行政院國家科學委員會專題研究計畫 成果報告

人工髖關節置換後髖臼杯聚乙烯凹陷區域體積之演算理論推導以及成因區分(第 2 年)

研究成果報告(完整版)

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中 華 民 國 98 年 10 月 27 日

行政院國家科學委員會補助專題研究計畫 ■成果報告 □期中進度報告

人工髖關節置換後髖臼杯聚乙烯凹陷區域體積之演算理論推導以及成因區分

計畫類別：■個別型計畫 □整合型計畫
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計畫主持人：陳建宏
共同主持人：
計畫參與人員：徐淑玲

成果報告類型(依經費核定清單規定繳交)：□精簡報告 ■完整報告

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執行單位：中山醫學大學物理治療學系

中華民國98年10月27日

髖臼杯內襯磨耗分析與驗證
WEAR ANALYSIS and VALIDATION for ACETABULAR CUP LINERS

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一、中文摘要

本研究分析半球型髖臼杯內襯之磨耗形態與體積缺損量之計算公式，並且提出兩種方法以驗證分析之正確性。第一種方法為數值模擬方法，藉由 CAD 軟體 SolidWorks®建構出數個在不同磨耗方向與磨耗深度之三維磨損區域結構。第二種方法為實驗方法，利用綜合加工機切削塑鋼(POM)以製造出數個具有磨損與未磨損之內襯承載面。結果顯示，SolidWorks®確實是呈現內襯磨損區域形態與缺損體積之良好工具；並且證實本研究對半球型內襯之磨耗形態與缺損體積公式之分析都較現有文獻之公式更為清楚與正確。本研究之成果有助於評估現有臨床使用之半球型髖臼杯之效益，並且有助於新式髖臼杯之設計。

關鍵詞：磨耗、髖臼杯、內襯、聚乙烯

Abstract

This study analyzed wear patterns of, and wear volume formulae for, hemispherical acetabular cup liners used in total hip replacement. This study also proposes two methods for exploring the wear volume of a worn liner. The first method is a numerical method, in which SolidWorks® software is used to create models of the worn out regions of liners at various wear directions and depths. The second method is an experimental one, in which a machining center is used to mill polyoxymethylene to manufacture worn and unworn liner models, then the volumes of the models are measured. The results show that the SolidWorks® software is a good tool for presenting the wear pattern and volume of a worn liner. The formulae and wear patterns described herein are crucial for more accurate performance evaluation of existing hip components implanted in patients, as well as for designing new hip components.

Keywords: Wear, Acetabular Cup, Liner, UHMWPE

二、緣由與目的(Introduction)

Many authors have studied 2D and 3D linear wear [1-4] and calculated the acetabular cup liner volume loss [5-12]. Charnley [5] first pointed out that the wear trajectory of an artificial femoral head is a straight line and that the wear volume is the maximal cross-sectional area of the femoral head multiplied by the wear depth. Kabo [6] proposed a formula and pointed out that the wear volume should be calculated from not only the wear depth, but also the direction of femoral head motion. However, Kabo's formula has been found to produce errors as high as 45% [9, 11]. After comparing many published formulae, Ilchmann [12] presented a new formula for a liner with a cylindrical portion. However, we found that all the formulae provided in the literature not only failed to show the wear patterns, but also produced some unreasonable results outside the theoretical upper limit.

Although acetabular cup liner loss is due to wear, creep, and/or the effects of the ageing of polyethylene (PE) [13-16], this study did not attempt to distinguish between the different causes, but rather analyzed the shape of the bearing surface and the volume loss of worn regions at a given wear depth and direction. To be consistent with commonly used expressions, the wear volume is the total volume loss which is comprised of the effect of wear and creep.

三、材料與方法(Materials and Methods)

A. Type of acetabular cup liner

This study examined the hemispherical liner which is simply a hemispherical shell (Fig. 1) and has been studied by others (Table 1).

