Chapter

Application of Machine Tools in Orthoses Manufacture

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Abstract

CNC technology is widely used in the manufacture of medical products. An area in which CNC technology has proven to be extremely useful and innovative is Orthotics and Prosthetics (O&P). O&P laboratories are engaged in the manufacture of individual orthoses and prostheses. The usual manual manufacture of such products takes a long time and requires tremendous experience and skill. In this regard, any engineering solution that improves the quality of the production process; reduces production time, production costs, and physical human labor; and at the same time improves the environmental conditions of the production environment will be desirable. Various designs of CNC machine tools for the manufacture of orthoses or molds for their production are in use today. In most cases, customized commercially available numerical control lathes and milling machines are used, as well as industrial robotic arms, but there are also highly specialized designs. For the mentioned purpose, we also encounter the application of additive manufacturing (AM) devices. Due to the fact that issuing of orthoses is often the subject of cost reduction in healthcare systems, the pursuit of production systems that will be cost-effective and functional, easily implemented, and used primarily in small manufacturing practices is imperative.

Keywords: CNC, machine tools, orthoses, O&P

1. Introduction

O&P is a medical-technical profession involved in the manufacture of orthotic devices, prostheses, and similar products. Orthoses are aids that serve to compensate for a functional deficit, while prostheses serve to replace a missing part of the body.

The need for such aids is as old as the human species. Due to trauma, illness, or other circumstances, a person is exposed to the possibility of developing a disability, loss of working ability, and, generally, a reduction in the quality of life. With the application of various medical treatments, people have sought to solve this problem by using available things from their environment, or in this sense made simple props and devices, with which they have compensated the negative effects of their present deficit. Numerous events in the past have encouraged greater demand and need for a more comprehensive approach for the design and application of such aids, thereby improving their performance and quality.

It is well known that consequences of traumas, deformities, old age, certain pathological processes, or impaired human biomechanics can produce a deficit of the locomotor system. In these conditions, orthoses are used as the main aids in daily life.

Orthoses are roughly divided into:

- Craniofacial orthoses
- Trunk orthoses
- Upper extremity orthoses
- Lower extremity orthoses
- Orthopedic inserts (**Figure 1**)
- Orthopedic shoes

The application of modern technologies has enabled the simplification of otherwise demanding procedures such as taking measurements and making the orthosis itself.

In the standard procedure, these issues depend entirely on the level of expertise and experience of the individual or the laboratory in which the production takes place.

Mostly it is about a manual technique of manufacturing using available tools and machines, which are used to modify the plaster mold.

If we take spinal orthosis manufacturing as an example, this mold has the shape of a human torso (**Figure 2**). It is made by pouring gypsum into the primary plaster mold, which is formed by solidifying the plaster bandages wrapped around the body, which is a particularly unpleasant procedure for the patient [1].

The mold obtained in this way weighs tens of kilograms, is difficult to manipulate, fragile, and, what is particularly important, rigid; so, it is very complicated to carry out the desired modifications of the surface. Due to the imperfections of such a procedure, inadequate products are often made.

A team of experts in the fields of medicine, mechanical engineering, computer science, and other related professions participates in the orthoses design and its production for the patient. The application of CAD/CAM technologies has significantly simplified this process for the past 30 years.

Figure 1.
CNC milling machine with three spindles.

Figure 2.
Spinal orthosis and mold.

Although it is used in the manufacture of all types of orthoses, it is certainly most used for the purpose of making orthopedic insoles with the typical use of three-axis CNC milling machines (**Figure 3**).

Orthopedic insoles are made by direct machining of the materials (usually EVA—ethylene vinyl acetate) or by making molds from materials that include expanded polyurethane, expanded polystyrene, or MDF (**Figure 4**). The insoles are characterized by smaller dimensions (especially thicknesses) while the same cannot be claimed for other orthoses.

In the process of orthopedic insole design, the following is commonly considered:

- Clinical information
- Data obtained from diagnostic procedures (MRI, CT, standard radiograms, EMG, ENG, force, and pressure measurements) (**Figure 5**)

Figure 3.
Orthopedic insoles.

Figure 4.
Molds for foot orthoses production.

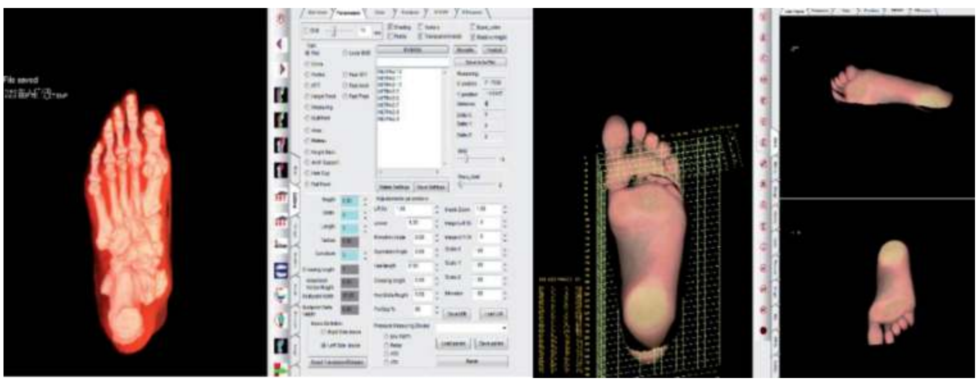

Figure 5.
Design of foot orthoses using CAD software.

