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CAD/CAM SYSTÉM PRE OBLASŤ VÝROBY VÝSTELIEK DO TOPÁNOK

CAD/CAM SYSTEM FOR INSOLE PRODUCTION

Úchvatný pokrok v medicíne zvýšil požiadavky na vysoko výkonné počítačové systémy, ktoré by zabezpečili podporu na merania a vizualizáciu, s vysokým stupňom presnosti a vysokými požiadavkami kladenými na plánovacie činnosti a aplikácie špecifických lekárskeho postupov. Ortopédia, ako jedna z oblastí medicíny, bola obohatená o nový prístup pri návrhu a aplikáciách protéz vo forme využitia CAD/CAM. Článok dáva prehľad o biomechanických vlastnostiach nohy, ktoré priamo predurčujú vlastnosti budúcej výstelky. Kvôli jednoznačnosti každej nohy, princíp univerzality, napr. masová výroba výstielok do topánok, nedáva očakávané výsledky. A preto sa dáva prednosť výrobe výstielok podľa klinického a pedobarografického nálezu jednotlivca. Článok predstavuje fázy výroby výstielok použitím CAD/CAM. Opisuje vyvinutý CAD/CAM systém, umožňujúci účinnú koordináciu všetkých fáz výroby. Systém bol vyvinutý aplikovaním Open GL, Visual C++ a Visual Basic. Skladá sa z piatich modulov: databáza, modul na spracovávanie a prezentáciu zmeraných dát, modul na prezentáciu RTG obrázkov nôh, modul na modifikáciu a prispôbenie štandardizovaných výstielok a postprocesor.

Impressive strides in medicine enhanced a necessity for highly advanced computer systems which would provide measurement and visualization aids with a high degree of accuracy, and high standards for planning and application of specific medical procedures. Orthopaedics, as a medical branch, was enriched for a new approach in design and application of orthoses and prostheses, CAD/CAM. This paper gives an overview about biomechanical characteristics of the foot, which directly implies the features of the future insole. Because of the unity of each foot, the principle of universality, i.e. mass production of insoles, does not give the expected results. Therefore, the advantage is given to production of insoles according to the clinical and pedobarographic finding of the individual. The paper presents the phases in production of insoles by applying CAD/CAM. It describes the developed CAD/CAM system, enabling efficient interfacing of all production phases. The system is developed by applying Open GL, Visual C++ and Visual Basic. It consists of five modules: data base, module for processing and presentation of measured data, module for presentation of the foot RTG pictures, module for modification and adjustments of standardized insoles, and postprocessor.

1. Introduction

The human foot contains, within its relatively small size, 26 bones (the two feet contain a quarter of all the bones in the body), 33 joints, and a network of more than 100 tendons, muscles, and ligaments. It is a complex yet marvelous structure of living machinery, and is designed to transport us through life and provide us with the mobility to ensure our survival. Other than the heart, there is no other structure that takes a beating like the foot. Its strong, flexible, and functional design enables it to do its job well and without complaint. The foot is stuffed into a variety of dark and cramped spaces, forced to go places and distances it might not normally choose for itself. Relegated to the bottom of the totem pole, it hardly ever requires personal attention and sometimes is denied even personal hygiene, yet manages to "carry on". Yes, it's quite a structure and performs its "feats" of strength, and eventually falls prey to natural abuse. It is for all intent and purpose, a locomotive structure, capable of initial shock absorp-

tion, performing in most cases at least 8,000-10,000 times per day. There is a lot of moving parts, each working in conjunction with the rest of the system. Some feet have lots of available motion and others have little. Certainly, some feet work better than others and fall prey to fewer problems but, all feet are prone to normal wear and tear and depending on usage can be pushed to problems sooner. Everything starts as the foot makes its first contact to the ground (with the heel). Motion in the foot takes place in preparation of weight being transferred through the body and into the foot. As this process continues, two things happen 1) the arch of the foot moves towards the ground and 2) the muscles try to control the speed and depth at which the arch moves. Eventually, the arch falls as close to the ground as possible. At this very moment in time is when the foot is at its weakest, most unstable and vulnerable to the forces passing through (a bag of bones as it were). Every joint is twisted to the max, which in turn allows the body above to also move in correlation to this instability and vulnerability. The "soft tissue" (muscles, tendons, ligaments) are also

