



2015 North American Orthopedic Alignment Technology Innovation Award



F R O S T & S U L L I V A N



50 Years of Growth, Innovation & Leadership

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Background and Company Performance

Industry Challenges

Arthroplasty is an orthopedic surgical procedure to “resurface” or replace damaged articular surfaces of musculoskeletal joints. It is an elective procedure that can be performed on any joint in the body, but is most commonly used to treat the damaged weight-bearing joints of the knee and the hip. Age, trauma, and diseases such as osteoarthritis and rheumatoid arthritis tend to wear down the cartilage at the interface of two bones, leading to pain, inflammation, and ineffective functioning of the joints. A suitably designed prosthetic implant replaces either the whole (total joint replacement) or a portion of the joint (partial or unicompartmental arthroplasty).

The family of joint replacement surgeries (knee, hip, wrist, ankle, shoulder, and spinal disk) is one of the fastest growing surgical segments. A nationwide study, conducted by Mayo Clinic, a nonprofit medical practice and research group, has found that over 7.2 million Americans have undergone hip or knee replacement procedures. The study reports that approximately one million joint procedures are performed every year in the United States alone. The Centers for Disease Control and Prevention has estimated that nearly one in every two Americans is likely to develop osteoarthritis in the knees, while one in four is likely to suffer from painful hip arthritis. These statistics, along with emerging trends such as population aging and the increasing incidence of obesity, underscore the growing importance of joint replacement surgeries.

The success of joint replacement surgeries depends on many factors, such as the surgical technique employed, implant design, and perhaps the most subjective of all, alignment of the implant. Optimal alignment of the implant with bones and soft tissues, such as tendons, ligaments, and muscles, is critical to restoring functionality and a full range of motion to the joint. Many orthopedic surgeons have listed implant instability and misalignment among the top reasons for the failure of an implant. According to the estimates of various clinical groups and government registries, between 7% and 36% of implant failures could be attributed to misalignment. A misaligned implant causes discomfort, pain, and incomplete recovery. Moreover, the cost of a revision surgery could be as high as \$25,000, and the recovery time could further burden the patient.

There has been a spate of innovations that have, at various times, been heralded as harbingers of disruption in arthroplasty and, indeed, in the entire orthopedic surgery space. However, each of these technologies, such as computer-assisted surgery (CAS), patient-specific surgical guides, and intra- and extra-medullary navigation guides, has its limitations. The error margins of navigation guides with respect to alignment accuracy have been found to be rather high. Similarly, CAS instruments, despite improved precision, are bulky devices that impede surgical workflow, lengthen the procedural time, and require millions of dollars in capital investment.

The need of the hour in the orthopedic surgery industry is the development of a portable, cost-effective, and surgeon-friendly alignment guide that improves surgical efficiency by ensuring the precise alignment of an implant.

Technology Attributes and Future Business Value

Industry Impact

OrthAlign Inc. (Aliso Viejo, California) has developed an alignment technology platform to aid surgeons during arthroplasty procedures. The technology has been incorporated into two navigation devices, KneeAlign® and OrthAlign Plus®, which are used in total knee and hip replacement procedures.

Building on a powerful and sensitive navigation platform, these products not only surpass conventional mechanical guides in performance, but also match the precision of CAS devices, which are widely accepted as the industry standard. OrthAlign deserves credit for successfully offering a single-use hand-held device without any capital investment as an alternative to the million-dollar, space-consuming CAS device. Development of these products marks an important milestone in the design of surgical navigation devices.

Product Impact

OrthAlign has designed its products with a view to addressing the key market requirements for portable, manageable, and user-friendly surgical navigation devices. The design combines the accuracy of the large console CAS equipment with the convenient form-factor and user-friendliness of conventional mechanical guides.

OrthAlign's products are elegantly designed, reflecting the company's advanced technology architecture. The devices dispense with visualization support that necessitates large processors and display modules. Instead, they incorporate cutting-edge navigation and missile guidance technologies that are usually the domain of aerospace and defense industries. OrthAlign's products leverage accelerometers and optical sensors to guide surgeons in accurately registering implants and obtaining feedback on implant alignment.