- Biometric data, including measurement of the range of motion of an individual body part
- Geometric description of the topography of a body part of interest obtained by the 3D scanning
- Thermographic images
- Other available information (body posture and gait analysis, stabilometry, etc.)

While in the standard procedure, these data (e.g., standard radiograms) are reviewed and decisions are made on modifications of plaster molds based on them, in the digital procedure they are imported in digital form into the appropriate CAD program as data records, where they are used as a basis for modification or navigation during design (**Figure 6**).

Upon completion of the design, tool paths for the selected manufacturing process and hardware are generated, and then either an orthosis or a mold for orthosis is made (**Figure 7**). Regarding the application of digital solutions in the manufacture of molds for orthoses, additive technologies and machining technologies are used.

The application of additive technologies [2] in the manufacture of orthoses is of recent date (**Figure 8**). This approach far surpasses other technologies in the ability to create complex shapes, but despite great technological advancements both in materials and hardware solutions, as well as initially promising results, it still

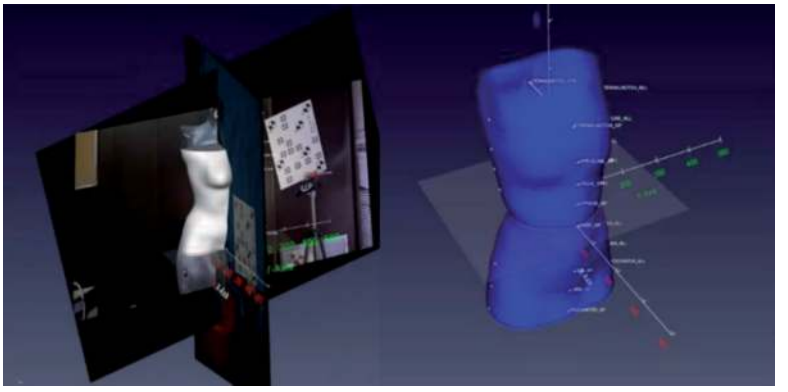

Figure 6.
Spinal orthosis design—CAD.

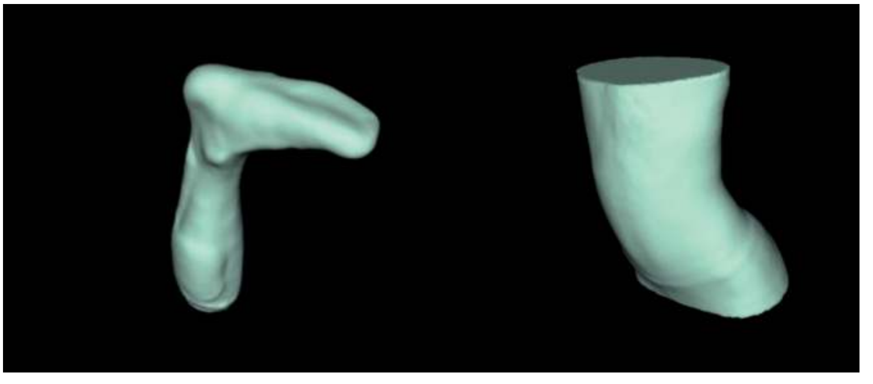

Figure 7.
Completed design for AFO and spinal orthosis.

Figure 8.
Additive manufacturing of foot orthosis.

requires more significant research efforts and improvements to become a full-scale manufacturing technology. It is expected that new solutions will overcome the present problems of mechanical properties of the product, the cost of production of larger volume forms, as well as the time of making orthosis.

These issues are raised particularly when it comes to implementing such a manufacturing system in smaller orthotic laboratories engaged in the manufacture of various types of orthotic devices, and where the implementation of new technological solutions is of great significance for business stability.

However, even after more than 30 years of application of digital technologies, the manufacturing procedure itself remains a significant problem—it is still expensive, not practical enough, often too complicated, and it is common to question the feasibility of investing in its implementation.

With CAD/CAM technology, the biggest financial share is the price of the machine. There are a number of special solutions currently present on the market with the primary purpose of making molds for orthoses. The use of such solutions certainly simplifies the manufacturing process, but they are expensive and are usually found in larger laboratories.

The performance of such machines is often related to the production of only certain types of orthoses, and they need to be modified for other applications because they do not have the proper functionality, which is neither easy nor affordable.

In addition, the kinematics of such machines is often inappropriate for machining molds of more complex geometry, which requires additional human labor.

2. CAD/CAM

The introduction of CAD/CAM systems into the production of orthoses has led to a great advancement in orthotic practice [3].

Its application has brought a major change over the classical (traditional) approach, in which orthoses are made manually.

