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CUSTOMIZED PRODUCT DESIGN BASED ON MEDICAL IMAGING

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1. Introduction

Design is a very complex task even for an experienced designer. Only designer who are capable of creative and analytical thinking combined can solve complex design problems. Technological innovation pushes the creativity to new limits and therefore designers are forced to design new products with new functionality within ever shorter time to market deadlines [Ye et al. 2008]. Computer Aided Engineering (CAE) software, especially Computer Aided Design (CAD) software has made great progress recently. Thereby the designer has comprehensive tools to meet the expectations of the company, although the creative and innovative thinking cannot be stimulated through this software.

Products are usually mass produced in order to keep the production costs at lowest level and are therefore designed to suit a wide population. However there has been an increased market demand of customized products which incorporate whole product customization or customized parts [Merle et al. 2010]. Major part of companies or institutions who utilize customization can be attributed to medical applications (medical prosthesis, implants, splints, etc). Recent extensive development in various technologies such as medical imaging, 3D scanners and rapid prototyping has impacted also customization within luxury products and in products where high stresses an exceptional performance is expected such as high performance tools and gear, professional sports equipment and military equipment. In order to produce a customized part, the designer has an even more complex design process to overcome. It is crucial, that the designer understands the bio-mechanical properties of the subject's anatomical body part which will be in interaction with the customized product. Traditional user - centered design techniques such as designing with recommendations, designing based on anthropometric data and derived mathematical models do not incorporate enough subject data to design a customized product with best fit to a specific subject. To overcome limitations of traditional design, there has been an increase in use of multidisciplinary medical imaging approach to reverse engineer 3D CAD models of human anatomical parts to incorporate them into the design process in CAD software or to utilize Finite Element Analyses (FEA). For example, 3D models of human foot based on medical imaging are increasingly being used in the design process of footwear. They are used to utilize CAD and FEA in order to optimize the performance and comfort rate of the users [Franciosa et al. 2011]. There has been also an extended use of medical imaging in generating 3D digital human models, which can be utilized for user - centered design, although they are usually used for workplace ergonomics and cannot be used in customized product design.

Therefore this paper presents theoretical background and newly developed methods to design customized products based on medical imaging for perfect fit to a specific subject. The paper is organized as follows: Section 2 presents the importance of the Human – product interaction, in Section 3 most common data acquisition techniques are discussed, Section 4 provides 3D reconstruction techniques, Section 5 presents reverse engineering process and Section 6 describes and discusses a case study of designing a customized cross-country ski pole handle using methods described in the theoretical sections.

2. Human – product interaction

The human body is a sophisticated and complex bio-mechanical machine. In any mechanism, living or dead, the functional capacity is dependent on of the structural characteristics and also the nature of the control system that manages the system. It is crucial to have deep knowledge of both mechanical - anatomical areas, as well as cognitive - sensory. Therefore, analyses and simulations of biological systems are extremely complex, requiring deep knowledge. One of the key functions of the human is the interaction with the physical environment, therefore designer has to consider the product-human interaction in order to develop products with high rate of efficiency and comfort. Modern CAE and CAD software allow the designer to evaluate the new product virtually. If a product will be human operated, the system performance is also human dependant, therefore designer has to consider ergonomics in order to achieve the expected system efficiency [Hogberg et al. 2008]. Utilization of ergonomic principles in the design process is a very important task, although there is still a lack of dedicated ergonomics software in the field of product ergonomics which would make evaluation and analysing of the proposed design at the virtual stage possible.

In a human - product interaction, the designer has three constraints which have to be considered to design an efficient product. Design attributes of the product define the Task and Product constraints, the Cognitive and bio-mechanical constraints are defined with the user. If there is a viable human-product interaction possible, all three constraints must overlap to some extent (Figure 1). Somewhere inside the intersected area is the optimal human-product interaction. To find the optimum, the designer has to set his objective function and perform optimization. To achieve that, task and product constraints can be altered with different design attributes. Therefore designer has to have knowledge about the user cognitive and bio-mechanical constraints about the target user in order to adapt the product design for the optimal human - product interaction.