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straining because they too are being stretched and off their best “track”. As this mechanical action repeats heat builds up (called inflammation). This marvel of engineering, however, is designed to perform this task, repeatedly in fact. The body will release endorphins to “cool” the heat build up, it will adjust the entire system if it recognizes a “pattern” of inefficiency. This adjustment may in time produce a recognizable inefficiency further promoting a “new” adjustment. Meanwhile heat continues to build and build until the system’s endorphins can no longer manage the upper limits. Here then starts the process of trying to reverse the pain. Self-treatment, modern medicine, old world medicine, external devices, and maybe even prayer all methods used and abused to treat a “step in time”(3,4).

The foot can be divided into two anatomic portions: forefoot and rearfoot. The forefoot is composed of the bones and joints, located forward to the midtarsal joint. This includes the bones that help form the arch of the foot, the cuneiform bone, navicular, metatarsals, and the bones of the toes, the phalanges. The rearfoot is located underneath and posterior to the midtarsal joint, and is composed of the calcaneus and talus. The most important joints in the normal function of the foot during movement are the metatarsophalangeal joints of the forefoot and the subtalar joint of the rearfoot, which functions differently during certain portions of the gait cycle, at one point acting as a rigid level and at another time as a mobile adapter to the terrain. The soft tissue components of the foot include the muscles, tendons, ligaments, fascia, and fat pads, all of which have specific functions during standing and walking. The pull of the muscles and tendons produce joint movement, and the ligaments help provide stability between the bones. The plantar fat pad has two components: the heel fat pad and the fat pad beneath the heads of the metatarsal bones. Both act as cushions that distribute the pressure of the underlying bony structures to the weight-bearing surface (1, 2).

The gait cycle is divided into two phases: the swing and the stance phase. During the swing phase, the foot is completely off the ground and is preparing for heel-strike, which is the initiation of stance phase. The stance phase, which represents the weight-bearing phase, is divided into three periods: contact, midstance, and propulsion. The contact period begins with heel-strike, at which point the extremity receives weight to the rearfoot, and the vertical ground reactive forces are increased. During the midstance period, the vertical ground reactive forces are very decreased, and the body’s weight is fully loaded on the foot in a static distribution, converting it from a mobile adapter to a rigid lever necessary to produce forward propulsion. The propulsive period begins with the heel lifting off the ground and continues with the weight excursion being carried across the hip and knee joints and developing into plantar flexion of the foot, and then the first toe lifts off the ground.

The highest plantar forces develop at the beginning of stance phase, when the heel strikes the ground, and at the end of the same period, when there is propulsion of the foot from the ground. An inability of the subtalar joint to absorb the shock produced by the heel-strike or of the forefoot to distribute the high forces

required for propulsion can result in the development of high foot pressures, [1].



Figure 1. Measurement of foot pressure

2. Foot orthoses

The purpose of orthopedic insole is to reduce the feet pressure beneath the level that can cause biomechanical disturbances or lesion of foot tissue and to limit the total range of motion available to the foot as it coils to the ground (called “pronation”). Although just a small part of orthotics, the insoles are necessary for the orthotic shoes and for all other orthosis whose goal is to enable as adequate distribution of plantar pressures as possible, and to reduce those pressures beneath the level that can cause biomechanical disturbances or lesion of foot tissue.