B. Notation illustration

Figure 2 shows the wear patterns and related notations of the liner. The inner radius of the hemispherical shell is given by r. The trajectory of the femoral head that penetrates the polyethylene

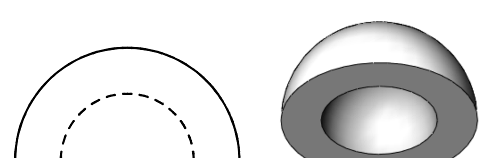

Fig. 1 Shape of hemispherical liner

Table 1 Comparison of existing formulae for the volumetric wear of an acetabular cup liner

Reference	Formula
Charnley [5]	$V_{Charnley} = \pi r^2 w$
Kabo [6]	$V_{Kabo} = \pi r^2 w - r^2\left[w\cos^{-1}\left(\frac{w\tan\beta}{r}\right) - \sqrt{\frac{r^2}{\tan^2\beta} - w^2} + \frac{r}{\tan\beta}\right] - \frac{r^3}{3\tan\beta}\left[\left(1 - \frac{w^2\tan^2\beta}{r^2}\right)^{\frac{3}{2}} - 1\right]$
Kosak [10]	$V_{Kosak} = \frac{r^2 w}{2}(\pi + \pi\sin\beta)$
Hashimoto [8]	$V_{Hashimoto} = \frac{r^2 w}{2}\left(\pi + 2\beta + \frac{w}{r}\sin 2\beta\right)$
Ilchmann [12]	$V_{Ilchmann} = \frac{r^2 w}{2}\left(\pi + \pi\sin\beta + \frac{w}{r}\sin 2\beta\right)$

Note: V = volume, r = inner radius, w = wear depth, β = wear direction

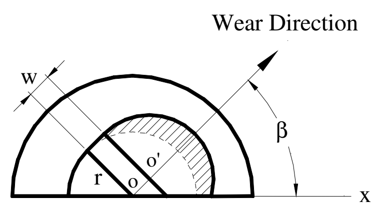

Fig. 2 Notation illustration. The striped region is the worn out region of the liner, the volume of which is called the wear volume.

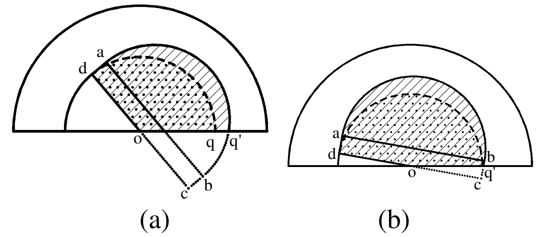

Fig. 3 Conceptual models for calculating wear volume. (a) Pattern A wear model, (b) Pattern B wear model.

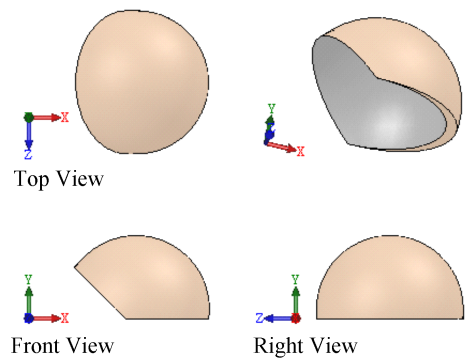

Fig. 4 3D model of liner loss built with SolidWorks®.

liner is assumed to be translational motion [5] and the displacement of the center of the femoral head, $\overline{oo'}$, is given by the wear depth, w [17]. The dashed and solid lines in Fig. 2 denote the unworn and worn surface of the inner surface, respectively. The arrow denotes the direction of femoral head penetration.

C. Wear pattern classification and volume calculation

In Fig. 3a, point b is below the edge of the opening and the wear curve aq' is an arc, which is a well-known pattern, which we will refer to as Pattern A. When the wear direction is close to the normal line of the acetabular cup with a slightly increased wear depth, then point b is above the edge of the opening and wear curve aq' is formed by the arc ab and the line segment bq'; this is referred to as Pattern B (Fig. 3b). Pattern B wear has not been reported in the literature [5, 6, 8-10, 12].

D. Wear volume computation

Both wear patterns can be processed by subtracting the dotted region from the striped region to obtain the liner volume loss (Fig. 3).

E. Validation I –numerical method: SolidWorks® 3D wear models

SolidWorks® is as a highly capable drafting tool for designing parts and models and can determine the volume of any given solid and was therefore used in this study without pre-processing or post-processing software to construct 3D solid models of the "worn out region" of a liner with a given inner radius, wear direction, and wear depth. Figure 3 shows the conceptual diagram for directly constructing the 3D model of a worn out region, daq'qd of a hemispherical liner in SolidWorks®, where both $\overline{da}$ and $\overline{cb}$ are straight lines that represent the moving trajectory of the edges of a femoral head. The 3D model of the striped region daq'od was first constructed, then the 3D model of the worn out region daq'qd (Fig. 4) was obtained by cutting out the dotted region dqod from the striped region. It should be noted that the models constructed were the "worn out region" of a liner, as shown by the striped region in Fig. 2, and not a whole worn or unworn liner.

