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DOI: 10.16078/j.tribology.2020261

国内全髋关节置换磨损测试及数值模拟研究进展

杨抒^{1,2}, 崔文¹, 张小刚¹, 张亚丽^{1*}, 解凤宝², 任旭辉³, 陈臻贤⁴, 靳忠民¹

(1. 西南交通大学机械工程学院摩擦学研究所, 四川 成都 610031;

2. 北京市春立正达医疗器械股份有限公司, 北京 101100;

3. 浙江省医疗器械检验研究院, 浙江 杭州 310018;

4. 长安大学工程机械学院道路施工技术与装备教育部重点实验室, 陕西 西安 710064)

摘要: 髋关节假体磨损及磨损颗粒所导致的无菌性松动是髋关节置换失败的重要原因。本文作者对国内髋关节磨损研究时采用的运动学与力学曲线以及针对国人测绘的相应曲线进行了差异性分析, 并对国内发表的全髋关节磨损体外模拟机测试试验及结果, 数值模拟模型及结果进行了总结、对比和分析。结果显示: 1) 国人测绘的运动学与力学曲线不能直接用于全髋关节磨损评估的加载条件, 国内关节力的测量方法仍有待进一步改进; 2) 国内体外磨损测试的研究结论与国外发表的结论相似, 但不同机构间的测试结果存在一定差异; 3) 国内髋关节磨损仿真研究还处于起步阶段, 仿真计算得到的磨损率普遍低于体外测试结果。因此, 建立基于国人行为力学的磨损评估标准、对磨损模型进行合理优化并采用有限元和骨肌多体动力学相耦合的分析方法对髋关节假体临床前磨损性能进行评估是未来的研究方向。

关键词: 人工髋关节; 磨损; 体外磨损测试; 计算机磨损仿真; 步态加载条件

中图分类号: TH117.1

文献标志码: A

文章编号: 1004-0595(2021)06-1004-15

In-vitro Wear Test and Computational Wear Prediction of Total Hip Replacement in China

YANG Shu^{1,2}, CUI Wen¹, ZHANG Xiaogang¹, ZHANG Yali^{1*}, XIE Fengbao²,
REN Xuhui³, CHEN Zhenxian⁴, JIN Zhongmin¹

(1. Tribology Research Institute, School of Mechanical Engineering, Southwest Jiaotong University, Sichuan Chengdu 610031, China

2. Beijing Chunlizhengda Medical Instruments Co Ltd, Beijing 101100, China

3. Zhejiang Institute of Medical Device Testing, Zhejiang Hangzhou 310018, China

4. Key Laboratory of Road Construction & Equipment of MOE, School of Mechanical Engineering, Chang'an University, Shanxi Xi'an 710064, China)

Abstract: The wear particles of hip prosthesis will cause osteolysis, which in return triggers aseptic loosening in the prosthesis itself. It is reported that one of the major reasons for revision total hip replacement is wear and the aseptic loosening caused by it. Under such a background, the pre-clinical evaluation on wear performance of hip prosthesis is becoming increasingly important. Currently, the major approaches of the pre-clinical wear assessments are the in-vitro

Received 26 November 2020, revised 15 March 2021, accepted 17 March 2021, available online 28 November 2021.

*Corresponding author. E-mail: zhangyali@swjtu.edu.cn, Tel: +86-28-87634954.

The project was supported by the Science and Technology Plan Project of Sichuan Province (2020YJ0032) and the National Natural Science Foundation of China (51775460, 52035012).

四川省科技计划项目(2020YJ0032)和国家自然科学基金项目(51775460, 52035012)资助。

wear test and the computational simulation. Compared with other countries, the domestic pre-clinical wear study of hip prosthesis is in the primary stage where there are very few articles on the above two approaches. Therefore, it is very important to understand the basic research status of friction and wear of hip prosthesis in China. This article firstly compared the kinematic and dynamic input of gait curves that are used in domestic hip wear assessments with the Chinese measurement gait curves. Then this article summarized, compared and analyzed the results from both domestic in-vitro simulator test and the computational simulation. And lastly this article discussed the limitations and future development directions of the hip pre-clinical wear assessments. The main findings were: 1) The gait motion curves of the Chinese were similar to the Western. The main difference lied in the gait joint force curves. And the Chinese measurement curves cannot be directly used in hip wear evaluate tests as the measurement method of hip joint force needs to be improved. 2) The domestic and the international research findings of in-vitro wear tests conducted according to the ISO 14242-1 standard were similar but the results according to other testing standards (e.g., ISO 14242-3) showed differences. This meant the accuracy of domestic in-vitro wear test results were influenced by the testing standards and testing equipment. 3) The simplified dynamic curves according to the ISO 14242-1 can be input to the finite element model to reduce the computational time. The wear rates of the domestic computational simulation were generally lower than those of the in-vitro wear tests. As a result, the accuracy of domestic computational wear models needed further improving. There were also some limitations on the current domestic wear assessments and researches. The first one was the gap between the Chinese standards and international standards. Some extreme conditions like third body wear, edge load and micro separation were not considered in current Chinese standards. Secondly there was still no gold standard on extraction of wear debris. Thirdly it was difficult to consider simultaneously the factors from patients, doctors and manufacturers that impacted on the wear performance of hip prosthesis. In order to catch up the international wear research progress of hip prosthesis, the future domestic pre-clinical wear assessments should focus on: 1) Building the national wear assessment standard that is appropriate for domestic patients; 2) Improving the extraction method of wear debris; 3) Promoting the accuracy of computational model by adopting more realistic dynamics inputs and by optimizing the wear models; 4) Combining the approaches of finite element analysis and force dependent kinematics to study the impact of patients' situations, doctor's techniques, products parameters on the wear performance of hip prosthesis.

Key words: hip prosthesis; wear; in-vitro wear test; computational wear simulation; dynamic inputs of hip gait

髋关节是人体最大、最稳定的关节之一,如果髋关节发生病变,会给病人带来诸多不适.全髋关节置换术可以治疗髋关节疾病、减轻患者病痛以及恢复关节功能.根据瑞典关节置换登记系统(Swedish hip arthroplasty register) 2019年的年报,磨损和磨损颗粒引起的无菌性松动是导致手术翻修的主要原因,占比为56%^[1].且临床结果表明,很大一部分患者会因为磨损和磨损导致的无菌性松动而进行二次手术^[2-3].因此人工髋关节磨损和润滑机理的研究和髋关节假体及材料耐磨性能的评估,对延长假体的使用寿命至关重要.

