EFFECTIVENESS OF POLYTETRAFLUOROETHYLENE PLUGS IN PREVENTING WATER LEAKAGE DURING KNEE ARTHROSCOPY FOR ANTERIOR CRUCIATE LIGAMENT INJURY

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ABSTRAK

Kebocoran cairan dari terowongan atau portal merupakan masalah umum selama artroskopi lutut, yang berpotensi menyebabkan kekeruhan, gangguan visualisasi, dan waktu operasi yang lebih lama. Polytetrafluoroethylene (PTFE) adalah bahan yang dikenal karena sifatnya yang hidrofobik, tidak reaktif, tahan panas, dan tidak menyebabkan iritasi, sehingga banyak digunakan dalam aplikasi medis. Penelitian ini bertujuan untuk mengevaluasi efektivitas PTFE sebagai bahan penyumbat portal dan terowongan selama prosedur artroskopi. Penelitian eksperimental ini dilakukan pada 30 pasien yang didiagnosis mengalami cedera ligamen anterior cruciate (ACL), dan dijadwalkan menjalani artroskopi lutut di Departemen Ortopedi dan Traumatologi Rumah Sakit Hasan Sadikin (RSHS) Bandung, pada tahun 2024. Pasien dibagi menjadi dua kelompok: 15 orang menjalani operasi tanpa sumbat PTFE (Kelompok A) dan 15 orang dengan sumbat PTFE (Kelompok B). Usia rata-rata pasien adalah 24 tahun, dengan mayoritas berjenis kelamin laki-laki. Rata-rata penggunaan larutan NaCl pada Kelompok A dibandingkan Kelompok B adalah 13,3 vs. 7,767 liter. NaCl yang dikumpulkan melalui mesin hisap adalah 8,633 vs. 5,333 liter, dan NaCl yang ditemukan di lantai adalah 4,7 vs. 2,467 liter. Uji normalitas menunjukkan bahwa data terdistribusi normal ($p > 0,05$). Uji T tidak berpasangan menunjukkan perbedaan yang signifikan antara kelompok ($p < 0,05$). Penggunaan sumbat PTFE secara signifikan mengurangi kebocoran cairan dan meningkatkan efisiensi prosedur bedah. Keuntungan tambahan termasuk distensi sendi yang lebih baik, pengurangan kebutuhan akan torniket, dan efek tamponade terhadap perdarahan. Sumbat PTFE menawarkan alternatif yang hemat biaya dibandingkan dengan kanula silikon atau artroskop yang tidak memiliki fitur anti-balik cairan.

Kata kunci : artroskopi lutut, ligamen anterior cruciatum, *polytetrafluoroethylene*

ABSTRACT

Fluid leakage from the tunnel or portal is a common issue during knee arthroscopy, potentially causing cloudiness, obstructed visualization, and prolonged surgical time. Polytetrafluoroethylene (PTFE) is a material known for its hydrophobic, non-reactive, heat-resistant, and non-irritating properties, making it widely used in medical applications. This study aimed to evaluate the effectiveness of PTFE as a portal and tunnel plug material during arthroscopy. This experimental study was conducted on 30 patients diagnosed with anterior cruciate ligament (ACL) injuries, who were scheduled for knee arthroscopy at the Department of Orthopedics and Traumatology, Hasan Sadikin Hospital (RSHS) Bandung, in 2024. Patients were divided into two groups: 15 who underwent surgery without PTFE plugs (Group A) and 15 with PTFE plugs (Group B). The average age of the patients was 24 years, with the majority being male. The average comparison of NaCl used in Group A vs. Group B was 13.3 vs. 7.767 liters. The NaCl collected in suction machines was 8.633 vs. 5.333 liters, and NaCl found on the floor was 4.7 vs. 2.467 liters. The normality test showed data were normally distributed ($p > 0.05$). An unpaired T-test revealed significant differences between groups ($p < 0.05$). The use of PTFE plugs significantly reduced fluid leakage and improved surgical efficiency. Additional advantages include improved joint distension, reduced need for tourniquets, and tamponade effect on bleeding. PTFE plugs offer a cost-effective alternative to silicone cannulas or arthroscopes without anti-backflow features.

