Evolution of Industry-Academia Relationships in Development of Orthopaedic Implants

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Introduction

Whether for translational research or product development purposes, studies involving biomechanical testing of current device designs and those yet to enter the market are commonplace in the orthopaedic academic literature. The clinical impact of these studies cannot be underestimated, as the sheer volume and variety of orthopaedic devices available to practicing surgeons today makes investigating all potential options using clinical trials an impossible task. Published biomechanical research studies are in some cases the only evidence aside from feedback from colleagues available to surgeons regarding the mechanical competence of a particular device or combination of devices for a given application. In conducting biomechanical studies for orthopaedic device research and development, it is common for academic surgeons and engineers to partner with the orthopaedic industry to provide the devices needed for the study – which are cost-prohibitive to purchase at list prices – and, in many cases, to fund the research itself. Although it would be unfair to assume that industry sponsors are completely uninterested in the scientific aspects of biomechanical research, there is substantial marketing potential in sponsoring these studies, and this situation creates a definite potential to bias study outcomes in favor of the industry sponsor [1, 2]. To date, there has been little research on the incidence and characteristics of industry-academic collaborations in orthopaedic biomechanics research.

The goal of this study is to determine historical and current trends for orthopaedic biomechanics research. The specific aims were: (1) to characterize the trends in the volume of biomechanics research activity and the percentage of research related to orthopaedic devices; (2) to determine whether the source of funding between device and non-device related research differed historically and currently; and (3) to investigate whether other historical trends in the field, namely, market size for orthopaedic devices and the number of practicing surgeons, correlates with trends in academic publications.

Methods

Included in the study were all in-situ biomechanical studies from 1950 to the present (7,332 articles). A MEDLINE search was performed using the following algorithm: cada* NOT “disease models, animal”[MeSH] AND “musculoskeletal physiological phenomena” [MeSH] OR “musculoskeletal physiological phenomena” [MeSH] AND English [LA]. The Müller AO Classification scheme was applied to categorize articles by the affected orthopaedic joint. To determine whether a medical device was associated with each article, the MEDLINE entries were filtered for medical subject headings (MeSH) under the MeSH term “Prostheses and Implants” (inclusive), and this filter was validated by manually examining the abstracts of all articles from the time period 2005-2009. Funding source was determined by a first-order sort using the MEDLINE filter, followed by manual examination of 80% of all articles. Funding classifications were: Not Reported, Industry, Academic Group, Private Foundation, Foreign Government, and US Government. Market size for the orthopaedic device sector was determined from investor reports from two of the major implant manufacturers (Stryker and Zimmer), and these values were adjusted for inflation using the consumer price index. The number of board-certified orthopaedic surgeons and residents was provided by the American Board of Orthopaedic Surgery (ABOS).

Results

Over the past four decades, the number of research publications involving biomechanical testing of orthopaedic devices has increased exponentially from 11 in 1968 to 626 in 2008. This trend strongly correlates with market size for orthopaedic devices (exponential increase from $3.63 billion in 1990 to $35.6 billion in 2008; r=0.99, p<0.05).

Publication volume showed a strong, positive correlation with the number of practicing orthopaedic surgeons (r=0.99), but it was not correlated with the number of residents (r=0.03, p=0.05). Considering anatomical distribution, research activity was and continues to be heavily concentrated in the lumbar spine and hand and wrist (Figure 1).

The proportion of all biomechanics activity related to devices as increased from less than 5% between 1965-1969 to greater than 30% since 1985-1989. A large percentage of all research activity (approx. 50%) continues to be undisclosed, and the rate of non-disclosure is comparable for device and non-device focused work (46% vs. 51% for device vs. non-device, respectively). For device-focused studies with a disclosed funding source, rates of industry funding have risen from 16% to 59% from the time period 1985 to present, while US Government funding has declined from 50% in 1985 to 2% currently (Figure 2). Industry funding for non-device related work has increased modestly (2% to 20% from 1985 to present), and US Government funding has decreased from a high of 41% in 1970 to 12% currently.

Discussion

The results of this study indicate that a substantial percentage of all biomechanical research (approximately 30%) is focused on medical devices, and that a large portion of this academic activity (45%) is industry funded. The volume of research publications has increased exponentially over the past decades. Although this trend is not unique to orthopaedics [3,4], we have for the first time demonstrated that, at least for orthopaedics, this increase in academic activity is strongly correlated with market revenue for orthopaedic device firms and the number of practicing orthopaedic surgeons. While the scope of this study is limited to orthopaedic biomechanical testing - which is an important sub-field in the product development and marketing cycle for orthopaedic devices – there is no reason to believe that these trends would not hold for other medical disciplines with similar reliance on technology. High rates of industry funding are neither surprising nor troublesome for a field such as biomechanics, which represents the intersection between engineering and medicine. Partnership with industry is necessary to bring new technology to market and to evaluate existing products. That said, industry-academic collaboration should be publicly disclosed and well regulated to ensure the highest quality scientific information is passed to the clinicians administering patient care.

References

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