国内外学者对髋关节假体磨损做了大量研究,根据研究手段的不同,主要分为临床研究和体外研究.临床研究的方法有两种,其一是跟踪拍摄病人的X光片,优点是能够真实反映假体在人体内的磨损情况,但该方法只能评价穿透深度(线磨损率),无法直接评价磨损体积,且测量精度较低;另一种临床研究的方法为临床取出物体外磨损评估,或是对植入假体周围组织液中的磨屑进行提取研究,这种研究方式能够直接评估假体的磨损性能,反映临床使用情况,但存在样品数量有限和变量不可控等弊端.假体磨损的体外

研究主要分为关节模拟机测试和计算机仿真研究.髋关节模拟机通过模拟假体在体内的运动和受力情况,实现对髋关节假体磨损的定量化评价.我国2017年发布的《髋关节假体系统注册技术审查指导原则》中要求新设计及使用新材料的髋关节假体应在临床前选取预期配合使用的最差型号规格,按照ISO系列标准ISO 14242《外科植入物全髋关节假体的磨损》(国内等同标准YY/T 0651)及ISO 17853《外科植入物材料的磨损 聚乙烯和金属磨损颗粒的分离及表征》(国内等同标准YY/T 0652)进行磨损试验和耐磨性能评估^[4-5].但是磨损试验流程复杂,设备昂贵,时间和测试成本都很高,这种方法在国内还处于起步阶段,且设备数量尚无法满足科学研究的需求.另一种研究手段为计算机仿真,计算机磨损仿真的优点是可以作为磨损试验典型型号选择的辅助工具,同时节约时间和成本,便于参数化分析,为假体设计提供理论依据.但是,计算机磨损仿真分析不能完全模拟髋关节假体在体内的情况,仿真结果和实际结果存在一定差异.

国外的髋关节磨损研究比国内起步早几十年,仿真和试验测试的方法都更为成熟,相关研究涵盖假体

的规格^[6]、假体表面处理^[7]、摩擦副材料^[8-11]、固定方式^[12]、磨粒^[13-15]、加载方式^[16]、润滑油选择^[17]和磨损的测量方法^[18]等方面,国内关节磨损研究的很多关键参数、性能指标和方法均依据国外文献进行选取,但西方人与国人的生活习惯及生物力学环境存在一定的差异,比如深蹲、下跪和盘腿坐等动作的次数东方人较西方人更多,这些动作需要较大的髌关节运动角度^[3],并且东方人的身材相对西方人更加矮小,骨骼和关节尺寸同西方人存在不同程度的差异,因此,国外的生物力学曲线及磨损研究成果对国人髌关节磨损的适用性还需进一步的验证.此外了解国内髌关节假体摩擦磨损的基础研究现状,对指导国内假体磨损性能评价和产品研发、提升假体临床使用寿命和改善患者生活质量也非常必要.

本文作者回顾了国内髌关节磨损研究采用的力学和运动学加载曲线并与针对国人测绘的曲线进行了差异性分析,另外对国内发表的全髌关节磨损数值模拟及试验测试研究的结果进行了总结和对比,为建立国内髌关节的磨损评估体系及检测标准奠定基础,为提升髌关节假体的设计和质量提供帮助,为未来优化临床前磨损评估方法提供指导性建议.

1 文献查找方法

1.1 资料来源

检索时间范围:2010年9月至2021年3月

检索数据库:在清华知网数据库、万方数据库、PubMed数据库和Web of Science数据库通过关键词查阅相关文献.

检索词:中文检索词为“人工髌关节,磨损”以及“步态运动,测量”.英文检索词为“Hip simulator” and “Wear”,“Computational”或者“Hip” and “Wear”(地址限定为“China”).

检索文献类型:期刊/硕博学位论文、学术专著、标准及检测报告.

1.2 入选标准

纳入标准:(1)有关国内髌关节磨损测试结果的文献;(2)有关国内髌关节数值仿真预测结果的文献;(3)有关国内髌关节运动和力曲线测绘的文献.

排除标准:(1)不典型报道和与研究目的相关性差;(2)内容重复且陈旧性研究文献.

1.3 资料提取方法

检索共得到487篇文献和报告,通过阅读标题和摘要进行初筛,去除研究目的与本文相关性差的文献

共404篇,排除内容重复性研究46篇,查看全文及参考文献进行筛选后共37篇文献及报告符合标准,其中中文22篇,英文15篇.

2 髌关节运动学和力学加载条件

2.1 髌关节运动学和力学测量

髌关节作为多轴性关节,能够进行屈伸、收展、内外旋和复合等运动^[19].髌关节的运动和载荷包括屈伸角(Flexion-Extension, F/E)、内收外展角(Abduction-Adduction, A/A)、内外旋转角(Internal-External, I/E-R)及前后、左右和上下关节力.准确的动力学输入是保证准确的髌关节仿真计算和模拟测试结果的前提,髌关节的运动学曲线可以通过运动捕捉系统或双荧光镜测量获得.运动捕捉系统是通过在测试者表皮黏贴标志点的方式对解剖标志点进行标定,然后通过刚体运动学求解获得髌关节的运动.双荧光镜系统是通过双平面透视系统采集关节运动过程中的位置变化,求解两体节的相对运动实现关节运动的获取^[3].运动学求解包括:时间参数、空间参数及时空参数等^[3].髌关节的力学曲线一般是利用足底力学板测量系统,通过骨肌多体动力学模型的逆向动力学计算获得运动过程中的关节力^[3].髌关节的力学曲线也可以通过带有力学传感器的假体植入患者体内测量,目前只有少量的测量结果发表(Bergmann等^[20]).国内在这些方面起步较晚,利用运动捕捉系统和足底力测量平台所采集的数据计算髌关节的关节力是现行的途径^[3,21-26],但这种方法获得的生物力学数据不能完全反映体内关节的受力情况.因此国内髌关节假体磨损研究采用的力学和位移曲线大都是国际标准或国外学者测绘的曲线^[19,27-34].

