Approach Study to a Model of Integration Technologies for Ideation of Customized Implants

Clara I. López, Edna Bravo, Juan Carlos Moreno, and Luis Eduardo Bautista
Universidad Industrial de Santander, Bucaramanga, Colombia
Email: clara.lopez@correo.uis.edu.co, erbravoi@uis.edu.co, fedor@uis.edu.co, luis.bautista@correo.uis.edu.co

***Abstract*—The main purpose of this research is formulating an integration of technologies model for design and evaluation implants, from the technological innovation management approach. The relevance of reverse engineering integration in design and evaluation method of customized and standards implants were valued. The process requirements were obtained by: unstructured literature review on implant design topics and the design process at present used in QE Company. Subsequently, a model of technology integration, with several interoperability flows, between Bio-CAD, CAD and CAE software, based on requirements was proposed. Results were analyzed using ANOVA to establish significant differences arising from integration model. Finally, a workflow to design and evaluation of more efficient implants, based on requirements to evaluation, skills and development time, was proposed.**

***Keywords*—Bio-CAD, CAD, CAE, implants, technologies integration, reverse engineering**

I. Introduction

The last twenty years have seen an increase in research activities and technological development in orthopedic, implants and biomedical field[1], due to the frequency of occurrence of fractures and tooth loss. In related researches, over 70% of fractures and trauma cases, generated by muscle-skeletal injuries are treated through surgical reduction using insertion of orthopedic implants, mainly type plates and screws. [2]. Moreover, in implants field, a prosthetic element known as a dental implant is used to replace cases of dental losses.

Derived from orthopedics studies, highlighted in literature research on orthopedic and dental customized implants or specific patient implant [2]. In consensus, customized implants are designed to be adapted at geometry and bone density, and ensure proper adjustment and bone fixing, according fracture kind to reduce. [3]. This is possible due advances and integration of software technologies, allowing generating new design methods based on inclusion of image technics and Reverse Engineering RE, in an environment called by some authors as Bio-CAD software [4] or CAD (Computer Aided Design) Systems [5].

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Reverse engineering software has been developed to convert tomographic images of living tissues on 3D virtual models to be used as benchmarks in design of devices and implants. Models resulting from this technology use, have been integrated to other CAD software tools, CAE (Computer Aided Engineering) and RP (Rapid Prototyping) to improve the design process of customized implants, facilitating the implants design with adjust to skull bone tissue, face, jaw, hip and femur [6] [7] [8].

Studies have been developed to integrate these technologies into the design of hip prostheses [9], design and validation of lower limb prostheses [4], validating implant materials structures [5], characterization and evaluation of new materials to skull custom implants [6], design and evaluation of dental implants, to implant geometry comparison [7], algorithms formulation to bone implant interface evaluation [8], development of computational tools to tissue reconstruction [9], surgical planning, among other [10].

Consensus about importance of integrating Bio-CAD software in the development of custom products in specific cases is evidenced on several studies [11]. However, incorporate CAD CAE RP workflow packages in design process requires investment on infrastructure, computational resources, human talent with scientific and technological skills and others [12]. Now integrate the Bio-CAD in this one workflow for apply to bone reconstruction, implant design and biomechanical evaluation, this involves invest more resources to development of skills in the use of advanced software tools, to prevent an excessive time on bone volume reconstruction. Moreover, the requirements identified that in addition to assessment of biomechanical behavior, it is required to perform comparative evaluations through simulations used to materials selection and implants geometries. Furthermore, it is possible to omit the use of virtual bone models for conducting the last two analyses.

From technology management approach, in the present paper aims to establish an integration of technologies, conducted to generate specific workflows based on requirements from design and evaluation implants, focused on get the design and the prototype under a sustainable service development of custom implants. The relevance of integration of Bio-CAD or CAD systems

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software in implants design process was analyzed, based on: Identification of implants design requirements, the complexity of study case and results that will be evaluated and compared. From this analysis, possible models of workflow were proposed, and it was subsequently tested. The results allowed understanding the relevance of RE integration in technology integration model, based on requirements for assessment of bone interface behavior, materials and geometry strength.

In this work, a non-structured literature review was conducted to identify the technologies used in design and mechanical evaluation of implants. Subsequently, requirements for design and evaluation of implants were defined. These requirements were basis to developing and implementing models of technology integration. The main results were analyzed using ANOVA, establishing the existence of statistically significant differences between the models of technology integration. This research was conducted to establish relevance the integration of RE-based methods and their application in design customized implants.