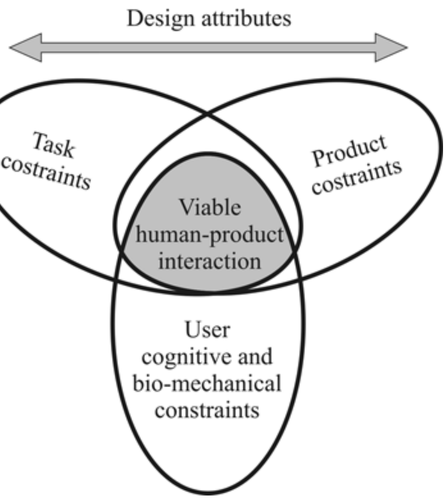

Figure 1. Viable human-product interaction and its constraints

In customized products the User cognitive and bio-mechanical constraints are even more rigorous. Therefore the designer has to carefully utilize design attributes in new customized product design to define the optimal human - product interaction. The customization of a product while considering user cognitive and especially bio-mechanical constraints can be undertaken with different design methods. In this paper we present methods for product customization based on medical imaging as described in following sections. They allow high consideration rate of bio-mechanical constraints and try to reach the optimal human-product interaction for increased performance and comfort. Described methods are especially useful for product development where use of traditional user - centered design methods is not possible because of the nature of the human body.

3. Three dimensional data acquisition

Three dimensional data acquisition in engineering practise is usually utilized with methods such as Coordinate measuring systems and increasingly often with new methods such as Laser and Optical scanners. Because of nature of the human body, most appropriate and therefore also used method in tissue three dimensional data acquisition is Magnetic Resonance Imaging (MRI) and Computed Tomography (CT) [Sun et al. 2005]. CT still provides images with higher spatial resolution where two different anatomical structures can be separated at small distances. However MRI provides images with better contrast resolution which provides great ability of differentiation of tissue and recognizing border regions of anatomical structures. CT differentiation is possible based on contrast segmentation where structures are selected based only on tissue density. Therefore CT is best suited for modelling of hard tissue such as bones, since the difference is seen in different grey values of the tissue. MRI is according to health risk way superior to CT, since it does not expose the subject to ionizing radiation. The use of CT can be justified only in applications where life threatening condition of patient is present, therefore it is appropriate to use MRI in proposed product design process. The field of medical imaging has grown immensely and therefore it has gained extended use in medical applications such as medical diagnostics, surgical planning, medical implants, etc. Additional, there has been an increased use as a data acquisition method to develop bio-mechanical 3D models for utilization of CAD and FEA in product development process. Such methods have been already successfully used in footwear industry to analyse the existing footwear design with CAD and FEA and develop new one which increases performance and comfort. Other authors have used this kind of data acquisition to develop more general 3D human models, which allow the designer to consider the size of a specific user or population in all three dimensions for the product or workplace design.
Since CT or MRI acquisition techniques are usually not in the domain of traditional designers, collaboration between a designer and radiological engineer or technician should be established to get best possible results. Because of the long imaging times of about ten minutes, the imaged anatomical part should be fixated properly. If movement occurs, images may be distorted which makes the segmentation and 3D reconstruction described in following sections difficult or impossible. If a specific posture of the imaged anatomical part has to be withheld during the imaging, a mould should be considered, which effectively fixates the anatomical part. Orthotic moulds are most appropriate, since they have good ability to mould to anatomical contours. Use of orthotic mould for anatomic part fixation is described in the section six. Modern CT/MRI machines usually provide images in the DICOM file format (Digital Imaging and Communications in Medicine) where distance between each slice can be set to 1mm or even less. Lower slice distance theoretically provides more anatomical detail and therefore provides better starting point for segmentation and 3D reconstruction, but it also extends the time of imaging. If the imaging time is long and subject has to hold an uncomfortable position of the imaged anatomical part, muscle twitching occurs which affects the accuracy of the images. Therefore it is crucial to find a compromise between the slice distance and imaging time. Based on literature and experiments performed the time is around ten minutes, but it differs a lot from anatomical part, muscle type, posture and subject. The process of three dimensional data acquisition is schematically displayed in Figure 2.

