Optimization of a dynamic intervertebral lumbar implant

Yann Ledoux [a] *, Michel Mesnard [a], Jorge Andrés Peñaloza Sandoval [b], Nicolas Perry [c]

a Université de Bordeaux, Institut de Mécanique et d'Ingénierie, CNRS UMR 5295 - 33405 Talence, Fr
b Instituto Politécnico Nacional, Centro de Investigaciones Avanzadas - 07360 México, Mx
c Arts et Métiers ParisTech, Institut de Mécanique et d'Ingénierie, CNRS UMR 5295 - 33405 Talence, Fr

* Corresponding author. Tel.: +33-556-845-414. *E-mail address:* yann.ledoux@u-bordeaux.fr

Abstract

For the surgical treatment of lumbar pathologies, there are essentially two medical devices that are implanted. Spinal fusion by means of a screwed plate generates a loss of intervertebral mobility, whereas a spinal dynamic implant (SPD) allows relative displacements and thus preserves the adjacent segments and discs. The main goal of this study is to structure the design and to optimize such SPDs. An analytic model based on geometrical and mechanical relations is set up. The characteristics derive from data taken from bibliographical studies. Optimization of the implant characteristics is carried out (materials used, component stiffness, orientation associated with bone tissue degeneration, etc.). To do this, the optimization problem is structured to combine design variables, the mechanical behavior of the medical device (MD) and functional requirements into a single design model allowing the optimization of the MD behavior through a global index.

Keywords: Design structuring, Design optimization, Multi-criteria decision analysis

1. Introduction

The natural behavior of the lumbar spine provides a compliant structure subjected to the action of the weight of the upper body, muscular actions as well as external loads. The functional spinal unit is composed of an intervertebral disc and two vertebrae. The intervertebral disc insures a slight motion at the facet of the vertebrae, providing flexibility and stability of the column. These joints allow bending or twisting motions between vertebrae. Several pathologies can lead to malfunctioning of the lumbar spine, like spinal disc herniation or degeneration. In such cases, surgical treatments are sometimes envisaged through two main approaches. The first consists in avoiding any motion between vertebrae. This is achieved using medical devices like a screw plate placed in the back of the spine or interbody parts inserted between vertebrae. The second approach, using a spinal dynamic device (hereafter SPD), tends to preserve intervertebral motion. These SPD are either artificial disc replacements or particular medical devices located on the spine back face, composed of screws and flexible links. Due to the motion disparities of patients and to the pathology severity, designing a MD aiming to preserve motions is not an easy task. This is one of the major concerns of this study. To achieve this design, we propose to use a general framework called OIA (Observation, Interpretation and Aggregation phases) to structure the design problem. The structure of the design problem includes by itself the design constraints and objectives expected on the MD.

To follow this framework, a parsimonious model based on the geometrical and mechanical behavior of the device is defined. Construction is based on data from the experimental mechanical definition and a bibliographical study of displacements and transmitted actions, producing a model of the behaviors associated with the medical device and its environment (functional anatomy, implant techniques, etc.). According to the implantation characteristics and the stiffness of the device it is possible to determine its mechanical behavior. Optimal ranges and load distributions can then be identified, which correspond to the functional requirements. From these data, a global structuring model is built incorporating the mechanical behavior and functional requirements of the device into one single objective. From the feasible ranges of every design parameter, sets of solutions are then tested as a function of spinal damage grades. A trade-off is then proposed to design the most suitable device for the majority of patients.

2. Setting up the mathematical model

2.1. Literature review

Based on the literature, two main types of modeling of the lumbar spinal zone can be identified. The more advanced models are mainly based on finite element methods which study the local behavior of the spine. Such models usually include the non-linear mechanical behavior of vertebrae (nucleus pulposus and annulus fibrosus), the intervertebral disc, the influence of muscles, etc. Many studies can be cited, such as [1, 2]. This detailed modeling is suitable in cases of implantation study or calculation of local stress between the elements that make up the spinal vertebra.

Since the objective of this study is to have a predicted mechanical model for the design phase of spinal dynamic implants, the previously mentioned finite element models are not suitable. In the architectural design phase, a more tractable model is required. In the literature, a pseudo-rigid-body type model seems to be more relevant, as proposed by [3]. This type of model is based on identifying an equivalent mechanical model of the spinal zone. The natural mobility between vertebrae is modeled as a mechanical joint with angular stiffness and every vertebra is assumed to be a rigid body.

