A Study upon Durability of the Artificial Knee Joint with PVA Hydrogel Cartilage*

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An experimental investigation upon the durability of the artificial knee joints with PVA hydrogel articular cartilage is presented. PVA hydrogel is manufactured by the cyclic freezing/thawing and annealing methods; femoral component is a disc made in stainless steel. This work is original in the meaning that: a weighting method to differentiate the worn mass from the mass of exuded water for PVA hydrogel is suggested; an original wear test rig, which simulates the anterior-posterior displacement of the knee motion during walking is proposed; wear factor variation against the number of walking cycles (durability curve) for PVA hydrogel is reported. The lowest wear factor obtained is on order of 10^{-6} - 10^{-5} mm^3/Nm. PVA hydrogel with reduced water content (45 - 50%) produces the smallest wear factor, for the same polymerization degree. Reduction of the wear factor is on order of 10^4 when the PVA polymerization degree increases from 1 800 to 12 300. PVA hydrogel manufactured on a hydrophobic substrate (PTFE) presents a 16 - 27% lower wear factor than that prepared on a hydrophilic substrate (glass). When layer thickness increases from 2 to 3.6 mm, the wear factor reduction is 18%. Influence of the standing interval in start-up conditions on the wear factor is also investigated.

Key Words: Biomechanics, Artificial Knee Joint, Wear, Artificial Cartilage, Biomaterial, Polyvinyl Alcohol (PVA) Hydrogel

1. Introduction

Replacement of joint, e.g., knee, hip is an effective surgical treatment to relieve pain and to restore the locomotion function for patients with damaged joints, due to the serious forms of osteoarthritis and rheumatoid arthritis, congenital deformities, and particular kinds of posttraumatic conditions. For the majority of patients treated in this way, initial results following surgery are quite good[1]. Despite this success, wear remains the major problem facing the long-term success and survival of the artificial joints [1],[2]. One of the main reasons of failure of the artificial joint fixation into the host bone is the cellular reaction against wear debris, which causes the bone resorption around the implant[1],[2]. Replacement of failed prosthesis requires a new surgical intervention, called joint revision, which is more expensive and has poorer outcome than the original surgery. If joint replacements are to be performed in patients who are younger and more active, better wear performance is imperative for long-term durability[1],[2].

In the case of healthy natural synovial joints, a poro-elastic-hydrated layer of articular cartilage covers the bones ends and a fluid film separates the joint surfaces throughout many physiological activities[2]. In comparison with the natural joints, most of the actual artificial joint components are made in non-porous and much more rigid materials: ultra high molecular weight polyethylene (UHMWPE) for tibial plateau (knee joint) or acetabular cup (hip joint), metallic or ceramic materials for femoral condyle

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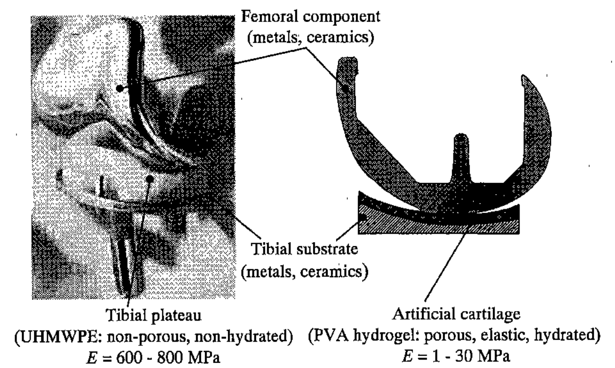
(knee joint) or femoral head (hip joint). Artificial joints operate in a boundary or mixed lubrication regime [2],[3], consequently the surfaces are allowed to come into contact and wear debris are generated[2].

One of the methods proposed to reduce the amount of wear debris, generated in the artificial joints, is the improvement of the lubrication regime by replacing the UHMWPE with a more compliant artificial cartilage [2],[4]. In the case of such prosthesis (Fig. 1), called "cushion bearings"[4], the artificial cartilage similar in stiffness with the natural cartilage can deform both macroscopically and microscopically in order to enhance the fluid film between the bearing surfaces and to substantially reduce the contact stress[4]. For instance, the replacement of UHMWPE tibial plateau by a soft cartilage made in polyurethane produced a thicker fluid film and a very low friction, in the case of normal walking[4]. However, under adverse lubrication conditions, especially at start-up, the polyurethane cushioned knee showed an unacceptable high friction[5]. Substituting the polyurethane, by a poro-elastic-hydrated material (e.g., hydrogel), the friction under start-up conditions was considerably reduced[6].