2.2 髌关节磨损研究的运动学和力学加载条件

行走是人最主要的动作行为,以足跟着地为起点,从足跟着地到足尖离地为支撑相(约为步态周期的0%~60%),再从足尖离地到足跟着地为摆动相(约为步态周期的60%~100%),整个行走步态周期持续时间大约为1秒.国内髌关节假体的磨损研究主要基于步态曲线,分别是ISO 14242-3标准推荐曲线^[35](图2曲线ISO-3)、ISO 14242-1标准推荐曲线^[26](图2曲线ISO-1)、Bergmann测绘曲线^[19,36](图2曲线Bergmann)、Prosim模拟机输入曲线^[23](图2曲线Prosim)、ASTM F2582标准推荐曲线^[37](图2曲线ASTM)、上海大学模拟机输入曲线(图2曲线Hua)^[38]、Johnston运动曲线^[39-40](图2曲线Johnston)和Paul力学曲线^[41](图2曲线Paul).此外国内

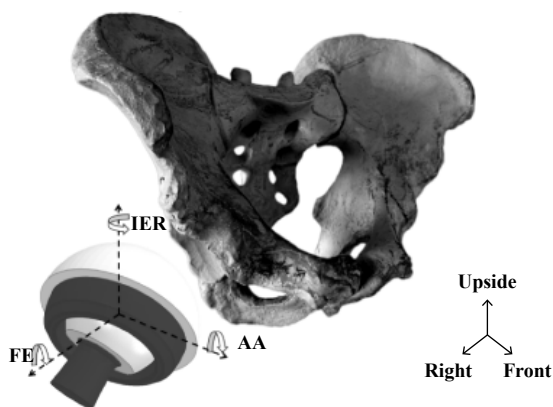


Fig. 1 Diagram of three-dimensional coordinates of load and motion on the right side of hip joint

图1 髋关节(右侧)载荷和运动三维坐标示意图

学者通过测量和计算得到的髋关节步态下的动力学曲线有:上海交通大学团队^[42-43]测量的运动和力学曲线(图2曲线Wang、Tang),北京体育大学刘筱璐^[25]绘制的运动曲线(图2曲线Liu),上海大学张书涛^[21]绘制的运动曲线(图2曲线Zhang),图2对这些运动和载荷曲线进行了汇总.需要说明的是为了方便比较,运动曲线的空间坐标系按图1的坐标系进行了转化(屈伸为正、外展为正、内旋为正).另外由于个别曲线的初始位置不统一,在本文中统一以足跟着地为起始位置^[3,19,21-25,40-41],因此Tang曲线向前平移了40%相位,此外关节力的单位统一为体重百分比,计算时体重取85.2 kg^[22].

从图2中可以看出,屈伸(F/E)相上ISO-3、ISO-1、Bergmann、Hua、Wang、Johnston、Liu及Zhang的曲线都很相似.而Prosim曲线与其他曲线间存在相位差,ASTM曲线的幅度最为平缓与ISO-1曲线相比约降低了70%.外展内收(A/A)除了ASTM和Prosim曲线,其余曲线的走势都类似.Wang、Tang、Johnston、Liu和Zhang曲线的幅度与ISO-1曲线相当,Hua曲线幅度与ISO-3曲线相同.Bergmann曲线与其他曲线相比在A/A相上整体处于内收位,而Prosim曲线在A/A相上没有施加运动.在内外旋(I/E-R)相上Bergmann曲线相较于其他曲线整体偏外旋,所以曲线位置整体偏下.ISO-3曲线在I/E-R相上没有施加运动.其余曲线在I/E-R相上的数值相当,走势相似.另一方面,从图2中可以看出用于磨损研究的力学加载曲线中只有Bergmann曲线有完整3个方向上的受力,ProSim、ISO-1、ISO-3和Paul曲线只有上下方向上的载荷.通过对比图2国内与国外测绘的曲线,国人在步态支撑相上普遍较西方人偏外旋,在摆动相上普遍偏内旋和内收.而在整个步态周期内,国人步态运动的整体幅度要小于国外

运动的幅度,这可能是由国人的骨骼尺寸较小引起的.此外国内力学曲线的整体数值低于国外,存在较大的差异.可能原因是由于国内采用足底测力板的方法获取关节力,且国人计算的肌肉力可能不够精确,所以国内关节力的测量方法有待进一步完善.最后国人与西方人在步态时的受力也可能确实存在差异,这有待通过相同的测试方法进行进一步的研究.总体来说,国人与西方人在行走时的运动曲线间差异不大,主要的差异还是在髋关节的受力上.综上所述,尚无基于国人行为力学的曲线被用于髋关节的磨损研究,造成这种现象的主要原因为国内采用理论计算的方法获取髋关节关节力,无法等同于患者髋关节的真实受力,然而由于国外和国内患者的生活习惯及生物力学环境存在一定的差异,基于国人的运动和力学曲线是评估国内患者体内假体耐磨性能的最佳输入条件,为了解决国人行为力学曲线适用性低与提升国内髋关节磨损研究质量之间的矛盾,带有力学传感器的假体植入患者体内直接测量关节力的方法应该被采用和推广.

3 国内髋关节假体体外磨损测试

体外磨损试验主要是以人工关节模拟试验机为载体,通过模拟关节的运动和承载,进而模拟人工关节在体内所受到的摩擦磨损情况.最早的髋关节模拟机是上世纪90年代末出现的^[44],发展至今市面上的髋关节模拟机已有数十种^[45].按模拟机的运动合成方式不同,可以大致分为轨道轴承型(Orbital hip joint simulator)和多轴型(Anatomic or multi-axis hip joint simulator)^[5].轨道轴承型的运动是在360°的周向内合成摆动,而多轴型由于各运动轴间相对独立,能够分别进行运动调整,但其传动系统相对复杂,增加了许多额外的影响因素(如系统的装配误差等)^[38].而根据关节的安装位置不同,可以将模拟机大致分为正生理位置安装的关节模拟机(髋臼在上,股骨头在下)和反生理位置安装的模拟机(髋臼在下,股骨头在上),其中正生理位置由于能够有效避免第三方颗粒和蛋白析出物附着在关节运动表面,因此这种设计的模拟机更符合实际^[19].国内髋关节模拟机的研究起步较晚,中国矿业大学黄传辉等^[46]自主研发了国内第一台两轴髋关节模拟机,且在髋关节磨屑分离提取方面做了大量工作.上海大学华子恺等^[38]自主研发了国内第一台多站髋关节多轴型试验机,能够很好地进行假体的磨损测试.除此之外,国内许多检测机构、公司和科研机构也配备