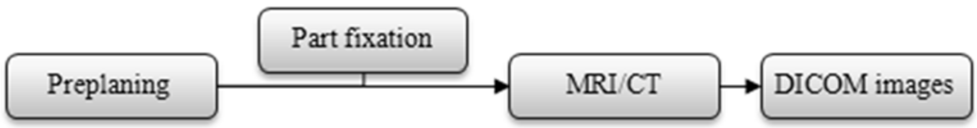

Figure 2. Three dimensional data acquisition for customized product design

4. 3D reconstruction

After the data acquisition based on CT or MRI, the images have to be 3D reconstructed in order to obtain a CAD model of the imaged anatomical part. 3D reconstruction for CAD modelling is usually performed with segmentation [Sun et al. 2005], which is a process where digital images are being partitioned into multiple segments to determine inner and outer contours of living tissue. Each segmented image is then stacked together with preset distance according to imaging slice distance.

The stack of segmented images is then a reference for solid reconstruction. Many segmentation algorithms have been developed in order to improve the speed and accuracy of the segmentation process, although this is beyond the scope of this paper. Therefore only most suitable segmentation techniques which can be used for the CAD model development will be discussed. The simplest segmentation is based on tresholding technique, where a threshold level is used to segment a specific anatomical region. If no anatomical differentiation is needed on the imaged anatomical part, segmentation based on tresholding is the fastest and simplest method to extract the shape of the imaged part and develop a CAD model. If differentiation of anatomical parts is needed to construct a bio-mechanical CAD model to perform kinematic analyses or FEA, segmentation techniques such as Region growing or similar should be used which allows segmentation of different anatomical parts. Development of different segmentation techniques has evolved rapidly and there is a comprehensive list of different techniques. The designer has to choose the one which offers best segmentation results within acceptable time. Because of the nature of imaging techniques, noise and other image errors are usually present, therefore the designer has to utilize noise and other image cleaning tools. Workflow of 3D reconstruction process can be seen in Figure 3.
Rapid development of medical imaging has influenced also the development of various professional medical imaging and bio-medical research and development software. Most software packages provide comprehensive tools for 2D image manipulation, segmentation, measurement, 3D reconstruction, etc. Majority of the software is commercial, such as Mimics® by Materialise, Amira® by Visage Imaging®, MedCAD®, etc., but there are also some free open source software packages such as 3D Slicer, etc.

Figure 3. Process of 3D reconstruction on the obtained images

5. Reverse engineering and CAD, FEA

After the segmentation has been done and the imaged anatomical part has been 3D reconstructed, the obtained 3D representation has to be exported in a file format that is supported by CAD software of choice. Most of the modern medical imaging software allows export of STL (stereolitography) file format of the 3D reconstructed model. The obtained model does not include any geometric topological relations. Therefore no feature based CAD solid modelling techniques and no FEA are possible which require vector-based modelling environment [Sun et al. 2005]. The obtained 3D reconstructed model of the imaged anatomical part has to be reverse engineered into a Non-Uniform Rational B-Spline (NURBS) function. Some of the medical imaging software already includes reverse engineering modules, which allow the generation of a CAD model based on the obtained 3D reconstructed model. Usually some solid modelling techniques are also integrated, although the modelling is usually attributed to implant modelling, surgical planning, etc and is not suited for the product design modelling. Therefore in customized product design process it is necessary to use CAD software which a designer is used to, such as standalone reverse engineering software (for example Geomagic® by Raindrop Inc, etc) or CAD software packages which offer plug-ins for reverse engineering (for example: Solidworks with Rapidform® plugin). Some of CAD software packages already incorporate reverse engineering modules (for example Catia®). Solutions with build in or plug-in reverse engineering modules are streamlined and provide comprehensive reverse engineering techniques inside existing CAD software which allows rationalization of development time.
The point data form of the STL file has to be triangulated in the reverse engineering software to form a freeform NURBS surface model. The result is usually a surface model which consists of surface patches. Because of the noise and the inconsistencies in obtained images and therefore also STL file, additional smoothing and refinement is appropriate. The surface model is then converted into a solid model which enables classic solid CAD modeling. Since most of the human anatomical parts are organic shapes, feature recognition on the CAD model is not needed in customized product design and FEA, therefore a solid model is sufficient.