II. Literature Review

A non-structured literature review was made, based on topics and concepts identified, this review allowed data collection and information analysis related with integration of technologies used to develop a method to implants design of patient specific. In a preliminary review topics were identified such as: [13], software tools [14], product development [15], design and geometry of implants [16]; after, other topics were identified such as: Reverse Engineering (RE), Computer Tomography (CT) and imaging technique [17]; biomechanics, simulation and finite analysis method FEM [18] Rapid Prototyping (RP) [19] and biomaterials [20]. Then, relevant concepts about implants, integration of technologies, and software tools for implants design were described.

A. Implants

Dental implants are used to replace the tooth root and support the prosthesis [21]; These implants, are made by Companies like Nobel Biocare™ and Bicom™, among others, their implants are made with standards geometries. The orthopedics implants are components designed to reduce and adjust the fracture of any kind of bone tissue as plane, large and short [22]. The implants are made under ASTM Standard. However, some cases the implants are not adapted to specific patient needs or cannot be adapted, by high development costs, arising from additional implant adaptations [23].

The specific patient implant concept is evidenced since 1996, research on implants for hip replacement that is manifested in need for adaptation and customizing implants [24]; then, since 1998 the first cases about specific patient implants for skull were developed [25]. These kind of implants are custom devices based on specific patient requirements [26]. This concept has promoted to develop new techniques of design, integrating RE to reconstruction of bone tissue in 3D model, to technique enhance for implant design. The main effects are, reduce patient recovery time and overall cost of treatment [27]. Nevertheless, the customizing important factor of this kind of device is to minimize development time, thus it is necessary obtains an accurate shape. For this reason, researchers has proposed RE integration using software such as Mimic's®, to reconstruct 3D model of bone tissue used to enhance the design process.

B. Integration of Technologies

Yang y Cols. [28] propose integration of technologies as mechanisms to attaching or exchange independent systems that interoperate, and promote results optimization, automation and reduce of process time [29]. The integration is characterized by the compatibility, the interoperability and design process automation. The data structure compatibility providing the experience on use of technologies and to establish a better user-software interface; interoperability on design process and technology required, allowing a flow in the methodology process [27]; automation of design process to expedite response to operation changes, accuracy, quality and shortening ideation and verification of developed implant. [30]. Chandrasegaran proposes the architecture based on integration of specific interoperable software tools [13].

C. Software Technology to Implant Design

The first research about specific patient implant design, the use of the Tomographic to tissue bone 3D model reconstruction, implant design CAD, it was realized to generate tomographic edges and CAE analysis to evaluate of biomechanical implant bone interface behavior [24][23]. The last years, RE has generated a conceptual change related to new product development to implant design; actually has been development software tools to objects reconstruction that are used as reference to propose new products and applications [31]. The main effect of imaging techniques integration is related with RE integration into method used to implant design compared to other products design methods to obtain standard implants [13], this, has made it possible to obtain 3D virtual models of tissues with high precision, according to kind of fracture to reduce [3].

Some authors are agreeing about phases of design and evaluation; however the integration of technologies remains continuously updated. Heissler, obtained CT transverse to 3D reconstruction on CAD software, also design an implant using edge method with close adjust; and obtain an model by stereo-lithography used for cast Titanium implant manufacturing [25]. Rotaru used the pre-and post-operative CT to verify quality implant, later an 3D modeling was performed to RP used to construct a plaster mold, finally an implant in PMMA was manufactured [16]. At University of Campinas, a research group developed a RE Open Source software for 3D reconstruction known as InVesalius®. The last one was used to reconstruct of an individual cranial implant bulky on PMMA and then was printed from a rapid prototype (RP)[29]. Lantada explains the importance of integrate the framework about CAD CAE CAM package for

product development, into the academy and industrial field to be more competitive [12].

According with cases reviewed, first stage method begins with image reconstruction of bone tissue in a 3D virtual model [31], followed by a stage of implant design and modeling conducted in CAD Software [17]; In a next stage, implant model adapted to bone geometry must be evaluated through mechanicals tests in a CAE Software [30]; some design methods, including a model display stage, become a physical model obtained using the technique of rapid prototyping [19].