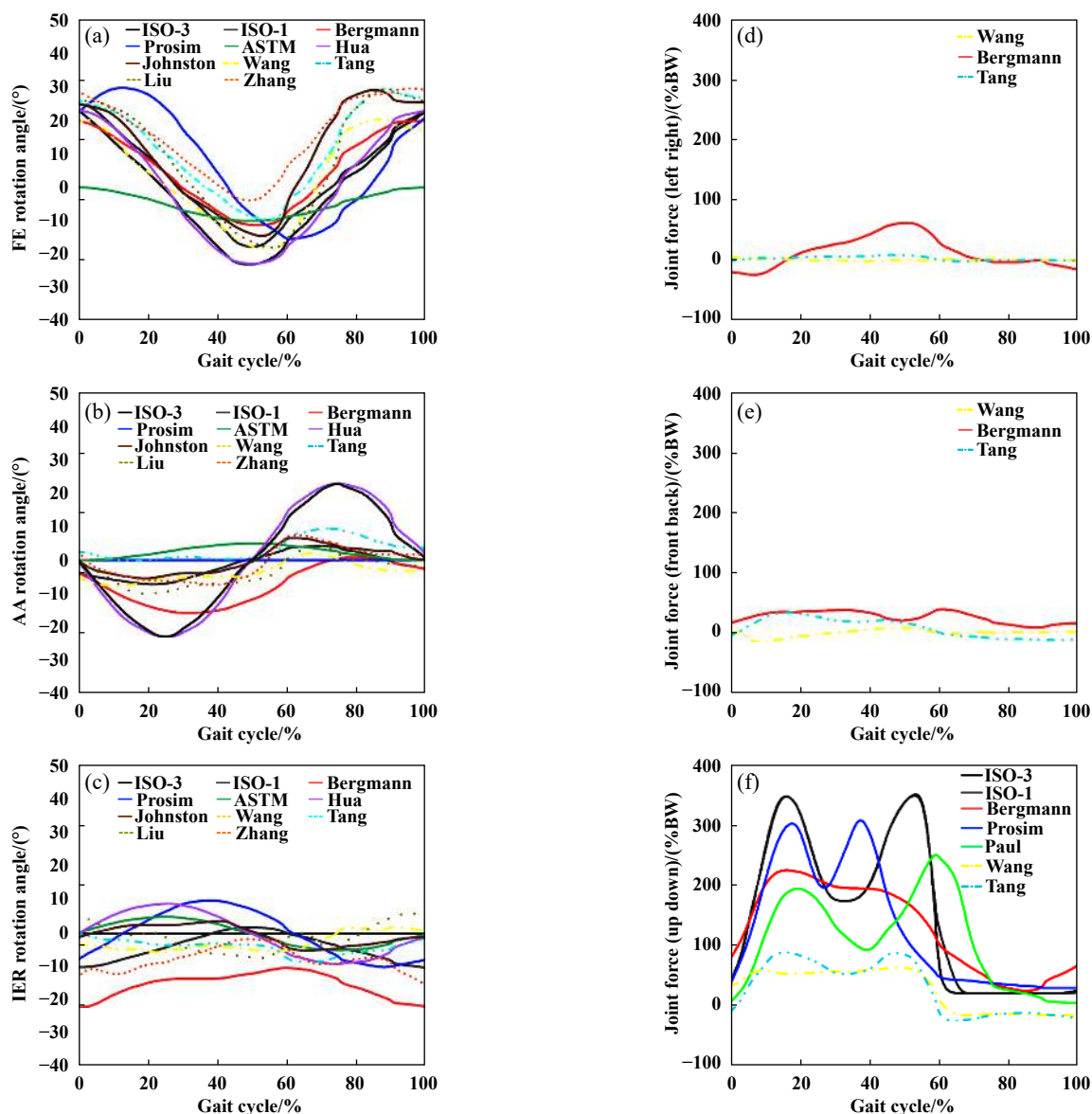


Fig. 2 Comparison diagram of kinematic and dynamic input curves and domestic measurement curves in walking condition: (a) F/E rotation angle; (b) A/A rotation angle; (c) I/E-R rotation angle; (d) Joint force on left/right direction; (e) Joint force on front/back direction; (f) Joint force on up/down direction

图2 国内髌关节步态周期内运动及关节力磨损研究输入曲线与国人测量曲线比对图 (a)屈曲/伸展角变化图; (b)外展/内收角变化图; (c)内/外旋角变化图; (d)左右关节力变化图; (e)前后关节力变化图; (f)上下关节力变化图

有进口的髌关节模拟机, 分别用于关节产品的耐磨性能测试及相关的学术研究。配备有AMTI (<https://www.amti.biz/about-us.aspx>)的单位有北京市医疗器械检验所和西安交通大学; 配备PROSIM (<http://www.prosim.co.uk/index.php>)的单位有天津市医疗器械质量监督检验中心、上海市医疗器械检验所、江苏省医疗器械检验所、山东省医疗器械产品质量检验中心、无锡宝通新材料科技有限公司、威高上海研究院、中国矿业大学、内蒙古医科大学和西安交通大学及西南交通大学; 同时, 浙江省医疗器械检验研究院也已完成MTS

(<https://test.mts.com/en>)的采购。

体外磨损试验方法较临床试验有诸多优点, 比如过程更为简单、结果更易观察和分析、干扰因素较少且成本更低等。国外学者已积累了大量研究经验。随着国内人工关节的研究和发展, 自2008年起陆续有国内科研机构的髌关节体外磨损测试结果发表。为了确保磨损测试的规范性、重复性及测试结果的准确性, 国际标准化组织(ISO)发布了髌关节体外磨损测试的详细要求和指导流程, 在此基础上, 我国医药行业对ISO标准进行了等同采用, 即YY/T 0651系列标准^[47-48]