Keywords *: anterior cruciate ligament, knee arthroscopy, polytetrafluoroethylene*

INTRODUCTION

Arthroscopy is a minimally invasive procedure that is the most common orthopedic surgical procedure today, especially knee arthroscopy (Crimmins et al., 2019). One common occurrence when performing knee arthroscopy surgery is the leakage of fluid from the tunnel or portal that can flow under the tourniquet and out of the arthroscopy surgical field so that it can interfere with the operation. This can cause bacterial contamination, (Bartek et al., 2020a) the duration of surgery to be longer and interfere with the visualization of the operator's field of view (Cerulli et al., 2013; Lu et al., 2020). To overcome this problem, one of them is using a flexible silicone cannula (PassPort^{TM}, Arthrex^{TM}) in the anteromedial arthroscopy portal, but silicone cannulas are not yet available in Indonesia, are expensive and can only be used once. Polytetrafluoroethylene (PTFE) [TeflonTM](Johnson et al., 2012) has been widely used in medical applications, (Johnson et al., 2012; Radulovic & Wojcinski, 2014a), but no one has used it as a material to make portal & tunnel plugs during arthroscopy.

PTFE has hydrophobic, non-reactive, good insulator, and non-irritating characteristics. Compared to silicone, PTFE has stiffer properties and can be reused because of its heat-resistant properties (Johnson et al., 2012). Therefore, PTFE has the potential to be used as a portal & tunnel plug material during arthroscopy. In addition to the technical challenges that occur during arthroscopic procedures, such as fluid leakage from the portal and impaired visualization, the need for efficient, cost-effective, and reusable auxiliary tools is becoming increasingly urgent, especially in developing countries like Indonesia (Jaiprakash et al., 2017). Although single-use silicone devices are effective, their high cost and limited availability are major obstacles. Therefore, innovation is needed in selecting alternative materials that are more economical yet still meet the requirements of biocompatibility and functionality for arthroscopic procedures (Krishnamurthy et al., 2024).

Polytetrafluoroethylene (PTFE), commonly known by the trade name Teflon™, is a synthetic polymer material that has been widely used in various medical applications such as artificial blood vessels, catheters, and surgical instruments (Gaines, 2023). Its chemically inert nature, hydrophobic properties, high-temperature resistance, and non-irritating characteristics make PTFE ideal for use in sterile and dynamic surgical environments (Radulovic & Wojcinski, 2014b). Additionally, the stiffness of this material provides mechanical advantages in maintaining the shape and position of the plug when used as a portal or tunnel seal during arthroscopic procedures (Dhanumalayan & Joshi, 2018).

The development and evaluation of PTFE as a base material for arthroscopy portal plugs could represent an innovative breakthrough in the field of orthopedic surgery. The reusability of PTFE, which allows for repeated sterilization processes, also supports cost-efficiency principles in healthcare services (Rahman et al., 2023). With this alternative, it is hoped that reliance on expensive imported single-use products can be reduced and that the adoption of more affordable surgical technologies in healthcare facilities across Indonesia can be accelerated (Zhao et al., 2005a). This study aims to examine the potential of PTFE as an alternative plug material in knee arthroscopy procedures and to evaluate its characteristics and advantages compared to conventional materials such as silicone (Zhao et al., 2005b).

Moreover, the implementation of PTFE as a portal plug material also aligns with the growing emphasis on sustainability and environmentally friendly medical practices. Reusable surgical tools not only reduce medical waste but also contribute to long-term cost savings for healthcare providers (Jianyun et al., 2021). In low- and middle-income countries where budget constraints often limit access to advanced medical technologies, adopting PTFE-based devices could improve the standard of care and ensure more consistent surgical outcomes (Vasan & Friend, 2020). Preliminary physical evaluations of PTFE show that the material maintains its structural integrity under typical autoclaving conditions, indicating its feasibility for repeated

sterilization without compromising performance (Şimşek et al., 2022). Its rigidity can help maintain a seal in the portal tunnel, preventing fluid escape and maintaining a clearer surgical field. Furthermore, PTFE's widespread availability and relatively low cost make it an attractive alternative for local development and manufacturing (R. Wang et al., 2017). With proper design and clinical validation, PTFE plugs could become a valuable solution to improve arthroscopic procedures, especially in resource-limited healthcare settings.

