行政院國家科學委員會專題研究計畫成果報告

全人工關節元件損壞原因之探討及其改善方法之研究-子計畫二：

人工膝關節中UHMWPE 元件之破壞機轉分析(I)

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主持人：楊台鴻　　執行機構及單位名稱：台大醫學院醫工中心

ABSTRACT

The mechanism resulting in damage to and failure of ultra-high molecular weight polyethylene (UHMWPE) tibial inserts was investigated on clinically retrieved components. The severity of the subsurface damage increased with the length of time that the component had been implanted. A theoretical analysis was developed to account for the generation of subsurface damage based on a heat transfer model. Friction generates surface heat during articulation of total knee systems. Due to the cooling effect of body fluid on the surface, the rise in temperature on the UHMWPE surface is lower than that below the surface. The peak temperature was estimated to occur on a plane positioned about 1-2 mm below the surface. This result was similar to the bulk temperature variation observed during in vivo and in vitro studies by other investigators. Although the difference in temperature on and below the surface is only a few degrees, the thermal effect becomes apparent after a long time and may be explained by the viscoelastic behavior of polymers: temperature-time equivalence. It is therefore suggested that this thermal effect is another contributory factor to material damage, in addition to high stress and oxidative degradation (in appropriate cases). Therefore, any technological efforts aimed at improving the performance of artificial joint prostheses should minimize thermal effects at the subsurface of articular components.

Keywords: UHMWPE, subsurface yellowing, thermal effect.

INTRODUCTION

The long term performance of the articulating system and materials in the design of artificial joints is very important, particularly for younger, heavier and more active patients. One of the most significant factors that has led to revision in total joint arthroplasty has been damage to and failure of ultra-high molecular weight polyethylene (UHMWPE)[1,2]. Although many factors can affect the performance of UHMWPE in artificial joints, most investigators have adopted a purely mechanical force approach, e.g. estimation of stress distribution or trials to increase the strength of materials[3]. In addition, post-irradiation oxidative degradation of UHMWPE is also receiving attention as a potential factor influencing the performance of UHMWPE[4]. However, one aspect previously ignored with regards to long-term performance is the tendency for the articulating systems to generate frictional heat[5].

MATERIALS AND METHODS

Two hundred and seventy six New Jersey low-contact stress (LCS) total knee arthroplasties were followed up at Mackay Memorial Hospital, Taipei. Ten failed UHMWPE inserts were retrieved and studied. Ten knees were deemed to be failures by radiographic evidence of wearing of UHMWPE tibial inserts and subluxation of the knee joint[6] performed 3 to 9 years postimplantation. Each tibial insert was directly observed for damages using a stereomicroscope. In addition, the retrieved components used for detail examinations were fractured at liquid nitrogen temperature and sputtered with gold. Cross-sections were investigated using a scanning electron microscope (S-2400; Hitachi, Japan).

RESULTS AND DISCUSSION

In 6 of these prostheses, the yellowing phenomenon was observed in the UHMWPE tibial insert. The duration of implantation and the yellowing extent are summarized in Table 1. The yellowing extent was determined with naked eyes to qualitatively depict the yellowing phenomenon of the UHMWPE tibial insert as no change, slight, moderate and strong, respectively. It is seen that there is a direct qualitative correlation between the severity of yellowing phenomenon and the duration of implantation of the component. The yellowing subsurface is parallel to the articulating surface at a depth of about 0.1 mm and extends to a deeper zone under the scanning electron microscope.

We propose that the subsurface yellowing is essentially a consequence of chain scission in the amorphous region due to oxidation. It has been known that UHMWPE oxidizes after gamma sterilization[4]. However, if one considers that the peak in the absorbed dose is probably the reason for the subsurface yellowing, there should be a subsurface peak of the oxidation and yellowing lying beneath any surface following the contour of the implant. Retrieval analyses have shown that the yellowing phenomenon is principally located on contact between the articulating surfaces. Therefore, the yellowing phenomenon was not caused by the process of gamma sterilization only. Frictional heat effects should be added to the list of causes previously proposed; namely, high stresses and oxidative degradation (in cases where the component was gamma irradiated, especially in air).

For simplicity, we treat the heat transfer in UHMWPE under loading as a one-dimensional process in the proximal-distal (x) direction and assume that:

(i) The UHMWPE tibial insert is at T_0 (37°C) initially and its thickness in the proximal-distal direction is $x = L$ (15 mm).

(ii) For times t>0, the boundary surface at x=0 is subjected to a frictional heat per unit area, q. The heat is equal to the normal loading multiplied by the coefficient of friction multiplied by the relative velocity of the femur to the tibia. The load history comprising 60% for stance and 40% for swing at one cycle per second. The maximum stress is assumed to be 50 MPa[7]. The coefficient of friction and the surface velocity are assumed to be 0.022[8] and 26 mm/sec[9], respectively.

(iii) Since the UHMWPE tibial insert is immersed in the body fluid, a significant fraction of frictional work is dissipated by body fluid when friction energy is fed into the UHMWPE. Therefore, for times t>0, the boundary at the articulating surface of the UHMWPE tibial insert (x=0) is subjected to convection due to body fluid.

(iv) The environment and body fluid are maintained at a constant temperature T_0 to ensure that this model mimicks actual physiologic temperature.

(v) The physical properties of polyethylene and water are used to replace those of UHMWPE and body fluid, respectively.