Hydrogel represents a three-dimensional network of crosslinked polymeric chains, which is able to accumulate large amount of water. Synthetic hydrogel, employed as artificial cartilage, resembles to articular cartilage, which in fact represents also a natural fiber-reinforced composite hydrogel[7]. Polyvinyl alcohol (PVA) hydrogel have been specifically proposed as a promising biomaterial for the artificial articular cartilage[3],[7],[8]-[13]. Nearly 30 years ago it was suggested that PVA hydrogel might be a suitable material for synthetic articular cartilage application[8]; the mechanical properties of PVA hydrogel were measured under tension and values of tensile strength were in the range 0.1 - 2.8 MPa while for



(a) Conventional design of the artificial knee (b) PVA hydrogel cushioned artificial knee

Fig. 1 Conventional (a) and PVA hydrogel cushioned (b) artificial knee

tension modulus the values were 0.3 - 4.6 MPa. Peppas[9] increased the mechanical strength of PVA hydrogels with 50 - 90% water contents, at tensile strengths of 8 - 14 MPa and modulus values of 5 - 9 MPa. Sasada et al.[10] reinforced PVA hydrogels by a freezing/thawing process, obtaining tensile strengths of 1 - 10 MPa, but modulus values smaller than 1 MPa. When applied as a cushion in the socket of a total hip prosthesis, the friction coefficient was smaller than 0.02 ; the frictional behavior as measured by a free oscillating pendulum was very similar to that exhibited by a canine hip joint[10]. Frictional behavior of the PVA hydrogel versus stainless steel surface was compared with that of the natural cartilage[3]; although the hydrogel initial friction coefficient was higher than that of the natural cartilage, it decreased with the number of walking cycles, and after 500 cycles approached the friction level of the natural cartilage[3]. Concerning the problem of biocompatibility, it was found that the UHMWPE wear debris caused intense inflammation, while PVA hydrogel wear particles were well tolerated by the living tissues[11].

In order to be accepted as artificial cartilage, the hydrogel layer should be wear resistant. PVA hydrogel was articulated against surfaces made in stainless steel, hydrogel and natural cartilage[12]. The highest wear factor was found for PVA hydrogel versus stainless steel and the lowest one was obtained for PVA hydrogel against natural cartilage[12]. Other studies[11],[13] were dedicated to the wear performances of PVA hydrogel in comparison with UHMWPE. Wear tests in the case of unidirectional motion showed that the PVA hydrogel had a lower wear factor than UHMWPE[11],[13]. On the other hand, in the case of reciprocating motion, when the sliding speed becomes zero at the ends of each stroke, wear factor of the PVA hydrogel was higher than that of the UHMWPE[11],[13]. Compared with the conventional prosthesis, which employ UHMWPE, the cushion knee joint with artificial cartilage made in hydrogel exhibits thicker fluid film, superior frictional performances and biocompatibility[11]. However, further studies concerning the knee joints with soft artificial cartilage are necessary in order to improve their durability and to achieve a product, adequate for clinical use[3].

This paper presents an experimental investigation upon the durability of an artificial knee joint with PVA hydrogel, used as articular cartilage. Femoral component is considered as a circular plate made in stainless steel. Poro-elastic-hydrated layers of PVA hydrogel with various water contents and polymerization degrees are manufactured by the cyclic freezing/

thawing and annealing methods. Wear experiments are performed on a test rig, which simulates the anterior-posterior (A-P) displacement pattern for the knee motion during the walking cycle[14]. Wear mass of the PVA hydrogel sample is determined by the weighting method and the wear factor is evaluated. The influence of the number of walking cycles and PVA hydrogel characteristics, i.e., water content, polymerization degree, and layer thickness upon the artificial cartilage durability is illustrated. Effect of the wettability of the substrate employed for PVA hydrogel preparation and influence of the standing interval in start-up conditions on the wear factor is also investigated.

2. Materials and Methods

2.1 Artificial articular cartilage

Artificial articular cartilage is made in PVA hydrogels with various water contents ϕ_1^f and polymerization degrees n (see Table 1). The cyclic freezing/thawing method[15] was used in order to prepare PVA hydrogels with high water content (77, 81 and 85%), similar with the fluid amount of the natural articular cartilage (about 78%[16]). On the other hand, PVA hydrogels with moderate water contents (45 and 50%) were manufactured employing the annealing method[11].

Table 1 PVA hydrogels employed as artificial cartilage for wear experiments

Symbolization of PVA hydrogel	Polymerization degree of PVA, n [-]	Water content, ϕ_1^f [%]	Preparation method	Substrate used for preparation
18PVAH85	1800	85	Cyclic freezing/thawing	Hydrophilic
18PVAH81	1800	81	Cyclic freezing/thawing	Hydrophilic
18PVAH77	1800	77	Cyclic freezing/thawing	Hydrophilic or Hydrophobic
18PVAH50	1800	50	Annealing	Hydrophilic
45PVAH77	4500	77	Cyclic freezing/thawing	Hydrophilic
45PVAH45	4500	45	Annealing	Hydrophilic
123PVAH77	12300	77	Cyclic freezing/thawing	Hydrophilic

2.2 Femoral component

Femoral component is considered as a circular plate of diameter D=25 mm and 15 mm thickness (Fig. 2), made in stainless steel (SUS304). Its surface was mirror finished in order to achieve a mean roughness R_a=0.02 μm, similar to that of the actual knee prosthesis[2].

2.3 Lubricant

Lubricant used was deionized water instead of periprosthetic liquid.

