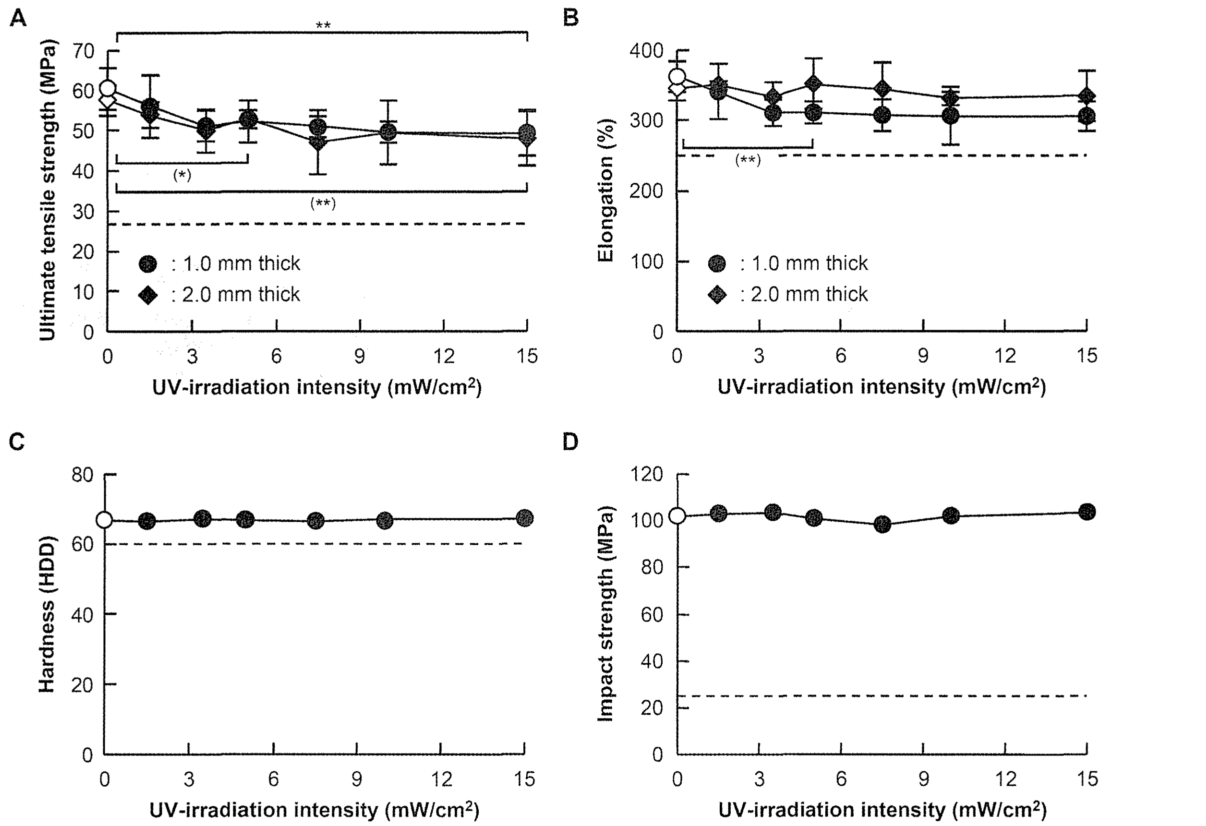

FIGURE 6. Mechanical properties of PMPC-grafted CLPE as a function of UV-irradiation intensity. (A) Ultimate tensile strength; (*) and (**): one-factor ANOVA and post-hoc test, significant difference ($p < 0.05$ and $p < 0.01$, respectively) as compared with the ultimate tensile strength of 1.0 mm thick test specimens, and **: significant difference ($p < 0.01$) of 2.0 mm thick test specimens. (B) Elongation; (**): one-factor ANOVA and post-hoc test, significant difference ($p < 0.01$) as compared to the elongation of 1.0 mm thick test specimens. (C) Hardness and (D) impact strength. Open symbols indicate untreated CLPE. Data are expressed as mean ± standard deviation. Broken lines indicate lower limits of ASTM requirements.

resistance. This suggests the grafting of PMPC may be a promising approach for extending the longevity of THA.