F. Validation II – experimental method: POM models

Mizoue [11] found that the fluid-displacement method is the most accurate method for determining volumetric wear in retrieved cups. In this study, water was selected as the fluid, as it is non-reactive with most polymers used. Although UHMWPE has been widely used as the material for an acetabular cup liner, the specific gravity of PE is only about 0.9, which prevents its sinking in water. In contrast, the specific gravity of polyoxymethylene (POM) is

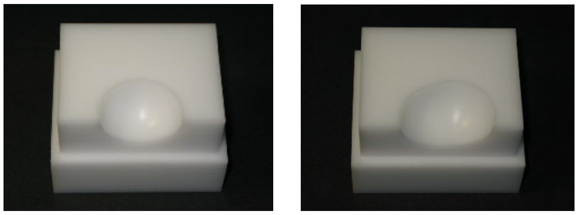

Fig. 5 Manufactured POM models with the indented region resembling half of the inner surface of an unworn (a) or a worn acetabular (b) liner.

about 1.4, which overcomes the problem of the low specific gravity of PE. In additional, the mechanical attributes of POM make it more appropriate than ceramics or metals for machining.

POM blocks were milled using a three-axis machining center with a tolerance of 0.01 mm. To stabilize the POM body and avoid overcutting during machining, the POM block was machined to form a base with an indented region resembling half of a worn or unworn surface of a real acetabular liner. (Fig. 5)

Each POM liner model was suspended by a thin silk yarn and fully immersed in water in a beaker on an analytical balance.

In this study, the volume of the worn POM model (Fig. 5b) was subtracted from that of the unworn POM model (Fig. 5a) to obtain the volume difference. The wear volume of the worn liner, i.e., the volume of the dotted region shown in Fig. 2, was then calculated by doubling the volume difference.

G. Published formulae

The results obtained using five published formulae (Table 1) were compared to those obtained using the formulae proposed in this study.

H. Formula accuracy criteria

The following conditions are reasonable and must be met:

1. The largest wear volume V_{max} arises in forward wear ($\beta = 90°$), $V_{max} = \pi r^2 w$.
2. The smallest wear volume V_{min} arises in lateral wear ($\beta = 0°$), $V_{min} = \frac{1}{2}\pi r^2 w = \frac{1}{2} V_{max}$.

四、結果(Results)

The wear pattern and corresponding wear formula were determined according to the decision-making flowchart (Fig. 6).

Formulae $V_{W,A}$, $V_{W,B}$, and $V_{W,90}$ are:

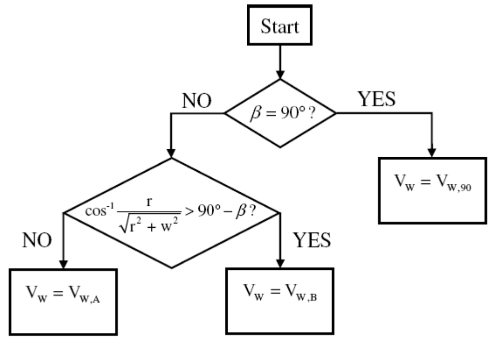

Fig. 6 Decision-making flowchart of wear pattern classification.

$$V_{W,A} = \int_{w\sin\beta}^{r\cos\beta} \left\{ x_2 \sqrt{r^2 - \frac{1}{\cos^2\beta} x_2^2}\ \tan\beta + (r^2 - x_2^2)\sin^{-1}\left(\frac{x_2 \tan\beta}{\sqrt{r^2 - x_2^2}}\right) \right\} dx_2$$

$$+ \int_0^w \left\{ y_1 \sqrt{r^2 - y_1^2 \tan^2\beta}\ \tan\beta + r^2 \sin^{-1}\left(\frac{y_1 \tan\beta}{r}\right) + \frac{\pi}{2} r^2 \right\} dy_1$$

$$+ \frac{2}{3} r^3 \left(\frac{\pi}{2} - \beta\right) - \int_{w\sin\beta}^{r\cos\beta} \left\{ \frac{\pi}{2}(r^2 - x_2^2) \right\} dx_2$$

$$V_{W,B} = -\int_0^{\frac{\cos\beta}{\sin\beta} r} \left\{ -y_1 \sqrt{r^2 - y_1^2 \tan^2\beta}\ \tan\beta - r^2 \sin^{-1}\left(\frac{y_1 \tan\beta}{r}\right) + \frac{\pi}{2} r^2 \right\} dy_1$$

$$+ \int_0^w \pi r^2 dy_1 + \frac{2}{3} r^3 \left(\frac{\pi}{2} - \beta\right)$$

$$V_{W,90} = \pi r^2 w$$

As shown in Fig. 7, most volumes yielded by SolidWorks® for hemispherical liners satisfied criteria. Due to errors resulting from machining and measuring, some data for POM models exceeded the theoretical maximum value, V_{max} , but, despite this, the measured volumes for the POM models reflected the variation in the actual wear volume of a liner at different wear directions.