III. METODOLOGY

In this section, experimental development is described, based on technologies integration for virtual design and simulation. Based on this methodology, results analysis and the discussion about experience were made, contrasted in according with literature identified.

Using the integration technology model and software requirements, workflows are proposed to establish relevance of reverse engineering software integration in design implants method. Based on previous work, it is established, a stages reduction and thus number of operations to design and evaluation, depending on requirements, technological complexity of scientific study, and scope of evaluation results. Therefore, the following assumption was formulated: Inclusion of virtual bone models in simulations, is necessary when it ś want to know the biomechanical behavior at implant bone interface and is not significant for analyzes are conducted to compare geometries or materials because the simulation results do not change its trend.

The study case was the design of an implant and the analysis by a static load of insertion torque, with 35 N/cm value. Evaluation requirements were defined, establishing three types of analysis: first, evaluate biomechanical behavior of bone-implant interface; second, implant geometries comparison; and third requirement was to evaluation comparative of two titanium alloy, Ti6Al4V and TiNbZr. Table I, summarizes three studies proposed; the technologies integration formulated according to each study with their workflows, skills required for study development and results comparison of integration changing effect.

TABLE I. EVALUATION MODELS BASED ON IMPLANT REQUIREMENTS

Integration of technology		Work flow	Knowledge requirements
I1	Bio-CAD CAD CAE	1. Reconstruction in 3D bone model 2. implant 1 modeled (Ti6Al4V) 3. Integration 4. Evaluation by finite element	Reverse engineering 3-Level basic and vanced draw. -Advanced knowledge echanical engineering
I2	CAD- CAE	1. bone modeled 2. integration bone modeled-implant 1 3. simulation implant-bone interface	2-Level basic and vanced draw. knowledge to mechanical engineering
V1	Comparison between I1 and I2		
I3	CAD CAE	1-Implant 2 modeled (Ti6Al4V) 2- simulation implant 1 y 2	Level basic and medium aw. -Knowledge to mechanical engineering
V2	Comparison between I3 and I1		
I4	CAD CAE	-changes of material of mplant 1 (TiNbZr) 2-Simulation to implant 1 Ti6Al4V) and implant 1 TiNbZr)	Level basic and mediu aw. knowledge to mechanical engineering
V3	Comparison between I4, and I1		
Output variable: Comparison strains between implants and interface bone			

I1 and I2- Evaluation of bone-implant interface behavior
I3 Evaluation of implant geometries.
I4 Evaluation of Ti6Al4V and TiNbZr materials

According to first requirement, using two kinds of integration technologies I1, BioCAD / CAD / CAE was proposed. Software to reconstruction and bone modeling, implant modeling, as well as for virtual integration on simulation and evaluation models were chosen. In another parallel integration of I2 technologies, based on CAD / CAE was proposed, the bone and implant were modeled and integrated into same CAD software and were subsequently evaluated using simulations.

In second analysis type (I3), based on assessment requirement implant geometry, CAD / CAE integration was proposed; the study started from modeling of two implants, to compare simulation results; results were also compared with I1, to identify possible turning points of stress-strain mechanical behavior of implant.

Third type analysis I4 based on assessment requirement and TiNbZr Ti6Al4V materials; CAD / CAE proposed an integration used on geometry implant, same load type is applied to other analysis and two simulations were performed once with each implant material. This comparative study was again conducted in model integration technologies Bio-CAD / CAD / CAE, to know, if efforts and deformations on implant unit followed the same trend.

IV. RESULTS

Then, results of the experimental analysis, based on models verification of technologies integration for design and evaluation of implants are described. In Table I, information was structured from left to right, identifying four models of technology integration I1, I2, I3 and I4. In the next column, evaluation requirements were identified for analysis by simulation; next to column by the response variable Strain (m/m), in which values obtained from each strain simulation were recorded.

Finally, the each stage time was registered, that is, the I1 integration model time of the three stages was defined by: 3D bone virtual model reconstruction, the implant modeling and evaluation of bone-implant interface. According to results, the I1 integration model required more development time with an estimated 24 hours, equivalent of 3 working days approximately. Moreover, the integration model I3, where requirements evaluations

were based on geometry comparison, obtained 8 hours as an estimated time. Likewise, the I4 model, where evaluation was based on materials comparison, development time was 4 hours. The last models with faster development time. A strong correlation of 0.951 was found between the developments stages defined in integration models based on total time of process development.