等同采用ISO 14242系列标准,但国内标准在更新时间上与国际标准存在一定的滞后性^[2],如YY/T 0651.3-2020^[49]预计2022年才正式实施,因此国内发表的绝大多数磨损测试是依据现行ISO标准进行的。ISO 14242-1《外科植入物全髋关节假体的磨损第1部分:磨损试验机的载荷和位移参数及相关的试验环境条件》及ISO 14242-3《外科植入物全髋关节假体的磨损第3部分:轨道轴承型磨损试验机的载荷和位移参数及相关的试验环境条件》对髋关节测试的加载、频率、时间、样品的配置和测试环境进行了规定,但是因其缺少对设备及润滑条件的明确要求,导致了各测试机构间存在由于国际标准规定外的差别而引起的测试结果间的差异。ISO 14242-2《外科植入物全髋关节假体的磨损第2部分:测量方法》规定了利用质量法或体积法评估标准磨损测试后髋臼组件的磨损,其中体积法的优势在于不会受到夹具和样品吸水的影响,而缺点在于测量需要进一步的程序处理,测试方法复杂。西安交通大学的彭希锋等^[50]率先在国内应用三坐标测量体积法评估假体的磨损率。任旭辉等^[19]用两种磨损测量的方式进行了相互验证,将称重法的测量结果转化为体积磨损率并与三坐标法测得的磨损率进行对比,结果分别为 $17.3\pm 1.9\text{ mm}^3/\text{MC}$ (称重法)和 $16.9\pm 1.4\text{ mm}^3/\text{MC}$ (三坐标法),研究发现两种方法测出的磨损量一致性较好。从根本上说这两种方法没有优劣之分,无论是称重法还是体积法,测量精度取决于操作者的熟练程度、机器精度及后处理程序^[50]。一般考虑到时间和成本等因素,磨损评估只需选择其中一种方法即可。本节汇总了国内各机构进行髋关节体外磨损测试的结果,并对其进行了分析。

表1从假体的摩擦副材料、规格、试验依据的标准、使用模拟机的品牌型号及使用的润滑介质等几个方面对国内不同机构的磨损测试结果进行了对比。从1表中可以看出:西安交通大学(XJTU)任旭辉^[19]和彭希锋等^[53]、上海大学(SHU)华子恺等^[38]、中国矿业大学(CUMT)刘洪涛等^[51]、南京医科大学(NJMU)范卫民等^[27]、江南大学Chen等^[28]、西南交通大学(SWJTU)刘恒君等^[52]及春立医疗^[30]对钴铬钼(CoCrMo)和超高分子量聚乙烯(UHMWPE)配副的假体进行了磨损测试,其中西安交通大学彭希锋等^[53]对比了国外与国内厂商生产的假体磨损率,发现两者无显著差异。西南交通大学刘恒君等^[52]研究了表面改性对UHMWPE磨损率的影响,发现类金刚石(DLC)及注氮改性反而会加剧UHMWPE的磨损,主要原因为表面改性增加了关

节面的摩擦系数及表面硬度。春立医疗^[29]进行了CoCrMo对含维他命E的超高分子量聚乙烯(VEXLPE)材料配副假体的磨损测试。西安交通大学任旭辉^[19]及春立医疗^[31]对陶瓷材料的磨损进行了测试和研究。中南大学Chen等^[33,53]和南京医科大学第一附属医院Liu等^[34]对金对金摩擦副的假体进行了磨损测试并分别研究了材料碳含量、径向间隙和白杯变形对磨损率的影响。除Chen^[33]、Liu^[34]与黄传辉^[46]的研究外,其余研究均采用28或36 mm外径的球头作为测试样品,这两个规格也是目前市场上常用的规格。此外从表2中汇总的数据可以看出,上海大学华子恺等^[38]及中国矿业大学黄传辉^[46]通过自制的模拟机在相同试验条件下研究了不同润滑介质对磨损率的影响。

通过对比国内外的测试结果可以发现^[8,18,54-57],国内依据ISO 14242-1标准进行的磨损测试结果与国外测试结果基本相当,而采用其他运动(ISO 14242-3)和力学输入条件的测试结果普遍要大于国外测试的结果,国内基于ISO 14242-3标准的磨损测试采用的都是国产自制模拟机,自制模拟机的可靠性可能是造成国内外磨损结果差异的原因,这有待进一步的试验验证。通过横向对比国内不同测试机构间的结果,发现即使采用相同条件的假体,结果间仍存在一定的差异,这也佐证了测试设备和操作方法对测试结果有一定的影响,另外影响髋关节体外磨损测试的因素还有很多,比如假体的规格及摩擦副材料等,通过对比表1中的数据,可以直观得到的参数与磨损率大小之间的关系有:对于金对聚乙烯、陶瓷对聚乙烯及陶瓷对陶瓷摩擦副来说,大规格球头的磨损率要大于小规格球头,这与Leeds大学的研究相当^[58];在相同样品测试条件和测试标准的情况下,可得到CoCrMo对UHMWPE的磨损率最大,CoCrMo对高交联超高分子量聚乙烯(HXLPE)次之,接着是陶瓷对UHMWPE,CoCrMo对VEXLPE,CoCrMo对CoCrMo,磨损率最小的是陶瓷对陶瓷配副。这样的大小排列规律也基本符合临床应用的结果,临床研究表明全金属或陶瓷组合假体的磨损率要优于金属-UHMWPE组合关节的磨损率^[59-60]。另外因氧化会降低超高分子量聚乙烯材料的机械性能,基于UHMWPE表面改性技术如射线辐射交联和维他命E扩散等技术已成功应用于临床,改性后UHMWPE的磨损率明显低于普通UHMWPE^[42],国内测试结果发现储存时间长的聚乙烯假体磨损率要大于储存时间短的,这符合氧化作用对聚乙烯磨损性能的影响。另外国内测试结果表明含碳量低的CoCrMo假体磨损