Scalability

KneeAlign® has received the 510(k) market clearance from the United States Food and Drug Administration (US FDA) for a single use of the device during total knee replacement surgeries. The device has the capability of combining tibial and femoral replacement navigation, and easily enables surgeons to locate the center of the femoral head. OrthAlign Plus®, on the other hand, is used for both knee and hip replacement procedures, and is expected to emerge as the company's flagship product. OrthAlign Plus® has received the US FDA clearance as well as the CE mark for clinical use in Europe.

The platform is robust, flexible and reproducible – all key characteristics of scalability. The *modus operandi* of the devices opens up possibilities for their use beyond knee and hip arthroplasty. Although OrthAlign remains focused on consolidating its market leadership in this area, it is cognizant of the far-reaching potential of its accelerometer-based, hand-held navigation devices both within and outside the domain of orthopedic surgery.

Visionary Innovation

The stated objective of OrthAlign has been to empower surgeons with cost-effective navigation products for precision in implant alignment. The company deserves credit for realizing this lofty goal with its game-changing innovation and product design. Its successful visionary innovation is underscored by the efficient performance of its products in various clinical studies.

Studies conducted by independent research groups have recorded that approximately 96% of patients had tibial alignment within two degrees of a neutral mechanical axis, compared to a meager 66% undergoing similar procedures using mechanical guides. In some cases, OrthAlign devices have even outperformed the highly efficient CAS devices in total knee replacement procedures.

Application Diversity

KneeAlign® offers navigation guidance to surgeons during total knee replacement procedures, while OrthAlign Plus® offers guidance during both hip and knee replacement procedures. The devices enable more than 18 niche applications and/or features during femur, tibia, and hip arthroscopy procedures. For example, the devices provide information on the flexion angle of the joint, knee stability, inclination angle, cup placement target, and so on. These devices also have the potential to further improve on their product features and expand the scope of their application.

Customer Acquisition

Within a remarkably short time span, OrthAlign has been successful in positioning its products as a cost-effective alternative to CAS devices without compromising on accuracy. In January 2015, OrthAlign celebrated the 25,000th clinical use of KneeAlign® in total knee replacement procedures. This represents a growth of more than 46%, far outstripping the industry's average growth rate. Since its inception, OrthAlign has raised more than \$20 million in venture capital funding. The most recent round was completed in November 2014, with OrthAlign securing a total funding of approximately \$15 million.

The rapid customer acquisition and the funding history underscore the value these devices have added to the surgical suite, amid global economic uncertainties and intense competition in the industry.

Conclusion

According to Frost & Sullivan's analysis, OrthAlign, Inc. has developed a best-in-class solution for implant alignment in arthroplasty procedures.

Frost & Sullivan joins leading orthopedic surgeons in commending OrthAlign's innovative product design. Its products, OrthAlign Plus® and KneeAlign®, elegantly package cutting-edge navigation and sensor technology platforms into palm-sized devices. The products seamlessly integrate into the surgeon's workflow, and meet and exceed all alignment benchmarks, while offering a price point that competing technologies would find difficult to match.

With its strong overall performance, OrthAlign, Inc. has earned Frost & Sullivan's 2015 Technology Innovation Award.

Significance of Technology Innovation

Ultimately, growth in any organization depends upon finding new ways to excite the market, and upon maintaining a long-term commitment to innovation. At its core, technology innovation or any other type of innovation can only be sustained with leadership in three key areas: understanding demand, nurturing the brand, and differentiating from the competition.



Understanding Technology Innovation

Technology innovation begins with a spark of creativity that is systematically pursued, developed, and commercialized. That spark can result from a successful partnership, a productive in-house innovation group, or the mind of a singular individual. Regardless of the source, the success of any new technology is ultimately determined by its innovativeness and its impact on the business as a whole.

Key Benchmarking Criteria

For the Technology Innovation Award, Frost & Sullivan analysts independently evaluated two key factors—Technology Attributes and Future Business Value—according to the criteria identified below.

