



Towards a Set Up of National Registries In Asia-Pacific Countries Upon Orthopaedic Implants Within The Aegis Of APAC-Med: The OrthoWave Proposal

Jean-Alain Epinette M.D.

jae@orthowave.net

1 - Background

Health care and its many complexities are changing weekly, if not daily all over the world, and in particular in Asia and Pacific countries. As a moving target, each National health care system and what it will be in 2 years or 10 years is difficult to predict based upon a number of variables, the vast majority over which we have little control. However, one underlying theme has and always will be constant in medicine: the need to understand if our treatments, both surgical and non-surgical, actually work. And, if they do not, we must ask, "Why not?". Providing answers makes not only scientific sense but pragmatic and economic sense as well. Answering this question meaningfully with respect to specific treatments is the crux of the matter; the proper application of software, hardware, and relational databases when properly designed and understood by its users can help us in evaluating complex issues surrounding the answers to this critical question.

The mission of [APACMed](#) is to improve the standards of care through innovative collaborations among stakeholders to jointly shape the future of healthcare in Asia Pacific. Based upon this very enthusiastic means of "shaping the future of healthcare", we would like to introduce our computerized outcomes studies tool, the OrthoWave™ on line software suite (ARIA Ltd, Houdain, France) which would be able after 20 years of successful use in Europe, to bring a consistent, proven, and efficient mechanism to the Asia-Pacific countries in an attempt to harness the complexities of outcomes research by focusing on orthopaedic implants placed in extremities of patients at a rate and volume known to no other registry in the world.

This OrthoWave project seems to us on perfect line with the APACMed Business Focus and could at best, through effective partnerships with any organization or companies based in Asia and/or Pacific countries, meet the expectation of APAC upon initiatives and activities addressing the needs of the diverse healthcare markets in the region relating to access, innovation and collaboration: In such a way, these partnerships would improve access to high quality healthcare for patients in need by working in close collaboration with regulators, policy makers, healthcare providers, payers and patients to develop and propose policies that ensure effective and efficient courses of treatment within the area of orthopaedic implants. This innovative outcome study tool, which could easily get extended to other areas of surgical treatments or medicine, would help to promote a cost-effective, value-based approach

to healthcare in Asia Pacific by showing the socio-economic weight of innovative medical technology that improves healthcare outcomes and quality of care. Such an initiative could be of value to raise one of the goal of APAC, i.e. developing new and unified solutions to meet the demands of the diverse and complex healthcare markets in Asia Pacific and provide a platform for knowledge exchange.



2- Up for the challenge

Our global APAC registry project is leveraging Software as a Service (SaaS) in the delivery of an orthopaedic outcomes-based software application, i.e. OrthoWave™, to facilitate the development of Asia-Pacific registries, be they simply epidemiologic or fully observational. OrthoWave™ (OW) is a software suite built on a relational database, providing end-user client applications and storage analysis tools. The software has been developed by surgeons for surgeons for the evaluation of joint arthroplasty, and represents a mature, refined, and widely used system in Europe for this particular purpose, summing a huge on line (cloud computing) observational database of more than 200,000 hip and knee prostheses, fed by more than 1000 orthopaedic surgeons to date including the so-called “regular databases OW-RDB”, as well as “scientific databases OW-SDB” and “monitored databases OW-MDB”.

As outlined below, our OrthoWave organization plans to participate with the leading orthopaedic joint replacement outcome research centers in the Asia and/or Pacific countries in the development of the registries and offer OW to orthopaedic surgeons to facilitate the collection of outcomes data. This on line study tool would thus offer a tested, affordable, easy-to-use, and robust relational database to collect and manage arthroplasty outcomes in real-time, allowing orthopaedic surgeons and researchers to draw meaningful and timely scientific and economic conclusions. These conclusions will lead to improved patient care, research, regulation, and standards. Healthcare Cost savings will, in turn, be secured due to improved data analyses that lead to the use of the best implants, reducing the number of unnecessary or revision surgeries.

The establishment of such registries sponsored by the APAC partners will result in orthopaedic surgeons - getting involved in related countries - being strongly encouraged or required to report the outcomes of their arthroplasties. The data to be collected by the registries will provide critical information to practitioners, regulatory bodies, insurance carriers, manufacturers, and patients. To this date, attempts to establish national registries have often failed in many countries. The failures have been attributed to

variety of reasons, all related to the size and complexity of the market, and that healthcare software providers lacked adequate outcomes knowledge, resulting in poorly designed databases and a wide spectrum of (mostly in-house developed) software to collect, transmit, query and analyze the data. The OrthoWave organization offers a unique opportunity to assist APAC in the development of Asia-Pacific outcomes registries and to provide surgeons and researchers with a tool to collect and transmit data to the registries with a tried and tested system that has undergone 20 years of continuous development, refinement and use across lots of institutions spanning various continents.