In the CAD process of designing the customized product, a rough solid model which will be in interaction with the subject should be modeled and positioned over the obtained CAD model of the anatomical part in order to obtain the shape with best fit. Then Boolean operations (Add, Remove, Intersect), which are common tools of the most CAD software, are being used to define the intersecting volume and therefore get the shape of the product with perfect fit. After the shape has been obtained, designer can use usual CAD tools to improve the design of the customized product based on his skills and experiences.
The outline of processes to utilized CAD-FEA with medical imaging can be seen in Figure 4.

Figure 4. Needed processes for CAD model extraction from medical images

Described theoretical background and methods haven been utilized to develop customized cross-country ski pole handles for a professional athlete in order to increase performance, improve comfort and lower the risk of task related disorders (TRD). Design process is described in following section.

6. Customized cross country ski pole handle - case study

6.1 Background

Professional cross-country skiing is a sport discipline where high physical effort is expected from an athlete. One of the essential equipment of every cross-country skier are cross-country ski poles which have to be designed to meet all three human-product interaction constraints described in section two. Cross-country skiers provide considerable push force with ski poles, therefore it is justified to develop customized cross-country ski poles adapted to a specific professional athlete in order to increase performance, improve comfort and prevent TRD.

6.2 Handle design

Tool handle design was extensively researched by many authors in the past. Most authors have provided recommendations and mathematical models for cylindrical handle design in order to increase performance, comfort and to avoid TRD, but none of them considered the anatomical shape of the handle, which could additionally improve the ergonomics of the handle. Excessive loading on hand can result in discomfort, pain, ischemia and also in other task related disorders such as carpal tunnel syndrome [Eksioglu 2004]. It has been also shown, that power grasp can yield in contact pressure of the fingertip of 80kPa, which is excessive loading for skin and subcutaneous tissue. Objects that follow the shape of the hand result in much lower local contact pressures, which can prevent discomfort and several disorders [Wu and Dong 2005]. Therefore a customized handle can provide improved ergonomics which can lead to increased performance, comfort, stability and can prevent TRD.

6.3 Methods

6.3.1 Human - product interaction: Defining the optimal power grip posture

The shape of the handle cannot be determined using traditional methods with recommendations, anthropometric measurements or simple mathematical models. Therefore methodology described in theoretical sections was utilized to develop a customized ski pole handle with optimal shape to increase the performance, comfort and especially the pole stability in the hand. Firstly anthropometric measurements were performed to manufacture an optimal cylindrical pre-handle with variable diameters. The optimal handle diameters for each finger were determined based on literature to maximize the grip force exertion and comfort [Garneau and Parkinson 2010]. To get shape of the hand in its optimal power grasp posture with undeformed soft tissue with maximum precision, an outer hand mould out of orthotic material was manufactured to maintain the diameters and shape of the hand softly holding the optimal cylindrical pre-handle.

6.3.2 Magnetic resonance imaging, segmentation and 3D reconstruction

The MRI was performed at the Radiological Department of University Medical Centre Maribor. MRI machine was a GE medical systems Signa HDxt 3.0T. Slice thickness was set to 1mm to avoid unnecessary small anatomical structures and surface details. Before the scanning, the optimal cylindrical pre-handle was used to fine adjust the correct size of the outer hand mould. The pre-handle was removed during the scanning to get undeformed skin and subcutaneous tissue. The subject was told to hold the hand in open position touching the mould during the scanning to maintain the proper diameters and shape of an optimal power grasp. The imaging time was less than ten minutes, therefore muscle twitching did not occur and good results were obtained. Scanned images were provided in DICOM format. For the segmentation and 3D reconstruction of the DICOM images, a professional medical imaging and editing software Amira® 5.3.3. (Visage Imaging®) was used. Segmentation was done with LabelVoxel module and simple tresholding technique since only surface of the hand is needed and no differentiation in anatomical structure of the hand is necessary. A threshold value of 200 proved to be the best value to obtain best segmentation. Small inclusions and segmentation errors were corrected with “remove islands” and “fill holes” commands. To get smoother surface Resample module was added to the segmentation and 3D reconstruction process. The result is a smooth 3D representation of the specimen´s hand in optimal power grasp posture. 3D reconstructed hand was then exported in STL file format.