2.4 Test rig and the anterior-posterior (A-P) displacement pattern

Figure 2 illustrates the assembly drawing and a photo of an original wear test rig. The sample of PVA hydrogel works completely immersed in water, since it is bonded on a rigid tibial substrate, which is fixed into the water tank. The cartilage layer articulates against the femoral component, which is elastically supported by a lamella spring. The loading screw produces a compressive force, which is applied upon the vertical axis on the femoral component via lamella spring. A strain gauge bonded on the lamella spring is used to measure the applied normal load. AC servo-motor drives the ball-screw into rotation movement; as a result, the ball-screw nut translates together with the slider of the LM guide and drives the water tank. Consequently, the tibial substrate covered by the PVA hydrogel moves into the horizontal plane, simulating the A-P displacement pattern (Fig. 3) of the knee motion during walking cycle[14]. A multifunctional programmable controller, assisted by

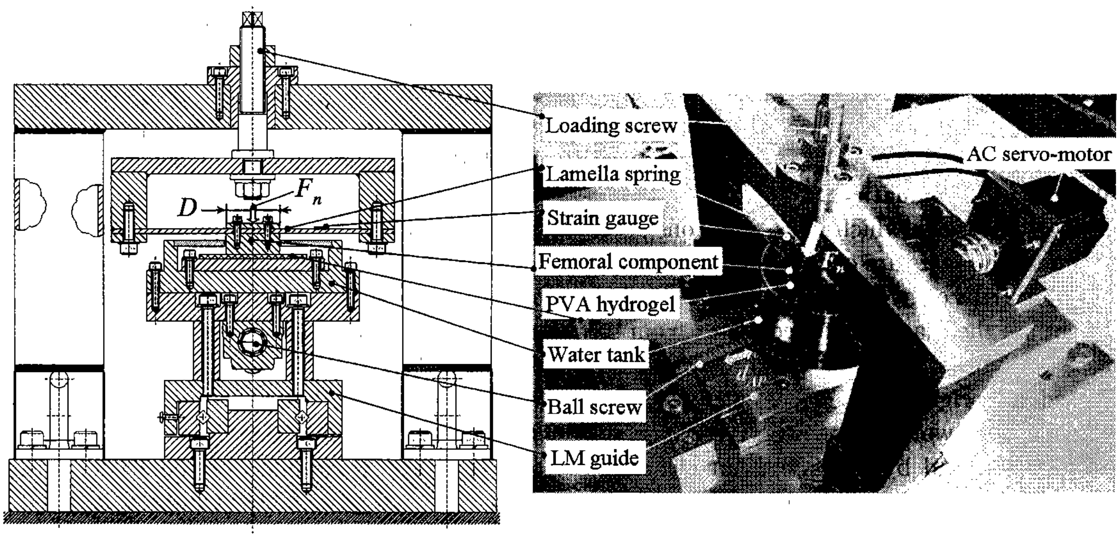


Fig. 2 Wear test rig

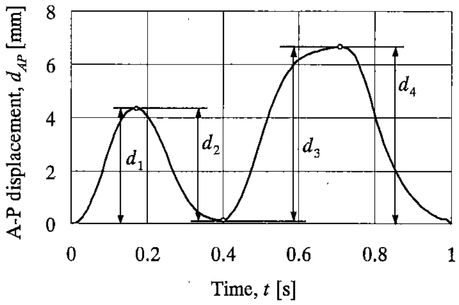


Fig. 3 Anterior-posterior (A-P) displacement pattern of the knee joint during one walking cycle[14]

computer, assures the required A-P motion pattern.

2.5 Loading

In different human activities, the knee joint is time varying loaded[3],[14]. In this study the loading was simplified and only a constant applied normal load F_n=490 N was considered (Fig. 2). Taking into account the loading pattern of the total knee joint prostheses, recommended by ISO/WD 14243-000[14] for a mean human body weight of 80 kgf, one estimates an average normal force of about 1 200 N. Since the femoral component has two condylar contact surfaces, and considering for tests only one contact surface, the mean normal force becomes 600 N. Since in Japan the average body weight is around 65 kgf, it results a value of the mean applied normal force of about 490 N.

2.6 Number of walking cycles

Since other papers concerning PVA hydrogel reported friction and wear tests for $N=10^3$ - 10^5 walking cycles[3],[11]-[13], in this work wear experiments were performed until $N=10^5$ walking cycles. This number of walking cycles $N=10^5$ is not enough, since the ISO/WD 14243-000 standard[14] recommended $5 \cdot 10^6$ cycles (about 5 years of functioning in the human body). However, tests done in this work are not industrial (maker tests) ; here it is presented only a first and preliminary attempt to determine the curve shape of the wear factor variation against the number of walking cycles (durability curve) for PVA hydrogel.

2.7 Wear factor evaluation

An important issue which must be considered when wear measurements are carried on poro-elastic-hydrated materials (i.e., hydrogels, natural cartilage) is to differentiate the mass of exuded water from the worn mass. Taking into account this requirement, it was proposed an original and accessible weighting method, in which the worn mass of the PVA hydrogel sample was determined by employing an electronic balance with a resolution of ±0.1 mg. In this method, first the PVA hydrogel test sample is weighted before the wear experiment. Tests were carried-out until

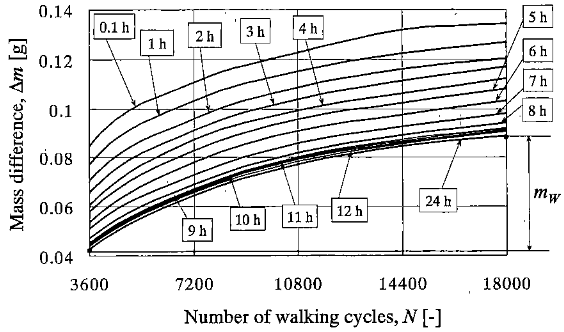


Fig. 4 Variation of mass difference Δm and PVA hydrogel wear mass m_W versus the number of walking cycles (18PVAH77 ; h_1=2.8 mm ; p_a=1 MPa ; T_R=0.1, 1, ···, 24 h)