Figure 2. The samples of the insole

How really insole works? For proper answer it is necessary to look back in the time when the foot was not the only organ between the human and the ground. In those times foot also served as an organ for catching. From, so far, unknown reasons, few million years ago, our ancestors pass on the two-footed walking, and started the journey from Africa towards theirs and our today’s homelands.

However, from the anthropological point of view, the period of few million years is not the period in which the morphological and functional feature of any organ could be so much changed that we could talk about complete adaptation on new conditions. Considering bipedal model of walking, the foot function is one of the youngest achievements of human kind. The foot becomes an organ that should simultaneously enable the carrying of body weight, propulsion of walking, and alleviation of the forces and stability of the whole body. The development of cognitive capabilities of our ancestors, initiate the development of foot protection what could be considered as early footwear. It helped them to do

their duties longer, easier and in various weather conditions. The shoes became unavoidable article, and started to take over the basic foot function.

Unfortunately the development of shoes design was more influenced with fashion, and less with biomechanical needs, what resulted in some negative trends (present even today), especially in design of ladies shoes.

With development of civilization, almost all urban surfaces are hard covered what significantly increase the forces acting on the foot. The static foot hardships, except those caused by disease or genetically determined, became pandemic problem. As an answer on the foot pains, the first orthosis, that had the most characteristics of today's insoles, was designed at the beginning of this century. Even without enough knowledge about foot stresses, and by using the method of trial and error, it enabled the walking with far less symptomatology. It is also the time when the first scientific papers about static of the normal foot and distinction between normal and abnormal were published. Some of the theories were defined, that are valid even today. Such one is TRIPOD theory that says that the foot relies on the ground in three points that are mutually connected with arcs. Although the TRIPOD theory has a lot of opponent, there is still no firm proof that can dispute this theory. There are also some attempts to realize the devices that could measure the forces between the foot and ground. First measuring devices were very innovative, but simple and with poor reliability and accuracy. Optical pedobarography was a significant improvement, but the treatment of individual patient and design and production of custom made insoles, was enabled with development of CAD/CAM and contemporary measuring devices with needed level of reliability and accuracy. The measuring of plantar

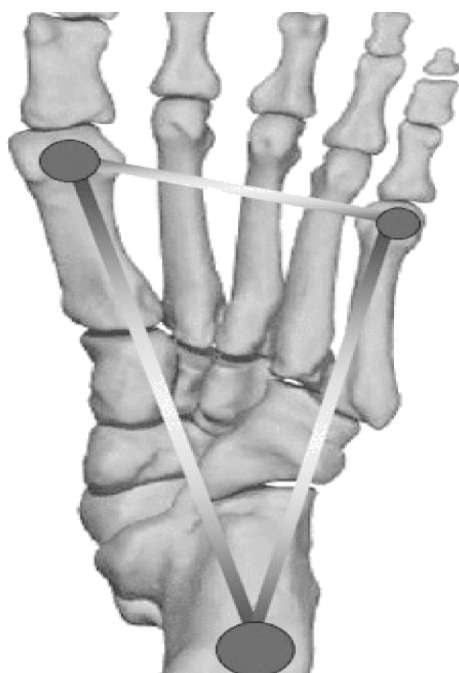


Figure 3. The TRIPOD theory

pressures proof to be very important for the persons with disturbed sensing system (5).

In Western societies, the main cause of the insensate foot is diabetes mellitus, while in poor Far East countries is Hansen's disease. The other conditions in which studying of plantar pressure distribution might be helpful include rheumatoid arthritis, sports medicine, orthopaedics, and pathologic changes of foot shape elicited by biomechanical abnormalities.

The components of feet work together, sharing the tremendous pressures of daily living. An average day of walking, for example, brings a force equal to several hundred tons to bear on the feet. This helps explain why feet are more subject to injury than any other part of body.

Foot ailments are among the most common of our health problems. Although some can be traced to heredity, many stem from the cumulative impact of a lifetime of abuse and neglect. Studies show that 75 percent of Americans experience foot problems of a greater or lesser degree of seriousness at some time in their lives; nowhere near that many seek medical treatment, apparently because they mistakenly believe that discomfort and pain are normal and expectable.

