron)	Thickness Range of Automatic Casted Film (micron)
Sample 1	120 – 250	160 – 200
Sample 2	110 – 260	170 – 200
Sample 3	130 – 230	165 – 190
Sample 4	110 – 250	170 - 200
Sample 5	120 - 260	170 - 200

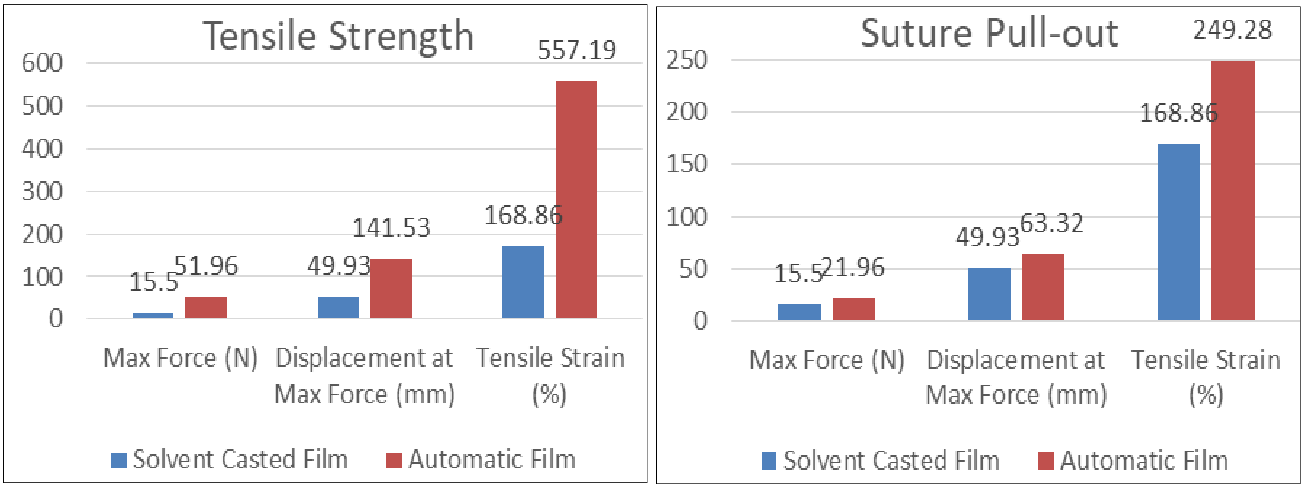
The homogeneous thickness distribution achieved by the film applicator is consistent with literature on blade-coated films, which report very narrow thickness distributions when the process is well-controlled. In industrial settings, solvent casting with proper spreading (slot dies or doctor blades) can achieve thickness tolerances better than ±10% for thin films. In our lab-scale trials, use of film applicator achieved visibly uniform films (no discernible thick or thin spots by eye or touch).

It should be noted that the traditional casting can be improved by techniques such as slowly levelling the solution or using a larger volume to naturally self-level to a uniform thin layer. In this study, we attempted to allow the solution to spread out in the petri plate. Despite these precautions, minor edge effects were present. Small thickness non-uniformities might be acceptable in some applications, but for critical implantable devices where precise thickness is tied to performance, the film applicator method provides a clear advantage.

Effect of Thickness Uniformity on Drying Behaviour and Defect Formation: Thickness uniformity also influenced drying behaviours. The traditional cast films, with some regions thicker than others, dried non-uniformly – thinner regions solidified faster, while thicker regions remained wet longer. This prolonged the total drying time, since one must wait for the thickest part to fully dry. Moreover, differential drying can introduce internal stresses or minor defects (e.g. “wrinkling” or “wave” formation in areas that dried earlier). In contrast, the uniformly thin films from the applicator method dried more evenly and in a shorter time. We observed that a ~1700 µm uniform film dried in just a few hours to a tack-free state, whereas a film of equivalent average thickness cast traditionally (but uneven) took over 10-12 hours to fully dry, because the concentration of solution is smaller than doctor blade technique and the volume is twice than doctor blade technique. The even thickness likely also mitigated stress development – the film did not exhibit visible warpage or gradients. No bubble formation was seen in either method when drying at room temperature; however, rapid evaporation in any method can trap bubbles, waves or cause pores if not managed (e.g. drying above solvent boiling point is discouraged to avoid bubbles and other defects).