Knowledge and experience is power and secures more effectiveness, particularly in the field of outcomes research. The OrthoWave team, which includes Dr. Jean-Alain Epinette, a renowned hip and knee replacement surgeon from France and creator of OrthoWave™, possesses a critical working knowledge of the successful European registries. Dr. Epinette has been a leader in technical innovations for gathering, feeding, retrieving and analyzing data with respect to such registries through the world-leading software package that he and his team from France have created.

3 – What's next?

The OrthoWave software suite is owned by the ARIA Ltd company, which aims to settle any partnership directly with any organization or sub-organization belonging to APAC, or alternately with any CRO or Medical/Computer company which would be interested in the project, within the aegis of APAC or aside.

The OrthoWave Global Organization (OWGO) would help to contact the leading centers which have been identified as likely applicants for the APAC registries. Aside this global APAC registry project, OrthoWave and its partners in ASIA/PACIFIC will tend to approach a newly-created orthopaedic outcomes data gathering market. The primary goal will be to market the OW facilities to organizations and practitioners as a SaaS (Software as a service) offering. The SaaS model will minimize upfront investment costs for hardware and software, minimize ongoing costs for technology personnel to manage the system in-house, and provide access to the latest software version at all times, thus offering to practitioners consistent ease of use, minimal upfront software and hardware investments, and superior trend reporting.

OWGO will provide implementation, data collection, and training services to practitioners acquiring OW as a SaaS or in-house solution. The OrthoWave team would in addition offer consulting services to these applicants to assist in the design of any new development by leveraging the knowledge of the already functioning registries and software suites, especially in the field of related health data compliance requirements. OWGO will help bridge potential communication, time zone and business management issues, as well as the logistics of assisting the French software development team, while ensuring that the software for the APAC registries has a familiar 'look and feel' to users, a fully competent commissioning, maintenance and support base, and a highly competitive cost/price.

Strategic alliances will be a significant component of the OWGO approach to sharing the ASIA-PACIFIC market, while establishing relationships with key healthcare software providers. In addition to practitioner access, these large software providers have systems that OrthoWave may need to interface

with to transfer data to OW and then to any newly created or existing registry. OWGO will direct alliance efforts at those organizations with the most significant market penetration or promise of such penetration in orthopaedic surgery. In addition, OWGO would also explore potential relationships with any direct software competitors, should they arise and show promise.

In order to help ensuring a close cooperation at the time the project gets started as well as in the view of future developments and maintenance, The OrthoWave team naturally envisions any future contact and/or visit to the APAC organization, upon mutual interest in such a plan. One member of our OWGO team comes from international business with a Major in Finances (Regents, London UK) and speaks fluently French, English and Chinese (Mandarin). He would stay permanently in Singapore or in any other location in Asian countries in order to help keeping the project on the rails at any time, whilst offering a constant link with our French organization.



Welcome to OrthoWave

The Ultimate Tool for Outcome Studies in Orthopaedics

OrthoWave V6™

the ultimate tool for Outcomes Studies in Orthopaedics

www.orthowave.net

Designed by Surgeons for Surgeons, for Clinical Follow-up and Evaluation of Joint Arthroplasty in Orthopaedics

This software suite allows at best for friendly collection and management of any clinical or radiological data, images or videos, and offers a broad range of statistical analyses, secured storage and graphic enhancement of images and x-rays.

This multilingual software can be regarded as the most advanced tool for 'on real time' follow-up and evaluation in Arthroplasty.

Main Features of OrthoWave™



Follow your patients

OrthoWave is a medical scientific software devoted to Clinical Research in Orthopaedics, and namely evaluation of results in Joint Arthroplasty...Evaluation has become a Master Word in the realm of Orthopaedic Surgery, which gets many actors involved in a huge challenge, be they Surgeons, Scientific Societies, Health Department Authorities, Journal Editors, and Orthopaedic Devices Manufacturer. The OrthoWave V6 software Suite, has been designed by Surgeons for Surgeons as the most competitive outcomes studies tool in Orthopaedics.

Manage your Data

OrthoWave™ V6 enables friendly Data Collection through easy windows, with logical and hierarchic layout of fields and buttons. Data entry, facilitated by drop down lists, pre-designed items and short cuts, can be done either directly or through any optical reader gear. All items inputted in a specific language, are automatically translated into any other selected language, to allow international multi center studies... V6 provides one form per patient, and a sub-form per prosthetic component, which is mandatory for partial revision surgery to build in consistent survivorship analyses. Multicriteria Search engine allows for any kind of selection and sub-selection of criteria, including the self-customized items created by Users themselves.