Figure 8 demonstrates that the calculated results using the proposed formulae and those of the SolidWorks® models were very similar and the volume curve trends were consistent. The maximal

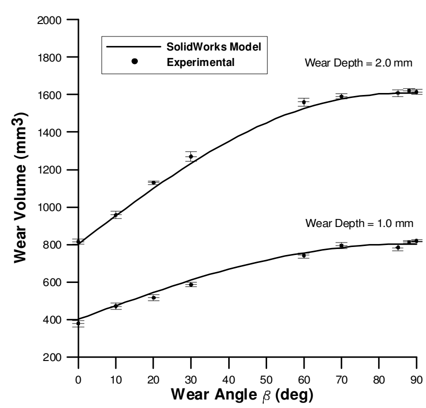

Fig. 7 The variations in the wear volume curves yielded by SolidWorks® software are consistent with the measured POM model wear volumes.

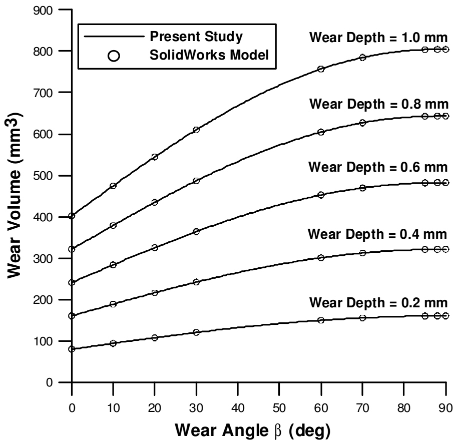

Fig. 8 Comparison of wear volumes obtained using the proposed formulae with those obtained using SolidWorks®.

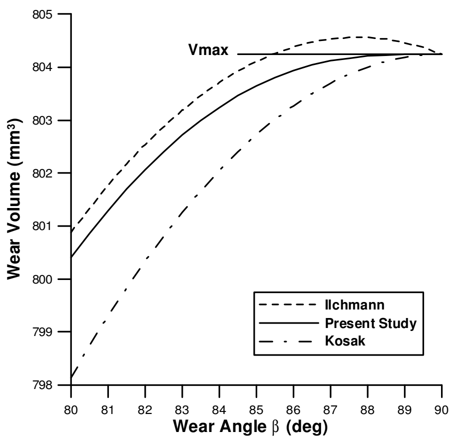

Fig. 9 Comparison of values obtained using the formulae proposed in this study with those obtained using published formulae.

difference was approximately 0.006% (88°, 0.2 mm).

Figure 9 shows a comparison of the results obtained using the proposed formulae and those in the literature for a liner diameter of 32 mm and a wear depth of 1 mm.

Figure 10 shows the percentage difference between the results obtained using the Ilchmann formula and the proposed formulae. With a liner diameter of 32 mm and a wear depth of 1.0 mm, the maximal difference was 0.06%; when the wear depth was 5.0 mm, the maximal difference was 1.22%. For a 22 mm liner with wear depths of 1.0 mm and 5.0 mm, the maximal percentage differences were 0.12% and 2.35%, respectively.

五、討論(Discussion)

Friction against the femoral head and impact during the gait cycle (from toe-off to heel strike) creates indentations in an artificial acetabular cup liner during long-term use. Debris generated by wear that accumulates between the acetabular cup and femoral head results in more profound indentation. Lombardi [18] found that, during a gait cycle, the artificial femoral head briefly separates from the acetabular cup and impact occurs when the heel strikes the ground. Dennis [19] noted that this micro-separation increases the hip joint force, which produces PE debris, causing prosthetic loosening. A study on ceramic acetabular cups indicated that micro-separation accelerates wear and causes a narrow band of wear around the acetabular cup opening [20]. Besong [21] concluded that micro-separation significantly raises the contact stress, which becomes concentrated in the contact region of the superolateral rim of the cup, including the opening edge. Recently, Hara [22] reported the importance of wear debris generated from neck-cup impingement, which itself might be a prime cause of osteolysis. Thus, precise analyses of the acetabular cup liner volume loss and wear pattern at the edge of the opening are very important. However, previous studies have not carefully confirmed the accuracy of the proposed formulae [5-8, 10, 12].