Pronation is a series of motions in the foot designed to absorb shock and prepare the foot to propel us forward. Pronation begins when the heel hits the ground. Pronation reaches its maximum when the whole foot is on the ground and has gone through its entire range of motion. It is at this moment, when the foot is stretched to the maximum, that the breakdown process begins. Running compounds this by stretching even further. Inflammation (biomechanical inflammation) and structural breakdown (e.g. bunions) begins to accumulate through life of walking and running. This repeated stretching and trauma builds upon itself eventually become INJURY. We are not all affected the same way. Some of us develop arch or heel pain (plantar fasciitis), some develop unstable ankles, some develop runners knee and of course many other symptoms can develop especially low back or hip pain resulting from a "functional shortage" (5).

A variety of factors dependent on time and trauma dictate how we will respond to "biomechanical malalignment" (which we know as pronation problems). We all have biomechanical malalignment, a human machine designed to break down over time. Each of us is vulnerable to the "natural condition" of our own biomechanics.

Most prescription orthoses do this. In fact many non-prescription supports do it too. However, the closer the orthoses is to the individuals own functional prescription, the more comfortable it will be to get used to, to wear, and above all else produce results. Foot orthoses unfortunately do not offer an instant resolution. Some people do respond quickly, although this is the minority. Some people are more complex for whatever reason and they may take up to six months to begin to respond favorably. The majority of people feel a 40-60 % minimum average

improvement in their symptoms within 8 weeks; (this is not the same as being cured). As time continues it is possible to feel like progress has stopped or that the pain is coming back. As you wear the orthoses you begin to absorb the prescription so you may start to feel the residual inflammation and tension temporarily. If orthoses are comfortable and you are able to wear them most of the time they are working.

The healing of biomechanical inflammation takes time. It can take 1-2 years for an orthoses to generate its maximum effective range of healing. As foot flexibility increases, the optimal position of alignment will change (due to reduction in tension and inflammation). Then regardless of your symptoms you need to get another prescription in order to keep your feet and body working to their best efficiency. If your orthoses work correctly you can expect 2-3 changes in your lifetime. Most of these changes should occur in the first to the second year. The next change should be very gradual over the next 4-6 years. After that changes may or may not occur. If they do it will take a long time.

So to clarify is there an orthoses so ideal as to prevent foot problems it. Depends on what problems we are looking to prevent. If we are looking to prevent injuries from inadequate training, excessive distances, increasing mileage too quickly, anatomical or functional abnormalities, accidental sprains or strains, uneven surfaces, and aging, probably not. But if there are biomechanical reasons for something to eventually happen e.g. structural (like a bunion or heel spur), then it is possible to, at least, slow down the process and possibly prevent this from occurring enough to not let it be a problem in your lifetime.

Research in the field of gait analysis and orthotic function has become an area of great interest as computer generated gait analysis.

2.1 Overview of Foot Pressure Measurement System

Of the greatest importance in insole design is introducing in foot static condition on which the orthosis will be applied. It has been a long way from pioneer works of Beely to the today state-of-art and in-shoe pressure measuring devices that show plantar pressure distributions. Such devices have provided that thousands of diabetic and neuropathic patients walk today almost without risk of plantar ulceration development.

Force, or ground-reactive force, is defined as the total or net load acting on the foot against the supporting surface, and pressure measures the amount of force applied over a unit of area and is calculated by dividing the total force by the area on which it is applied. There is no homogeneous distribution of the pressure under the foot, especially during walking when high forces are developed under certain areas of the foot. In healthy subjects these high forces can easily be distributed in large areas of the foot, and this is the main reason that body weight and the size of the foot do not relate to foot pressures and are usually not high. In pathologic conditions, inability to distribute high forces is one of

the first noticed abnormalities and leads to the development of high foot pressures.