6.3.3 Determination of the customized cross-country ski pole handle

The STL file obtained in Amira® software was imported into CATIA® V5R20, where the reverse engineering module Quick Surface Reconstruction was used to obtain NURBS model. To get the optimal custom handle for power grasp posture variety of cylinders were used (circular, conical, elliptical). It has been shown, that best result can be obtained with an elliptical cylinder, since it follows the shape of the hand best and it provides greatest contact area in the palmar region. The size and the position of the elliptical cylinder were determined so that the cylinder fully overlapped the palmar empty volume created by the hand in optimal power grasp posture. To get the shape of the handle Boolean operation “Remove” was used which removed the cylinder model volume which was in overlap with the hand model volume. The result is smooth handle with perfect fit to the target subject. In Figure 5 all methods utilized for the development of the customized cross-country ski pole handle are plotted.

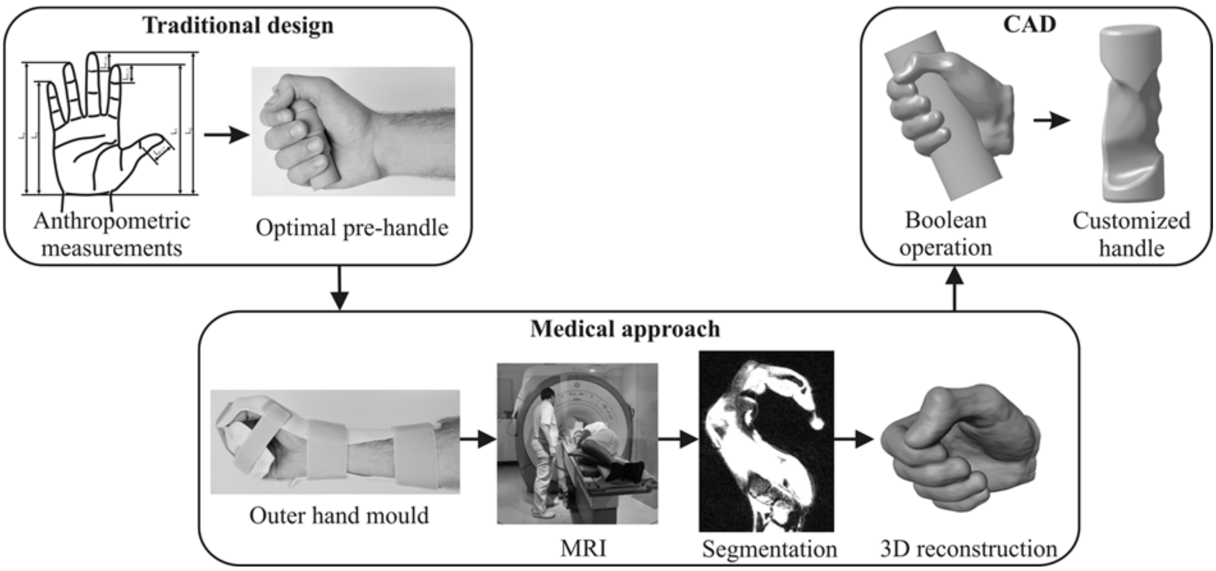

Figure 5. Methods used for the development of the customized handle

6.4 Results and discussion

Development of cross-country ski pole handle with customized shape would not be possible without utilizing the design approach with medical imaging. The design takes also into account the shape of the hand in its optimal power grasp posture with soft tissue underformed and therefore provides best fit for the athlete's hand. All current studies are concentrated on optimal diameters, but lack the shape determination which could improve the user performance, comfort and prevent TRD. The obtained CAD model of the customized handle was virtually evaluated using CATIA®. The diameters were checked and it has been shown, that they were kept by the outer hand mould during the MRI within small deviations, therefore the maximum grip force can be exerted [Seo and Armstrong 2008] and subjective comfort rating is maximized [Kong and Lowe 2005]. The contact area with the customized handle was compared to a cylindrical handle. The mean contact area of the cylindrical handle was $A_{cir}=80{,}80cm^2$. The contact area of the obtained custom shaped handle was measured virtually in CAD software and was $A_{cust}=101{,}34cm^2$. Contact area is increased by $20{,}54cm^2$, which is an increase of over *25%*. The increase of the contact area is due to the fact, that the custom shaped handle exactly follows the shape of the hand in its optimal power grasp posture and thereby provides the greatest contact area possible. Therefore high local and overall contact pressure can be avoided which provides greater comfort rate and likely prevents task related disorders than a cylindrical handle. With use of anatomically shaped handle the stability is also increased since outer forces and moments are transferred with the shape of the handle and not mostly with friction as with a cylindrical handle. Therefore a lower normal grip force can be exerted in comparison to the cylindrical handle and the customized ski pole can be stable held in the hand.