Technology Attributes

- Criterion 1: Industry Impact
- Criterion 2: Product Impact
- Criterion 3: Scalability
- Criterion 4: Visionary Innovation
- Criterion 5: Application Diversity

Future Business Value

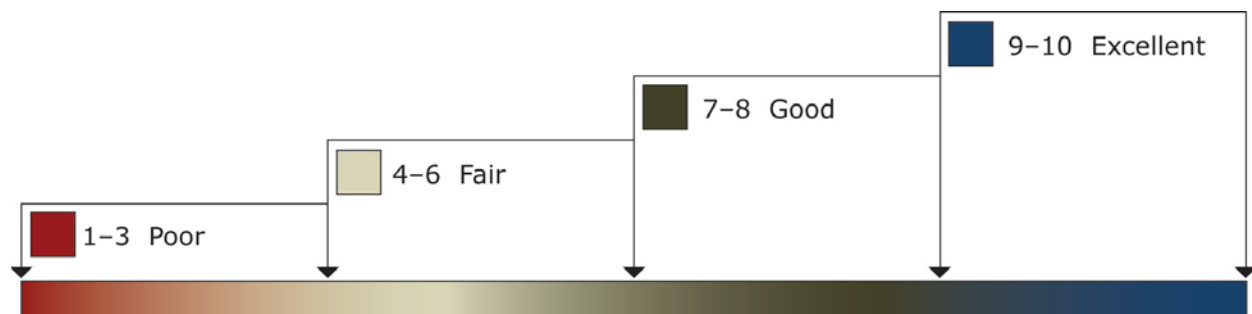
- Criterion 1: Financial Performance
- Criterion 2: Customer Acquisition
- Criterion 3: Technology Licensing
- Criterion 4: Brand Loyalty
- Criterion 5: Human Capital

Best Practice Award Analysis for OrthAlign, Inc.

Decision Support Scorecard

To support its evaluation of best practices across multiple business performance categories, Frost & Sullivan employs a customized Decision Support Scorecard. This tool allows our research and consulting teams to objectively analyze performance, according to the key benchmarking criteria listed in the previous section, and to assign ratings on that basis. The tool follows a 10-point scale that allows for nuances in performance evaluation; ratings guidelines are illustrated below.

RATINGS GUIDELINES



The Decision Support Scorecard is organized by Technology Attributes and Future Business Value (i.e., the overarching categories for all 10 benchmarking criteria; the definitions for each criteria are provided beneath the scorecard). The research team confirms the veracity of this weighted scorecard through sensitivity analysis, which confirms that small changes to the ratings for a specific criterion do not lead to a significant change in the overall relative rankings of the companies.

The results of this analysis are shown below. To remain unbiased and to protect the interests of all organizations reviewed, we have chosen to refer to the other key players as Competitor2 and Competitor3.

DECISION SUPPORT SCORECARD FOR TECHNOLOGY INNOVATION AWARD

<i>Measurement of 1–10 (1 = poor; 10 = excellent)</i>			
Technology Innovation	Technology Attributes	Future Business Value	Average Rating
OrthAlign, Inc.	9.5	9.5	9.5
Competitor 2	8.5	7.5	8.0
Competitor 3	8	7	7.5

Technology Attributes

Criterion 1: Industry Impact

Requirement: Technology enables the pursuit of groundbreaking new ideas, contributing to the betterment of the entire industry

Criterion 2: Product Impact

Requirement: Specific technology helps enhance features and functionality of the entire product line for the company

Criterion 3: Scalability

Requirement: Technology is scalable, enabling new generations of products over time, with increasing levels of quality and functionality

Criterion 4: Visionary Innovation

Requirement: Specific new technology represents true innovation based on a deep understanding of future needs and applications

Criterion 5: Application Diversity

Requirement: New technology serves multiple products, multiple applications, and multiple user environments

Future Business Value

Criterion 1: Financial Performance

Requirement: High potential for strong financial performance in terms of revenues, operating margins and other relevant financial metrics

Criterion 2: Customer Acquisition

Requirement: Specific technology enables acquisition of new customers, even as it enhances value to current customers

Criterion 3: Technology Licensing

Requirement: New technology displays great potential to be licensed across many sectors and applications, thereby driving incremental revenue streams