Despite these promising results, our study has a number of limitations. First, *in vitro* findings do not always translate to a clinical success. However, we conducted multicenter clinical trials of PMPC-grafted CLPE liners between 2007 and 2009 in Japan.[22] Based on other related evidence and these clinical trials, the Japanese government (Ministry of

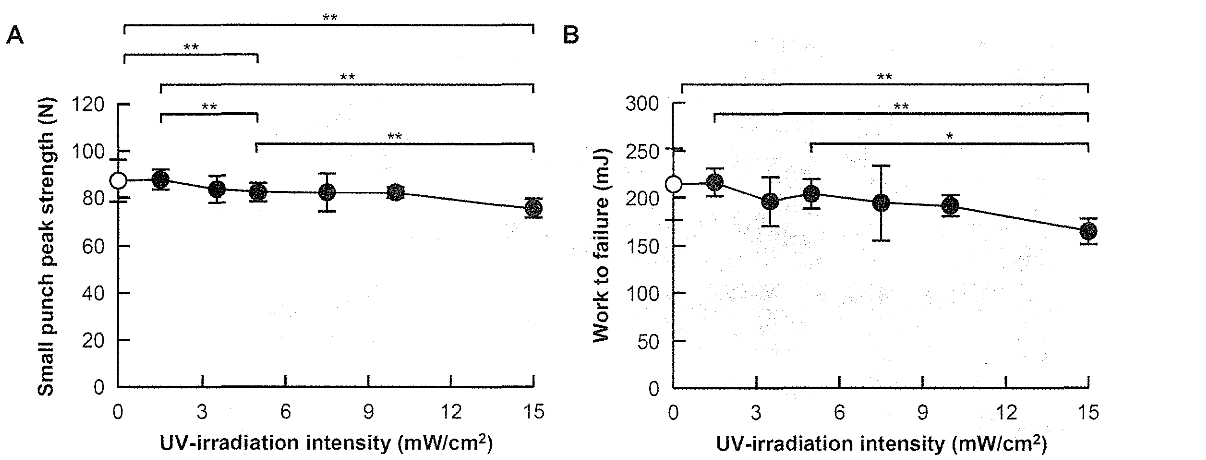

FIGURE 7. Small punch test properties of PMPC-grafted CLPE as a function of UV-irradiation intensity. (A) Small punch peak strength; **: one-factor ANOVA and post-hoc test, significant difference ($p < 0.01$) as compared with the peak strength in four groups of untreated and PMPC-grafted CLPE. (B) Work to failure; * and **: one-factor ANOVA and post-hoc test, significant difference ($p < 0.05$ and $p < 0.01$, respectively) as compared with the work to failure in four groups of untreated and PMPC-grafted CLPE. Open symbols indicate untreated CLPE. Data are expressed as mean ± standard deviation.