表1 体外磨损测试结果对比
Table 1 Comparison of in-vitro wear test results

Material	Size	Test standard	Hip simulator	Lubricant (protein concentration)	Testing results/(mm ³ /MC)	Data source	Notes
	28 mm head	ISO 14242-1	Simulation Solutions Prosim	30 g/L calf serum	54.8±1.8	XJTU ^[19]	
	28 mm head	ISO 14242-1	Simulation Solutions Prosim	17 g/L calf serum	49.7±7.0 48.2±8.5	XJTU ^[19]	Foreign samples Domestic samples
	28 mm head	ISO 14242-3	Simulator developed by SHU	0 g/L calf serum	20.8	SHU ^[38]	
	28 mm head	14242-3 and load is 784 N	CUMTH	20 g/L calf serum	171.8	CUMT ^[51]	
CoCrMo-UHMWPE	28 mm head	Motion per ISO 14242-3 and load is 2 100 N	Simulator developed by Montagne	25 g/L calf serum	24.7±8.2 38.9±12.1	NJMU ^[27]	The samples were stored for 1 year The samples were stored for 4 years
	28 mm head	Motion per ISO 14242-3 and load per Paul curve	CUMT II	25 g/L calf serum	171.8±40	Jiangnan University ^[28]	
	28 mm head	Load per ASTM F1714-96	MTS	25 g/L calf serum	54.9±5.2 88.0 80.9	SWJTU ^[52]	No surface treatment DLC surface treatment Nitrogen injection surface treatment
CoCrMo-HXLPE	36 mm head	ISO 14242-1	Orthotek	20 g/L calf serum	91.1±12.5	Chunli Medical ^[30]	
	28 mm head	Motion per ISO 14242-3 and load per Paul curves	CUMT II	25 g/L calf serum	93.5±9.0	Jiangnan University ^[28]	
CoCrMo-VEXLPE	28 mm head	ISO 14242-1	Orthotek	20 g/L calf serum	46.8±9.0	Chunli Medical ^[29]	
Ceramic-ceramic	28 mm head	ASTM F2582	EATM882	20 g/L calf serum	0.1±0.04	Chunli Medical ^[31]	
Ceramic-UHMWPE	28 mm head	ISO 14242-1	Simulation Solutions Prosim	30 g/L calf serum	16.8±2.1	XJTU ^[19]	
	36 mm head			30 g/L calf serum	21.9±1.5		
	40 mm head	ISO 14242-1	AMTI	30 g/L calf serum	0.4±0.2 0.3±0.2 36.5	Central South University	Low-carbon alloy High-carbon alloy Radial clearance: 19 μm
	40 mm head	ISO 14242-1	INSTRON	30 g/L calf serum	48.3 77.9 87.3	Central South University ^[33]	Radial clearance: 38 μm Radial clearance: 106 μm Radial clearance: 149 μm
CoCrMo-CoCrMo	50 mm cup				4.3±0.1		
	52 mm cup				4.4±0.2		Deformation of cup
	54 mm cup	ISO 14242-1	Simulation Solutions Prosim	25 g/L calf serum	4.1±0.02	NJMU ^[34]	
	50, 52 and 54 mm cup				0.9±0.04		No deformation of cup

Note [1]: To unify, mass wear rate is converted to volume wear rate. The density of UHMWPE is 0.934 mg/mm³, VEXLPE is 0.93 mg/mm³ and ceramic is 3.96 mg/mm³.

Note [2]: MC stands for million cycles.

率要大于含碳量高的, 变形臼杯的磨损率要大于未变形臼杯的, 大径向间隙的金对金假体磨损率要大于小径向间隙的, 这些规律均符合国外学者的研究结论^[3]. 目前小牛血清浓度对磨损率的影响还未有定论, 但同等条件下, 国内测试结果表明高浓度小牛血清介质的磨损率要大于低浓度的, 这符合Sawae等^[61]的研究, 另

外测试中的润滑剂选择对测试结果的影响也十分重要, 上海大学的华子恺等^[38]对不同润滑介质下的CoCrMo-UHMWPE假体进行了磨损研究, 发现复合润滑液的润滑性能要优于其他对照组, 原因是复合润滑液能在UHMWPE表面形成蛋白质薄膜, 有助于减小磨损, 同时透明质酸也能有效降低UHMWPE的磨

表2 不同润滑介质的体外磨损测试结果
Table 2 In-vitro wear test results under different lubricating media

Material	Size	Test Standard	Hip Simulator	Lubricant	Testing results/(mm ³ /MC)	Data source	Notes
CoCrMo-UHMWPE	28 mm head	Load is 4.5 kN and motion range is 0~70°	Simulator developed by SHU	Compound lubricant A	4.3±0.1	SHU ^[38]	Sodium hyaluronate was used as matrix and γ globulin was added.
	28 mm head			Compound lubricant B	4.6±0.1		Sodium hyaluronate was used as matrix. γ globulin and sodium alendronate were added.
	28 mm head			Sodium hyaluronate	4.8±0.1		
	28 mm head			25 g/L calf serum	5.1±0.1		
	28 mm head			Deionized water	6.5±0.1		
Ceramic-UHMWPE	25 mm head	Motion per ISO 14242-3 and loads are 392 and 784 N	CUMT II	Distilled water	16.3 (392 N) 34.0 (784 N)	CUMT ^[46]	
				Blood serum	20.0 (392 N) 43.4 (784 N)		

损率. 中国矿业大学黄传辉^[46]研究了蒸馏水和血浆润滑条件下的磨损率,发现血浆润滑条件下的磨损因数更接近临床观测值,这与熊党生等^[62]的研究结果相似,因此采用人血浆作为润滑介质的试验更接近实际润滑情况.但是由于成本和可行性等方面的考虑,新生小牛血清是目前更为合适的关节生理滑液替代品^[42],国内大多数的测试也都采用小牛血清作为润滑剂.河南大学的王莹莹等^[63]研究发现基于石墨烯仿生关节滑液的生物相容性高且具有减摩抗磨性能,因此仿生滑液的开发与研究可能是解决人工关节润滑不充分的未来研究方向.此外,磨屑不仅包含大量的磨损信息,其生物学反应也对假体的植入效果有很大的影响^[64-65].体内UHMWPE磨粒尺寸集中在0.1~0.5 μm ,而体外试验的磨粒尺寸集中在0.1~1 μm 之间,这说明假体在体内环境中更易生成亚微米级微粒^[3].中国矿业大学及武汉理工大学对磨粒特征及分型表征进行了大量的研究,Yuan等^[66]利用原子力显微镜和计算机辅助图像分析技术获取并计算磨粒三维表面形貌及特征参数,吴竞萍等^[67-68]通过主成分分析及聚类的方法对磨屑进行了分类,葛世荣等^[69]、Liu等^[70]和张岚峰等^[71]采用雷达图及分形维数对磨粒轮廓进行了分形表征.这些研究有助于磨粒的定量分析与自动识别,推动了磨损机理的研究^[72].由于亚微米级别的磨屑极易团聚,且易被小牛血清等润滑介质中含有蛋白质大分子包裹,因此从组织润滑液中分离、提取出不含蛋白质的磨屑并进行分析是复杂且困难的.目前我国医药行业颁布了等同引用国际标准(ISO 17853-2011)的YY/T 0652-2016^[73],

其中提到酶消化法、碱消化法和酸消化法来分离金属、陶瓷和聚乙烯磨屑,但实际效果并不理想.此外,贾庆卫等^[74]和贾玉梅等^[75]分别采用梯度离心和超声辅助法提取溶液中的磨屑.但这些方法只有在特定的适用范围内才能保持较高的可信度^[65,75],且不同国际标准化组织(BSI、ASTM、ISO)给出的磨屑提取和建议存在相互矛盾的地方,目前还未有对于特定材料磨屑提取的金标准^[76],因此对于磨屑有效提取方法可能需要进一步深入的研究.