Insert your x-rays and videos

Get images being automatically linked to related Patient forms has been an outstanding progress by OrthoWave™ ...From the Patient form, simply click on any image stored anywhere on a hard disk, be it a radiograph or a colored picture, to get it instantaneously added to all other records of the given Patient. This image can be defined by key words, for easy search, and eventually scaled, modified and enhanced through the PictIn graphic module that allows for direct on-screen measurements.

Draw up your Statistics

All statistics directly available... Any data, be they continuous or categorical, from either the Hip or Knee databases, or other modules, are directly linked to StatWave™, as the statistical module of OrthoWave™. Descriptive statistics (1 single variable), Group Comparisons (A single variable analyzed in two different cohorts), Cross Correlations (2 variables in the same cohort), Survival Analyses (one cohort or comparison between 2 cohorts), or again Map of Radiographic Patterns can be performed upon the whole population, or through a multicriteria selection of samples. For each analysis, tables and charts are displayed upon various modes. The User can get the choice of reformatting the various tables.



Take advantage of the network

Even if some Surgeons classically prefer a 'solo work' option on their own database, while being a bit cautious about the Internet, it becomes obvious that Surgeons will more and more agree that sharing their database with others is a fantastic opportunity, or simply being able to work on their own database with no limits at OR, at office, at home, or elsewhere...

Publish your Clinical Series

Publishing is the logical aim of any evaluation... OrthoWave™ allows to efficiently participate in the life of our Orthopaedic Community by offering a complete tool for preparing reports on Orthopaedic matters. Since it is always frustrating to spend a lot of time for years to feed the computer, without getting any investment back while trying to dig out the results at the end of the day, OrthoWave™ provides, as a single and complete software suite, direct access to clinical data, evaluations, complications, images, statistics, and thus makes studies to be carried out easy and immediately available without the help of any computer specialist...



[More on the OrthoWave Web site !](#)

OrthoWave™: A huge scientific background

Context

The proposed improvement work has been carried out by the Center of Research and Imaging Center in Arthroplasty as a computer department of ARIA (Houdain, France), led by Jean-Alain Epinette, an Orthopaedic Surgeon, in order to provide the Orthopaedic Community with a valuable outcome study tool fully devoted to the computerized clinical follow-up of Joint Arthroplasty, named OrthoWave¹. The development of the OrthoWave™ suite, since 1996, has got involved clinical studies coordinators, software engineers, orthopaedic surgeons, and statisticians.



Problem

Health care and its many complexities have become a critical concern and a moving target, difficult to predict as based upon a tremendous number of variables, the vast majority of which we have little control. However, one underlying theme has and always will be constant in Medicine: the need to understand if our treatments, both surgical and non-surgical, actually work. Providing answers makes not only scientific sense but pragmatic and economic sense as well. Answering this question meaningfully with respect to specific treatments is a crucial matter. The proper application of software, hardware and relational computerized databases when properly designed and understood by its users can help in evaluating complex issues surrounding the answers to this critical point, and as a main concern, offer better treatments to patients. In such a way, Evaluation has become a master word in the realm of Orthopaedic Surgery, which thus gets many actors involved in a huge challenge, be they Surgeons, Scientific Societies, Health Department Authorities, Journal Editors, and Orthopaedic Devices Manufacturer. As a result, using OrthoWave™ makes clinical data capture quick, yet accurate, and allows the user to better follow patient outcomes and perform complex statistical analyses and comparisons of treatments.

Assessment of problem and analysis of its causes

While bearing in mind that more than a million of Hip and Knee replacements are worldly performed annually and there are thousands of devices and device combinations in use to achieve arthroplasties and repair procedures, these replacement procedures have to be properly evaluated. A computerized outcomes study software needs to allow for easy and user friendly collection of clinical data and related images, upon on-line highly secured Internet web-based procedures to allow for multicenter studies and connection to Joint registries, while preserving privacy of patients and their personal data. Then statistical analyzes affording any type of descriptive statistics, cross correlations and comparisons between results of various clinical series, as well as precise tracking of radiographic changes and survivorship analyzes, being said that survey of implanted prostheses is a huge challenge as a long period of time, generally 10 to 15 years, is needed to assess significant differences between beneficial improvement afforded by a given implant. In addition, such a software suite must follow specific needs as to follow the FDA recommendations, including audit trail, highly secured hosting, personal check and versatility. The

¹ Epinette J.A ; Outcome Studies in Hip and Knee Arthroplasty: A 14-Year Experience With the Ortho Wave Software Suite; http://www.bijprocs.boneandjoint.org.uk/content/94-B/SUPP_XXV/63.abstract

OrthoWave software has been widely used in Europe, and in other countries as Australia, firstly under the off line V5 version, and currently with the on-line Version 6, which has been released 4 years ago, and now available as a web-based secured "cloud computing" computer system.