Mechanical Properties of Polymeric Films

Appropriate mechanical properties are critical for cardiovascular biomaterials, particularly for implantable medical devices. In this study, polymeric films were developed using an automated casting method to achieve superior mechanical performance compared with the conventional solvent casting technique. Tensile strength measurements showed that the automatically cast polymeric films exhibited significantly higher mechanical strength than those prepared by traditional solvent casting (Fig. 3A). Furthermore, suture retention testing demonstrated that the automatically cast films possessed markedly greater suture retention strength relative to solvent-cast films (Fig. 3B). These findings indicate that the polymeric film fabrication using automatic film applicator method significantly enhances mechanical properties, which can be attributed to optimized processing steps and controlled process parameters.



(A) (B)

Fig 3: Mechanical properties of Polymeric Film. (A) Representative mean tensile strength curves. (B) Mean suture pull-out curves of Polymeric Film

Surface Morphology

Visual Appearance: The surfaces of the TPU films obtained by traditional casting versus the film applicator method were noticeably different upon inspection. The traditionally cast films often had a glossy top surface (air side) and a very smooth bottom surface (mold side, which replicates the smooth glass or metal pan). However, slight undulations could be seen on the top surface corresponding to where solvent evaporated a bit unevenly. In some instances, minor ripple-like patterns or a faint "coffee ring" effect at the edges were present, indicating non-uniform solvent flow during drying. In contrast, the film applicator films appeared uniformly matte or glossy (depending on the substrate) across the entire surface, without visible thickness-related patterns. If the doctor blade had any minor grooves or if the casting was done manually with imperfect steadiness, faint striations in the direction of coating could sometimes be observed under light reflection. But these were minimal in our case, yielding a consistent appearance.

Surface Roughness: The surface roughness measurements indicate a noticeable difference between solvent-cast and automatic-cast polymeric films. For the solvent-cast films, the recorded roughness values were 0.142 µm (Polymeric Film-1), 0.26 µm (Polymeric Film-2), and 0.21 µm (Polymeric Film-3), showing relatively higher variability and an overall higher roughness range. In contrast, the automatic-cast films exhibited lower and more consistent roughness values of 0.195 µm, 0.147 µm, and 0.14 µm for Films 1, 2, and 3, respectively. Notably, the highest roughness was observed in the solvent-cast Film-2 (0.26 µm), whereas the lowest roughness was recorded for automatic-cast Film-3 (0.14 µm). Overall, the automatic casting method demonstrated improved surface uniformity and reduced roughness variation, suggesting better control over film formation and enhanced surface smoothness compared to the conventional solvent casting technique.

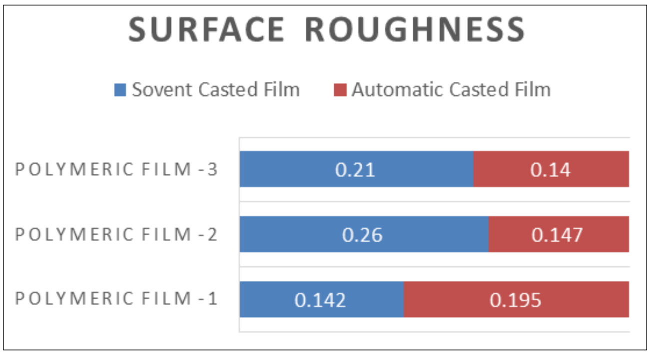


Fig 4: Surface Roughness Data chart of Solvent Casted Film and Automatic Casted Film

Processing Steps and Time: From a workflow perspective, the traditional solvent casting is simpler in setup but can be slower in overall turnaround. It involves fewer active steps (basically pouring and waiting), whereas the film applicator method adds an active step of spreading the film. In practice, we found the actual labor time for both methods to be comparable – preparing the solution is identical, and the extra step of using the applicator takes only a minute or two. However, the drying time differed: the traditional cast films, especially if thicker in parts, required a long drying period (overnight or longer) to reach a stable state, while the uniformly thin films from the applicator dried much faster (potentially within a few hours). If multiple layers or thicker films are needed via the applicator, one strategy is to do successive coatings (drying in between); this still can be faster than waiting for a single thick pour to dry since each thin layer dries quickly.