The use of digital technology in O&P practice is mainly based on results from a volumetric measurement. The classic volumetric measurement necessary for the design of orthopedic inserts is obtained by taking foot impressions in polyurethane foam and plaster molding. In both cases, it is implied that plaster needs to be poured into resulting impressions and one needs to wait for it to solidify. Issues related to this process include the fact that the foam box is brittle, that taking the impression requires some experience (otherwise, a distorted foot shape is obtained), and that the plaster molding is only as good as it was carefully and qualitatively shaped over the foot surface (because it is taken in the non-weight-bearing position). Finally, the molds obtained are rigid and require considerable manual work to achieve proper shape, over which the material can be thermoformed to obtain an insole shell. Sometimes, it is not possible to completely modify the mold while retaining its baseform, because it is rigid, and it is often necessary to add material to one part of the mold and to subtract it in the other part. Also, it is complicated to add and to form corrective elements (e.g., a metatarsal pad feature), because during the molding the shape changes and thus loses its initial form; so, such a "design" depends largely on the experience of the practitioner. With this process, it can take up to 6 h to obtain a mold that is suitable for thermoforming the material. An additional problem is the transportation of the obtained plaster moldings or foam boxes since they are brittle, and the transport itself requires a considerable amount of time and human labor. In contrast, digital technology enables rapid 3D scanning of the entire foot and ankle surface. The information provided is in digital form and can be easily transmitted to a remote location. In such a digital form, the data are fed into a CAD program where they can be manipulated and modified in a much faster and easier way, and without the expense of materials. Such a process, which involves acquisition and design, takes an average of up to 20–30 min depending on the experience of the designer. The use of digital technologies generally provides for the possibility that the locations where scanning, design, and production are performed are different. In practice, we often find the cases where data acquisition and design are performed on one location while orthoses manufacturing is made in a central laboratory that is technically equipped to produce orthoses on a larger scale.

This approach certainly has its advantages and disadvantages. The advantages are found in the fact that the service seeker does not need to possess production equipment. However, due to the large volume of production in such laboratories, there is a potential risk of extended insole delivery time, variations in the quality of the product, and other disadvantages of economic nature.

Modern technologies also allow the use of other information in the design of orthoses, which is especially important in the complicated cases that are often encountered in clinical practice. By using them, it is possible to obtain the surface that is a basis for the design, to conduct simulations of the influence of the insole surface configuration on the displacements of anatomic structures (using models obtained by reconstruction from existing sets of DICOM images obtained at CT and MRI diagnostic procedures; e.g., to define the surface of the skin border and surrounding environment; it is also possible to reconstruct the internal bone structures and use them for navigation during design), and to carry out FEA analysis (e.g., using the abovementioned reconstructed anatomical models and information obtained from the pedobarographic measurements). The quality of design can also be improved by the use of other information such as thermographic images, as well as those that give us additional insight into the shape or function of the part of the body of interest to which the orthosis will be applied.

The application of the CAD/CAM system, unlike the classical methodology, allows both the manufacture of molds (which can be recyclable material and are lighter than plaster) and manufacture of orthoses by direct material machining. This fact is especially emphasized in the production of an orthopedic insole base. The use of CAD/CAM technology also makes it possible to machine both the top and the bottom sides of the insole, either by using special machines that allow for simultaneously machining both insole sides, or in two setups, each insole side in separate setup. This makes it possible to realize an insole in a high degree of completion and with a minimal need for additional human labor. **Table 1** shows the comparison of the methods of making orthopedic inserts using classical and digital procedures. The data are based on years of experience of the authors.

Procedure	Classical	CAD/CAM
Acquisition of information about the shape of the part of the body to which the orthoses will be applied (min–max time)	15–60 min	5 s–8 min
Design and manufacture of the orthoses mold (min–max time)	1–6 h	5–30 min
Production of the orthopedic insoles by molding and finalization (min–max time)	20–40 min	20–40 min
Ability to create the orthoses without mold	Very low (+)	Very high (+++++)
Creating the orthoses basis by direct material machining (min–max time)	2–3 h	5–15 min
Repeatability of the appearance and properties of the orthoses	Low (++)	Very high (+++++)
Cost of manufacture (excluding the cost of machines and their depreciation)—material, time, design, supplies (average)	100–250 €	50–130 €
Ability to achieve the targeted mechanical properties of the orthoses	Low—high (+++)	Very high (+++++)

Table 1.
Comparison of features of classic and CAD/CAM approaches in the production of foot orthoses.

The data presented undoubtedly point to the advantages that modern digital technologies provide in acquiring the information needed to define orthoses and of applying modern manufacturing technologies over the classical process. Digital volumetric measurement takes shorter time, and since it is most commonly performed with non-contact scanners, it does not require the consumption of materials, and given the digital nature of the information obtained, there is a minimal possibility of damaging them through transmission. The CAD design is carried out in the environment where many editing tools are provided. Using these tools, targeted corrections are achieved, and if not satisfied, this action may be terminated and design returned to the previous state. CAD module enables measurements (e.g., angles, Euclidean and geodesic distances, ranges, curvatures, area, etc.) that could be used to predict the volume and shape of the workpiece material and other materials needed to assemble the orthoses (e.g., appearance and surface of the insert top cover material that will be applied to the insole top aspect, or the size and contour of the material that will be molded over the mold by thermoforming). This material can also be cut using a CNC machine with a tangential knife, laser head, or a machining tool. The given approach saves material and prevents possible errors. By using appropriate software tools, it is also possible to smooth the surface in such a way that its main features will be preserved, while this is not the case in the classical procedure. Here, the mold is mostly obtained by pouring plaster into the impression of a foot in foam. After a considerable amount of time for the mold to solidify, there follows a physically demanding procedure for shaping the mold to achieve an adequate form with adjustments and a smooth surface. This involves the addition and subtraction of material on the rigid mold, which inevitably loses its shape. Measurements on such a mold are more complicated and more inaccurate. As previously mentioned, applying CAD/CAM in insole design may also include machining of the insole bottom, which results in an insole ready to use with just minimal additional processing. In the classical approach, forming the insole bottom is very rarely applied because it is extremely time-consuming. One very important feature of the CAD/CAM technology in making an orthosis is the ability to make a multiple copies of the orthosis mold or the orthosis itself. Using CAD/CAM technology, repeatability is very high, and all copies of the orthosis will have exact shape. This is, again, not the case in the classical procedure. The procedure here depends on the experience of the expert who is making the orthosis, the quality of the mold previously used, and other related issues. For this reason, users of the classically made orthosis copy often suggest that there is a significant difference in the properties and appearance of the orthosis when compared with the previously made one, and additional modifications are often required. Creating an orthosis using CAD/CAM technology also makes for great savings in material, time, and energy. One of the biggest reasons for this is that during the design of the orthosis, several parameters can be considered, based on which it is possible to select the appropriate blank size (whether for direct orthosis machining or for orthosis mold), to adjust the machining parameters, and to optimize the trajectories to obtain appropriate characteristics and quality of the surface. Also, the need for human labor has been sharply reduced, so the cost of manufacturing is almost halved compared to making an orthosis with the classical procedure. A particular aspect of the application of CAD/CAM technology is the technical quality of the product and the question of achieving the desired mechanical properties. If one considers the classical process of insole making, it is mostly carried out by thermoforming the material on the mold in a vacuum press. The heated (usually polymeric) material is formed over the mold surface. In this process, it changes its nominal properties and often loses those that are needed to achieve an appropriate therapeutic effect. This is especially manifested in conditions that are very common in clinical practice, which require the use of very soft materials (e.g., diabetes, rheumatoid arthritis, etc.). Since these materials are the most often porous, the pressing process in a vacuum press pushes the air out of the cells of material, and they becomes tiffer. Direct machining of materials in the CAD/CAM process minimizes loss of their properties, especially if the parameters are well adjusted.