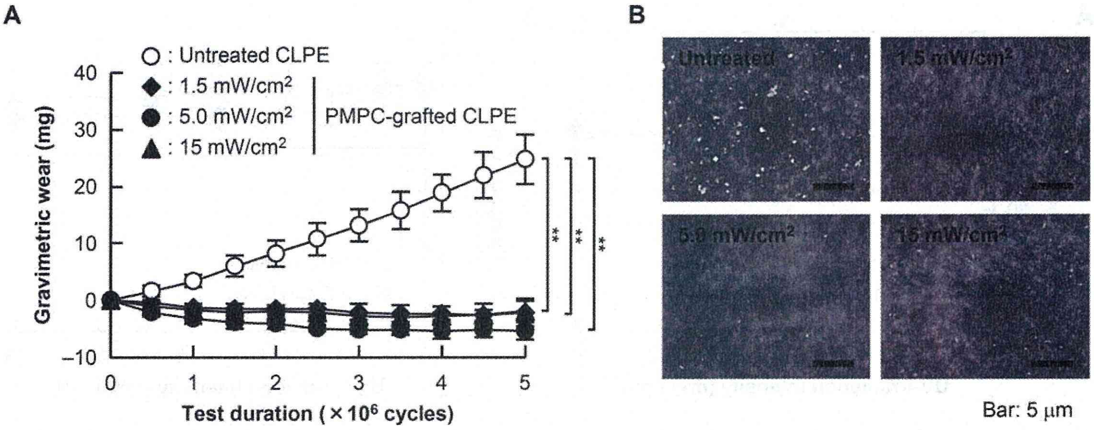

FIGURE 8. A: Time course of the gravimetric wear of the PMPC-grafted CLPE liners obtained using various UV-irradiation intensities. Data are expressed as mean ± standard deviation. **: one-factor ANOVA and post-hoc test, significant difference ($p < 0.01$) as compared with the gravimetric wear after the test in four groups of untreated and PMPC-grafted CLPE. B: SEM images of wear particles from PMPC-grafted CLPE isolated from lubricants of the hip simulator wear test.

Health, Labor, and Welfare, Japan) approved the clinical use of PMPC-grafted CLPE acetabular liners (Aquala® liner; KYOCERA Medical Corp.) in artificial hip joints in April 2011. We observed neither osteolysis nor a need for revision surgery up to 6 years of follow-up. Second, we used a confined period for the hip simulator wear test. Although experiencing 5.0×10^6 cycles in the hip simulator is comparable to 5 years of physical walking, the duration may not be sufficiently long for young active patients. We are now running the hip simulator for longer, and thus far, have confirmed almost no wear on the PMPC-grafted CLPE liners after 1.5×10^7 cycles.[29] Third, we did not entirely capture the range of loading and motion conditions of the *in vivo* environment in terms of the variety of positions, the magnitude of loading, or the daily routine; however, in accordance with ISO 14242-3, we believe that these results can provide a good indication of wear performance. Fourth, the procedure for the isolation of wear particles in this study was not able to capture the contribution of wear particles with a diameter of less than 0.1 μm, as previously reported.[30] Cellular response to particles is thought to be dependent upon factors such as particle number, size, shape, surface area, and material chemistry. If nanometer-scale particles are generated *in vivo*, it will be important to determine their biological activity in relation to that of micrometer-scaled particles. Fifth, the wear performance we report is only valid for this specific combination of Co–Cr–Mo alloy femoral head with a diameter of 26 mm and PMPC-grafted CLPE liner. Although aseptic loosening is one of the most common reasons for late revision surgery, dislocation is the biggest short-term problem.[3] A large femoral head not only allows for an increased head/neck ratio, which is directly related to the