$N=10^5$ walking cycles, but after every 3 600 walking cycles (1 hour functioning), wear measurements were done. Thus, at every one hour of wear tests, the PVA hydrogel is unloaded and introduced in water for rehydration for about 24 hours. Periodically, at rehydration instants T_R=0, 1, 2, ···, 24 hours, the PVA hydrogel sample is removed from water, it is blotted with absorbent tissue and weighted. In this way, one determines the difference $\Delta m(T_R)$ between the PVA hydrogel mass before and after wear experiment, at a certain moment T_R, during the reydration process :

$$\Delta m(T_R)=m_i-m(T_R)=m_{Ex}(T_R)+m_W. \qquad (1)$$

Here, m_i is the mass of the PVA hydrogel before the wear experiment, $m(T_R)$ is the PVA hydrogel mass after the experiment at rehydration instant T_R, $m_{Ex}(T_R)$ is the part of the total exuded water, not yet reabsorbed into the hydrogel layer at the instant T_R and m_W is the wear mass of the test sample. At full rehydration of the PVA hydrogel, the difference Δm rests constant, since all the exuded water was reabsorbed ; it represents exactly the worn mass of the sample : $\Delta m(24\text{ h})=m_W$. Figure 4 illustrates an example of the weighting method application for the measurement of the wear mass of 18PVAH77 layer by thickness h_1=2.8 mm. The upper curve, obtained for T_R= 0.1 h, represents the mass difference variation $\Delta m(T_R=0.1\text{ h})$ with the number of walking cycles, determined immediately after the wear experiment ; it includes the wear mass of the PVA hydrogel plus the entire quantity of exuded water. The lowest curve, determined at full rehydration (T_R=24 h), which means that all exuded water was reabsorbed into the hydrogel layer, illustrates the target result, i.e., the variation of the PVA hydrogel wear mass m_W with the number of walking cycles.

Once the wear mass of the PVA hydrogel was measured, the wear factor can be calculated as [11] :

$$f_W=m_W/(\rho F_n d_T), \qquad (2)$$

ρ is the PVA hydrogel density, F_n is the applied normal load and d_T is the total sliding distance. Density of the PVA hydrogel was calculated by estimating the mass and the volume of a certain sample. The influence of the water content and polymerization degree of the prepared hydrogels upon their densities was found as negligible. Thus, the following average value can be accepted for the PVA hydrogel density: $\rho=1.004\cdot10^{-3}\,\mathrm{g/mm^3}$. The total sliding distance during a certain wear experiment can be calculated by multiplying the sliding distance $d=d_1+d_2+d_3+d_4=21.812$ mm (see Fig. 3), corresponding to one walking cycle, with the number of walking cycles N.

First, influence of the parameters related to the characteristics of the PVA hydrogels, on its tribological performances, were investigated. Wear tests with smooth femoral component against PVA hydrogel layers prepared on hydrophilic substrate, which have the same polymerization degree, the same thickness, but different water amounts, were performed in order to investigate the influence of the PVA hydrogel water content ϕ_1^f on the wear factor. Wear factor reduction due to the variation of the PVA hydrogel water content $S_{R-water}$ was estimated taking as reference the hydrogel with $\phi_1^f=77\%$:

$$S_{R-water}=[f_W(\phi_1^f=77\%)-f_W(\phi_1^f\neq77\%)]/f_W(\phi_1^f=77\%)\cdot100[\%], \quad (3)$$

where $f_W(\phi_1^f=77\%)$ is the wear factor of PVA hydrogel with $\phi_1^f=77\%$ and $f_W(\phi_1^f\neq77\%)$ is the wear factor obtained for PVA hydrogels with $\phi_1^f=45, 50, 81$ and 85%.

PVA hydrogel layers prepared on hydrophilic substrate, which have the same water content ϕ_1^f and thickness h_1, but different polymerization degrees n, were tested in order to investigate the influence of the PVA hydrogel polymerization degree on the wear factor. Reduction of wear factor due to the increasing of the polymerization degree S_{R-n} is evaluated considering as reference the PVA hydrogel with $n=1\,800$:

$$S_{R-n}=[f_W(n=1\,800)-f_W(n\neq1\,800)]/f_W(n=1\,800)\cdot100[\%], \quad (4)$$

where $f_W(n=1\,800)$ is the wear factor of PVA hydrogel with $n=1\,800$ and $f_W(n\neq1\,800)$ is the wear factor obtained for PVA hydrogel with $n=4\,500$ or 12 300.

