

# On the Horizon From the ORS

## Frontiers in Medical Device Design: An Approach for Making Arthroplasty Affordable Globally

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The global structure of health care and its service provision are in a state of flux and affect national budgets worldwide.<sup>1</sup> To meet the added healthcare burden associated with the expected increase in the number of arthroplasties,<sup>2</sup> there must be an active effort to design devices and instrumentation that are usable and affordable in the global market. We believe that to succeed in larger but more financially restricted emerging markets, device manufacturers must think globally but act locally. Consideration of economies of scale and “keeping it simple” may help promote affordability while novel approaches can help maintain access to and provide personalization of products in emerging markets.

The key to making arthroplasty affordable globally is to address regional or geographic anatomic diversity and economic and cultural needs. This strategy requires effective execution of services and adaptation on the part of healthcare providers to facilitate the incorporation of arthroplasty into the evolving global healthcare system.

Demographic shifts in age, longevity, and wealth distribution are mirrored in lifestyle changes that lead to obesity and decreased fitness as well as longer life expectancy; these changes affect bone density, musculoskeletal function, ligament strength, and the development of osteoarthritis.<sup>3,4</sup> Older populations have an increased risk of surgical morbidities as well as an increased risk of arthroplasty failure because Young’s modulus mismatch (ie, the force per unit area needed to stretch

or compress a material sample) is increased in persons with decreased bone mineral density. Therefore, evolving strategies for the global provision of arthroplasty should include system features that provide for different joint sizes and shapes and take into account activities of daily living in local populations; these patients may be obese, osteoporotic, and medically compromised, with limited access to health care.<sup>5,6</sup>

Recent significant technologic improvements have been achieved in terms of the materials, design, and manufacturing of arthroplasty devices.<sup>7</sup> These advances have addressed the challenges of device longevity, surgical technique, manufacturing, and cost.<sup>8</sup> The five major emerging national economies—Brazil, Russia, India, China, and South America (ie, BRICS), but especially India and China—present a substantial opportunity for expansion in market size for medical device companies.<sup>9</sup> However, it is important to keep in mind that advanced services associated with arthroplasty, such as smart or personalized instrumentation, computer-assisted surgery, three-dimensional printing, and even cross-sectional imaging (ie, CT or MRI), add costs that cannot be borne in these emerging economies.<sup>10</sup> Therefore, when creating strategies to enter these markets, simpler, novel solutions need to focus on the principle that less is more.

Solutions for emerging economies need not shy away from personalized medicine. Novel prostheses

that are designed for both clinical success and price-conscious manufacturing in a local market, and the use of simpler, reusable surgical instrumentation that aids optimal prosthesis placement and that tests mechanical results, should provide price competitiveness as well as good clinical outcomes.<sup>11</sup> Additional solutions include improved, mechanically sound prosthesis modularity and native bone preservation.<sup>6</sup>

A strategy to make arthroplasty globally affordable would begin with structural analysis of a specific joint for a specific population. Advanced statistical and machine-learning analyses that incorporate imaging and computational modeling can identify bone features and parameters for normal and pathologic joints, which can be used to develop robust prosthetic and instrumentation designs for a specific local population.<sup>11</sup> Proposed designs can then be compared using adaptive bone remodeling simulations that predict structural bone change following implantation.<sup>6,12</sup> Selected designs can then be physically prototyped and can undergo mechanical, kinematic, and kinetic testing.<sup>13</sup> Once a design has been selected for

manufacturing and sales, routine clinical surveillance, including information collected by joint registries, can be used to initiate changes in design, when necessary.

## References

*Evidence-based Medicine:* Levels of evidence are described in the table of contents. In this article, reference 5 is a level IV study.

References printed in **bold type** are those published within the past 5 years.

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