This study is expected to serve as an initial step in exploring the application of PTFE as an alternative material for arthroscopy portal plugs. By investigating its physical characteristics, functional performance, and potential for sterilization and reuse, this research seeks to provide scientific evidence that supports the feasibility of PTFE in orthopedic surgical applications. Ultimately, the goal is to enhance surgical efficiency, reduce operational costs, and improve access to quality surgical tools in healthcare systems with limited resources.

METHODS

Patient Selection

The inclusion criteria of this study were patients of the Orthopedics and Traumatology Department of Hasan Sadikin General Hospital Bandung with anterior cruciate ligament (ACL) injuries who underwent knee arthroscopy procedures in 2024. The exclusion criteria were patients with ACL injuries accompanied by other injuries (meniscus injuries, posterior cruciate ligament injuries, etc.). And the drop out criteria were patients who underwent open arthrotomy during intraoperatively. The number of samples was 30 people who were divided into 15 patients who did not use PTFE plugs (group A) and 15 patients who used PTFE plugs (group B) during knee arthroscopy surgery.

Procedure

The procedure begins with designing the PTFE plug, followed by selecting the appropriate material for its production. Once the suitable material is identified, an order is placed with the manufacturer according to the specified design and material. The cost of producing the PTFE plugs is IDR 1,500,000 (approximately USD 94.5) for 8 pieces in four different sizes: 2 cm, 3 cm, 5 cm, and 7 cm. Prior to surgery, the patient undergoes either general or regional anesthesia. The patient is then positioned supine on the operating table, with the knee flexed at 90 degrees on the affected side. A knee stabilizer is placed under the foot, and a lateral thigh support is positioned parallel to the tourniquet. The surgical portal is selected based on the needs of the procedure, including options such as anterolateral, anteromedial, superomedial, superolateral, posteromedial, posterolateral, transpatellar, proximal superomedial, and far medial or far lateral portals. Aseptic procedures are carried out, followed by an incision at the trocar insertion site, and the arthroscopic trocar is introduced. Normal saline (NaCl 0.9%) is then inserted to inflate the joint space for better visualization. After joint distension, the PTFE plug prototype is installed at the portal and tunnel to prevent fluid leakage. Once the operation is complete, the total volume of fluid used is recorded by calculating the difference between the amount of fluid provided and the remaining fluid, indicating the total volume of NaCl 0.9% used during the procedure.

Statistical Analysis

Data analysis to test the hypothesis of the effectiveness of PTFE plugs will be determined after the data obtained is known to have a normal distribution or not using Shapiro-Wilk analysis. The use of an unpaired t-test if the data is normally distributed, this test is chosen because sampling is only done once with the dependent variable in the form of quantitative (numerical) data. The data obtained are processed using the Statistical Package for the Social

Science (SPSS) 26.0 program. The significance criterion used is the p value, if p≤0.05 means it is statistically significant or meaningful, and p>0.05 is not statistically significant or not meaningful.

RESULT

Table 1. Demographic Data

Variable	Frequency or Mean±SD
Age (year)	24,83±9,082
Sex	
Man	26
Woman	4
PTFE plug	
Use	15
Not use	15
Operation duration (minute)	94±15,724
NaCl used (litre)	10,550±3,0636
Not use PTFE plug	13,333±1,1598
Use PTFE plug	7,767±1,2228
NaCl in suction machine (litre)	6,983±1,9095
Not use PTFE plug	8,633±1,0933
Use PTFE plug	5,333±0,7237
NaCl on floor (litre)	3,583±1.2804
Not use PTFE plug	4,700±0,5278
Use PTFE plug	2,467±0,6673

Based on table 1, the average age of patients undergoing ACL surgery was 24 years, with the youngest being 16 years old and the oldest being 51 years old. The majority of patients were male. The total number of patients was 30, which were then divided into 2 groups, namely 15 patients using PTFE plugs and 15 patients not using PTFE plugs. The average duration of surgery was 94 minutes. Descriptively, the amount of NaCl fluid used, NaCl in the suction machine, and NaCl on the floor were lower in the group using PTFE plugs.