A particular issue is the achievement of certain mechanical characteristics of the orthosis by determining the thickness of the material in a particular region. This is a common requirement and is much easier to implement with CAD design than through manual forming in the classical procedure.

From mentioned above and other indicators, it can be concluded that the implementation of the CAD/CAM procedure has contributed that the process of manufacturing an orthosis became:

- More massive
- More practical
- More specific
- Faster
- More predictable
- More accurate
- More repeatable and
- The application of the appropriate CAD program enables to carry out such corrective actions that cannot be easily achieved in the classical approach.

Generally, the benefits resulting from the application of digital technologies in manufacturing orthoses include:

- Portability
- Reduced manufacturing complexity
- More time available to work with the patient
- Reduction of storage and production space
- Simplicity of copying and manufacturing the same orthoses
- Simplicity of upgrading the production process
- Possibility of distributed production
- Reduced labor costs
- Higher productivity

The particular benefit of using digital technologies is the achievement of more humane working conditions, that is, excluding people from jobs that are:

- Physically demanding
- Boring
- Repetitive
- Dangerous

The introduction of the CAD/CAM technology into O&P has led to faster and higher manufacturing of quality orthoses and has accelerated and simplified the procedure itself for both the patient and the orthotic practitioner [1].

3. Literature review

Although there are numerous descriptions of manufacturing orthoses in the literature, a review of their production using CNC machine tools is relatively scarce. We can find a large number of articles that generally describe the application of the CAD/CAM technology in orthotics and prosthetics, but there is little information with a more detailed description of the technical design of such systems.

- Orthotic practice has been radically changed by the implementation of digital technologies [3].
- Particular progress in orthotic practice has been achieved through the implementation of contactless scanners of human body parts and CAD/CAM technology. The application of scanners reduces the time of defining the shape of a body part. Also, it eliminates physical work involved in the process of acquisition of the human body geometry, enables storing of information in digital form without the accompanying problems of mold storage, enables transmission of data over the network, and provides high accuracy of acquired results [1, 3–5].
- Although the application of the CAD/CAM technology is unlikely to completely eliminate the need for human labor, its application in the production of orthoses has made a major technological breakthrough, and progress in technical quality and efficiency of the orthosis performance, with overall simplification of the procedure, and reduction of the need for otherwise hard work [5, 6].

It is evident that larger workpiece dimensions require more space, larger machines, and therefore more financial appropriations.

In addition to the three-axis, we also often encounter four-axis milling machines, turning centers and multitasking machine tools. Industrial robots are also increasingly used in O&P practice [7–11] (**Figure 9**).

However, the mentioned solutions still do not fully cover the main requirements of the practice: availability, greater efficiency, flexibility, and applicability within healthcare institutions.

The application of digital production systems is closely related to the beginning of the 3D scanning application. The use of a 3D scanner allows the reduction of time for defining the shape of a body part of interest (as well as elimination of the physical labor used to define the shape of an orthosis or its mold in the classical procedure) and load the results of scanning into a CAD program (**Figure 10**).

Figure 9.
Robot-assisted spinal orthosis molds production.

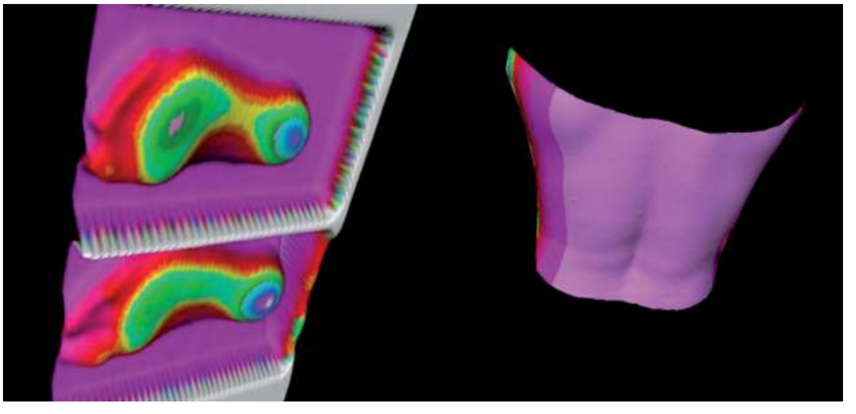

Figure 10.
Results of 3D scanning of foot foam box impressions and patient's back.