2.2 The Methods for measurement of the forces and pressure

There are a number of methods for force and pressure measurement. One of the possibilities to classify measuring methods is following:

- *semiquantitative* - a number of measuring methods could be classified in this group. They extend from earliest methods back in 1882, up to the methods that rely on application of video cameras. Some of the methods and devices are still used in clinics. The major limitation of these methods is impossibility to give the quantitative data on both, the force and pressure distribution.
- *quantitative* - the application of quantitative methods started at the beginning of 70-ties. They enabled to establish the relationships between some foot diseases and plantar foot pressures (for example the relationship between body weight, plantar foot pressures, and foot ulceration in diabetic patients). It was a big stimulus for further improvement in insole design and production.
- *optical pedobarograph* - this is a method for measurement of dynamic plantar pressure. This system has high spatial resolution, which allows the accurate measurement of high foot pressures under small areas of the foot with satisfactory repeatability and reliability. The optical pedobarograph has been used widely in the study of diabetic foot problems. The main disadvantage of this system is that it is limited to measurements of pressures of bare feet and does not allow the evaluation of in-shoe pressure (7).
- *computer-assisted foot pressure measurements* - developments in computer technology over the last two decades have enabled the development of microprocessor-like recording systems that can measure in-shoe foot pressures. Some of the most known systems are: EDG System, EMED System (Novel Electronics which yields an accuracy of $\pm 5-10\%$), the F-Scan System (Tekscan), [7], etc.

Today is possible to measure plantar pressures with high accuracy, and that is the base of computer design of orthopaedic insoles and other orthoses.

According to acquired cognition about static and dynamical foot stresses and their connection with foot topography and most frequent foot diseases, orthopedic insole could significantly improve the distribution of foot pressures. Generally speaking, the insole could be of big importance for pain relief caused by disease or genetically determined difficulties. In certain circumstances the insole could even be successfully used to make some corrections in the musculoskeletal system of human, which otherwise could cause a serious consequences for human health. So far applied technologies for insole production could not fulfill the expectations, while the whole process was quite dependent on the skill of orthotist. Feedback information on insole quality was mostly verbal. It was

not possible to analyse the effects of little smaller or little bigger modifications on insole, because repeatability was minor, and experiments, considering technology for insole production, were very expensive and unreliable. The application of computers and new technologies has enabled the new approach to insole production.

3. CAD/CAM System for design and manufacturing of insoles

The application of computers and new technologies has enabled the new approach to insole production. The efficient insole design could help in pain relief caused by disease or genetically determined difficulties. Repeatability, desired modifications and even production are no more big obstacles for experimental work. The whole procedure is more determined, the skill of orthotist is no more of vital importance, because it could be "algorithmised" and transferred into the software for public use. The new possibilities for establishing models of pressure distribution, new

methods of numerical analysis could be applied, and insole production is very much supported by engineering knowledges.

3.1 Design of CAD/CAM system

The goal of CAD/CAM system is to provide the means for qualitative, fast and inexpensive manufacturing of insole [8]. During clinical checkup, the physician establishes the foot problems and defines the way to solve them. CAD/CAM system should be able to offer to the physician and orthotist the "tools" for converting the standard insole (template) or the foot casting into the insole that will be response for achieving the wanted effects. The developed CAD/CAM system, figure 4, consists of three modules:

- Input module
- Module for modification and final adjustments
- Postprocessor

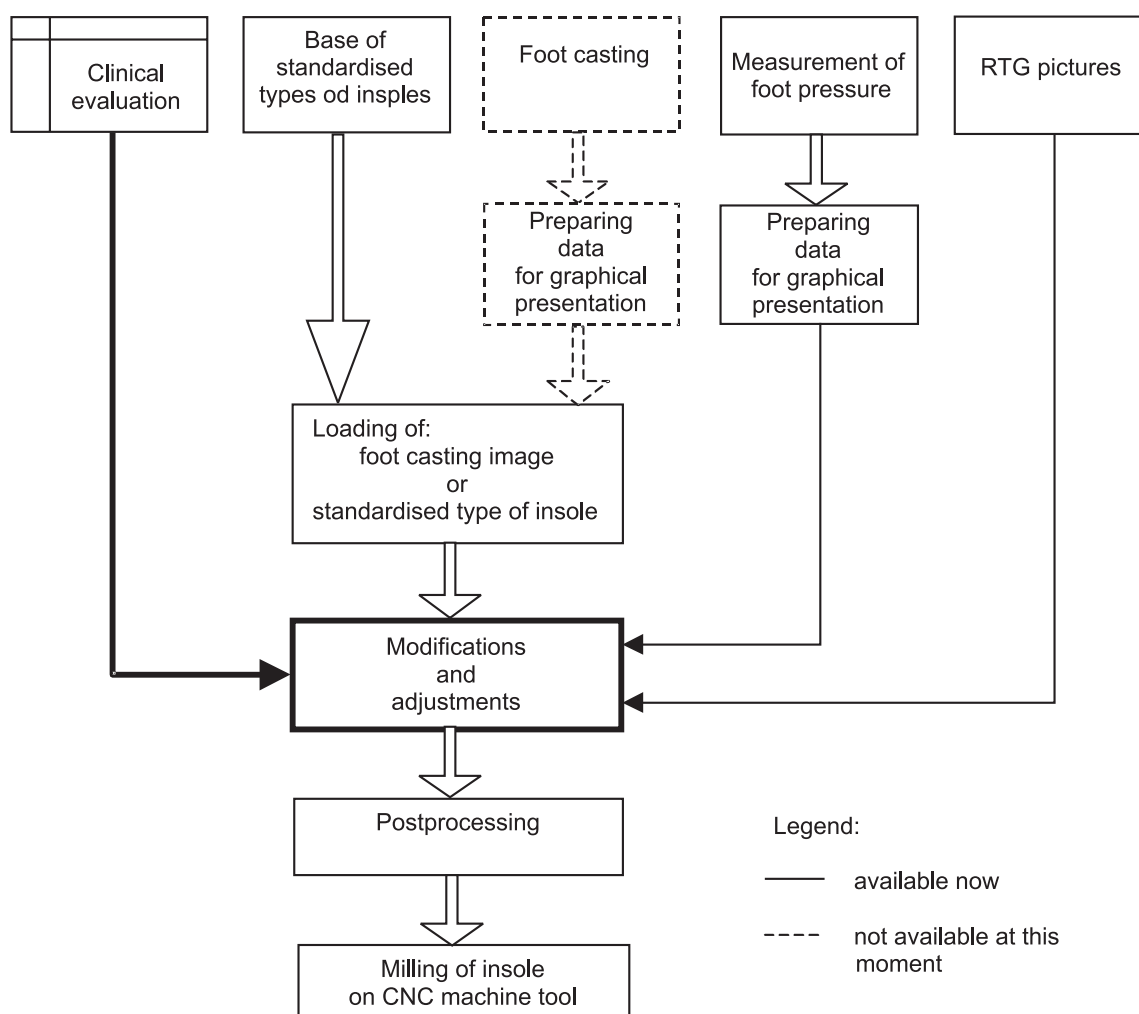


Figure 4. The phases in insole design and manufacturing

The input module of CAD/CAM system is capable of loading and graphically presents the data from foot casting, the data for standardized types of the insoles (templates), and data from the plantar pressures measuring device, Fig. 5. Some foot diseases and deformations could not be properly treated without RTG pictures. The module enables various manipulation of the images, like moving, rotating, different kind of presentation (point, surfaces, lines), depending on the designer, who can also decide to remove the picture from the screen.