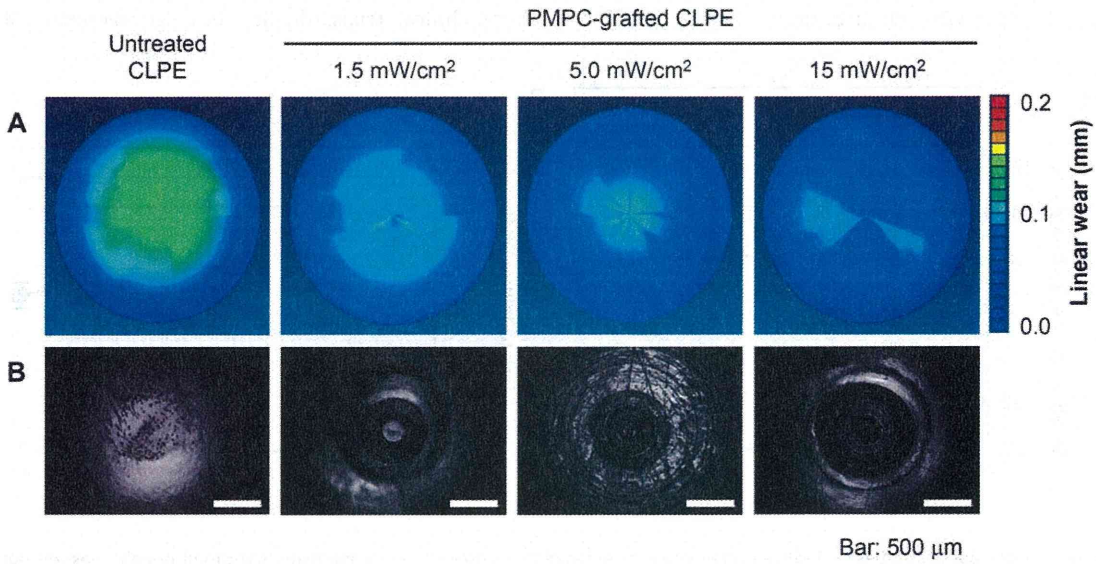

FIGURE 9. (A) 3D coordinate measurement images and (B) confocal laser scanning microscopy images of the PMPC-grafted CLPE liners obtained using various UV-irradiation intensities after 5.0×10^6 cycles. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

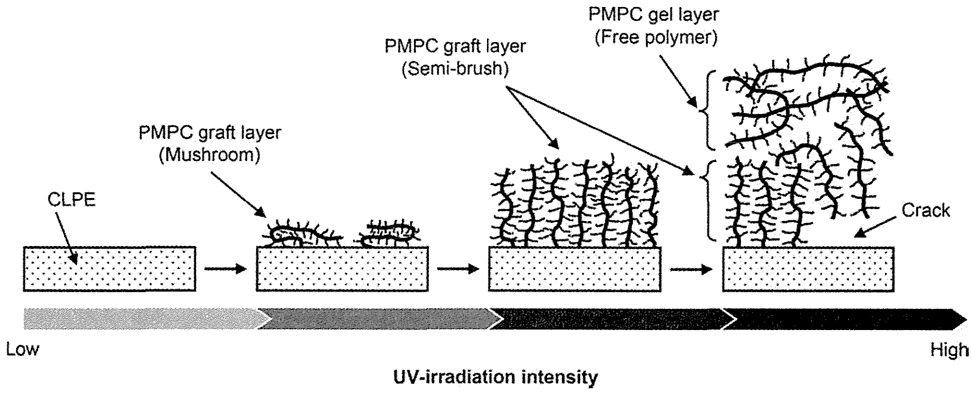

FIGURE 10. Schematic illustration of the PMPC-grafted CLPE surface obtained with various UV-irradiation intensities.

range of motion prior to impingement of the trunnion on the liner, but also increases the jump distance. Hence, larger femoral heads have recently come into more frequent use to improve the stability of the bearing surface. We believe that this drawback is partially offset by the long duration of simulation. We are now running the hip simulator test with larger Co–Cr–Mo alloy and zirconia toughened alumina ceramic femoral heads and thin acetabular liners.