The resulting surfaces serve as the basis for design that will be modified or, upon superimposition onto the surface of the template, will be modified in terms of defining the corrective elements that give the functionality to orthosis. Upon completion of the design, the tool path is generated and transferred to the CNC machine tool [3, 12].

The use of CAD/CAM systems has not yet become widespread. There are reports in the literature that digital technology is currently in use in approximately a quarter of orthotic laboratories in developed countries, with the primary reasons being price, impractical performance, inconsistency, and the size of production systems. CAD/CAM technology is still a relatively new approach to O&P practice. The use of this technology has aroused great interest, but experiences are still being gathered and the approach is still evolving. Initial expectations from such systems were quite high in terms of increasing production, reducing manufacturing time, and obtaining high-quality products with a high degree of completeness, thus significantly reducing the required manual work. However, in a significant number of commercially available systems, this was not the case and such a system needs to be significantly refined to be adjusted for application in O&P. With implementation of new technologies, there is usually an initial doubt and hesitation in its application, especially if it is fundamentally different from the usual principles and if it requires the possession of additional knowledge in the IT and technical fields. However, it is undoubted that the cost of the initial investment in such production systems is the leading reason why they have not been widely implemented in practice. Other reasons include the problem of implementing this technology in production environments with limited space, impractical performance, and excessive complexity in use. From the above, it is concluded that any technological advancement of existing systems will be well received in practice [6, 13, 14].

Even a very detailed analysis of the available literature does not provide specific information on the important technical characteristics of the machines used in orthoses manufacture, through which it is possible to look at the design needs and modes of operation of the machine in the processing of different types of materials, and to optimize the production process. In practice, such data are generally obtained by trial and error [15].

It is also very rare to find data on the application of machines based on parallel kinematics [16].

4. Machine tools in orthotics

The classic three-axis CNC machine tools are characterized by rigidity and the possibility of heavy loads during operation.

The kinematic characteristics of most of the available machines, which are commonly used to make orthotic molds, assume mainly three- or four-axis milling CNC machines.

In general, the following characteristics are expected from machines used in the orthotic industry:

- High machining speed and high feed rate speed
- Adequate quality of the machined surface
- High repeatability
- High flexibility of use in terms of the possibility of making molds for orthoses and prosthetic allowances of different uses
- Appropriate work space for making the molds of maximum expected dimensions
- Adequate rigidity
- Energy efficiency
- Quiet operation
- Compactness and the least possible dimensions
- The possibility of extending the functionality with additional equipment for performing measurements

These aspects are further complemented by economic issues, which must certainly take into account the fact that the final performance of the machine must be satisfactory since it is a major requirement for its implementation in practice. It is also imperative that the machine is safe for operation and that the necessary safety and technical conditions are met.

5. Machine concept and realization

The most represented machines in orthotic practice are the three-axis CNC milling machines, which are generaly less demanding versions of standard metal cutting machines. When a specific machine for orthoses manufacture is being developed, this activity is complex and involves consideration of many aspects from the medical and technical side.

Methods for achieving technical realization of the machine and related software support include:

- Defining the required dimensions of the machine workspace, machine's external dimensions, its characteristics defined by the needs of the profession

- Development of a method for the solution of machine kinematics (solution of direct and inverse kinematics for the selected configuration), with the development of a software simulator to validate the kinematic model under virtual conditions

- Development of a software support that enables the generation of compensated tool paths

- Development of a simulation program with the possibility of realistic spatial simulation of machining the blank

- Development of the machine prototype, including all necessary stages: design, definition of drive and control components, simulation, preparation of project documentation, procurement of parts and all necessary materials, assembly of the machine and its start-up, implementation of necessary tests and corrections in order to ensure minimum technical requirements and meet all safety needs

After the machine realization follows the implementation of activities aimed at determining the correctness of the assumptions that the application of this solution contributed to the advancement of the orthoses manufacturing, accelerated and simplified production, reduced the need for human physical labor, and generally improved the current state of technology.

Except for the use of industrial robotic arms in mold machining, machines with five degrees of freedom are rarely encountered in orthotic practice.

In regard to experimental purpose, one also considers designs of machines that are based on parallel kinematics, which are expected to give some answers to problems arising through the application of conventional CNC machine designs. As the orthoses manufacture requires a high productivity to meet the requirements set by practice, the machining of materials in terms of generating complex surfaces, the production of large models (we often encounter the need to create models with a height of more than 800 mm and radii larger than 250 mm), there is a need for a technical solution that will improve and integrate these characteristics, as this is a disadvantage of classic designs.

This requirement is complemented by the fact that the materials used to make the orthoses or their molds (or base materials for the orthoses) are blanks made of cork, EVA, expanded polyurethane, polystyrene, MDF, or, less frequently, wood. All they belong to relatively soft materials, what significantly reduces the requirements on rigidity and power of needed for CNC machine tools applied in metal cutting.