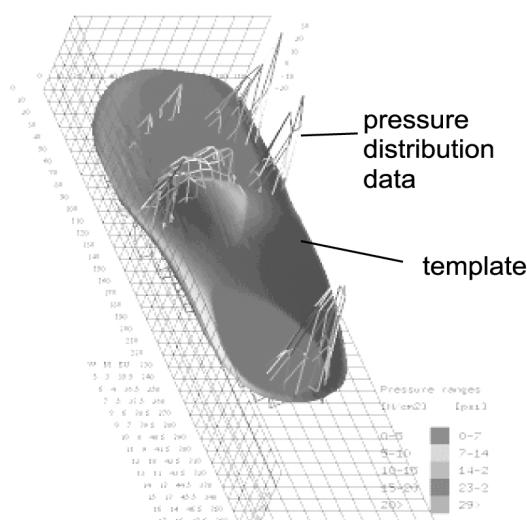


Figure 5. The pressure distribution data mapped over the template

The data from measuring platform and clinical checkup are basis for physician decisions on the shape and magnitude of necessary modifications of the template (standardized type of insole).



Fig. 6. The subroutines and functions in edit mode

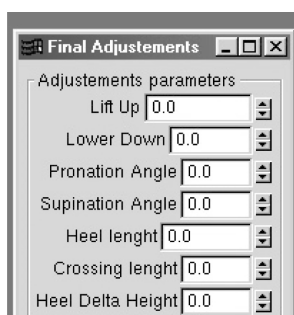


Fig. 7. The subroutines and functions in submodule final adjustment

The next module is module for modifications and adjustments of standardized insoles. It consists of two sub modules: edit mode and final adjustments, figures 6 and 7. Each submodule consists of number of subroutines defining different possibilities for design and modification of insole. The most of the subroutines in edit mode and final adjustments use 3D-bspline function. The parameters enable the user to change the degree of bspline function (curvature) and to change the effective width, i.e. the width of

the area connecting affected and unaffected area. The subroutines in the submodule final adjustment are developed for final modification of insoles, like heel design, supination, pronation, lift up of insole or lower down of complete insole, Fig. 7. Depends on the designer (physician or orthotist) selection, the system enables any combination of images to be displayed at the same time, Fig. 8, in order to make the insole design as easier and more efficient.

The postprocessor module converts the data of redesigned insole into the commands for CNC milling machine. The generated code could be checked on the screen, before it is downloaded in the controller of the CNC machine tool, Fig. 9. The postprocessor can generate the code for machining of the insole upper surface, and code for machining the contour. Presently, the generated cutting motions are directed along Y-axis (longitudinal axis of insole), Fig. 9.

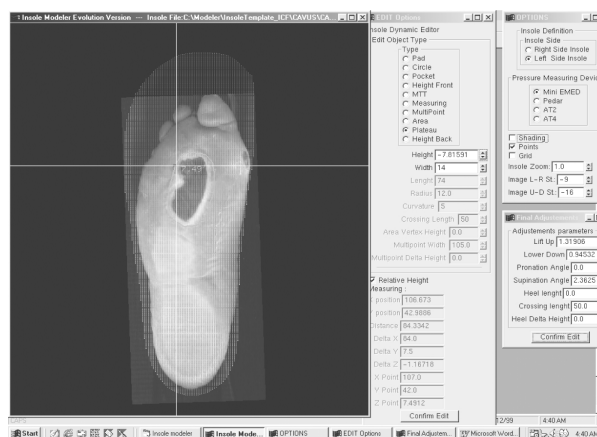


Figure 8. Application of function PLATEAU for designing "valley" below the ulcers projection in order to reduce or eliminate the pressure and pain

Finally, as a part of CAD/CAM system there is database module. It is difficult to imagine serious medicine based software without presence of database. In this case database provides to the end user appropriate review of all previously examined patients, both their clinical findings and results of different exams (Rx, pressure data, IR data etc.).