The mathematical formula for the equation is given as

$$\frac{\partial^2 T(x,t)}{\partial x^2} = \frac{1}{\sim}\frac{\partial T(x,t)}{\partial t} ,$$

at 0≤x≤L, for t>0 (1)

$$T = T_0 ,$$

at 0≤x≤L, for t=0 (2)

$$-k\frac{\partial T}{\partial x} + h(T - T_0) = q ,$$

at x=0, t>0 (3)

$$T = T_0 \quad ,$$

at $x = L$, $t > 0$ (4)

where α = thermal diffusivity,

k = thermal conductivity,

h = convective heat transfer coefficient.

The equations (1)-(4) were calculated using the finite difference method written in Fortran language. The physical properties used in the computations were h for water = 4.26 W/m^2K , k and α for polyethylene = 0.45 W/mK and $2.9*10^{-7}$ m^2/s, respectively[9].

The temperature-versus-thickness data were plotted for different walking times (Figure 1). The model, though a simplification, gives a general idea. Friction generates surface heat during articulating movement. The tendency to produce a rise in temperature in the subsurface is very evident. This is attributed to a better cooling rate on the surface due to the body fluid. Therefore, the peak temperature occurs below the surface. For each period of walking, the peak temperature was observed at about 1-2 mm below the surface. This result was similar to the temperature variation observed during in vivo and in vitro studies by other investigators[8,9].

As the temperature of the UHMWPE component increases, its wear, creep and oxidative degradation (if present) would be accelerated. Although the difference in temperature at and below the surface is only a few degrees, the magnitude of this effect becomes apparent after a long period of time and can be understood from the viscoelastic behavior of polymers. Stress relaxation and the creep behavior of polymers obey the time-temperature equivalence principle. The result of stress applied to a polymer at low temperatures levels and long periods of time is equal to that at high temperatures levels and short periods of time. In other words: time shortening can be compensated by a temperature increase. For crystalline polymers, a simple Arrhenius type of equation can be applied as follows

$$\log \frac{t}{t_R} = \frac{E_{act}}{2.3R}\left(\frac{1}{T} - \frac{1}{T_R}\right) \quad (5)$$

where t_R = an arbitrary time selected as the reference time (for example, clinical design life).

T_R = an arbitrary temperature selected as the reference temperature.

R = molar gas constant (= 8.314 J/mole/K).

E_{act} = activation energy.

For polyethylene E_{act} is about 235.2 KJ/mole[10]. Although this value has not been determined for UHMWPE, it is probable that the value of UHMWPE will be similar to that of other linear polyethylenes. Therefore, if we select T_R=310 K (37°C) and t_R= 20 years for equation (5), then t is 14.5, 10.2, and 8.4 years when T is 311, 312, and 313K, respectively. Thus, the estimated clinical service life of the UHMWPE component drops dramatically as a result of a very small increase in its temperature.

In addition to the peak temperature, the maximum von Mises stress may also occur below the surface depending on conformity between the metal and UHMWPE components[3]. Bartel et al reported that the largest von Mises stress for the knee occurs between 1 and 2 mm beneath the surface for all designs. The values can reach as high as 20-30 MPa under a 3000-N load, which is already close to or even higher than the yield strength of UHMWPE (~20 MPa)[1]. In addition, the yield strength of UHMWPE is decreased when the temperature rises. Therefore, the combination of stress and high temperature causes the stress at the subsurface to be much higher than the yield strength of UHMWPE. Finally, distortion of and cracks in the material always occur preferentially at the subsurface. Delamination is caused when the subsurface damage continues to propagate. An accumulation of subsurface damage will occur that may lead to bulk UHMWPE failure. This result is consistent with clinical observations. The alterations were most severe near the surface of the samples. Therefore, the explanations of the observed yellowing are applicable to all UHMWPE components, irrespective of the methods used to sterilize them.

Table 1. The yellowing degree of retrieved implants

PatientNo.	Duration of Implantation	Yellowing degree
1	8 yr	strong
2	8 yr	strong
3	8 yr	moderate
4	7 yr and 4 m	strong
5	7 yr and 4 m	slight
6	6 yr	slight
7	5 yr and 2 m	no change
8	5 yr and 2 m	no change
9	4 yr and 1 m	no change
10	3 yr	no change

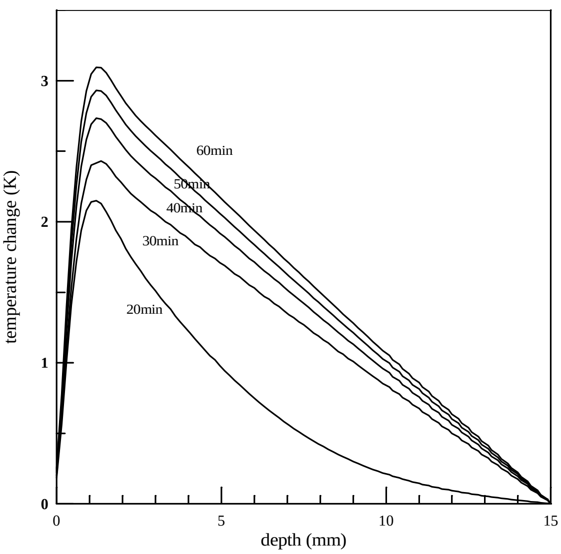

Figure 1. Temperature-distance profile in the UHMWPE component for five different walking times.

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