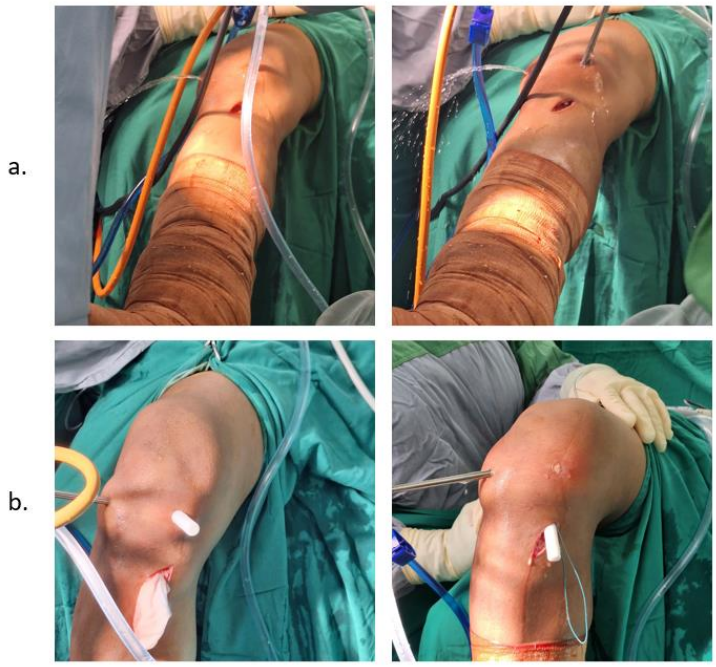

Figure 1. The difference between ACL surgery without PTFE plug (photo row a.) and with PTFE plug (photo row b.)

Based on the clinical photos in Figure 1, the difference between ACL surgery without PTFE plug and with PTFE plug is clearly visible. In ACL surgery without PTFE plug, there is quite a lot of water leakage, while in ACL surgery with PTFE plug, there is no significant leakage.

Table 1. Normality Test with Shapiro-Wilk

	PTFE plug	Shapiro-Wilk Statistic	df	p-value
NaCl Used	Not use PTFE plug	.937	15	.344
	Use PTFE plug	.961	15	.711
NaCl Suctioned	Not use PTFE plug	.948	15	.500
	Use PTFE plug	.930	15	.274
NaCl on Floor	Not use PTFE plug	.866	15	.029
	Use PTFE plug	.924	15	.224

The total sample in this study was 30, because the number was <50, the normality test with Shapiro-Wilk was used. Based on the table above, all p-values were >0.05, meaning that the data in this study were normally distributed. So, for bivariate analysis in this study, an unpaired T test was used.

Table 2. Unpaired T Test

		t-test for Equality of Means						
		t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
							Lower	Upper
NaCl Used	Equal variances assumed	12.792	28	.000	5.5667	.4352	4.6753	6.4581
	Equal variances not assumed	12.792	27.922	.000	5.5667	.4352	4.6752	6.4582
NaCl Suctioned	Equal variances assumed	9.748	28	.000	3.3000	.3385	2.6066	3.9934
	Equal variances not assumed	9.748	24.294	.000	3.3000	.3385	2.6018	3.9982
NaCl on Floor	Equal variances assumed	10.167	28	.000	2.2333	.2197	1.7834	2.6833
	Equal variances not assumed	10.167	26.590	.000	2.2333	.2197	1.7823	2.6844

Based on the unpaired T-test, all p-values were <0.05, meaning that there was a significant difference between the groups using PTFE plugs and those not using PTFE plugs. In the group using PTFE plugs, the total volume of NaCl used, NaCl on the suction machine, and NaCl on the floor was less than in the group not using PTFE plugs. Therefore, the use of PTFE plugs can significantly reduce the amount of fluid used and water leakage during surgery in ACL injury patients.

DISCUSSION

The anterior cruciate ligament (ACL) is one of the most commonly injured knee ligaments, and ACL reconstruction is a treatment option for individuals with functional instability due to ACL deficiency (Longo et al., 2021; C. Wang et al., 2021). The incidence of ACL injury is approximately 35/100,000 people (Irarrázaval et al., 2016). ACL reconstruction is one of the most common sports medicine procedures performed in the United States, with approximately 100,000 performed each year (Csintalan et al., 2008). In this study, the average age of patients

was 24 years with the majority of patients being male. This finding is consistent with a study by Longo et al. which stated that ACL reconstruction is most often performed in the 20–24 year age group with an average male/female ratio of 4.54, implying that men are more likely to undergo this surgery (Longo et al., 2021).