Wear tests with 18PVAH77, manufactured on hydrophilic, respectively hydrophobic substrate (see Fig. 5), were performed in order to establish the influence of the substrate wettability on the wear behavior. It seems that the hydrogel prepared on hydrophobic substrate produces a reduced friction coefficient[17]. Wear factor reduction due to the use of a hydrophobic substrate made in PTFE for PVA hydrogel preparation S_{R-PTFE} is defined relative to the PVA hydrogel prepared on a hydrophilic (glass) substrate:

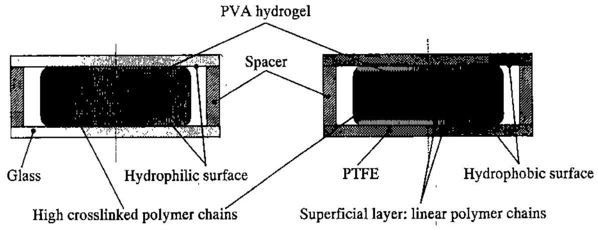


Fig. 5 Utilization of hydrophilic or hydrophobic substrates for PVA hydrogel preparation

$$S_{R-PTFE}=[f_W(glass)-f_W(PTFE)]/f_W(glass)\cdot100[\%], \quad (5)$$

where $f_W(glass)$ is the wear factor obtained for PVA hydrogel prepared on glass and $f_W(PTFE)$ is the wear factor of PVA hydrogel made on PTFE (Teflon) substrate.

In order to express the influence of the thickness of the PVA hydrogel layer on the wear factor, one calculates in the case of 18PVAH77 the wear factor reduction $S_{R-thick}$ for layers of thickness $h_1=2.8$ and 3.6 mm, relative to the PVA hydrogel of thickness $h_1=2$ mm:

$$S_{R-thick}=[f_W(h_1=2)-f_W(h_1\neq2)]/f_W(h_1=2)\cdot100[\%], \quad (6)$$

where $f_W(h_1=2)$ is the wear factor obtained for $h_1=2$ mm and $f_W(h_1\neq2)$ is the wear factor for $h_1=2.8$ or 3.6 mm.

Start-up after standing a certain period of time T_s was simulated by applying preloading of 1 MPa for $T_s=15$, 30 and 60 min before starting the wear test. Wear factor increasing due to the preloading (standing) interval S_{I-S} was estimated by considering as reference the case without standing ($T_s=0$), when sliding motion started immediately after the PVA hydrogel loading:

$$S_{I-S}=[f_W(T_s\neq0)-f_W(T_s=0)]/f_W(T_s=0)\cdot100[\%], \quad (7)$$

where $f_W(T_s=0)$ and $f_W(T_s\neq0)$ are the wear factors of the PVA hydrogel obtained from tests without and with preloading.

During all these experiments, wear measurements were performed after every 3 600 walking cycles in order to determine the variation of the PVA hydrogel wear factor with the number of walking cycles.

3. Results and Discussions

The experimental results were obtained for different types of PVA hydrogel (see Table 1) sliding against a smooth femoral component. Hydrogel layers of thickness $h_1=2.8$ mm, prepared on hydrophilic substrate from glass, were used for most of the experiments. Exceptions are the hydrogels made on hydrophobic substrate or with different thickness (h_1=2 and 3.6 mm). Wear tests were carried out under constant applied pressure, $p_a=4F_n/(\pi D^2)=1$ MPa.

Figure 6 shows the variation of the wear factor f_W versus the number of walking cycles for smooth femoral component against artificial cartilage made in PVA hydrogel, 18PVAH50, 18PVAH77, 18PVAH81, 18PVAH85, 45PVAH45 and 45PVAH77, of the same thickness h_1=2.8 mm. For all types of PVA hydrogel one observes a similar tendency of the wear factor variation versus the number of walking cycles. In the initial, i.e., running-in period, the PVA hydrogel wear factor maintains almost constant; then, it decreases until a second constant level, which is kept up to surface damages are initiated; after that the wear factor sharply increases with the number of walking cycles. The second constant level of the wear factor is maintained for longer period of time, i.e., the moment when surface damages are initiated is delayed, for hydrogels with high polymerization degree (n=4 500) in comparison with the case of low polymerization degree hydrogels (n=1 800). Considering artificial cartilages with the same degree of polymerization but different water content, one observes that the moment when surface damages are initiated is delayed for hydrogels with smaller water content. Results presented here represent the first attempt to understand the variation of the PVA hydrogel wear factor against the number of walking cycles. Previously reported wear measurements[(11)–(13)] were performed only at the end of the wear test, i.e., only for a single moment of time. Results shown in Fig. 6 offer useful information concerning the evolution in time of the wear process and durability of the poro-elastic-hydrated materials, such as PVA hydrogels.

From Fig. 6, one observes that in the category of hydrogels with high water contents, i.e., ϕ_1^f=77, 81 and 85%, prepared through the cyclic freezing/thawing method, in the initial stage (about 10 800 walking cycles), the 18PVAH85 (highest water content) presents the lowest wear factor, followed by 18PVAH81 and 18PVAH77. Reduction of the wear factor due to the water content variation $S_{R-water}$ for 18PVAH85 and 18PVAH81 relative to 18PVAH77 is 33.7%, respectively 21.4%. However, after the hydrogel surface damages are initiated, the situation is reversed, i.e., the wear factor of 18PVAH77 becomes lower than those of 18PVAH81 and 18PVAH85. Comparing the hydrogels prepared by the annealing method, of moderate water contents, i.e., ϕ_1^f=45 and 50%, with those prepared by the cyclic freezing/thawing method, of high water contents, i.e., ϕ_1^f=77, 81 and 85%, one observes that PVA hydrogels manufactured by annealing method produced the lowest wear factor, even from the beginning of the initial stage. One concludes that the PVA hydrogel water content deeply influences its wear behavior when articulates against smooth femoral component; hydrogel with the lowest water content produces the lowest wear factor.