Effects on extent of PMPC grafting

It is important to be able to control the graft layer on CLPE surfaces in order to optimize lubrication and resistance to wear. In Figures 1 and 2, when the MPC concentration and UV-irradiation time were fixed (0.50 mol/L and 90 min), the extent of PMPC grafting on the CLPE surface increased with the UV-irradiation intensity, and then became almost constant at 5.0 atom% over 5.0 mW/cm^2. It is well known that the amount of photoinduced radicals depends on the photoirradiation intensity[31]; therefore, the extent of grafting appeared to be successfully controlled by varying the quantity of radicals produced during the radical polymerization process. Figure 10 shows a schematic that illustrates how the PMPC grafting is suggested to vary with UV-irradiation intensity during the polymerization.[32] The PMPC graft layer thickness linearly increased with UV-irradiation intensity above 7.5 mW/cm^2, reaching ~380 nm at 15 mW/cm^2. However, as shown in Figure 2(A), the sample produced using 15 mW/cm^2 UV displayed the formation of a crack at the interface between the PMPC layer and CLPE substrate. When the PMPC layer has a semi-brush-like structure (Fig. 10), the layer thickness may correlate with the molecular weight of the grafted PMPC. It is generally known that the reaction rate of radical polymerization is extremely high; therefore, the length (molecular weight) of the graft chains can be assumed to be controlled by the monomer concentration. However, the MPC concentration and UV-irradiation time were fixed in the present study,[27,33] and the graft polymerization reaction with free radicals was photoinduced by UV irradiation using benzophenone as a radical initiator. A certain amount of UV irradiation energy can directly produce free radicals from the methacrylic acid group of the MPC unit in the monomer solution. When the UV-irradiation intensity is high, graft polymerization can occur between the radicals on the CLPE surface and the MPC monomer, in addition to homopolymerization of MPC. The free radicals not only facilitate direct grafting of MPC to CLPE, thereby forming C–C covalent bonds between the PMPC and the CLPE substrate, but also induce homopolymerization of MPC, forming free polymer in solution. Moreover, the diffusion of the monomer might be disrupted in a solution with high homopolymer concentration because of high viscosity. When the monomer and initiator initially attached to the CLPE surface were subjected to UV irradiation, radicals would have freely formed on the CLPE surface in the early stage but not in the late stage of polymerization, probably because the increased polymer radicals and/or free homopolymer chains blocked the diffusion of the radicals to the CLPE surface. Therefore, it is supposed that areas of unmodified CLPE would remain below the PMPC gel (free polymer) layer, which would leave a gap (or crack) at the interface between PMPC and CLPE substrate. In summary, it is assumed that when the UV-irradiation intensity is low ($<$7.5 mW/cm^2), the rate of MPC graft polymerization is higher than that of MPC homopolymerization. In contrast, when the UV-irradiation intensity is high ($>$10 mW/cm^2), the rate of homopolymerization might be higher than that of graft polymerization. Moreover, while the rate of MPC graft polymerization increases with the UV-irradiation intensity, the entire polymerization system begins to show gelation, with the formation of PMPC gel layer (on the PMPC graft layer) at UV-irradiation intensities above 10 mW/cm^2, decreasing the grafting efficiency. Therefore, in order to obtain a stable PMPC grafted layer without gelation of PMPC, the UV-irradiation intensity should be carefully controlled.

The water wettabilities of the PMPC-grafted CLPE surfaces were found to be considerably greater than that of the untreated CLPE surfaces [Fig. 3(A)]. This is because of the presence of a nanometer-scale PMPC graft layer resulting from the polymerization of the highly hydrophilic MPC monomer. It can be observed in Figure 3(B) that the dynamic coefficients of friction of the PMPC-grafted CLPE surfaces were significantly lower than those of the untreated CLPE surface. This was attributed to the significant increase in hydrophilicity evident from the reduction in the static water contact angles of the PMPC-grafted surfaces. The fabrication of the PMPC gel layer clearly influenced the friction response, with the dynamic coefficient of friction for the PMPC-grafted CLPE obtained at 15 mW/cm^2 being less than half of the value for the untreated material at 0.98 N loading. In contrast, at 9.8 N loading, the dynamic coefficient of friction for the 15 mW/cm^2 sample was significantly higher than for those treated at 1.5 and 5.0 mW/cm^2 (Fig. 4). It was previously reported that the dynamic coefficients of friction of MPC polymer coated CLPE prepared by physical adsorption or weak chemical bonding, increased to the level of the untreated CLPE at loads above 1.96 N.[24] It was therefore assumed that these particular surface modification layers became dislodged from the surface at high loading, and were therefore ineffective. In the present study, it is suggested that the PMPC gel layer on the PMPC-grafted CLPE obtained with a UV-irradiation intensity of 15 mW/cm^2 was removed from the bearing surface, resulting in an increase in friction. On the other hand, interestingly, this same sample, but gamma-ray sterilized, expressed high lubricity regardless of loading. In our previous study, we reported that the higher energy radiation used for gamma-ray sterilization induced cross-links not only within the PMPC graft layer, but also between the PMPC graft layer and the CLPE substrate.[34] It was similarly reported that when a high energy beam was irradiated onto a polymer with a grafted layer, strong bonds were formed between the grafted layer and polymer substrate.[35] Moreover, Lewis et al. reported that the force required to remove a coating with cross-linking was greater than that without.[36] Generally, when a high energy gamma-ray beam is irradiated on a polymer, free radicals are formed by the scission of molecular chains.[37] This is followed by the re-termination and cross-linking of the molecules. Hence, it was speculated that in the present study, a higher degree of cross-linking, and perhaps adhesion of PMPC graft and gel layers to the substrate, was induced by the gamma-ray irradiation in comparison to the non-sterilized PMPC-grafted CLPE. This would result in a much stronger and stable PMPC graft layer on the bearing surface.