In terms of throughput, if many films need to be produced, the film applicator method could be more efficient. One can coat several films in succession on different substrates and have them drying, whereas traditional casting is often limited by available flat molds and the long drying per mold. Additionally, the applicator method typically yields consistent results without much rework, whereas traditional casting might occasionally produce a film with defects (requiring recasting) if, for example, the solution distribution was poor or if dust causes a flaw.

Advantages and Limitations of Both Method

To summarize the findings, we enumerate the key advantages and limitations of traditional solvent casting and the film applicator casting for TPU:

Advantages of Traditional Solvent Casting:

- **Simplicity:** Requires no specialized equipment beyond a container; easy setup and suitable for any lab.

- **High Thickness Possible:** Can cast relatively thick films in one pour (limited by solvent evaporation and risk of defects) which might be useful if a thick sheet is needed without layering.

- **Scalable Area:** Potentially cast larger areas if a large level tray is available (though uniformity may suffer without blade spreading).

Limitations of Traditional Solvent Casting

- **Non-uniform Thickness:** Prone to thickness variation (edges vs center) and formation of thicker "edge bead" regions or uneven distribution. This can lead to inconsistent device performance.

- **Long Drying Time:** Thicker sections dry slowly, prolonging overall processing time. Risk of solvent entrapment if not dried thoroughly.

- **Possible Surface Defects:** Might develop surface roughness or minor defects (wrinkles, cracks) if drying is not well-controlled. Also, dust contamination is a risk during long open drying.

Advantages of Film Applicator (Doctor Blade) Casting

- **Uniform Thickness:** Achieves highly uniform film thickness across the sheet, improving reliability of mechanical and functional properties.

- **Controlled Thickness:** Adjustable gap allows precise control of wet film thickness (and thereby dry film thickness), facilitating specific target thickness with fine tolerance.

- **Faster Drying:** Thinner, even films dry more quickly and uniformly, increasing throughput and reducing solvent exposure time.

- **Reproducible Process:** When parameters (gap, speed, volume) are kept constant, results are consistent from batch to batch, which is critical for quality control.

- **Better Surface Finish:** Typically yields smoother, defect-free surfaces on the air side as well as substrate side, which can be beneficial for implant performance or coating uniformity.

Limitations of Film Applicator (Doctor Blade) Casting

- **Viscosity Sensitivity:** The method assumes the solution remains uniformly flowable during the coating. If solvent evaporates too quickly or the solution viscosity changes during the casting process, it can affect uniformity. Working quickly and possibly adding flow agents can mitigate this.

- **Limited One-Pass Thickness:** Very thick films cannot be made in a single pass without risking runs or sag; multiple layers or a slower solvent evaporation might be needed for thickness above a certain limit (e.g. >400 µm).

- **Requires Equipment and Skill:** Needs a film applicator tool and a bit of practice to use correctly (manual inconsistency can introduce stripes or uneven regions if not careful.
- **Edge Effects:** Although thickness across the bulk is uniform, the edges of the coated region may have slight thinner where the coating ends (edge bead that often must be trimmed off).

- **Size Constraints:** The width of the film is limited by the blade length; making very large sheets might require specialized larger applicators or scaling to automated coaters. Also, coating very small volumes can be tricky (for very small samples, traditional casting might be easier).

Conclusion

This study compared traditional solvent casting and film applicator (doctor blade) casting methods for the fabrication of TPU sheets intended for implantable medical devices. Although both techniques successfully produced TPU films, notable differences were observed in thickness uniformity, drying behaviour, mechanical performance, and surface characteristics.

Traditional solvent casting resulted in significant thickness variation (110–260 µm), longer drying times, and higher variability in surface roughness. Non-uniform drying in thicker regions may contribute to internal stresses and reduced reproducibility. In contrast, the film applicator method produced highly uniform films (160–200 µm range), faster and more consistent drying, and improved surface smoothness.

Mechanical testing demonstrated superior tensile strength and suture retention in films prepared using the applicator method, indicating enhanced structural integrity and reliability. Overall, the doctor blade casting technique provides better process control, reproducibility, and mechanical consistency. Therefore, for implantable applications where dimensional precision and predictable performance are critical, the film applicator method is recommended over traditional solvent casting.

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