相较国外,国内缺乏大样本结果的对比和分析,很多影响髋关节磨损的因素目前还没有1个清楚的机理解释,而在目前的条件下受限于成本和各种问题,通过模拟机开展大量试验对这些因素进行研究无法深入开展,因此,磨损数值预测的方法正在逐步被国内学者用于髋关节假体的磨损评估.

4 国内髋关节假体磨损数值预测

由于髋关节体外磨损测试流程复杂,而且成本和时间花费都很高,这包括模拟机和相关测量设备价格昂贵、测试样品造价不菲以及依据ISO标准的1个完整磨损测试周期一般需要4~6个月等,因此通过数值计算模型对假体的耐磨性能进行预测,就成为评估人工髋关节产品磨损性能的重要替代手段.

磨损数值预测方法的理论依据是1956年Archard提出来的磨损定律,即认为磨损量与载荷和滑移距离成正比.随着对UHMWPE磨损机理的了解,学者们发现UHMWPE材料的磨损对于压力的敏感性较低,不

会像金属材料一样完全符合Archard公式,因此一些基于Archard模型的改进模型如考虑UHMWPE材料蠕变、交变剪切和接触应力等模型被开发出来并应用于磨损预测计算^[77-78].而对于硬对硬髌关节的磨损预测,Gao等^[79]将弹流润滑理论引入到金对金髌关节的磨损预测模型上,据笔者了解,国内在人工髌关节磨损预测的研究较少且建模和计算方法均参考国外已发表的方法,本节汇总并对比了国内学者利用计算机仿真方法对髌关节假体磨损性能的研究结果.

从表3中可以看出,胡铮铭等^[77]最先在国内使用计算机仿真的方法进行磨损预测,鲍雨梅等^[78]在此基础上对磨损模型进行了优化并通过销盘试验对模型进行了验证,他们的研究都是针对金对金髌关节的磨损预测,而任旭辉^[19]在Kang^[80]和Liu等^[81]的预测模型基础上研究了适用于UHMWPE人工髌关节的磨损预测方法,结果显示 Archard公式得到的磨损率为 $33.3 \text{ mm}^3/\text{MC}$, 交变剪切公式得到的磨损率为 $11.4 \text{ mm}^3/\text{MC}$, 而交变剪切和应力公式预测得到的磨损率为 $14.3 \text{ mm}^3/\text{MC}$, 如果认为28 mm的UHMWPE臼衬的平均磨损率为 $54.8 \text{ mm}^3/\text{MC}$ (体外磨损试验值^[19]), 则三种公式的误差分别为39.2%, 79.2%和73.9%. 通过对比可

以看到,虽然考虑交变剪切的两个公式与定磨损因子的Archard公式相比,预测值的误差更大.但任旭辉^[19]认为考虑交变剪切的预测公式理论上更为合理,数值的差异来自于模型本身的缺陷.Wang^[82]的研究也发现,UHMWPE材料在变方向运动时的磨损率会显著增高,即运动轨迹对聚乙烯的磨损影响很大.所以任旭辉^[19]进一步用交变剪切和应力耦合公式研究了不同步态下的髌关节磨损率,他依据Morlock等^[83]的步态比重计算了多步态综合作用下的磨损率,结果显示多生理活动的磨损率($15 \text{ mm}^3/\text{MC}$)高于只考虑行走时的磨损率($14.3 \text{ mm}^3/\text{MC}$).因此目前依据ISO标准进行的磨损测试方法(仅考虑步态)不能全面地评估假体在患者体内的耐磨性能,更接近人体实际活动的加载曲线应该被采用.任旭辉^[19]的研究结果也被其他国外研究者证实^[22, 84].另外上下楼梯运动和坐下站起运动的磨损率较高,这是较小交变剪切、较高接触应力和较大累计滑移距离综合影响下的结果^[19].最后关于ISO标准没有前后和左右方向的力是否影响磨损预测的结果,西安交通大学任旭辉^[19]分别用HIP98 (Bergmann)数据和ISO标准推荐的数据计算了髌关节步态运动时假体的磨损率,结果显示ISO标准步态的磨损率($14.3 \text{ mm}^3/$

表3 磨损数值预测结果对比
Table 3 Comparison of computational wear prediction results

Motion	Model	Equation	Parameter	Material	Input	Result/(mm ³ /MC)	Data source
Gait	Archard model	$V=KFS$	$K=5 \times 10^{-9} \text{ mm}^3/(\text{N} \cdot \text{m})$ (run-in time) $K=1.5 \times 10^{-9} \text{ mm}^3/(\text{N} \cdot \text{m})$ (steady-state stage) $a=3.88 \times 10^{-5}$ $b=6.69 \times 10^{-6}$ $c=-2.526 \times 10^{-4}$	28 mm head CoCrMo-CoCrMo	Load per Paul ^[41] , Motion per Johnston ^[39-40]	0.1*	Hu ^[77]
	Archard model	$V=(a+bp+cv^2)S$	$b=6.69 \times 10^{-6}$ $c=-2.526 \times 10^{-4}$	28 mm head CoCrMo-TC4+HA/ZrO ₂		302.1	Bao ^[78]
	Archard model	$V=KFS$	$K=1.066 \times 10^{-6} \text{ mm}^3/(\text{N} \cdot \text{m})$ $C=(32C_0+0.3) \times 10^{-9}$ $C_0 < 0.04$	28 mm head CoCrMo-UHMWPE		33.3	
	Improved Archard model (cross shear)	$V=C(C_0)AS$	$C=(1.9C_0+1.6) \times 10^{-9}$ $0.04 < C_0 < 0.5$	28 mm head CoCrMo-UHMWPE	ISO 14242-1	11.4	
Stair climbing Chair down/up Gait	Improved Archard model (cross shear, stress)	$V=K(C_0\sigma)FS$	$K(C_0\sigma) = e^{(a+b \ln(C_0+c\sigma_{AVE}))}$ Within: $a=-13.1, b=0.19, c=0.29$.	28 mm head CoCrMo-UHMWPE		14.3	Ren ^[19]
	Gait		The meanings of symbols please refer to note [2].	28 mm head CoCrMo-UHMWPE	HIP98 database ^[19, 36]	12.8	
	Knee bending Combined					7.9 15.0	

Note [1]: * Supposed that 1 million cycles are equivalent to 1 year.