Arthroscopic techniques are usually the choice for ACL reconstruction because they are less invasive than open surgery. During arthroscopy, irrigation fluids (such as NaCl solution, Ringer lactate, or carbohydrate solutions) are commonly used to stretch the joint and allow for adequate visibility (Stärke et al., 2018). One common side effect of irrigation fluid use is leakage of the fluid, which can lead to bacterial contamination of the sterile surgical field (Bartek et al., 2020b). According to data from Dr. Hasan Sadikin General Hospital in Bandung for the years 2022-2023, there were 76 ACL injury cases that underwent surgery, all of which experienced leaks in the arthroscopic tunnel or portal. However, innovations to reduce this leakage have not been widely studied. A study conducted by Ardolino et al. used the rubber plunger tip of a 10 cc syringe to plug the arthroscopy port. This technique creates a watertight seal around the tip of the arthroscopy port to ensure that no irrigation fluid is lost as backflow from the port. This allows the surgeon to concentrate on adequately cleaning the entire joint. It also allows for accurate assessment of the volume of fluid used and minimizes spillage onto the operating room floor (Ardolino et al., 2010).

Polytetrafluoroethylene (PTFE) is a non-toxic, biologically inert, and non-biodegradable synthetic polymer that is well tolerated by the body. PTFE is used in many surgical procedures, including: blood vessel grafting, cosmetic surgery, surgical implant placement, orthopedic joint implants, membrane implants in ophthalmic surgery, etc (Gu et al., 2018; Ham & Miller, 2003; Kim et al., 2003; Polykandriotis et al., 2022; Samaeili et al., 2021; Vaughan et al., 1979). PTFE is also used as a plug or filler in dental implant surgery (e.g., i-PLUG® PTFE plug) to fill the gap between the implant abutment and the crown. This material is considered more hygienic and easier to use than traditional fillers such as cotton pellets and gutta percha. This material is also autoclavable to prevent cross-contamination and minimize waste of unused material.(AD Surgical, n.d.) Because of these advantages, PTFE material was chosen in this study as the basic material for making plugs to reduce water leakage during surgery in patients with ACL injuries.

The results of the PTFE plug trial in this study were proven to significantly (p-value <0.05) reduce fluid usage and leakage from the arthroscopy portal and tunnel during ACL surgery compared to patients who did not use the PTFE plug. The results of this study are similar to the study conducted by Ardolino et al who used a rubber tip on the syringe plunger as a plug on the arthroscopy portal (Ardolino et al., 2010). The PTFE plug in this study was also considered cheaper (IDR 180,000 or USD 11.34 / 1 PTFE plug) when compared to flexible silicone cannula which is the gold standard for preventing water leakage during arthroscopy. In addition, this material has the properties of being able to withstand water, is semirigid, heat-resistant and inert so that it can be sterilized by autoclave, can be used sustainably and can be used in hospitals that do not yet have sterilization facilities using ethyl oxide (EtO) or plasma.

Another study by Hsiao et al. used an automated irrigation pump system to improve intraoperative visualization and control of fluid volumes. Advantages of this system over gravity flow systems include more consistent flow, greater joint distension, better visualization especially with motorized instrumentation, reduced need for tourniquet use, tamponade effect on bleeding, and reduced operative duration. Disadvantages include the need for additional equipment with higher cost and maintenance, learning and adaptation requirements for the surgical team, and increased risk of extra-articular fluid dissection and associated complications such as compartment syndrome (Hsiao et al., 2016). To reduce this risk of backflow, the FDA recommends using single-patient use arthroscopy pump tubing sets and using tubing sets that have features to reduce the risk of backflow, such as backflow check

valves (prevent fluid from flowing back through the tubing set) and touch-proof connectors (prevent contamination from entering the connection site).(Food and Drug Administration, 2021) The use of PTFE plugs may be an alternative for arthroscopy devices that are not equipped with backflow check valves and touch-proof connectors.

CONCLUSION

Polytetrafluoroethylene (PTFE) plugs can significantly prevent water leakage at the portal and tunnel during knee arthroscopy surgery in patients with anterior cruciate ligament (ACL) injuries. PTFE plugs are water-resistant, semirigid, heat-resistant and inert so they can be sterilized by autoclaving or other sterilization methods, and can be used sustainably.

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