Criterion 4: Brand Loyalty

Requirement: New technology enhances the company’s brand, creating and/or nurturing brand loyalty

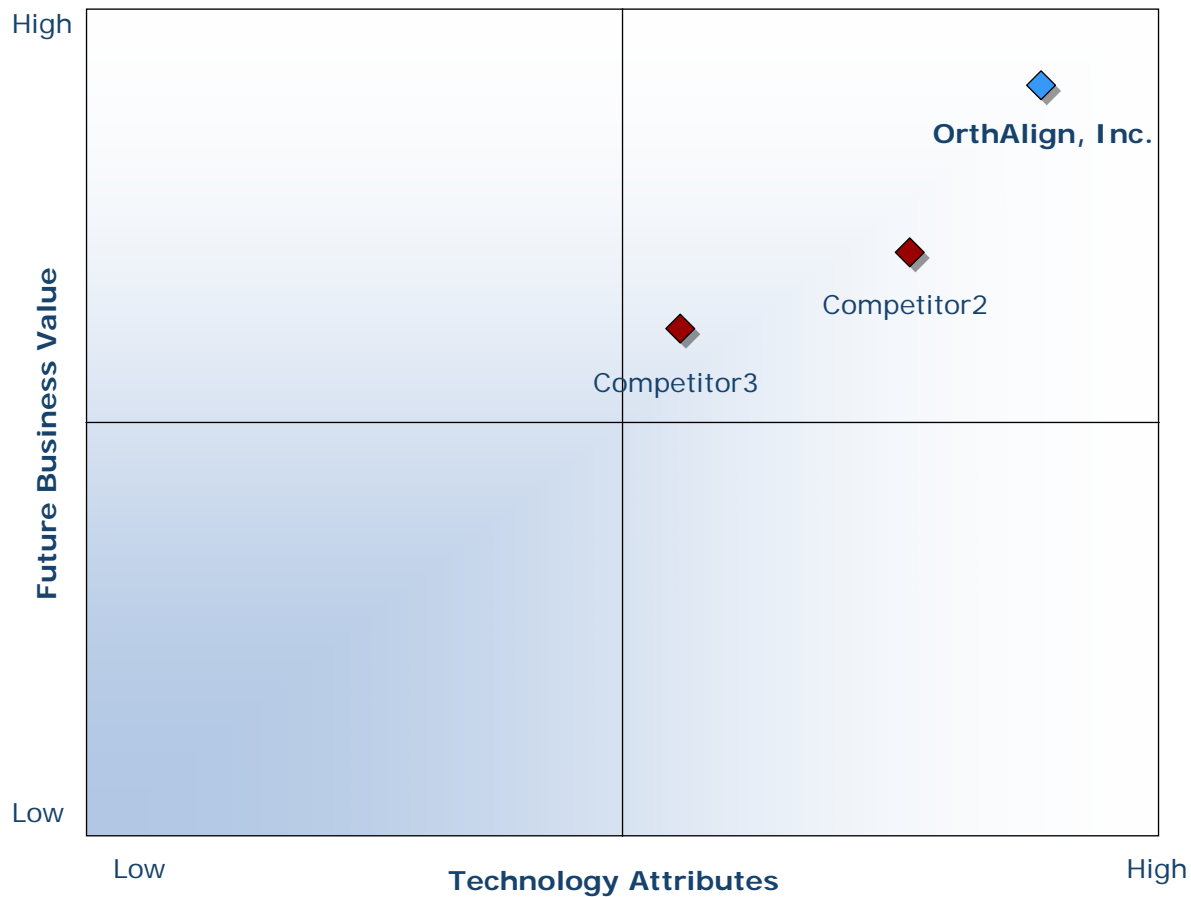
Criterion 5: Human Capital

Requirement: Customer impact is enhanced through the leverage of specific technology, translating into positive impact on employee morale and retention

Decision Support Matrix

Once all companies have been evaluated according to the Decision Support Scorecard, analysts can then position the candidates on the matrix shown below, enabling them to visualize which companies are truly breakthrough and which ones are not yet operating at best-in-class levels.