TABLE II. RESULTS OF DEPENDENT VARIABLES AS INTEGRATION MODELS DEVELOPED

IT Model	Variable	Strain (m/m)	Time of process (hours)
I1	G1* Ti6Al4V®	0,0013	24
	Bone interface	0,011	
	G 1 Tiadyne®	0,0029	24
	Bone interface	0,017	
I2	G1* Ti6Al4V®	0,00323	11
	Bone interface	0,018	
	G 1 Tiadyne®	0,00630	11
	Bone interface	0,0321	
I3	G 1 Ti6Al4V®	0,00131	8
	G 2* Ti6Al4V®	0,00181	
I4	G 1 Ti6Al4V®	0,000131	4
	G 1 Tiadyne®	0,0034648	
V1	I1Vs I3 (G 1 Ti6Al4V®)	0,0013/0,00131	
V2	Ti6Al4V Compare I1 Vs I4 Tiadyne Compare I1 Vs I4	0,0013/0,00131 0,0029/0,0034	

G1* Implant Geometry 1 G2* Implant Geometry 2

In Fig. 1, the conceptual map of the integration model I1 compared to the integration model I2 is observed.

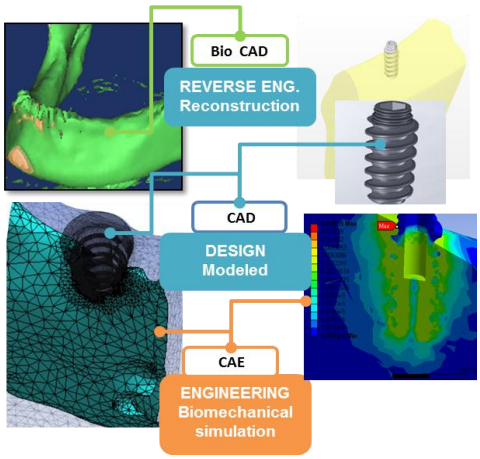

Figure 1. Comparison between I1 and I2 models

According to requirements, the two processes with materials Ti6Al4V and Tiadyne® were developed to evaluate bone-implant interface behavior. According to V1 verifier, ANOVA analysis of two factors with p-vaule of 0.05 was performed. An analysis of variance was performed to compare the strain values obtained in simulations for Ti6Al4V and Tiadyne® as materials inserted into bone-implant interface. A p-value of 0.03 was obtained, showing statistically significant differences between the materials tested with models of technology integration I1 and I2. However, the significance level compared between the strain values of integration models I1 and I2 were obtained p-value of 0.102, establishing that, there are not significant differences between the values of strain obtained from models of technology integration I1 and I2. See Table III. However, in Table II it is evident that the strain values were two times more with respect to I1 I2.

TABLE III. ANOVA TWO FACTORS MODEL I1 I2

Factors	*Square average*	*F*	*Probability*	*F critic*
integration model	9,4051E-05	5,41	0,102	10,127
output strain	0,00020813	11,98	0,035	9,276
Error	1,7366E-05			
Total				

In Fig. 2 is showed the method developed in I3 integration technology model based on CAD / CAE, for comparison between the geometries of implants. According to Table I, the equivalent stress and strain at elasticity limit point is less geometry 1 with respect to geometry 2.

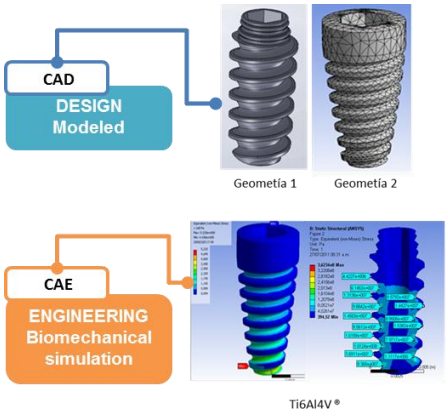

Figure 2. IT model I3 based on CAD / CAE

According to simulation test, the comparison results of geometries, seen in Table I and in Fig. 3, it can be seen the method developed, I4 integration technology model for comparing implant materials geometry 1.

