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Status on pre-surgical deformation apparatus for fracture fixation plates

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ABSTRACT

Purpose: This paper reviews the apparatus used for deformation of bone fracture fixation plates during orthopaedic surgeries including surgical irons, pliers and bending press tools. This paper extends the review to various machineries in non-medical industries and adopts their suitability to clinics-related applications and also covers the evolution of orthopaedic bone plates. This review confirms that none of the studied machineries can be implemented for the deformation of bone fracture fixation plates during orthopaedic surgeries. In addition, this paper also presents the novel apparatus that are designed from scratch for this specific purpose. Several conceptual designs have been proposed and evaluated recently. It has been found that Computer Numerical Control (CNC) systems are not the golden solution to this problem and one needs to attempt to design the robotic arm system. A new design of robotic arm that can be used for facilitating orthopaedic surgeries is being completed.

Keywords: Bone fracture fixation plate; Deformation; Pliers; Iron; Bending press; Vise; Implant shaper; Computer numerical control (CNC); Robotic arm

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MATERIALS

1. Introduction

Currently bone fracture fixation plates are precontoured during the manufacturing process regarding the intended anatomical region. In clinical applications, an anatomically well-fitting orthopaedic bone plate can facilitate the process of axial and rotational alignment the bone fragments [1]. It also may protrude less and minimise soft tissue irritations/impingement [2]. From a biomechanical point of view, the perfect fit between plate under-surface and bone is not compulsory. However, basic mechanics of fixed-angle locking plates dictates that load transfer is the most optimal when the plate screw interface is in the closest position to the neighbouring cortex. When the distance between plate and bone becomes greater, higher bending moment on the screw is required and the construct becomes less efficient for the load transfer [3]. Good fitting can also decrease the stress in fracture region during healing [1,4]. Therefore, the aim of this is to match each bone plate with the shape of its underlying bone. However, in many cases, the plate does not fit to a specific bone initially [1,5] because of the limited availability of plate shapes in comparison with the variation of corresponding bone morphology [6].

2. Preparing orthopedic bone plate for implantation on fractured bone

Currently, orthopedic bone plates are applied and stabilized on fractured bone in a 12-steps procedure [7]. First three steps include the plate and bone preparation for surgery. In these steps, the bone fracture region is isolated and a flexible template of real plate is fitted to the bone to find out the amount of gap between the plate and the bone in different sections of the fracture region. The plate is deformed (bent and twisted) to change the configuration of plate to that of bone. Various traditional tools that are used for fracture fixation applications are shown in Fig. 1.

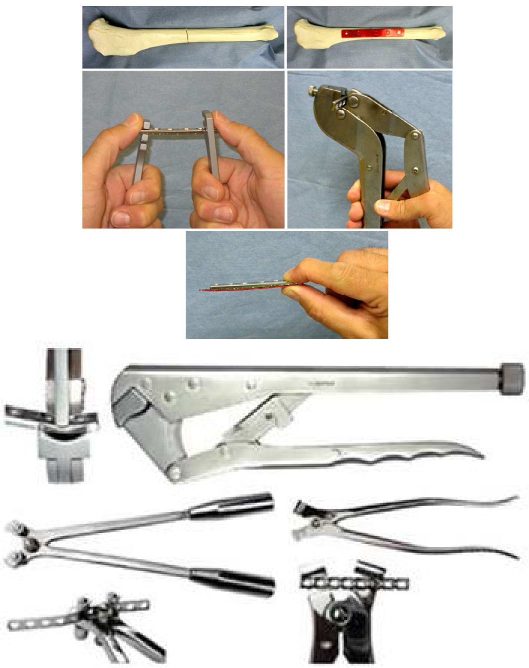

Fig. 1. Tools used in orthopaedic surgeries for fracture fixation applications

Deformations of the bone fracture fixation plates are usually conducted on different criteria to ensure the acceptable fitting. These criteria vary in different plates. For example, if a distal tibial plate does not fit to the underlying bone it needs to be deformed in four criteria [6]. For a medial distal tibial plate, the torsion is usually less than 22° and the bent is usually less than 6 mm. Geometric details of the deformations are defined by fit assessment. Besides to geometric details of deformation, other parameters, such as springback [8], affect on the quality of deformation. Similarly, screw threads of the plates are sensitive in caseof torsion and play a role in the quality of deformations [9].