Note [2]: V -wear volume, K -wear factor, F -contact pressure, S -sliding distance, P -pressure, v -linear velocity, A -contact area, C -friction coefficient, C_0 -cross shear rate, σ -contact stress.

MC)仅略高于Bergmann步态的磨损率($12.8 \text{ mm}^3/\text{MC}$)。说明ISO 14242中规定的曲线较实际人体行走的曲线所造成的磨损更高,这也符合按最严格条件进行磨损测试的初衷。ISO标准曲线虽然对载荷进行了简化,但仍可以用于预测髋关节步态下的磨损,这一理论也被Leeds大学的Liu等^[85]证实。因此在磨损仿真计算时,可以对步态情况下的动力学输入进行合理的简化以提升计算效率。此外,西安理工大学的张通等^[86]采用Archard磨损模型计算了不同球头直径对线性磨损率的影响,发现磨损深度随着球头直径的增大而增大,这也是国内学者将预测模型应用在产品参数化分析的典型。中北大学的廉超^[87]和冯莉等^[88]通过建立动力学仿真模型研究了不同摩擦副假体在分离条件下的边缘接触机制。

综上所述,磨损公式的合理性直接决定了磨损计算结果的准确性,随着对材料性能的研究深入,Archard公式也被不断地优化以适用于不同环境下的磨损预测。经过模拟机试验的验证,Gao等^[79]的弹流润滑理论公式能够很好地预测金对金摩擦副髋关节假体的磨损,Kang等^[80]的考虑交变剪切和蠕变的公式更适合UHMWPE材料的髋关节磨损预测。国内关于髋关节磨损预测的研究较少,有限的结果显示仿真预测的磨损值普遍低于体外测试的结果,但任旭辉^[19]通过横向对比体外试验的结果发现预测的磨损区域分布与测试的磨损分布一致,并且预测计算的效率显著高于体外磨损测试的效率,数值仿真的方法体现出成本和时间方面的优势,因此在保证计算机模型的准确性后(例如通过试验验证),磨损预测的方法是能够应用于假体的参数化研究的。

5 展望

髋关节磨损研究在国内还处于起步阶段,但近年来随着国内外学术交流的大力开展,国内外学者联合研究的模式促进了髋关节基础理论研究的快速发展,这为髋关节假体的设计、优化及临床使用提供了必要的理论支持。随着生活节奏的加快,年轻患者数量增加,老龄化加剧,人们对髋关节假体的寿命提出了更高的要求,而扎实的磨损理论基础是实现这一需求的有效手段。

从目前国内髋关节磨损研究中不难发现,几乎所有的体外测试均执行ISO标准^[89],然而ISO标准曲线与实际人体活动曲线还存在一定的差距,无法反映真实的临床应用,如何获取更贴近实际的关节受力和运动曲线是未来的研究方向之一,另一方面,国外学者对

恶劣条件下的磨损测试进行了大量的研究^[90-91],这些研究为国际标准的制定奠定了基础。新颁布的国际标准(14242-4:2018《外科植入物全髋关节假体的磨损第4部分:边缘加载条件下的假体测试》^[92]及ASTMF3047M-2015《硬对硬关节面磨损测试的标准指南》^[93])把臼杯安装位置、三体磨损、多倍体重及微分离等恶劣加载条件下的假体磨损纳入了考虑,和国际标准相比,我国标准的建立存在一定的滞后性,对恶劣条件的考虑还未有涉及,因此,加快我国标准跟进的速度,采用符合国人日常生活特点的运动参数,进而形成适合于中国人行为力学的标准是我国标准化工作的发展方向。此外,受限于国内模拟机的数量,大量的磨损研究需要借助计算机模型进行预测评估,但国内发表的髋关节磨损预测文章很少,也反映了国内计算机仿真研究的滞后。同时现有的计算机仿真方法也需进一步优化。目前髋关节生物力学和摩擦学研究相对独立,很难同时考虑患者和医生等多方面因素的影响,因此多尺度的全身有限元-骨肌系统性建模方法可能是今后磨损预测研究的发展趋势,而对磨损模型的探索和优化工作仍需持续进行。

可以肯定的是,结合计算机仿真和模拟机试验两种体外评估髋关节磨损方法的优势,通过有限的体外磨损测试结果来验证磨损预测模型的可靠性和有效性,进而根据磨损仿真预测模型进行产品参数化设计,利于提高设计效率,减少资源浪费。

6 结论

人工髋关节的摩擦磨损机理研究是提升髋关节假体的耐磨性能和延长假体使用寿命的基石,但是国内相关研究相较于国外还处于起步阶段,且存在一定差距。本文作者通过汇总和分析国内外髋关节生物力学曲线、国内髋关节磨损测试及数值模拟研究进展发现:

a. 国人与西方人在行走时的运动角差异不大,但由于测量方法的不同,国人测得的关节力普遍低于国外测得的关节力。带有力学传感器的假体植入患者体内的方法可用于直接测量关节力。

b. ISO 14242-1标准已然成为国内大多数髋关节体外磨损测试的操作指南和依据,相关测试的结果与国外结果相近。然而国内采用其他测试条件进行磨损测试时的结果要大于国外,这反映出国内测试结果的准确度受测试标准及测试设备的影响较高。另一方面,我国标准的建立和国际相比存在一定的滞后性,且ISO 14242-1标准曲线与实际临床应用间存在差距,

这些问题引发出对国内标准的完善和建立适合国人行为力学标准的诉求。

c. 计算机仿真具有节约时间和成本的优势, 简化髋关节的加载(只有轴向力)对步态下的磨损预测结果影响不大, 因此可以采用ISO等简化后的生物力学曲线作为计算机仿真研究的输入. 通过对比发现国内数值模拟的预测结果普遍低于体外测试的结果, 这说明仿真模型的可靠性和有效性有待进一步提升. 最后基于骨肌多体动力学和有限元宏微生物力学的系统性生物力学模型可综合研究多因素对摩擦磨损的影响规律, 可能是今后磨损预测研究的发展方向。

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