Auto Strut: a novel smart robotic system for external fixation device for bone deformity correction, a preliminary experience

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Abstract

Purpose: Several hexapod external fixators are used in the treatment of bone fracture and deformity corrections. One characteristic of all of them is the requirement for manual adjustment of the fixator struts. The purpose of this study was to introduce a novel robotic system that executes automatic adjustment of the struts.

Methods: Ten patients were treated for various bone deformities using a hexapod external fixator with the Auto Strut system. This new system automatically adjusts the fixator struts according to a hexapod computer-assisted correction plan. During each visit, the progress of the correction was assessed (clinically and radiographically) and reading of the strut scale numbers was performed and compared with the original treatment plan.

Results: All patients completed treatment during the follow-up period, achieving all planned correction goals, except from one patient who switched to manual struts due to personal preference. The device alarm system was activated once with no device-related adverse events. Duration of distraction ranged between ten and 90 days with a distraction index ranging between eight and 15 days/cm. Regenerate consolidation time between one and seven months. In total, 48 struts of eight patients were recorded and analyzed. In all, 94% of the final strut number readings presented a discrepancy of 0 mm to 1 mm between planned and actual readings, indicating high precision of the automatic adjustment.

Conclusion: This study presents preliminary results, showing that Auto Strut can successfully replace the manual strut adjustment providing important advantages that benefit the patient, the caregiver and the surgeon.

Level of Evidence: Level II

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Introduction

The Ilizarov surgical method was developed in the 1950s and was introduced to the Western world 30 years later, and has been used to achieve gradual correction of deformities, both congenital and acquired.¹-⁴ The use of Ilizarov circular external fixators for lengthening and axial correction requires mechanical hinges and translation mechanisms for constructing a custom-made frame for each patient.⁵ The method is principally based on the application of circular frames followed by osteotomy and gradual distraction or compression in three dimensions to attain the biomechanical environment for bone healing.⁶-⁸ Correcting a deformity in all planes requires multiple sequential adjustments during treatment. Such mechanical corrections may impose difficulties that have shown to decrease the accuracy of correction.⁹

Several technological improvements were developed and are in use today. A powerful tool for obtaining precise correction of limb deformities is the hexapod frame; a substitution of the threaded rods and hinges of the traditional Ilizarov frame with a hexapod system of six telescopic struts at the focal level. The first hexapod fixator that has been in use for more than 25 years is the Taylor Spatial Frame (Smith and Nephew, Memphis, TN) (TSF). The TSF, introduced by Charles Taylor in 1994, is a stable external fixation device with six-axis deformity apparatus.⁶,⁷,⁹,¹⁰ It has at least two circular rings connected by six...
telescopic crossing struts that allow external control in six
degrees of freedom.\textsuperscript{11} It does not require construction of
mechanical hinges and precise mounting of the ring fix-
ator, and relies on the adjustment of the strut lengths.\textsuperscript{12}
The surgeon assembles the computerized correction plan
via a frame software algorithm. It provides an initial and
final set of struts lengths aiming to achieve the planned
correction of a deformity.\textsuperscript{6} The patients and caregivers are
provided with the treatment plan and manually adjust the
struts to implement a multiplane simultaneous correction
plan.\textsuperscript{6,10,13,14}

The MaxFrame (DePuy Synthes USA, LLC) device,
which was introduced later, is designed as a multi-axial
correction system to reduce procedure complexity by
streamlining the surgical and software workflows.\textsuperscript{15,16} The
TSF and MaxFrame fixators require manual adjustment of
the struts several times a day. The duration of treatment
is defined by the deformity and the intended change and
could range between 30 days and several months, increas-
ing the burden on the patients and their caregivers.\textsuperscript{17}

Bright and colleagues\textsuperscript{18} described a prototype of motor-
ized distraction fixator based on the Ilizarov method. They
reported tibial lengthening with motorized distraction at
a rate of 1 mm per day in 1440 steps. Eren et al\textsuperscript{19} used the
Smart Correction fixator in a clinical study and demon-
strated higher deformity correction accuracy than the
Ilizarov external fixator.