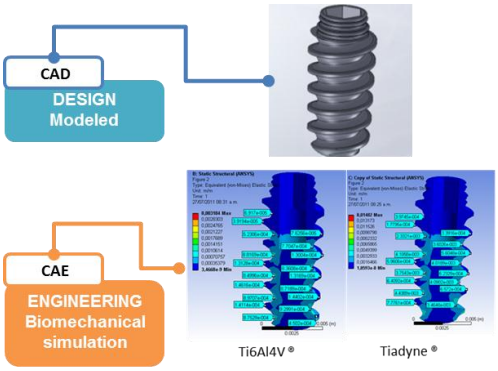

Figure 3. IT model I4 based on CAD / CAE

V2 and V3 were demonstrated verifiers applied a ANOVA statistics made from strain variable response mm/mm to Ti6Al4V material; comparing models of technology integration I1 with respect to I2 and I4 ANOVA with a significance level of 0.05 showed a p-value of 0.949 between the three models of integration, which allows us to affirm, that there is not statistically significant difference between the results of I1 model with respect to I2 and I4, See Table IV.

TABLE IV. ANOVA MODELS I1 I2 I4

Factor	*Squere average*	*F*	*P-value*	*Critic F*
between TI	7,3205E-09	0,00444	0,949	5,987
Between groups	1,6486E-06			
Total				

V. DISCUSSION

The management of integration of technologies, based on design and evaluation of implants and requirements made by an experimental study, allowed definition of practical strategies for integrating technologies by requirements, reducing operations and consequently a shorter development time. Based on above, this experimental study helped to establish the relevance of integration of technologies, also allowed us to know the potential difficulties during its development.

Results of comparison of variable strain response obtained in simulations corresponding to I1 and I2 models were not statistically significant. This result may support the development of studies based on obtaining bone models using CAD software, instead of using reconstructed models, thus helping in reducing analysis time.

Moreover, although integration model I1, based on BioCAD software inclusion provides a positive effect on virtual reference models development for implants design, to implement this kind software requires a significant effort, not only at level of specific knowledge, concepts domain for software tool use, also the investment on development time of analysis were increased. This explains differences in development time of design and analysis between models I2 and I1.These results can be explained by impact of software tools integration and the number of procedures associated with each integration model proposed, which had an impact on analysis development time, evidenced through strong correlation of 0.91 between development time and integration models.

However, results obtained from comparisons between I1 and I2 models are inconclusive, if cases studies, require to obtain bone complex geometries; however, results obtained from comparisons between I1 and I2 models are inconclusive, if cases studies, require to obtain bone complex geometries; according to literature, the importance of RE integration to get complex 3D models of bone that cannot be easily obtained using CAD software.

Moreover, the ANOVA results performed on I1, I2 and I4 models, allowed to establish that there is no significant difference between materials or geometries; therefore it is evident that under these requirements evaluation, an integration of technologies CAD / CAE is recommended.

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Clara I. López is come from Bucaramanga Colombia. She is graduated as Industrial Designer, then she finished the studies of master degree in materials engineering. Actually is a Doctoral in engineering, Innovation and management Area. All her studies has been made at the Universidad Industrial de Santander. She is working to like a teacher at the same University. She is researching about de methodological framework to propose a management model for innovation biomedical field. She is working too as designer in the development of specific patient implant or customized implant. Her multidisciplinary formation allowed that she began this kind of research and it has a important experience for her life. Hence her has made research and technical papers about topics related with biomaterials to implant and design of implants and methods to obtain best practices for design orthopaedic and dental implants.

Edna Bravo. Actually she is a professor at the university has a Ph.D. in Business Administration from the Technical University of Catalonia. She is also researcher at the Center for Technology and Innovation Management Research in the Industrial University of Santander. Her current research interests include Innovation management, technology management, design thinking, innovation strategy, strategic play and knowledge Management models.

Juan C. Moreno is an Industrial Designer graduated from the National University of Colombia in Bogotá, Colombia. He completed graduate studies in Industrial Design at Universidad Autonoma de Mexico, UNAM. He is currently researcher at INTERFAZ Research Group and assistant professor in Industrial Design program at Universidad Industrial de Santander, Colombia. His research focuses on biomedical and assistive products development.

Luis Bautista is an Industrial Designer with a Master of Degree on Computer Science from Universidad Industrial de Santander. His research it is aimed at the images analysis applied on biomedical products design. Actually is professor on Industrial Design Program at Universidad Industrial de Santander.