Effects on CLPE substrate

The tested physical and mechanical properties of CLPE were altered slightly by the PMPC grafting, as shown in Figures 5–7. Most previous studies have assumed that photoinduced polymerization is a surface restricted phenomenon.[26,38] However, in reality, the changes (i.e., cross-linking and chain scission) of the polymer structure under UV radiation can result in changes to the bulk physical and mechanical properties (swelling ratio, cross-link density, and tensile- and small punch-tests properties) of thin test specimens, such as those with a thickness of 0.5–2.0 mm that were used in this study. In the case of the photoinduced cross-linking and scission of the CLPE substrate, one aspect that has been evaluated is the relationship between initiation and the depth of UV penetration. Shyichuk et al. reported that the photoinduced cross-linking and scission of (low-density) PE was observed in the surface region of PE in the range 0–1.5 mm, after UV-irradiation with an intensity of 0.2 mW/cm^2 for over 3 weeks.[26] Hence, it was thought that the observed changes in physical and mechanical properties would be the result of a complex combination of cross-linking and scission effects in a surface restricted region. In particular, it is assumed that when the UV-irradiation intensity is low (<7.5 mW/cm^2), the rate of cross-linking is higher than that of chain scission. In contrast, when the UV-irradiation intensity is high (>10 mW/cm^2), the rate of scission might be higher than that of cross-linking. However, it should be noted that these phenomena would also be combined with the effects of other polymerization conditions, such as temperature, dissolved oxygen concentration of monomer solution, and photoinitiator concentration. The retention of the bulk properties of the substrates is extremely important in clinical applications because the biomaterials used as implants act not only as surface-functional materials, but also as structural materials *in vivo*. As mentioned above, dislocation is the biggest short-term problem associated with THA.[3] A thin acetabular liner against a large femoral head not only allows for an increased head/neck ratio, which is directly related to the range of motion prior to impingement of the trunnion on the liner, but also increases the jump distance. Hence, the use of implants with such dimensions is becoming more common in order to improve the stability of the bearing surface. Mechanical fracture attributed to scission of the PE molecular backbone in thin acetabular liners of PMPC-grafted CLPE by the possible impingements must therefore be monitored. From the data gathered to date, we have observed neither mechanical fracture nor complications in the clinical use of the PMPC-grafted CLPE liner for a minimum of 4 years and a maximum of 6 years of follow-up.

The production of wear particles in THA is recognized as the main factor behind the initiation of periprosthetic osteolysis and aseptic loosening.[4,5] The inflammatory cellular response to particles is thought to be dependent upon factors such as particle number, size, shape, surface area, and material chemistry. If nanometer-scale particles are produced *in vivo*, it would be important to determine their biological activity relative to that of the micrometer-scale particles. In the wear particle analysis carried out in this study, the collected wear particles from the PMPC-grafted CLPE liners were on the scale of sub-micrometers, regardless of the PMPC grafting and its UV-irradiation intensity. Considering the results of the wear particle analysis, we expect the biological response of the PMPC-grafted CLPE liners *in vivo* to be comparable with those of other conventional untreated CLPE.[39] However, attention must be paid to the abnormal wear particles (sub-micrometer-size and number) in the PMPC-grafted CLPE liner, formed by possible scission reactions of the CLPE substrate. The remarkably fewer wear particles isolated from the lubricants used for the PMPC-grafted CLPE liners compared with those from the lubricants used for the untreated liners may help predict whether the abnormal wear will occur.