Figure 7 shows the variation of the wear factor versus the number of walking cycles for PVA hydrogel, which have the same water content ϕ_1^f=77% but different polymerization degrees n=1 800, 4 500 and 12 300. Wear factor significantly decreases with the increasing of the polymerization degree, 123PVAH77 producing the lowest wear factor. Reduction of the wear factor due to the polymerization degree variation S_{R-n} obtained for 123PVAH77 and 45PVAH77 relative to reference case of 18PVAH77 is presented in Fig. 8. Thus, increasing the polymerization degree n from 1800 to 4500, a wear factor reduction S_{R-n} on order of 10^2 is obtained; additionally, using a PVA with very high polymerization degree, n=12 300, one finds a substantial reduc-

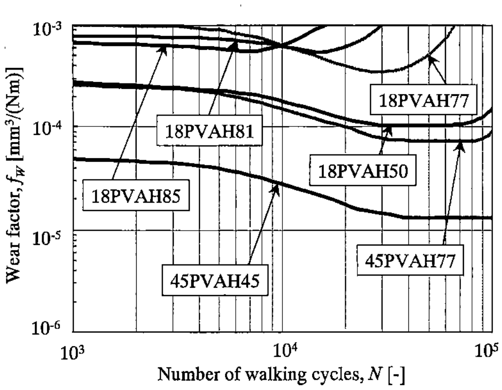


Fig. 6 Variation of the wear factor versus the number of walking cycles

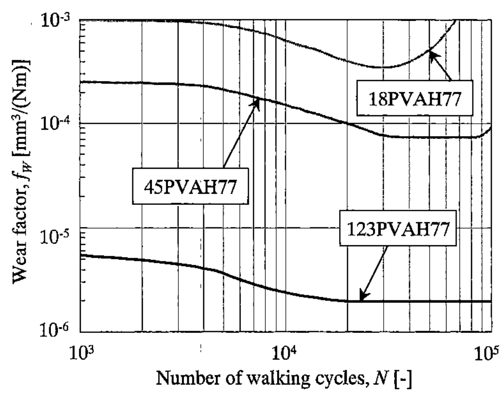


Fig. 7 Variation of the wear factor versus the number of walking cycles for 18PVAH77, 45PVAH77 and 123PVAH77 (h_1=2.8 mm; p_a=1 MPa)

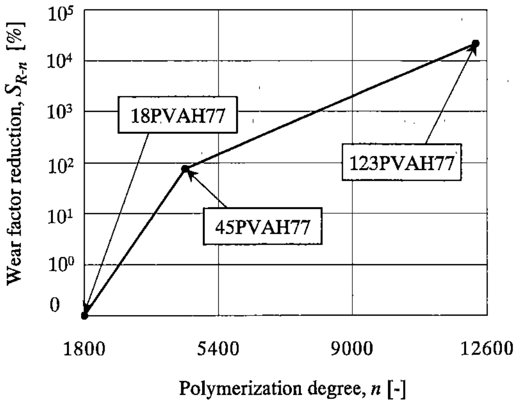


Fig. 8 Influence of the PVA hydrogel polymerization degree on the wear factor reduction S_{R-n} for 18PVAH77, 45PVAH77 and 123PVAH77 (N=3 600 cycles; h_1=2.8 mm; p_a=1 MPa; Reference case: 18PVAH77)

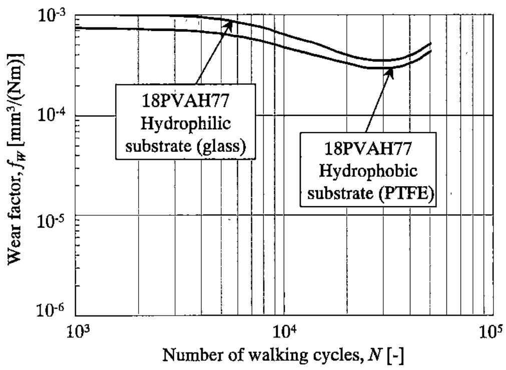


Fig. 9 Variation of the wear factor versus the number of walking cycles for 18PVAH77 manufactured on hydrophobic and hydrophilic substrates (h_1=2.8 mm; p_a=1 MPa)

tion of the wear factor on order of 10^4.

Influence of the wettability of the substrate used for hydrogel preparation is illustrated in Fig. 9. It appears that a hydrogel prepared on a hydrophobic substrate (Fig. 5) has a superficial layer with different properties from those of the bulk mass, formed by crosslinked polymer network. The superficial layer close to the hydrophobic substrate consists of linear polymer chains, which forms a kind of brush on the surface of the hydrogel[17]. Under shear stress the linear polymers of the brush are deformed much more easily than the crosslinked network; in other words, they oppose less shear resistance. Thus, PVA hydrogel with the same water content ϕ_f=77%, polymerization degree n=1 800 and thickness h_1=2.8 mm was prepared by employing either a hydrophobic (PTFE) or a hydrophilic substrate (glass). The 18PVAH77 prepared on PTFE substrate has lower wear factor than 18PVAH77 manufactured on glass (Fig. 9). The wear factor reduction S_{R-PTFE} is 27% at N=3 600