In this study, it was decided to model the mechanical behavior of the spinal lumbar region in the sagittal plane (plane in which the displacements are greatest during flexion-extension) for the upright position. The goal is to develop a mathematical model of the lumbar zone. The formulation of the model is mainly based on mechanical relations of an equilibrium system (Newton's first law). This model enables the behavior of the lumbar zone to be quantified with or without a spinal dynamic implant. Details of the model are given in the following sections.

2.2. Load identification

According to [4], changes in the loading on the vertebra correspond to four stages of degeneration (grades 1 to 4). For grade 1, with no pathology (Table 1), the vertical load is mainly supported by the contact between the vertebra and the intervertebral disc and is evenly distributed between the anterior and posterior halves of the vertebra body. A fraction of the load is supported by the neural arch (8%). Due to disc degeneration, the load is regularly transferred to the arch, with a maximal value at grade 4 of around 63%. These data were obtained from trials on cadaveric lumbar segments subjected to a load of 2kN. This vertical load of 2kN was confirmed by [5] in an upright position and for normal conditions (without additional external loads). It includes the weight of the patient's upper body and induced loads from the muscles; it corresponds to men with a mass of more than 70kg and a height of 1.70m.

Table 1. Load distributions according to [4]; Mean values ± SD for each grade of disc degeneration (n is the number of specimens).

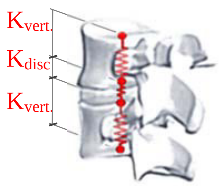
	Upright posture		
	Ant VB	*Post VB*	*N Arch*
Grade 1 (*n*=6)	44 ± 11	48 ± 5	8 ± 8
Grade 2 (*n*=11)	33 ± 16	48 ± 12	19 ± 14
Grade 3 (*n*=28)	19 ± 13	47 ± 14	34 ± 17
Grade 4 (*n*=19)	11 ± 8	26 ± 16	63 ± 22

2.3. Prosthesis model

Spine implants for the lumbar region are mainly based on the use of spring elements and tend to create an equilibrium between the compressive effect of the disc and the load distribution on the vertebra (interface between vertebra surface and disc). The challenge is to design an implant that maintains relative mobility, avoiding high loading on the arch without discharging pressure on the vertebra. The spring element is fixed to each vertebra using surgical screws and interfaces between screw and spring. Solutions can be found in the literature in [6, 7] and [8]. Such an implant is assumed to have a viscoelastic damping in addition to compressive stiffness behavior. According to an available in-vitro test in [8], it is possible to identify an equivalent mechanical model which considers only the spring behavior with a stiffness value of 1470N.mm^{-1}.

2.4. Equivalent mechanical model

An equivalent mechanical model of the lumbar region is built assuming only the stiffness of the different elements. It is composed of three spring elements arranged in series with a linear behavior between the load and the displacement. The identification of stiffness values is based on the studies of [9], [5] and [10] for the disc and vertebra behavior respectively. The different values are given in Fig. 1.

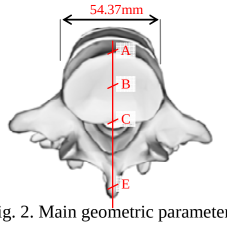


Spring stiffness value	
K_{vert}	3000 *N.mm*$^{-1}$
K_{disc}	926 *N.mm*$^{-1}$

Fig. 1. Main mechanical parameters

2.5. Geometric parameters and equivalent model

Defining a general morphological dimension for the vertebrae in the lumbar zone is not an easy task due to the evolution in size from L1 to L5 and above all, to the natural variability amongst individuals. To address this, it was decided to compile different data from the literature [11] and take an average of the dimensions. Figure 2 summarizes the data and associated parameters. From the geometrical model, it is necessary to include the influence of the biomedical prosthesis on the natural behavior of the lumbar region, with or without pathology.