Because of this deficiency, two methods for exploring the wear volume of a worn liner were proposed in the present study. The first was implemented using SolidWorks® and the second was an experimental method. Figure 7 shows that the SolidWorks® models yielded very similar results to the physical experiments. However, machining a POM block to form the indented region of a liner is more difficult than constructing a model of the worn out region through SolidWorks®; which suggests that SolidWorks® is a good tool for presenting wear patterns and volumes of worn liners.

Figure 10 shows the percentage difference between the results using the Ilchmann formula and the proposed formulae. When the wear depth

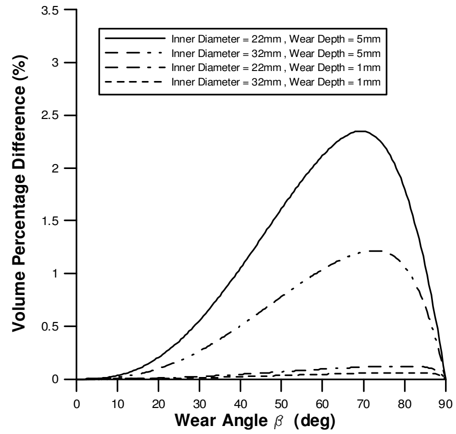

Fig. 10 Compared to the values obtained in this study, the wear volumes are overestimated using the Ilchmann formula.

increased or the liner diameter decreased, the error produced by Ilchmann's formula increased. When the liner diameter was 22 mm and the wear depth 5.0 mm, the maximal difference was 2.35%. The volume overestimation occurs because Ilchmann was not aware that the wear region aq' is comprised of arc ab and the line segment bq' when the wear is Pattern B (Fig. 2). In other words, Ilchmann assumed that line segment bq' was an arc with a diameter of 2r. As the wear depth increases, the line segment bq' becomes longer and the error produced from approximating a line segment as an arc increases with the length of the line segment. In addition, an arc with a smaller diameter has a larger curvature and, thus, has a larger deviation from the line segment than an arc with a smaller curvature. As a result, Ilchmann's formula produces a larger error when a smaller femoral head is used or a larger wear depth is created.

The formulae provided are just as complicated as the published formulae, but can be easily written as a computer program for clinical studies. In terms of accuracy, this study accounted for all wear patterns and no deviation from the proposed accuracy criteria occurred, and, thus, the proposed formulae are the most accurate and reliable.

六、致謝(Acknowledgment)

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八、成果自評

本二年期計畫成果已撰寫成兩篇論文被國際期刊接受發表，並於98年10月線上刊出(Published Online)。因版面有限，此報告係成果之精簡部分，讀者可線上查得全文。其中一篇將發表於國際知名期刊*Wear* (I.F.=1.509, 16/105，如後附件)，論文題目為「Wear patterns of, and wear volume formulae for, hemispherical acetabular cup liners」(doi: 10.1016/j.wear.2009.09.007)。為了使後續在此方面的研究者都能有一客觀合理的磨耗評估程序，另一篇論文將發表於國際生物醫學工程聯盟官方期刊*Medical & Biological Engineering & Computing* (I.F.=1.379, 31/94，如後附件)，名稱為「Evaluating the accuracy of wear formulae of acetabular cup liners」(doi: 10.1007/s11517-009-0535-z)。透過我們所提出的方法，即可有效驗證磨耗體積公式是否具有合理的可信度。整體而言，本計畫之成果是相當豐碩的。

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主旨:	Your Submission MBEC1815R1

Dear Dr. Jian-Horng Chen,

We are pleased to inform you that your manuscript, "Evaluating the Accuracy of Wear Formulae for Acetabular Cup Liners", has been accepted for publication in Medical & Biological Engineering & Computing.

Please remember to quote the manuscript number, MBEC1815R1, whenever inquiring about your manuscript.

If you would like to have your accepted article published with open access in our Open Choice program, please access the following URL: http://www.springer.com/openchoice

With best regards,
Jos Spaan
Editor in Chief
Medical & Biological Engineering & Computing