Blanks typically come as templates in the form of blocks, plates, rollers, truncated cones, and shapes for making specific orthoses or their molds, which by shape and dimensions are the closest to the part of the body to which they are applied. Predefined shapes, templates, significantly increase process efficiency by reducing machining time and volume of the removed material.

The use of robotic arms for purposes of machining has its greatest value in great flexibility in terms of designing different types of molds and manipulation of five, or more, degrees of freedom and a large working volume.

The designs of the machines used in orthosis production are largely defined by the type of orthoses or molds for the orthoses being made.

In addition, the technical requirements are also conditioned by the geometric complexity of the orthosis surface, the materials that will be processed, and the time required to complete the product.

From all of the above, it is evident that the production of orthoses and related products has specificities that are different from the usual use of CNC machine tools in the industry.

Although these technologies are also used for the production of "off the shelf" orthoses, in most cases individual products or molds for their production, after being machined, will require significant additional human labor (despite the fact that the manufacturing process is automated) in order to be ready for application. The orthoses are individual products with strong request for short production time. Therefore, in the part of the production process that is automated, all the operations should be as simple as possible to implement. The data defined in the design phase (type of material, surface quality requirements, cutting tools) allow the possibility to predefine a set of machining parameters that could be selected in the design phase. The tool path generation should also be simplified since it must be repeated when creating each individual item, which is a time-consuming process. Consequently, applied software should have a high degree of automation and ability to generate optimized trajectories especially for three-axis CNC machine tools with one rotational axis, since they have a problem of hidden areas, which, due to limited kinematic performance of such machines, cannot be machined. Since orthotic blanks of large dimensions and various shapes are often used in the manufacture of orthoses molds, in tool trajectory generation special attention is given to rough machining, which typically removes a large amount of material. This raises the next important question, the elimination of dust and chips created during machining, and the big problem we face in practice is their quantity and properties.

Although orthotics use materials that have been tested and certified for use, and these are usually polymers such as polyurethane, polystyrene, PP, PE, EVA (ethyl vinyl acetate), UHMWPE, etc. due to the machining process itself, the separated particles (chips) are electrically charged and attach to the machine components, which create a particularly big problem if the guides and other moving components are not adequately protected.

A further related problem lies in the fact that materials used are often porous, and internally still contain a significant amount of volatile chemicals that are released by machining, increasing their concentration in the machine's workspace. In addition to adversely affecting the health of employees, these substances, by depositing on moving parts of the machine, can create a film that damages the sealing elements in the pneumatic components, or dissolve dust particles and create a solid deposit that compromises the operation of the bearings.

Therefore, it is necessary to provide systems that allow efficient evacuation and safely dispose of the particles generated by machining, since these are lightweight materials and particles of this dust, even at very low air flow, fly away from the surface and create high concentrations in space. Given these facts, it is highly desirable that these machines have a closed cabin and a good chips and dust collection system.

Application of cooling is less commonly used in such systems. However, with some materials and when requiring the use of specific tools to achieve high surface quality (often in the case of production, EVA insoles that do not have an extra layer of cover material, or when making functional orthoses made of polypropylene), increase of tool heating can lead to the insole material melting or even igniting.

Although such situations can be substantially reduced by selecting the appropriate values of the cutting parameters, compressed air is directed to the tool for cooling purposes. It cools the tool, but its application is also useful in blowing chips. This is especially important for contouring performed to define the external orthosis boundaries.

An important issue we often face in the use of CNC machine tools in the manufacture of orthoses is related to the clamping of the blank. As mentioned above, these are lightweight materials that need to be clamped as quickly as possible in the machine's workspace. In most cases, the use of clamping devices, such as those used in clamping metal blanks, is not considered, with the exception of the manufacture of rigid molds (e.g., MDF material for the purpose of making molds for deep-profile plastic foot orthoses, or making molds for head orthoses when there is a high requirement for the accuracy of the resulting surface). Most often we come across simple manual clamping devices that are easy to manipulate and adjust the clamping force. This however is not simply applicable to all types of materials, which is particularly the case with materials that are softer and more elastic, where it is not easy to exert an adequate clamping force without significant deformation. The double-sided adhesive tape is commonly used to temporarily affix the blank to the machine's work table. Although quality material placement is achieved in this way, the process takes a considerable amount of time before and after completion of the machining, and in most cases the application of double-sided adhesive tape is a significant financial expense (**Figure 11**).

For machines of larger dimensions, a vacuum table is commonly used for clamping, and its application greatly simplifies the process of setting and fixing materials in the machine's work space (**Figure 11**).

When using CNC lathes or multitasking machine tools we also encounter designs of clamping devices in which a shaft is fixed to the rotary axis, with a longitudinal axis collinearly positioned to the axis of rotation.

The blank is attached to this shaft. To clamp such a blank, a nut with a thrust plate is used, which sometimes contains shallow, sharp pins that stick into the material, further securing it. Typically, there are designs of the machines where this shaft is mounted horizontally or vertically. In vertical designs, those with special

Figure 11.
Vacuum table and double-sided tapes for workpiece fixation to machine table.

assemblies for holding the blank are encountered, which additionally secure the blank from above and prevent machining vibrations.

Since the cutting forces in machining orthoses or their molds are incomparably less than those used in metalworking, the power requirement of the spindle motor often does not exceed 3 kW, and given the type of material being machined and the quality of the machined surface, there is a need for high rotational speed. It is desirable to achieve 20,000 RPM and above.