	Dimension (mm)	
AB	AC	AE
22.4	44.8	76.5

Fig. 2. Main geometric parameters

In terms of surgical constraints, the problem from the mechanical point of view remains one of symmetry along the sagittal plane. To address the evolution of the load distribution on the vertebra surface as a function of the degeneration phases (see table 1), an equivalent mechanical model is set up, based on the mechanical equilibrium of the external loads on the vertebra. This model is shown in Fig. 3. Based on the dimensions of every component, an equivalent stiffness can be computed respectively for the lumbar zone (called K_{eq}) and for the prosthesis (K_{pr}). The stiffness values are K_{eq} =872N.mm^{-1} and K_{pr} =1470N.mm^{-1}. It could be observed that the problem became one of symmetry along the sagittal plane. Its main characteristics are summed up in Fig. 4.

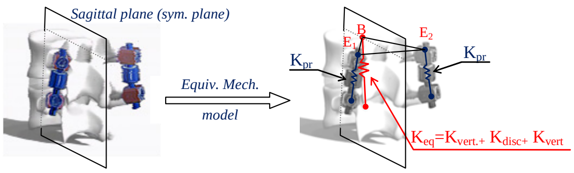


Fig. 3. Definition of the equivalent mechanical model

The equivalent mechanical model can be seen in Fig. 4. The external load of 2kN is applied to point O. The position of this point is a function of the degeneration grade (range from 1 to 4). Since the problem is symmetrical, the position of point O belongs to BE. Data from [4] is then used to define the load sharing in the lumbar spine, assuming a mechanical equilibrium of the load. Table 2 shows the change in distance BO according to the grade of disc degeneration. Due to the anatomical characteristics of the lumbar zone, it is assumed to have a typical angular value α of 25°. In addition, the distance between point B and the center of the added spring element is 77mm (corresponding to BE_1 and BE_2). From these dimensions, the static equilibrium of the mechanical system, including external load in O of 2kN, could be computed. The reaction in B of the natural spine and the added prosthesis in E_1 and E_2 are then deduced, applying Newton's first law to the system and assuming small displacements (eq1). The vertical displacement of these points could then be determined by the use of stiffness K_{eq} and K_{pr} (eq2) for ΔB, ΔRE_1 and ΔRE_2 respectively.

From the vertical displacement of points B, E_1 and E_2, it is possible to compute the final position of the vertebra through an angular value β (eq3).

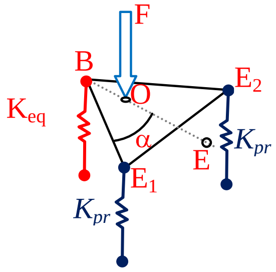


Fig. 4. Equivalent model

Table 2. Definition of the distance BO according to the degeneration grade.

	Load sharing along segments (%)			Distance (mm)
	AB	BC	CE	BO
Grade 1	44	48	8	3.4
Grade 2	33	48	19	9.3
Grade 3	19	47	34	16.5
Grade 4	11	26	63	25.7

$$\mathbf{R_B} + \mathbf{F} + \mathbf{RE_2} + \mathbf{RE_1} = \mathbf{0} \qquad (1)$$
$$\mathbf{OB}\times\mathbf{R_B} + \mathbf{OE_1}\times\mathbf{RE_1} + \mathbf{OE_2}\times\mathbf{RE_2} = \mathbf{0}$$

$$\Delta B = \mathbf{R_B.z} / K_{eq} \qquad (2)$$
$$\Delta E_1 = \mathbf{RE_1.z} / K_{pr}$$
$$\Delta E_2 = \mathbf{RE_2.z} / K_{pr}$$

$$\tan(\beta) = \frac{\Delta B - \Delta E_1}{BE_1.\cos(\alpha)} \qquad (3)$$

The results show the influence of the prosthesis on the final position of the vertebra. The closer β is to zero, the better the solution, since the prosthesis makes it possible to balance the degeneration of the disc. Angle β is relatively large for grade 2 (1.2°) and decreases regularly from 1 and 0.6° (grade 3 and 4 respectively). This behavior is due to the regular transfer of load F applied to point O (Fig. 4).

Table 3. Computation of reaction forces, vertical displacements and angular deviation

	Load (N)		Displacement (mm)		Ang. dev.
	R_B	$RE_1 = RE_2$	ΔB	$\Delta E_1 = \Delta E_2$	β (°)
Grade 2	1604	198	-1.84	-0.13	1.2
Grade 3	1298	351	-1.49	-0.24	1.0
Grade 4	906	547	-1.04	-0.37	0.6

3. Structuring of the design problem

The objective is to optimize the behavior of the prosthesis according to the different grades of disc degeneration. The ideal product provides the same solution whatever the degeneration grade of the patient. More to the point, even if the prosthesis is implanted into a patient with a relatively low grade of degeneration, he could evolve to the higher grades and the prosthesis would remain effective.