Pliers are used for performing both bending and twisting of both flexible and strong bone fracture fixation plates in orthopedic surgeries. In manual operation of pliers, the deformation process is time-consuming and tiring. Inaccurate results are highly probable because both the deformation and fit assessment are estimated qualitatively. Bending of orthopaedic bone plates is a manual universal apparatus, as shown in Fig. 2, normally used in light-duty pressing and punch-works, such as making badge and cloth button. There are slight differences in direction of force application and overall shape of these press tools. A bending pressure cannot twist bone plates and can change the plates only in a limited range.

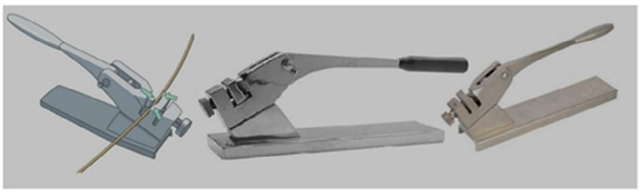

Fig. 2. Bone plat bending press

The main application of bending irons is deforming flexible bone fracture fixation plates, as is shown in Fig. 3. Structurally, it is a fixed-jaw F-shaped wrench which is widely used for dislocating and non-precise bending affairs. To date, neither bone plate bending iron nor F-shaped wrench has been registered as a patent independently. Only one type of F-shaped wrenches, with a movable jaw, has been registered in 1891 [10].

3. Techniques developed for deforming orthopaedic plates

Unlike the named tools of deforming bone plates, there are some apparatus that have been introduced, but are not used widely in orthopaedic surgeries. The patent of “orthopaedic bone plate bending irons” [12], registered in 1996, had aimed to apply bending moments over a short length of the plate to precisely bend it. The invention included two plates with several solid and predefined holes on each. In this patent two separate bending irons were used for performing the deformation (Fig. 4). Having fixed-shape holes, this apparatus cannot comprehensively cover all shapes and sizes of the plates. Additionally, due to having several similar holes on each part, and manual performance of the process, working with this apparatus needs appropriate skills and training. Besides, working with it is time-consuming.

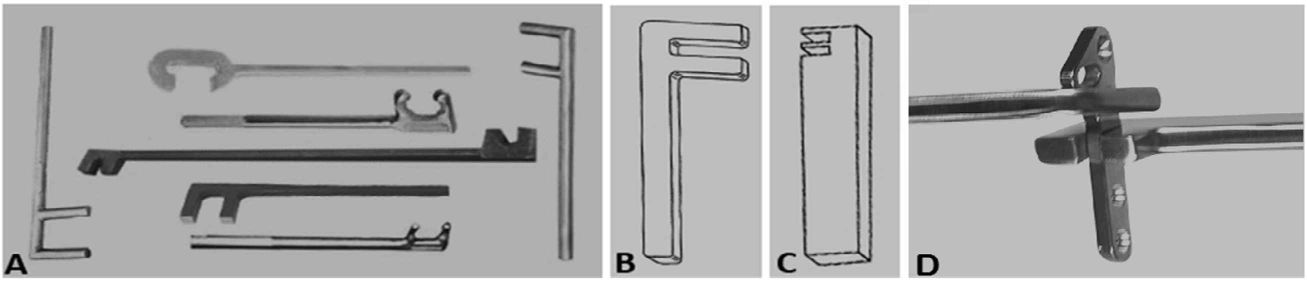

Fig. 3**.** (A) Industrial iron with different jaws and sizes; (B) & (C) Orthopaedic irons; (D) Bending the fracture fixation plate by two orthopedic irons [11]

a) b)

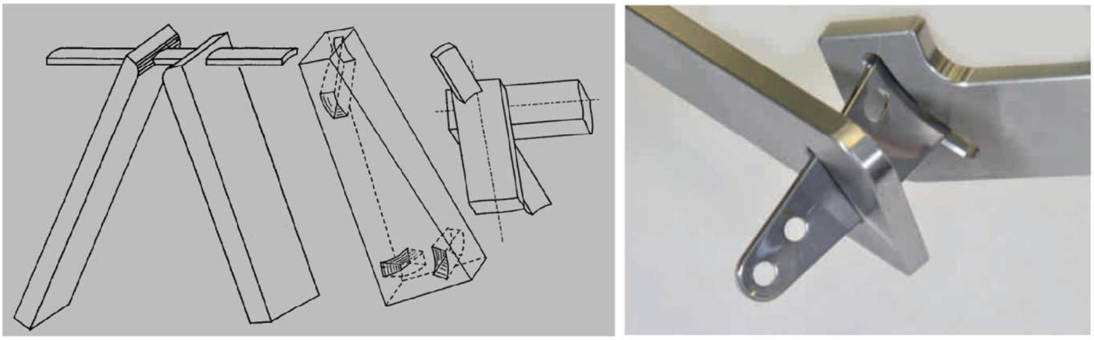

Fig. 4. (a) Bone plate bending iron [12] (b) Delta TPLO Plate Benders with Curved Slots [11]