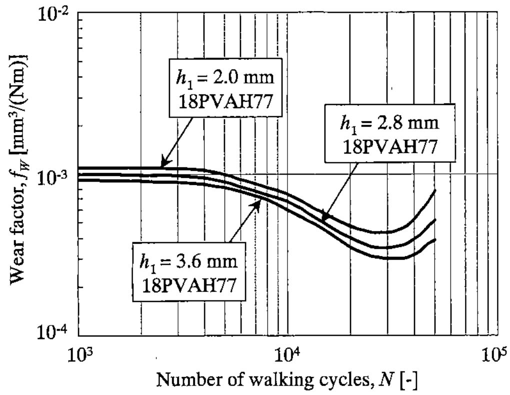


Fig. 10 Variation of the wear factor versus the number of walking cycles for 18PVAH77 (h_1=2, 2.8 and 3.6 mm)

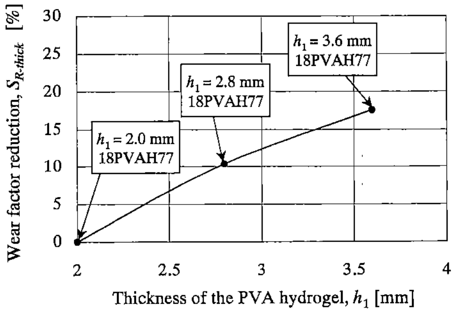


Fig. 11 Influence of the hydrogel layer thickness on the wear factor reduction $S_{R-thick}$ (p_a=1 MPa; Reference case: 18PVAH77 with h_1=2 mm)

cycles and 16.4% at N=32 400 cycles. Diminishing of the wear factor reduction S_{R-PTFE} with the number of walking cycles might be caused by the gradually wear out of the surface layer formed by linear polymer chains. However, although the difference between wear factors of 18PVAH77 prepared on glass and PTFE reduces with increasing the number of walking cycles, it does not cease even after 50 000 cycles.

Figure 10 presents the variation of the wear factor versus the number of walking cycles for PVA hydrogels with the same water content ϕ_f=77% and polymerization degree n=1 800 but with different layer thickness h_1=2, 2.8 and 3.6 mm. The thickest layer of PVA hydrogel, h_1=3.6 mm assures the lowest wear factor. Reduction of wear factor $S_{R-thick}$ for 18PVAH77 layers with thickness h_1=2.8 and 3.6 mm relative to 18PVAH77 with h_1=2 mm, considered as reference case, was 10.4% for h_1=2.8 mm and 17.6% for h_1=3.6 mm (Fig. 11). This data agree with the theoretical findings[18],[19] that a thicker layer of the artificial cartilage assures longer pressurization time. During pressurization, the fluid carries most of the applied load, in this way, a lower friction force on the solid matrix skeleton being maintained; consequently, the wear factor decreases. Also, wear data presented in Figs. 10 and 11 are in agreement with the previous measurements reported[20], which proved that a thicker layer of poro-elastic-hydrated cartilage produced a slower increasing of the friction coefficient in time.

Variation of the wear factor versus number of walking cycles for the simulated start-up conditions, after standing interval T_s, is illustrated in Fig. 12. Wear tests performed without preloading ($T_s=0$) and with preloading ($T_s=15$, 30 and 60 min) demonstrated similar variation of the wear factor against the number of walking cycles. Wear factor increases with the increasing of the standing interval, e.g., $S_{I-S}=4.2\%$ after 15 min of standing, respectively $S_{I-S}=13.8\%$ after 30 min of standing (Fig. 13). Extending the preloading interval from 30 min to 60 min, the wear factor does not significantly increase. Results presented in Fig. 13 might be explained on the basis of the theoretical findings, which stressed that the effective friction coefficient of a poro-elastic-hydrated material against stainless steel is time-variable and rests low as far as the interstitial fluid supports most of the applied load[18),(19]. Under constant load, after long interval of time, the cartilage reaches its equilibrium deformation, the fluid pressure subsides and the effective friction coefficient tends to the equilibrium friction coefficient, which is constant for a combination of two materials[19]. From Figs. 12 and 13 one observed that the wear factor increases with the increasing of the standing interval, as long as $T_s<30$ min. One might conclude that the standing interval plus the wear test interval, i.e., T_s+60 min, exceeds the pressurization time, i.e., the interval when interstitial fluid supports most of the applied load. For $T_s\geq 30$ min, it seems that the standing interval plus the wear test interval is long enough to presume that the equilibrium state was reached. In other words, fluid pressure already subsided and the effective friction almost equaled the equilibrium friction coefficient[19]; consequently, augmentation of the standing interval produced a negligible effect on the PVA hydrogel wear factor. Results presented in Figs. 12 and 13 agree with the experimental findings[21], which prove that in case of a poro-elastic-hydrated cartilage, under constant loading, the friction coefficient gradually increases with the augmentation of the preloading (standing) time, until reaches a constant equilibrium value.