To optimize the behavior of the product, it is proposed to structure the problem according to the Observation Interpretation Aggregation (OIA) formulation, as proposed in [12] or [13]. It is composed of three main models: i. the observation model comprising the mathematical model of the solution (detailed in previous section); ii. the interpretation model, which targets the interesting solution by defining the interpretation function, and finally iii. the aggregation model is used to translate a general multi-objective problem into a single objective to be optimized.

Such an approach has already been used for optimizing various design problems like flash-evaporator system for wine production [14] or in more classical design studies [13, 15]. In these applications, the main interests of this structure have been shown. It is possible to integrate into a single objective function the preference of the designer through definition of weights, to address the design constraints by the mean of the desirability curves and finally, the aggregation can be used to filter the solution as detailed in the works of [15].The general framework of the design model is shown in Fig. 5. In the next paragraphs, the different variables and the three models are presented.

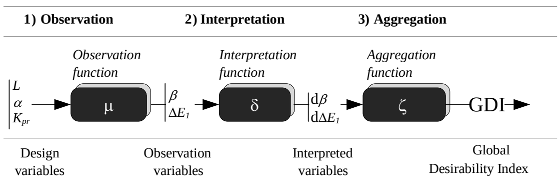


Fig. 5. Structuring of the design problem through observation, interpretation and aggregation model [13].

3.1. Design and observation variables and observation model

In the case of the problem studied here, it is possible to determine three design variables. The first is related to the length of the bone screw used to fix the biomedical device to the lumbar vertebra. This parameter, noted L, is the final distance between points B and E_1 in Fig. 4 according to the available screw dimensions selected. L ranges from 69.43mm to 99.43mm. The parameter α, shown in Fig. 4, corresponds to the angle the screw implantation. Due to morphology constraints, this could vary from 10 to 30°. Finally, the stiffness of the prosthesis is the last parameter. This value can be modified according to the geometry and the material selected. This K_{pr} parameter varies from 200 to 1500N.mm^{-1}. The observation model is composed of the model detailed in the next section. The observation variables are the angular deviation β expressed in degrees, and the vertical displacement of the points, ΔE_1 and ΔE_2 in mm.

3.2. Observation, interpretation, aggregation functions and variables

The acceptability of a design solution partially depends on its ability to satisfy every design criterion. These criteria are often expressed in different units, making a direct comparison between them difficult. The interpretation of design criteria consists in bringing criteria to a scale of comparison by qualifying their degree of satisfaction. In this way, desirability functions are a class of value functions which turn criteria into a satisfactory level ranging from 0 (undesirable value) to 1 (full satisfaction level). The interpretation functions correspond to Harrington's functions, shown in Fig. 6 ([17]). According to the constraint types, we used a one-sided desirability function for the parameters related to the vertical displacement ΔB and ΔE_1. Concerning the parameters $\Delta\beta$, since the objective is to target a value close to 0°, a two-sided function was selected. The interpretation functions are customized by the bound Y^-, Y^+ for one-sided functions and by Y^{--}, Y^{-+}, Y^{+-} and Y^{++} for two-sided functions. Their values are all listed in Table 4.

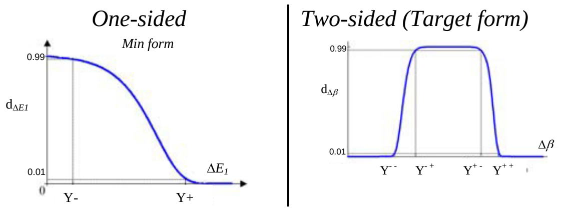


Fig. 6. Shape of Harrington's interpretation functions.

Due to the design of the prosthesis, the vertical displacement ΔE_1 should be limited to avoid an extreme position of the prosthesis (extrusion of parts, fatigue of parts, etc.). It was decided to reduce this distance from -2mm to 1mm. The angle deviation $\Delta\beta$ also has to be limited. This functional requirement is motivated by the need to insure a minimal load on the entire intervertebral disc. If this point is not respected, it could lead to osteoporosis. It is assumed that a maximal deviation of $\pm$0.5° is suitable in order to prevent the development of the osteoporosis phenomenon.