It is proven that surgery operations usually impose high level of stress to surgeons and it should be considered carefully in design of all medical equipments [13,14]. In other words, it is necessity to ease the functionality of medical devices to reduce the related risks. Regarding this parameter, the apparatus of "orthopaedic bone plate bending irons" is not suitable for deformation of the bone plates during surgery because surgeons have to do a lot of physical activities for a long time to prepare the plate for implantation.

The patent of "Bone plate vise" [15] including an elongated handle holding a clamp mechanism (Fig. 5a) was registered in 2000. The clamp mechanism was used to grip the bone plate during deformation. A bending iron or a second bone plate vise was supposed to be used with the first plate vise to twist or bend the plate. The Clamp assembly included a fixed jaw and a U-shaped movable jaw fixture with a channel. It was claimed that the movable jaw included an accurate plate-contacting surface to match the curvature of the bone plate. Assuming this patent is technically feasible, since the process is done manually, it does not solve the disadvantages of those previously discussed tools, i.e. the accuracy and the speed.

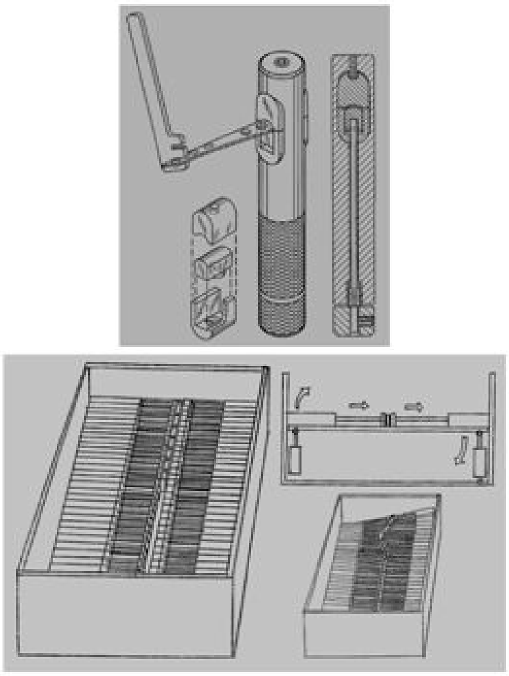

Fig. 5. (a) Bone plate wise [15], (b) Orthopaedic implant shaper [16]

"Orthopaedic implant shaper" [16] consisting a flexible fibre optic curvature sensor device, a computer and an implant-shaping machine (Fig. 5b) was registered in 2003. The fibre optic sensor was used to determine the required three-dimensional shape of the orthopaedic implant. The sensor was applied to the fractured bone through the surgery once it was reduced. Using a library of implants, which was supposed to be available in the computer, the operator inputted the data of the required implant, such as its type, length and number of its holes. Then the machine would adapt the data of the implant with the output of sensor. The information was transmitted to the implant-shaping machine to apply the settings for actual contouring and performing the deformations. The implant shaping machine consisted a series of hydraulic cylinders with dies set in rows on rocking platforms (Fig. 8). Each unit included a pair of four opposing hydraulic cylinders that worked inversely to move dies in relation to the metal fixation implant.

Orbay et al [17,18] introduced a new method of bone plate bending in 2010 (Fig. 6). Fastening a threaded drill guide tip to the plate and deforming the plate using these tips by means of two special benders was the core of this idea. The threaded tip and attached bender could not perform all kinds of deformations. Two different methods with their specific tools were then proposed to fill this gap. These methods and all suggested apparatus can be used only for flexible perforated threaded bone plates, and the whole process has to be performed manually. It means that it does not fill the existing gaps appropriately.