The most commonly used tools for machining of the material include the end mill, ball nose mill, and burr design mill. Typically, milling tools with high helix angles are used, which results in better particle removal and maintains a lower local temperature. The use of burr mills is found in cases where it is necessary to achieve high quality of the machined surface in the shortest possible time or when very soft materials are being machined. This entails the need for a very high spindle speed (≥30,000 RPM) (**Figure 12**).

When making orthoses, the most often used are the milling cutters with a diameter of 6–12 mm, while in the design of molds for body orthoses we encounter milling cutters with diameters up to 30 mm. Such milling tools can be longer than 300 mm, which places special requirement on the design of the tool clamping system.

In the design of such machines, it is expected that the access to the workspace and placement of blanks be extremely easy, since they can be larger in size and it is desirable to affix them to the work table in a way that excludes high clamping forces. In addition, often during machining there is a need to create a mold or product with complex geometry. In doing so, the possibility of fracture of the blank or its separation from the clamping device is increased (high centrifugal forces caused by unbalanced masses), which creates the need for rapid shutdown of the machine and easy access to the machine's working space.

The design of the machine is also expected to be as compact as possible; as such machines are most often installed in smaller sized orthotic laboratories that adapt to new tasks, causing machines and furniture to be moved frequently.

There is also a requirement for the machine to be very quiet, as such workplaces are often located near or within healthcare facilities where the general presence of a noise source is highly undesirable.

In addition to the manufacture of orthoses themselves, CNC machine tools with modifications are also used for other purposes.

In particular, by using them with a laser module or a tangential knife head, blocks of EVAe, cork, PP, HMWPE, UHMWPE, polyurethane, and other materials are cut into predefined shapes or contoured and allows other necessary cutting actions to be performed at high speeds.

In addition, in practice it is common to use mounted scanning module (camera with laser module or other vision devices) to scan surfaces (e.g., to scan foot

Figure 12.
Milled sponge back support and soft facial mask.

impressions in polyurethane foam), especially in machines with large work surfaces (e.g., three-axis CNC milling machines with large X and Y strokes).

Although rarely used, tool changer applications are very useful, especially in the manufacture of orthopedic insoles, in which ball nose cutters are used for machining the main surface, while end mill cutters with smaller radii are much more desirable for contouring.

Making each type of orthosis has its own peculiarities. The same product can be manufactured in a number of ways, although CNC machines can be used in all cases. Ideally, there would be a universal machining system, which is not the case at least for now.

In practice, the closest example of this might be the industrial robotic arm with at least five degrees of freedom, but for the time being there are some problems connected with use of this technology, which is why this manufacturing system is not overly present in orthotics.

6. Basic implementations of machine tools used in orthotics

In O&P practice, three-axis machine designs are used in most cases. Usually, these are standard industrial milling machines that are modified or upgraded by a simple operation for the needs of the specificity of such production (**Figure 13**).

The leading reason for the use of such implementations lies in the fact that generally in orthotics, CNC machine tools are most commonly used to make foot orthoses, primarily orthopedic insoles.

The use of three-axis CNC machine tools satisfies most of the requirements and by using them it is possible to make an orthosis or mold for it with a high degree of completeness, that is, with little need for additional modifications. Creating a pair of orthopedic insoles usually takes 6–16 min. The dimensions of these machines range from the very small ones on which it is possible to make a pair of inserts to those with a large work area commonly used in large laboratories. Three-axis CNC milling machines are also used for other purposes, such as machining of molds for craniofacial orthoses and masks.

Also, it is possible to make more complex molds, whereby the blank of known dimensions is after machining of one side rotated, for example, by 90° and fixed again on the work surface(**Figure 14**). If the dimensions of the working volume allow it, in this way it is possible to create molds for orthoses for various purposes. However, this procedure requires careful positioning and is time-consuming.

Figure 13.
Modern three-axis milling machine for foot orthoses production (courtesy of PedCAD GmbH).

Figure 14.
Molds made on three-axis milling machine and custom protective facial mask.

Upgrading the three-axis CNC milling machine with the fourth rotary axis gives a machine more functionality [11].

In practice, we come across versions that are simply modified for specific needs. For example, for the purpose of machining orthopedic insoles, an accessory with a flat work surface is used on which the blanks are affixed, while for the manufacture of molds for spinal orthoses, a machine tool accessory is used in which, instead of a table, there is a fourth rotary axis.

Generally, the rotary axis is a commonly used component in such machines, with the exception of those for making orthopedic insoles. The reason is that the molds used to make the orthoses resemble the part of the body for which the orthoses are made and are created by machining a blank that rotates around a defined axis. This enables the formation of a continuous surface and complex shapes.

Such machines include CNC lathes or multitasking machine tools. Typical designs are those with a rotary axis set vertically or horizontally. They are usually used for machining blanks from expanded polystyrene or polyurethane. They are characterized by a large working volume (they are used to make molds for all types of orthoses, and molds for footwear; they are not particularly suitable for the production of orthopedic insoles, although they are also used in this regard), high efficiency, and an extensive particle removal system during machining. The average

Figure 15.
Molds produced from expanded PU foam.

production of molds for orthoses of larger dimensions on standard versions of these machines takes between 25 and 60 min (**Figure 15**).

For these purposes, standard versions of machines with rotary axes are rarely used, since in most cases they are intended for metalworking; so, they have a relatively small working space and accompanying components are not intended for the dust produced during the processing of the aforementioned materials.