High wear resistance of PMPC-grafted CLPE liners

In the hip simulator wear test of the present study, the observed significant improvements in the water wettabilities and frictional properties of the PMPC-grafted CLPE liners resulted in substantial improvements in their wear resistances. The high friction of untreated CLPE surfaces is one of their main disadvantages because it results in greater wear, and possible seizure of bearing couples. The higher frictional properties of untreated CLPE surfaces were found to affect the wear properties, as determined by the hip simulator wear test. In contrast, as noted earlier, the water wettabilities of the PMPC-grafted CLPE surfaces were considerably greater. Fluid film lubrication (or hydration lubrication) of the PMPC-grafted surface was therefore provided by the hydrated layer. The fluid film-forming ability of a 10 nm thick PMPC layer would be equivalent to that of a micrometer-order-thick PMPC layer because the outermost layer is responsible for this property. The hip simulator wear test confirmed that the wear resistance was almost same in each of the three groups of PMPC-grafted CLPE with different PMPC graft layer thicknesses, with the 90 nm thick PMPC graft layer formed at a UV-irradiation intensity of 1.5 mW/cm^2 providing similar wear resistance to the 380 nm thick PMPC graft layer at a UV-irradiation intensity of 15 mW/cm^2. In our previous study, it was found that even a 10 nm thick PMPC graft layer exhibited improved wear resistance.[27] It was therefore speculated that the improved wear resistance was independent of PMPC graft layer thickness. Additionally, the retention of the improved wear resistance of the cross-linked PMPC gel layer combined with PMPC graft layer and/or the substrate (PMPC-grafted CLPE obtained with a UV-irradiation intensity of 15 mW/cm^2) is very interesting. As mentioned above, the cross-links produced by the extra energy of the gamma-rays was effective even for multidirectional high-loading of the hip simulator.

The obtained results confirm that orthopedic bearings using PMPC are able to mimic the natural articular cartilage that protects the joint interface from mechanical wear and facilitates smooth movement of the joints during daily activity.[13] The PMPC structure attracts water in a similar way to the extracellular matrix molecules present in cartilage, providing a lubricating layer on the surface that they are attached to.[15] This study therefore demonstrates the advantages that can be gained from investigating and subsequently mimicking natural structures and systems.

CONCLUSIONS

In this study, we confirmed that the UV-irradiation intensity affected the extent of PMPC grafting, along with cross-linking and scission reactions of the CLPE substrate. The extent of PMPC grafting on the surface of the CLPE gradually increased with increasing UV-irradiation intensity up to 7.5 mW/cm^2, and then remained constant above this value. It was found that in order to obtain a stable PMPC grafted layer without gelation of PMPC, the UV-irradiation intensity needed to be carefully controlled. When the CLPE surface under the grafted polymer was exposed to UV-irradiation, some of the physical and mechanical properties of the CLPE were altered slightly due to cross-linking and scission effects in the surface region. The hydrophilic PMPC layer grafted onto the CLPE surface significantly increased lubrication to levels that match articular cartilage. By mimicking the properties of the extracellular matrix of cartilage, the high wear resistance of the native tissue could be replicated by the use of an artificial polymer.

ACKNOWLEDGMENTS

The authors thank Mr. Takeshi Nizuka, Mr. Kenichi Saiga, and Mr. Kenichi Watanabe of KYOCERA Medical Corp. for their technical assistance. They further express our gratitude to Prof. Dr. Kozo Nakamura of the National Rehabilitation Center for Persons with Disabilities, Prof. Dr. Sakae Tanaka and Dr. Hiroshi Kawaguchi of the University of Tokyo for their valuable discussions and suggestions.

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