OrthoSpin Ltd (Israel, Misgav) has developed the Auto
Strut system which is intended to replace the manually
controlled struts in a hexapod fixator. Auto Strut includes
control units that are mounted on the fixator and are then
connected to the six motorized robotic struts. The con-
trol unit in accordance with a pre-programmed treatment
plan performs the execution of the strut adjustments
automatically.

The Auto Strut system received a Food and Drug
Administration approval (K191241) for utilization in com-
bination with the MaxFrame fixator. In accordance with
the approval, Auto Strut can be used for fracture fixation
(open and closed), pseudoarthrosis of long bones, limb
lengthening, joint arthrodesis, infected fractures or non-
union, correction of bony or soft-tissue deformities and
correction of segmental defects.

In this study we present our experience with ten
patients who underwent deformity correction using the
Auto Strut system.

Materials and methods

The study protocol and modifications for utilization of
the Auto Strut system in combination with the hexapod
fixator (TSF or MaxFrame) were approved by the Helsinki
Committee of our medical centre.

Device

The Auto Strut device is presented in Figure 1. The device
is comprised of one central control box connected to two
lateral control boxes.

After being mounted onto the fixator, each box is con-
ected to two adjacent struts via an electrical cable. The
addition of the Auto Strut components makes the fixator
approximately 760 g heavier than the manually adjustable
one.

System components

1. Motored strut: the mechanics of the motored strut are
based on a threaded tube that is extended by a rotat-
ing screw element. The struts are connected to the
pair of external rings in a similar way to the mechanici-
strut (i.e. same interface and locking bolt).
2. Motor and gear: the motor and gear lengthen or
shorten the strut according to the treatment plan.
Each motor is connected to an encoder that senses
its rotational positioning and enables the controller to
close the control loop.
3. Electronic controller: the controller is in command
of the motor’s speed and direction according to the
treatment plan. It provides hardware and software
protections that prevent any deviation from the treat-
ment plan and alert in case of any malfunctions.
4. Power supply: three standard 9 V lithium batteries
supply energy to the system. The alarm system is acti-
ved (red light) when the battery is running low.
5. Alarm system: activated automatically when a device
malfunction or connector assembly problem is
detected by the electronic controller.

Following a standard surgical procedure, a portable
document format (PDF) file of the treatment plan is pro-
duced by the MaxFrame or TSF software.

The PDF file is imported into OrthoSpin software and
uploaded to the central control box (Fig. 2) from the
external computer via a Universal Serial Bus (USB) cable.
The central control box controls the strut adjustments
in accordance with the plan without any involvement from
the patients/caregivers.

Patients and treatment procedure

Patients were assessed for suitability to be treated with
the hexapod external fixator.

Patients between three and 20 years old were eligible
to participate in the study. Exclusion criteria included an
allergy to any of the device components, active systemic
disease, malignancy or active infection. Prior to treatment
initiation, adult patients/parents of the minor patients
provided informed consent to being treated with the
novel device.
Following confirmation, a surgery was scheduled to place the fixator. The Auto Strut control boxes were mounted on the circular frames after the surgical procedure. A treatment plan for the strut adjustment was generated based on the characteristics of the limb deformity and hexapod external fixator mounting and then downloaded into the Auto Strut central control box. When activated, the control boxes carried out the strut adjustment automatically, in accordance with the treatment plan, with no intervention required from the patient or the caregiver. Patients arrived at the clinic for follow-up during the correction period until treatment completion.
Results
A treatment with a hexapod external fixator, in which the manual struts were substituted with the Auto Strut automatic device, has been initiated in ten 12- to 20-year-old patients (five girls). All patients completed the treatment plan. The alarm system was activated twice in one patient (patient 02), indicating a device malfunction (connector assembly problem). Although the malfunction was solved, the Auto Strut device was replaced with manual struts as the patient preferred not to go back to the Auto Strut.

Patients’ demographic characteristics and the aetiology of their orthopaedic impairment are presented in Table 1. Four of the ten patients had pre-existing medical conditions, which included fatty liver disease (patient 02), pervasive developmental disorder (patient 05), anxiety disorder (patient 07) and obstructive sleep apnea due to achondroplasia (patient 09). Out of the ten patients, only patient 07 reported concomitant medication use, treated with Olanzapine 10 mg once daily.