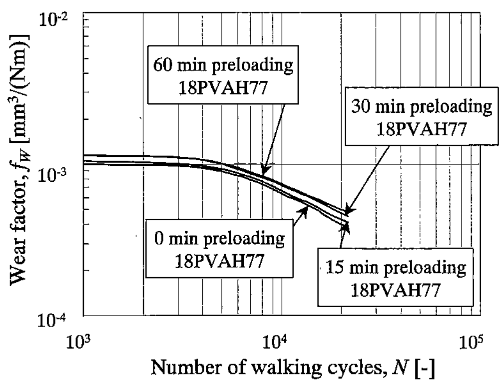


Fig. 12 Variation of the wear factor versus the number of walking cycles for the simulated start-up conditions: standing interval of $T_s=0$, 15, 30 and 60 min ($p_a=1$ MPa; 18PVAH77 with $h_1=2.8$ mm)

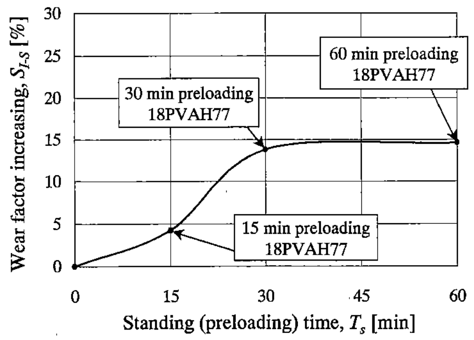


Fig. 13 Increasing of the wear factor S_{I-S} with preloading time T_s ($p_a=1$ MPa; 18PVAH77 with $h_1=$ 2.8 mm; Reference case: 0 min preloading)

A number of simplifications are introduced to accomplish this preliminary investigation in a long-term study upon the durability of the artificial knee joint with PVA hydrogel cartilage: the femoral component is modeled as a disc; the applied load is constant; the flexion-extension and internal-external rotation of the knee joint are not considered; the lubricant employed is deionized water; the number of walking cycles performed is limited to 10^5. However, despite of these simplifications, the results of the present study might be used for better understanding of the parameters, which influences the durability of an implant with a PVA hydrogel cartilage.

4. Conclusions

This paper presents an experimental investigation upon the durability of the artificial knee joints with PVA hydrogel, used as artificial cartilage. Other researchers have already discussed the possibility of PVA hydrogel as artificial joint cartilage. This work is original in the meaning that: a weighting method to differentiate the worn mass from the mass of the exuded water for PVA hydrogel (poro-elastic-hydrated material) is proposed; an original wear test rig was designed and manufactured; the curve shape of the wear factor variation against the number of walking cycles (durability curve) for PVA hydrogel was reported; the effect of the wettability of the substrate employed for PVA hydrogel preparation, the influence of the PVA polymerization degree, the influence of the layer thickness of PVA hydrogel, the influence of standing interval in start-up conditions, etc. were emphasized.

Wear tests with smooth femoral component against different types of PVA hydrogel illustrate that the wear factor varies with the number of walking cycles. In the initial, i.e., running-in period, the wear factor maintains almost constant; then it decreases until reaches a second constant level, which is kept up to surface damages are initiated; after that the wear factor sharply increases with the number of walking cycles. These results offer useful information concerning the evolution in time of the wear process and durability of the poro-elastic-hydrated materials such as PVA hydrogels.

Wear behavior of the PVA hydrogel is affected by its water content. PVA hydrogel manufactured with reduced water content (45 - 50%) produces the lowest wear factor, for the same PVA polymerization degree.

Reduction of the wear factor is on order of 10^4 when the PVA polymerization degree increases from 1 800 to 12 300.

PVA hydrogel manufactured on a hydrophobic substrate (PTFE) presents a 16 - 27% lower wear factor than that prepared on a hydrophilic substrate (glass). This effect occurs due to a superficial layer, consisted of linear polymer chains, formed in the vicinity of the hydrophobic substrate.

A thicker layer of poro-elastic-hydrated artificial cartilage produces lower wear factor (e.g., when layer thickness increases from 2 mm to 3.6 mm, the wear factor reduction is about 18%), since it is able to assure fluid pressurization for longer interval and consequently to maintain lower friction force on the solid matrix skeleton.

Increasing the preloading (standing) interval from 0 to 30 min, the wear factor increases. For longer standing intervals, it seems that the equilibrium state is reached, fluid pressure subsides and the subsequent augmentation of the preloading time has negligible influence upon the wear factor variation.

Our findings for smooth femoral component against poro-elastic-hydrated cartilage agree with the theoretical and experimental data reported in the literature.

The lowest wear factor obtained in this work for 123PVAH77 is on order of 10^{-6} - 10^{-5} mm^3/Nm. Laboratory tests in the case of UHMWPE (actual artificial knee joints) showed a wear factor on order of 10^{-9} - 10^{-6} mm^3/Nm[2], even long-term clinical studies for UHMWPE indicated wear factors greater than 10^{-6} mm^3/Nm[2]. However, the UHMWPE wear debris, due to the cellular reaction against them, causes the bone resorption around the implant and failure of the artificial knee joint fixation into the host bone[1],[2]. Even the durability of PVA hydrogel, as artificial cartilage, shown in this paper is still insufficient (artificial cartilage would be worn off after about 10 years) for clinical use, the results obtained are encouraging. However, not only the wear volume plays an important role in the long-term survival of the artificial joints. Size, morphology and biological response to wear particles are also important factors. Since the PVA hydrogel wear particles are well tolerated by the living tissues[11] they probably do not produce the bone resorption around the implant.

In order to improve the durability of PVA hydrogel, one might employ thicker layers of artificial cartilage, which have better wear resistance. Further on we intend to analyze the influence of a microporous structure, machined on the rigid surface of the femoral component, upon the wear performances of the knee prosthesis with tibial poro-elastic-hydrated cartilage. Such novel bearing system for artificial knee joints is susceptible to improve their durability.

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