In order to physically asses the obtained customized handle, a rapid prototype was manufactured. The target subject provided a subjective opinion on stability and comfort which was then compared to the optimal cylindrical handle. Target subject described the custom handle as more stable, since stability is greatly increased especially in the axis of the handle where outer torques are transferred with shape of the handle. Target subject described the optimal shaped tool handle as more comfortable since the handle suits the hand better with the anatomical shape. In order to assess the newly developed handle, more extensive testing will be conducted in future.

7. Conclusions

The increase of market demand for customized products and limitations within traditional design methods has led to development of new user - centered design methods based on medical imaging which are presented in this paper. Extensive development in the area of medical imaging has opened new possibilities. Quality and reliability of this technique can be used for the innovative design process to develop customized products which allow high consideration rate of bio-mechanical constraints and therefore provide best fit to the subject. The medical approach is especially suited for integrated CAE/CAD design process and FEA utilization. In order to develop a customized product firstly MRI or CT has to be conducted on the anatomical part which will be in interaction with the product. Obtained images have to be segmented to 3D reconstruct the anatomical part. The 3D reconstructed model has to be reverse engineered to allow traditional CAD solid modelling. Product with best fit is then obtained based on the CAD model of the anatomical part and Boolean operations.

Conducted case study confirmed that proposed design method based on medical imaging can be used as a reliable method for developing customized cross-country ski pole handle. This approach considers also the anatomical shape of the hand in development of the custom shaped handle, thereby reducing overall and local contact deformations of the soft tissue and therefore also reduction of contact pressure. An increase of over 25% in contact area was observed in comparison to the traditional cylindrical handle. The stability of the handle and subjective comfort rating are also increased. It has been shown that any institution or company with access to biomedical department with a MRI or CT machine can utilize the described methodology to design customized products. However dedicated purchase of MRI/CT equipment is usually not justified, since their price is too high for small companies. The proposed methods fulfil the requirements of the market for product customization, thereby providing a competitive advantage of the product and also of the whole company.

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References

Eksioglu, M., "Relative optimum grip span as a function of hand anthropometry", International journal of industrial ergonomics, 34, 2004, pp 1-12.

Garneau, C.J., Parkinson, M.B., "Optimization of Tool Handle Shape for a Target User Population", Proceedings of the Asme International Design Engineering Technical Conferences and Computers and Information in Engineering Conference, 5, 2010, pp 1029-1036.

Hogberg, D., Backstrand, G., Lamkull, D., Hanson, L., Ortengren, R., "Industrial customisation of digital human modelling tools", International Journal of Services Operations and Informatics, 3, 2008, pp 53-70.

Kong, Y., Lowe, B., "Optimal cylindrical handle diameter for grip force tasks", International Journal of Industrial Ergonomics, 35, 2005, pp 495-507.

Merle, A., Chandon, J.L., Roux, E., Alizon, F., "Perceived value of the mass-customized product and mass customization experience for individual consumers", Production and Operations Management, 19, 2010, pp 503-514.

Seo, N.J., Armstrong, T.J., "Investigation of Grip Force, Normal Force, Contact Area, Hand Size, and Handle Size for Cylindrical Handles", Human Factors, 50, 2008, pp 734-744.

Sun, W., Starly, B., Nam, J., Darling, A., "Bio-CAD modeling and its applications in computer-aided tissue engineering", Computer aided design, 37, 2005, pp 1097-1114.

Wu, J.Z., Dong, R.G., "Analysis of the contact interactions between fingertips and objects with different surface curvatures", Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine, 219, 2005, pp 89-103.

Ye, X., Liu, H., Chen, L., Zhang, S., Chen, Z., Pan, X., "Reverse innovative design - an integrated product design methodology", Computer Aided Design, 40, 2008, pp 812-827.

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