Measurement of improvement

This outcomes studies software allows for addressing improvement in assessing arthroplasty results which are of interest for Surgeons themselves, who need to evaluate themselves, for Governments and third-party payers who are in charge of financially support the costs of implants, for Industry which has to make sure potential improvements in their implants can be confirmed clinically, and above all by Patients themselves who more and more keep involved in the treatment they receive. Roughly speaking, OrthoWave addresses (1) data collection of surgeons themselves, able to self-evaluate their surgeries and awning their own data, (2) Local Registries, involving groups of Surgeons, to analyze clinical series, report preclinical findings and publish in the Literature about their results and conclusions, (3) Brand Registries, allowing for tracking upon large multicenter studies at an early stage any problem that might occur with any given implant, and thus prevent for any huge disaster with poorly designed prostheses or surgical technique, (4) and finally enabling each surgeons to get automatically connected with the national and International Joint Registries.

Effects of changes


Assessment of outcomes in Joint arthroplasty is a huge task, being said that epidemiology cannot properly embrace such a complex status, including fate of complications, social, economic and other factors associated with the long term functioning, as well as quality of life and other patient reported outcomes of various hip and knee implants. This OrthoWave software has permitted a "fine tuning" of clinical results, radiographic findings, survival rates and real assessment of quality of life. Some implants have been abandoned while affording excellent survival rates, thanks to tis software suite, which has highlighted some side problems as an unacceptable rate of dislocation, pain caused by stress shielding among the supporting bone, or again higher rate of adverse effects as osteolytic lesions. In addition, some improvements proposed by engineers based upon in vitro tests or biomechanics hypotheses has not been followed by significant benefits according to the precise follow-up afforded by this outcome software. Last but not least, self-generated links to existing National registries allows upon a single entry data procedure to both evaluate and check complex findings about the follow-up of patients, and participate in global registries. In such a way, best conditions are provided to link evaluation and epidemiology at once, helping to determine if implant composition or joint replacement features can be associated with decreased need for repeat surgery, mortality and other relevant outcomes in the elderly. In addition, OrthoWave allowed us to study determinants of joint replacement failure in large databases studies and to report the best methodological approaches to the assessment of failures in arthroplasty, as well as consequences of these failures in terms of functioning, quality of life and long-term disability.

Lessons learnt

Evaluation of Joint implants becomes more and more a priority. All along these almost 20 years of continuous use of this OrthoWave software suite, we have tried to help it to be more and more efficient and user friendly. A standalone computer system is no longer appropriate since the on-line solutions allow nowadays for reliable, secured and efficient global huge multicenter studies, while preserving the patient privacy and selecting the data to be shared or not. As a matter of fact, the secure servers of OrthoWave are hosting more than 200,000 hip and knee prostheses from more than one thousands of registered surgeons mainly in Europe but also in Australia and Latin America. The current version now meets our expectation, and is flexible enough to adapt itself to future needs and better treatments for patients all over the world and we aim this outcome study tool to get well known and widely used in Asian and Pacific countries, including of course China, South Korea, Japan, and India as well.

Message for others


(1) Orthopaedic Surgeons cannot skip evaluating their treatments and especially their results in arthroplasty, this has become an absolute priority, (2) In that matter, one must learn to waste a little amount of time at record of data, in order to save a big amount of time at reporting results and findings. (3) As a matter of fact, evaluation of joint implants is a very complex procedure and the needed computer system has to be very professional, designed by surgeons for surgeons, as OrthoWave has been conceived from the very beginning while offering soon 20 years of continuous expertise.



ORTHOWAVE V6

The Ultimate tool for Outcomes Studies in Orthopaedics

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OrthoWave™ is worldwide distributed by ARIA Ltd

The OrthoWave™ V6 Software Suite has been designed by Surgeons for Surgeons as the absolute reference in Evaluation of Joint Arthroplasty

Clinical Outcomes
in Hip and Knee Arthroplasty,
supported
by Orthopaedic Surgeons

Arthroplasty results
and statistical analyses
available in all major
published scores

Internet-based
on line data capture,
including x-rays, images,
videos...

Certified
data storage and
absolute protection
of privacy

High level
of item customization,
evaluations, and
image management

Tailored for any
personal evaluation,
multicenter studies and
connection to Registries

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