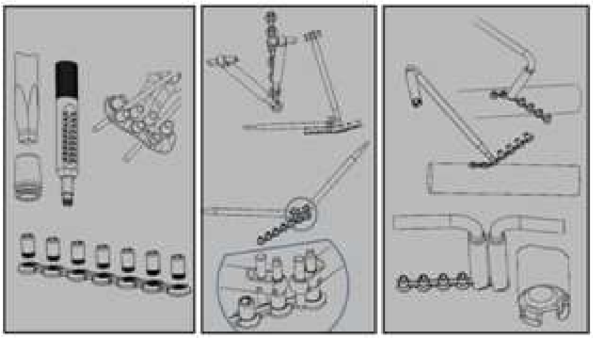

Fig. 6. Bone plate shaping system [17,18]

Improving their previous studies, Orbay et al [19] introduced a new design of bone fracture fixation plate, clamping apparatus and method for constructing a bone (Fig. 7). Regarding the patent, the plate includes several locking holes (central holes) and two small holes around the locking hole for gripping and deformation. Two manual pliers are used to deform the shape of the plate during surgery. In practice, this type of plate has limited applications in light duty bones and the pliers of this patent are only applicable for the plates of this patent. Even if they are applicable for other plates, they have most of disadvantages of the traditional deforming apparatus because of being manual. Raines et al [20] have introduced another design of benders for deforming the locking bone plates in 2009. This bender includes a threaded tip to engage with the threaded hole of the plate and a shoulder to transmit the mechanical force. This apparatus not only includes the disadvantages of all manual benders, but also is applicable only for the flexible perforated threaded bone fracture fixation plates.

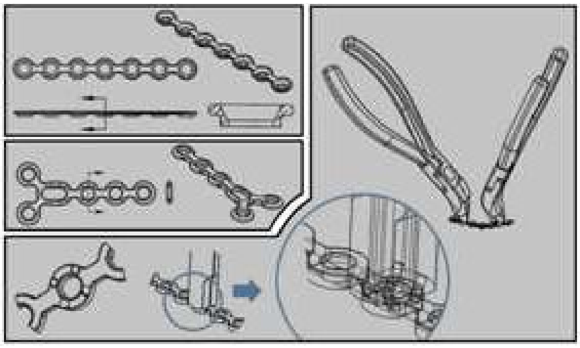

Fig. 7. Formable bone plate & deforming apparatus [19]

Overall, the tools and apparatus currently used for deformation of orthopaedic bone plates have the advantages of low cost, simplicity in structure, easy to work with no need for specific power generator. However, the distinct disadvantages are the low precision, low speed, low repeatability, poor performance, time-consuming, and physical demand for the surgeon. Surgery results depend on surgeon's skill and psychological conditions during the deformation process. Surgical operations are a combination of an intellectual exercise of decision making and performing mechanical tasks [21]. So, if the amount of mechanical task decreases or is simplified, then the surgeon's mental load decreases enabling the quality of decision making increase. Medical devices should therefore be designed to minimise stress for surgeon, and minimise the dependency of the result to the human being factor.

4. Development of related technology in non-medical industries

Despite all improvements and evolutions in various aspects of orthopaedic bone plates, their during surgery deformation equipment have not been improved simultaneously. This means that, today, deforming plates during surgery is done manually by primitive tools, including pliers, irons and bending press. Despite low cost, simple structure, easy to work and no need for specific power generator, they have many shortcomings, such as low precision, low speed, low repeatability, poor performance, time-consuming, exhausting to use, and dependent on the result to surgeon's skills and psychological conditions while performing the deformation. Though some patents have been registered in recent years, none are satisfactory. Most of them are manual and therefore include the disadvantages of the traditional apparatuses. So, it is essential to introduce a new generation of apparatus for deformation of bone plates during surgery.

5. CNC machines: feasibility study

Today, CNC machines and their configurations provide enormous manufacturing flexibility with modular options to produce an enormous range of geometrically complex components, from micro to multi-metre sized parts, from ductile materials to brittle ones [22]. In parallel, technology has become a major driver of healthcare and surgery. This is a time in the history of medicine when truly revolutionary change is occurring [23]. Telepresence surgery, robotics, tele-education, and telementoring have been introduced through this revolution. Using computer-aided systems, such as image-guided surgery, the next generation of surgical systems will be more sophisticated and will permit surgeons to perform surgical procedures beyond the current limitations of human performance [24]. These aspects should be considered and employed in any novel design for the apparatus of deforming bone fracture fixation plates during surgery.