DECISION SUPPORTMATRIX FOR TECHNOLOGY INNOVATION AWARD



The Intersection between 360-Degree Research and Best Practices Awards

Research Methodology

Frost & Sullivan’s 360-degree research methodology represents the analytical rigor of our research process. It offers a 360-degree-view of industry challenges, trends, and issues by integrating all 7 of Frost & Sullivan’s research methodologies. Too often, companies make important growth decisions based on a narrow understanding of their environment, leading to errors of both omission and commission. Successful growth strategies are founded on a thorough understanding of market, technical, economic, financial, customer, best practices, and demographic analyses. The integration of these research disciplines into the 360-degree research methodology provides an evaluation platform for benchmarking industry players and for identifying those performing at best-in-class levels.

360-DEGREE RESEARCH: SEEING ORDER IN THE CHAOS



Best Practices Recognition: 10 Steps to Researching, Identifying, and Recognizing Best Practices

Frost & Sullivan Awards follow a 10-step process to evaluate award candidates and assess their fit with select best practice criteria. The reputation and integrity of the Awards are based on close adherence to this process.

STEP	OBJECTIVE	KEY ACTIVITIES	OUTPUT
1 Monitor, target, and screen	Identify award recipient candidates from around the globe	<ul style="list-style-type: none"> • Conduct in-depth industry research • Identify emerging sectors • Scan multiple geographies 	Pipeline of candidates who potentially meet all best-practice criteria
2 Perform 360-degree research	Perform comprehensive, 360-degree research on all candidates in the pipeline	<ul style="list-style-type: none"> • Interview thought leaders and industry practitioners • Assess candidates' fit with best-practice criteria • Rank all candidates 	Matrix positioning all candidates' performance relative to one another
3 Invite thought leadership in best practices	Perform in-depth examination of all candidates	<ul style="list-style-type: none"> • Confirm best-practice criteria • Examine eligibility of all candidates • Identify any information gaps 	Detailed profiles of all ranked candidates
4 Initiate research director review	Conduct an unbiased evaluation of all candidate profiles	<ul style="list-style-type: none"> • Brainstorm ranking options • Invite multiple perspectives on candidates' performance • Update candidate profiles 	Final prioritization of all eligible candidates and companion best-practice positioning paper
5 Assemble panel of industry experts	Present findings to an expert panel of industry thought leaders	<ul style="list-style-type: none"> • Share findings • Strengthen cases for candidate eligibility • Prioritize candidates 	Refined list of prioritized award candidates
6 Conduct global industry review	Build consensus on award candidates' eligibility	<ul style="list-style-type: none"> • Hold global team meeting to review all candidates • Pressure-test fit with criteria • Confirm inclusion of all eligible candidates 	Final list of eligible award candidates, representing success stories worldwide
7 Perform quality check	Develop official award consideration materials	<ul style="list-style-type: none"> • Perform final performance benchmarking activities • Write nominations • Perform quality review 	High-quality, accurate, and creative presentation of nominees' successes
8 Reconnect with panel of industry experts	Finalize the selection of the best-practice award recipient	<ul style="list-style-type: none"> • Review analysis with panel • Build consensus • Select winner 	Decision on which company performs best against all best-practice criteria
9 Communicate recognition	Inform award recipient of award recognition	<ul style="list-style-type: none"> • Present award to the CEO • Inspire the organization for continued success • Celebrate the recipient's performance 	Announcement of award and plan for how recipient can use the award to enhance the brand
10 Take strategic action	Upon licensing, company may share award news with stakeholders and customers	<ul style="list-style-type: none"> • Coordinate media outreach • Design a marketing plan • Assess award's role in future strategic planning 	Widespread awareness of recipient's award status among investors, media personnel, and employees

About Frost & Sullivan

Frost & Sullivan, the Growth Partnership Company, enables clients to accelerate growth and achieve best in class positions in growth, innovation and leadership. The company's Growth Partnership Service provides the CEO and the CEO's Growth Team with disciplined research and best practice models to drive the generation, evaluation and implementation of powerful growth strategies. Frost & Sullivan leverages over 50 years of experience in partnering with Global 1000 companies, emerging businesses and the investment community from 31 offices on six continents. To join our Growth Partnership, please visit <http://www.frost.com>.