Application of CNC machine tools with five simultaneous axes in medical field is mostly present in manufacture of mold and dentures in dentistry [17, 18].

Such systems enable the production of all types of molds and orthoses, possess exceptional dexterity, and usually have a large working space. The problems associated with them concern their control, which is more complex than for the usual Cartesian machines; rigidity; speed; and several other issues. Some specific examples of their use in orthotic practice include performing specific automated actions such as applying adhesive by spraying, dyeing, cutting material using a laser module, and also forming the orthosis shape after adding a 3D printing head.

In use or in the form of realized prototypes, there are special machine designs that, by their construction and other characteristics, contribute to individual functionality, making such a machine more efficient, of more appropriate dimensions, or possessing other features that make it more applicable in O&P practice.

Among the many, mentioned here is a special design of an industrial prototype of an orthopedic insole making machine (IPASIOU Project, Faculty of Mechanical Engineering and Naval Architecture Zagreb, Croatia) [19], characterized by a high degree of automation, which, with the automated digitization of both feet, enables an automated process of designing orthopedic insoles, including the top and bottom sides of the insoles (enabling footwear application without the need for additional modifications), and an automated tool path generation for a seven-axis machine with four Z axes (two pairs of collinearly coupled Z axes, which are autonomous and enable simultaneous processing of four different surfaces). As a result of carrying out this procedure, a pair of individually made insoles are prepared that are ready for application in footwear without further modifications, and the whole process of making a pair of such insoles from digitizing the feet to extracting the workpiece from the workspace takes 8–12 min (**Figure 16**).

Another interesting example of a machine with special functionality, suitable for O&P, is found in a specially made CNC machine (Ortoflex, Faculty of Mechanical Engineering SlavonskiBrod, Croatia) [20].

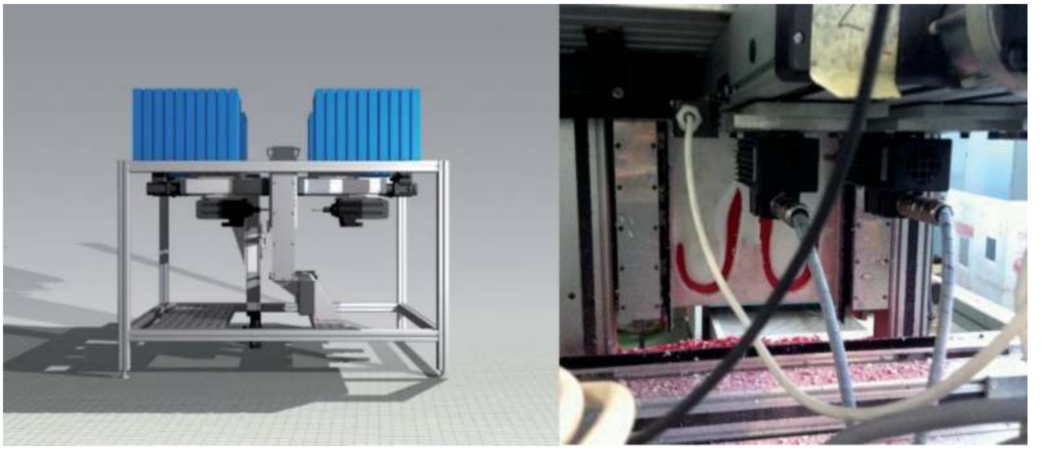

Figure 16.
IPASIOU system.

Figure 17.
Ortoflex five-axis milling machine based on parallel kinematics.

This machine is assembly based on a parallel kinematic design where the platform moves in the X, Y, and Z directions (**Figure 17**). The machine also includes two rotary axes. The primary purpose of the machine is to make molds for spinal orthoses, but it can also be used to make other molds as well. Its special feature is very high speed of movable platform on which the main spindle is located, and the possibility of machining shapes of complex geometry that cannot be easily realized on machines with four axes or fewer. Both projects, IPASIOU and Ortoflex, are the result of research aimed at improving the state of the art in the production of orthoses, in which the authors of this text participated. Of course, there are numerous other specific machine designs.

7. Conclusion

This review discusses the use of CNC machine tools in the production of orthoses and molds for their manufacture. In this area, the application of such systems becomes a standard.

A similar approach is used in the design of individual prosthetic devices, although there are significant differences in the applied materials and functionality of such aids and the methodology of their manufacture and application, which is a much broader context, so their manufacturing is not elaborated in this review.

There is also a range of other related products, the production of which is very similar to the production of orthoses such as individually made wheelchairs, inserts for standard seats, individually made mattresses, pillows, etc. where the use of CNC machine tools as well as industrial robots has enabled quick and precise workmanship.

Although there are still many open questions why the use of CNC machines in the O&P industry is not high, it is expected to become a standard manufacturing technology soon. The use of digital manufacturing technologies has radically changed the orthotic practice; made it simpler, better, faster, more accurate; and has introduced many other benefits. In contrast to the classical approach, it is also possible to exchange information and experience quickly, which contributes to the improvement of the methodology of orthotic design, to further optimization of the production process and the resulting savings. Certainly, the biggest beneficiary of this approach is the patient who gets more advanced orthosis in a shorter time.

Although competing technologies such as additive manufacturing are emerging, the advantages of the application of CNC machine tools in the manufacturing of orthotics will not be easy to achieve. Moreover, with the advancement of technology, it is expected that machine tools for this purpose will become more widely available and find wider application in the O&P field.

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