It is possible to add data, erase, seek, update and make a query. In database there is field for storing vectorised graphic files of the designed insoles. Any other module from the Insole modeler can be started, by simple mouse click on appropriate field (e.g. by clicking on pressure data automatically design program is loaded). Database can be viewed as a form or as a table and data may be sorted in different directions. For database programming Visual Basic 6.0 programming language have been used.

The next phase will include the module for processing of foot scan images, what could be used for persons that do not need the physician checkup, i.e. for the production of so called comfortable insoles. The next research project will investigate the possibility for developing a software module that will be able to automatically

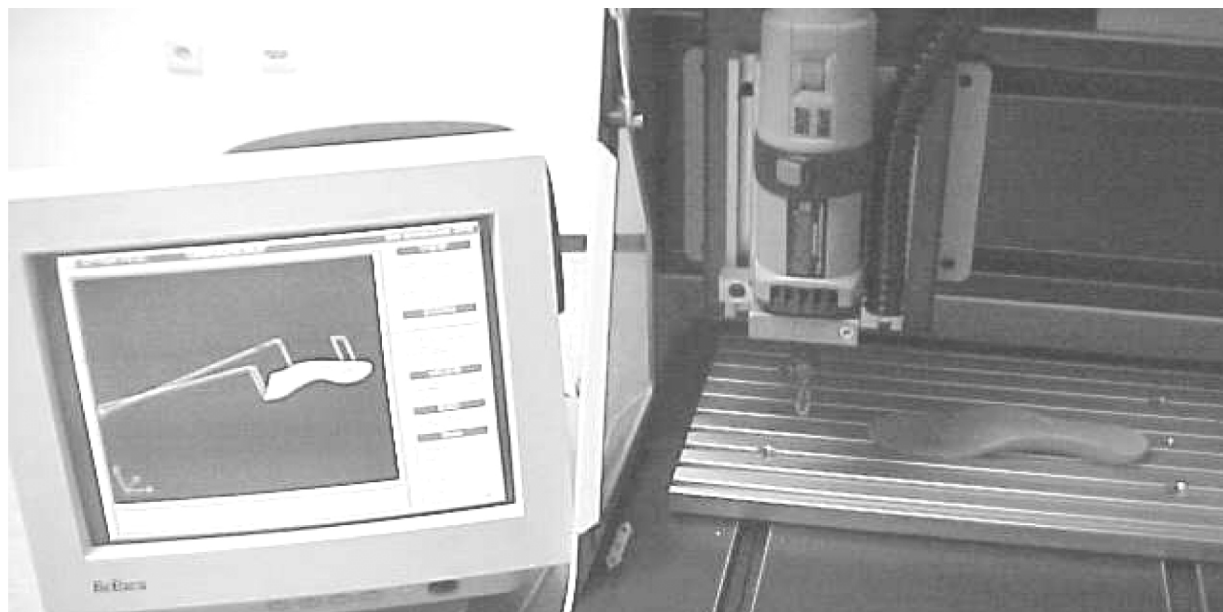


Figure 9. Simulation of cutting tool path generated with postprocessor

recognize a number of foot disease and deformities, and propose the solution. Diagnostic part of module would be based on pattern recognition techniques, while the "healing" part would be an expert system.

4. Conclusion

The application of CAD/CAM in prosthetics and orthotics is relatively new and offers a lot of possibilities and challenges. The advantages, when compared with conventional insole production, are numerous: repeatability, accuracy, easy modification, smaller

production time, and possibility to keep a track on insole efficiency. It is predictable that such systems will advance in stress analysis, definition of mathematical and logical connections between foot abnormalities and necessary modifications, same as in the material optimization for the different areas and modifications elements of insole. It is also to expect that new manufacturing technologies as rapid prototyping [9], and new data processing techniques as expert system and artificial intelligence, will contribute to insole production. Although strictly individual, insole production could reach much higher level of efficiency and automatisisation.

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