Table 4. Desirability boundary definition

	ΔE_1 (mm)	$\Delta\beta$ (°)	
	{Y^-, Y^+}	{Y^{--}, Y^{-+}}	{Y^{+-}, Y^{++}}
Grade 2 to 4	{-2, -1}	{-0.5, -0.4}	{0.4, 0.5}

Using the two different desirability values computed with the desirability curves, these indices were aggregated, as shown in relation 4. This aggregation was selected because it makes a compensatory effect impossible if one objective is not respected (desirability value equal to 0). The Global Desirability Index (GDI) ranges from 0 to 1 and it will be used to select the most relevant solutions.

$$GDI = \sqrt{d_{\Delta\beta} . d_{\Delta E1}} \tag{4}$$

4. Solving process

Since the design model is translated into an analytical relation to solve and it takes less than one second to evaluate one combination of design variables, it is proposed that a combinatory approach be used. A set of candidate solutions are generated for evaluation according to a regular grid. The α angular parameter varies from 10 to 30° with 1° increments, L ranges from 69.43mm to 99.43mm with 1mm increments and K_{pr}, from 200 to 1500N.mm^{-1} with 100N.mm^{-1}increments. Thus, the design space corresponds to a three-dimensional domain. The GDI is computed according to the three grades, and all results are shown in Fig. 7 to 9. These figures show the position of solutions according to their GDI values which translate into the gray intensity of the point color. Only solutions with a GDI under 0.2 are drawn. It can be seen that the higher the grade of degeneration, the fewer solutions are available. For grades 3 and 4, two different areas of solutions can be seen with interesting GDI values (close to 1); the solutions correspond either to low values of K_{pr} and L or high values of L and K_{pr}. For the last grade, this trend is confirmed, with similar design parameter values.

Fig. 10 is built by considering simultaneously all GDIs for the three grades. This objective is computed by the geometric mean of every GDI from the different grades. In Fig. 10, the drawn points represent the best feasible compromises among the three grades and design values are summed up in table 5.

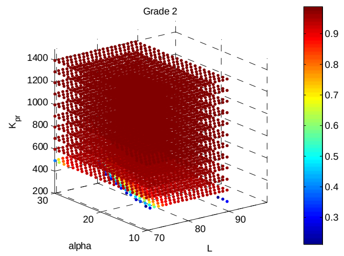


Fig. 7. Set of candidate solutions for grade 2.

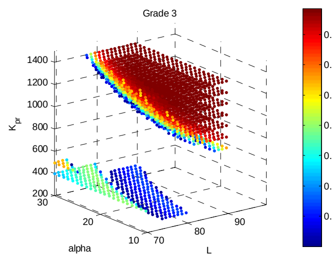


Fig. 8. Set of candidate solutions for grade 3.

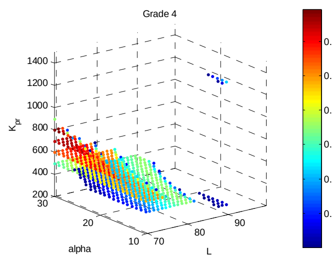


Fig. 9. Set of candidate solutions for grade 4.

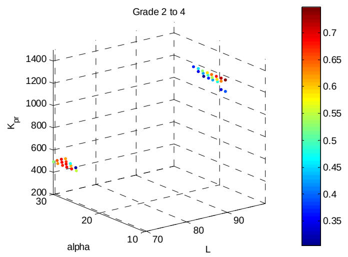


Fig. 10. Set of candidate solutions for grades 2 to 4.

Table 5. List of solution alternatives.

	Best solutions among grades (from 2 to 4)		
	L (mm)	*α (°)*	*K_{pr} (N.mm^{-1})*
# 1	70	27	500
# 2	90	10	1400

5. Conclusion

A general framework of the design problem has been proposed based on an Observation, Interpretation and Aggregation strategy (OIA). This structuring is a useful approach to integrate into the same model the mathematical model of the system, the design objectives and requirements through one single objective. A comparison and tradeoffs are also possible since results are expressed through a single value. A systematic combination of the design parameters allows the identification of the best parameter values among all the feasible combinations. The result is that it is possible to design a device suitable for every grade of degeneration. This preliminary study could be improved by considering other motions. In addition, the mathematical model could be completed by additional behavior, such as no linear stiffness. It has been assumed that the design parameters could be precisely defined during implantation of the medical device, however, the surgical act leads to imprecision in angle and position. In this context, it seems to be relevant to add robustness aspects into the search for a solution. This will help in the selection of more robust solutions.