The authors of the current paper proposed and then thoroughly assessed several conceptual designs of CNC technology based machines for performing the deformations of bone fracture fixation plates during surgery. In all the offered designs, it was tried to consider the noted two parameters about AMT and current medical devices as well as the previously mentioned selection criteria. Mechanical (springs), electrical, hydraulic and pneumatic systems were studied for power supplying. Magnets (temporary and permanent) were not chosen because of probable adverse effects on plates and also low power density. Similarly, vacuum systems could not be suitable because of low power density. First a spring power system was offered because of its advantages, including zero power consumption and also possibility of auto-locking/releasing (Fig. 8). Since in this system the overall size of the clamp became too big, a combination of hydraulics and spring was tried. But it was oversize even after modification. Additionally, in this design, the gripping system of the plate during deformation process was based on using threads of the plate. Since some of the plates do not have any threads, then this machine could not cover all plate types. So, the design concept should be thoroughly changed.

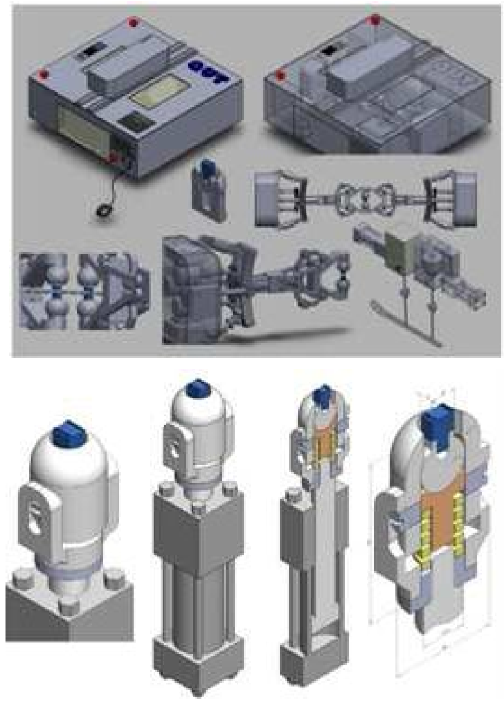

Fig. 8. Conceptual design of a CNC machine for deforming orthopaedic bone plates which uses spring power for clamping and threads for holding the plate during process

A design of hydraulic clamp and gripping system was then tried (Fig. 9). Since the hydraulics was selected as power generator of clamp, it was employed for other components as well. Unity of power generator reduces the costs of design, manufacturing and maintenance.

Despite solving all problems of the previous designs, it was big and heavy. Much more important, the centre of rotation was not located on the plate. Therefore, technically this design was not feasible and need to be changed. A new design was then proposed [9]. In the new trial, only the clamp was developed and evaluated initially. Size and weight of the machine was reduced. However, it could not solve the problem of locating the centre of rotation on plate. Therefore, technically it was not feasible as well.

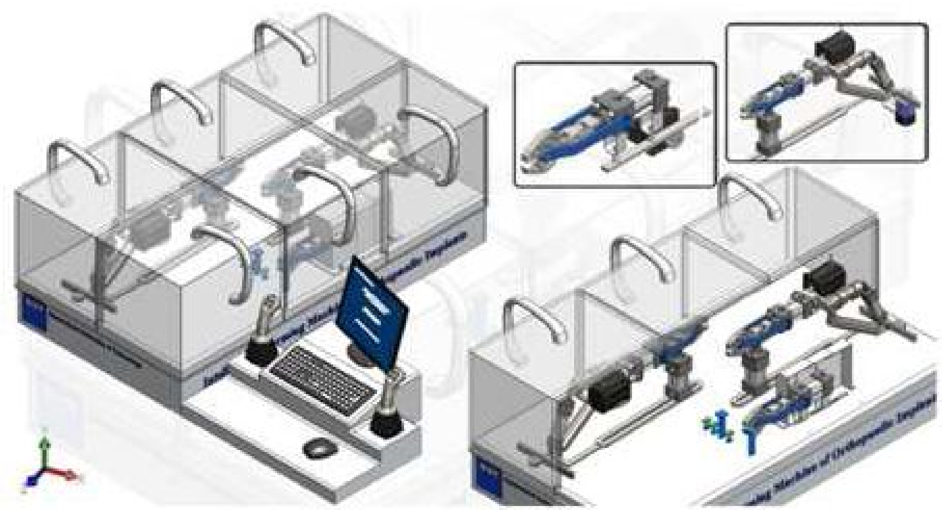

Fig. 9. Conceptual design of a CNC machine which uses hydraulics as driver

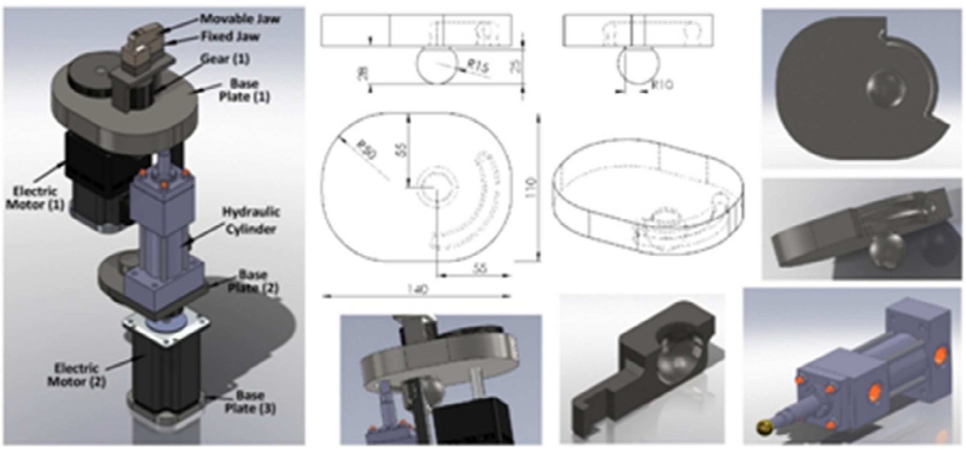

Fig. 10. Conceptual design of a clamp for deforming orthopaedic bone plates during surgery

Besides to the mentioned conceptual designs, some other ideas were tried as well. However, it was finally concluded that, regarding the structure of bone fracture fixation plates, the required moments/forces for performing the deformations, and the types and ranges of the deformations, it is not possible to design a small size clamp with sufficient degrees of freedom (DoF) and power. In other words, the clamp of such a machine has to only grip the plate during deformation process and the other components of the machine have to perform the deformations. So, inevitably, the overall size and weight of the apparatus will be larger. Also, with this approach, a robotic arm with sufficient DoF works much better than a CNC machine. Indeed, regarding the technical feasibility, overall size of the apparatus and the manufacturing costs, CNC concept is not advised as the first choice development of a novel apparatus for performing the pre-surgical deformations of the bone fracture fixation plates. At present the authors are trying different designs of robotic arms and are determining the technical specifications of such a system in detail. The findings of this approach will be published in the future accordingly.

6. Conclusions

Despite the significant evolution in various aspects of bone fracture fixation plates, the apparatus needed for performing pre-surgical deformations of these plates have not been improved properly yet. Currently, it is done by means of manual tools, mainly pliers, irons and bending press. The process is poor in precision, speed and repeatability. It is exhausting and the result depends on the human factors such as skill and psychological conditions. So, it is highly necessary to introduce a new generation of the apparatus. Some patents have been developed so far. However, they have not solved the mentioned shortcomings properly because, almost all of them were manual and therefore, they included most of the existing disadvantages of the noted tools. The automatic solutions were not practical and therefore have not been employed in clinical applications yet.

Later, the principles of the prospective machine and the selection criteria were defined; and the review was extended to non-medical machineries. It was revealed that the studied machineries are not suitable for deformation of bone fracture fixation plates during surgery because they cannot meet the given criteria. Regarding the existing gap any study in this field is valuable, the authors did not find any published academic reference investigating the apparatuses of deforming bone fracture fixation plates during orthopaedic surgeries.

All in all, it was tried to develop a novel machine from the scratch so that can meet the previously defined criteria and fill the gap. Regarding the advances in science and technology, it is expected that the novel apparatus to be intelligent and, ideally, have capability of analysis and process simulation. The authors developed and assessed several conceptual designs of CNC machines, and finally concluded that they cannot be the golden solution to the given problem. The size and shape range of the plates, overall size and cost of the developed conceptual machines as well as the concerning technical feasibility of the studied designs are the parameters that lead to this decision. The authors are currently underway to develop a novel robotic system with respect to the principles of the current paper. The new system will be addressed in detail in the future publications.

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Additional information

Selected issues related to this paper are planned to be presented at the 22nd Winter International Scientific Conference on Achievements in Mechanical and Materials Engineering Winter-AMME'2015 in the framework of the Bidisciplinary Occasional Scientific Session BOSS'2015 celebrating the 10th anniversary of the foundation of the Association of Computational Materials Science and Surface Engineering and the World Academy of Materials and Manufacturing Engineering and of the foundation of the Worldwide Journal of Achievements in Materials and Manufacturing Engineering.

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