6. References

[1] Shin DS, Lee K, Daniel Kim D. Biomechanical study of lumbar spine with dynamic stabilization device using finite element method. Computer-Aided Design, 39:559-567, 2007.

[2] Lafage V, Gangnet N, Sénégas J, Lavaste F, Skalli W. New interspinous implant evaluation using an in vitro biomechanical study combined with a finite-element analysis. Spine, 32(16):1706-1713, 2007.

[3] Peter A. Halverson, Anton E. Bowden and Larry L. Howell, A Pseudo-Rigid-Body Model of the Human Spine to Predict Implant-Induced Changes on Motion, J. Mechanisms Robotics. 2011;3(4):041008-041008-7.

[4] Adams, M. A., Pollintine, P., Tobias, J. H., Wakley, G. K., Dolan, P., & Al, A. E. T. (2006). Intervertebral Disc Degeneration Can Predispose to Anterior Vertebral Fractures in the Thoracolumbar Spine, 21(9).

[5] Kap-Soo Han, Antonius Rohlmann, Seok-Jo Yang, Byeong Sam Kim, Tae-Hong Lim. Spinal muscles can create compressive follower loads in the lumbar spine in a neutral standing posture. Medical Engineering & Physics, Volume 33, Issue 4, May 2011, Pages 472-478.

[6] Eric Dodgen, Eric Stratton, Anton Bowden and Larry Howell, Spinal implant development, modeling, and testing to achieve customizable and nonlinear stiffness, J. Med. Devices 6(2), 2012, 8p.

[7] Vijay K. Goel, PhD, Ali Kiapour, MS, Ahmed Faizan, BS, Manoj Krishna, FRCS, MCh(Orth), and Tai Friesem, MD, Finite Element Study of Matched Paired Posterior Disc Implant and Dynamic Stabilizer, SAS Journal, 2007;1: 55–61.

[8] Monede Hocquard, L. Évaluation clinique, caractérisation mécanique et modélisation pour l'évolution de la conception d'un implant rachidien dynamique. PhD thesis of University Bordeaux, 2012.

[9] O'Connell, G. D., Jacobs, N. T., Sen, S., Vresilovic, E. J., & Elliott, D. M. (2011). Axial creep loading and unloaded recovery of the human intervertebral disc and the effect of degeneration, Journal of the Mechanical Behavior of Biomedical Materials, 4(7), 933–42.

[10] Karadogan, E., & Williams, R. L. (2012). Three-dimensional static modeling of the lumbar spine. Journal of Biomechanical Engineering, 134(8), 084504. doi:10.1115/1.4007172

[11] Zhou SH, McCarthy ID, McGregor AH, Coombs RR, Hughes SP. Geometrical dimensions of the lower lumbar vertebrae – analysis of data from digitised CT images. Eur Spine J. 2000;9:242–248.

[12] Arnaud Collignan, Patrick Sebastian, Jérôme Pailhès, Yann Ledoux, Optimization of product in dynamic design space and selection through the arc-elasticity concept, International Journal on Interactive Design and Manufacturing, vol.5 n°4, (2011), pp. 243-254.

[13] T. Quirante, P. Sebastian, Y. Ledoux, A trade-off function to tackle robust design problems in engineering, Journal of engineering Design, 2013, 24 (1), pp. 64-81.

[14] T. Quirante, Y. Ledoux, P. Sebastian, "Multiobjective optimization including design robustness objectives for the embodiment design of a two-stage flash evaporator", International Journal on Interactive Design and Manufacturing, 6 (1), pp. 29-39, (2012).

[15] P. Sebastian, Y. Ledoux, A. Collignan, J. Pailhes, "Linking objective and subjective modelling in engineering design through arc-elastic dominance", Expert Systems With Applications 39 (2012), pp.7743-7756.

[16] T. Quirante, Modelling and numerical optimization methods for decision support in robust embodiment design of products and processes, PhD thesis of University Bordeaux, 2012.

[17] Harrington EC, The desirability function, Industrial Quality Control, v21, n10, pp.494-498, 1965.