Details on the planned corrections, distraction and consolidation parameters and treatment duration are presented in Table 2. Nine patients received unilateral treatment (seven left limbs and two right limbs) and patient 09 was treated bilaterally. The corrections involved axial lengthening for all patients, axial angulation for five patients, anteroposterior angulation (varus/valgus) for eight patients and lateral angulation (posterior/anterior) for three patients. Time to recovery, defined as the time between the placement of the device (date of operation) and the imaging results indicating three cortex regenerate between the device (date of operation) and the imaging results indicating three cortex regenerate, ranged between one and seven months. Duration of distraction ranged between ten and 90 days. The distraction index, defined as the period (in days) required per cm of change (lengthening/angulation), ranged between 8 days/cm and 15 days/cm. The length of distraction varied between 1 cm and 6 cm.

The planned corrections were fully attained in all patients who completed the treatment and no device-related adverse events were reported.

The precision of the automatic adjustment of the struts was assessed by calculating the absolute discrepancy of the final reading on each strut relative to the planned final number. Data from 48 struts (eight patients) was collected for precision analysis. Patient 01’s actual numbers on the struts were not recorded every office visit and patient 2 switched into manual struts during the treatment period. Of those 48 struts, 94% (45/48) of the final strut number readings presented a discrepancy of 0 mm to 1 mm. Final strut number readings from three struts (6%) presented a discrepancy of 2 mm to 3 mm. These differences probably stem from errors in strut readings as they are mainly associated with the struts that were located more internally (between the legs) or posteriorly, precluding comfortable visual access thus making the accurate reading more challenging. The discrepancy of 2 mm to 3 mm is clinically insignificant. The automatic adjustment readings of the six struts taken during the treatment course of a representative patient (patient 08) are presented in Figure 3, together with the planned adjustment.

Out of 36 readings (six reading per strut) obtained during the course of treatment, 26 showed 100% accuracy of adjustment, nine readings indicated discrepancy of 1 mm and a single reading showed 3 mm discrepancy, which is clinically insignificant.

Radiographic images of a representative patient (patient 09) three months after fixator installation surgery and six months after fixator removal surgery, are presented in Figure 4.

Table 1 Demographics

| Patient | Age, yrs | Sex | Weight, kg | Height, cm | Aetiology                      |
|---------|----------|-----|------------|------------|--------------------------------|
| 01      | 14       | M   | N/A        | N/A        | Idiopathic tibia vara          |
| 02      | 12       | F   | 47.5       | N/A        | Hemihyper trophy               |
| 03      | 17       | F   | 60         | 161        | Fibular hemimelia (Paley       |
|         |          |     |            |            | classification 3B2) with       |
|         |          |     |            |            | congenital short femur         |
| 04      | 14       | F   | 68         | 175        | Infantile Blount’s disease     |
| 05      | 16       | M   | 85         | 165        | Idiopathic tibia vara          |
| 06      | 14       | M   | 86.4       | 180        | Idiopathic tibia vara          |
| 07*     | 20       | F   | 60         | 164        | Post-traumatic equinus due to   |
|         |          |     |            |            | degloving injury around the    |
|         |          |     |            |            | ankle (soft-tissue distaction) |
| 08      | 14       | M   | 70         | 167        | Ollier syndrome - tibia valga   |
| 09      | 19       | F   | 68         | 120        | Achondroplasia – tibia vara     |
|         |          |     |            |            | bilateral                       |
| 10      | 18       | M   | 100        | 175        | Idiopathic tibia vara          |

*All patients were treated for tibia bone deformity correction except for patient 07 who underwent soft-tissue distraction due to fixed ankle equinus deformity

N/A, not available

Discussion
We have presented the successful utilization of an automated hexapod external fixator in the treatment of bone deformities.

The treatment duration, correction success and adverse events observed in our study indicate that utilizing the Auto Strut device with the hexapod external fixator for automatic gradual deformity correction is safe and as accurate as manually adjusted struts. Manual strut adjustment is dependent on patient/patient family collaboration and is prone to errors. Errors may rise as the numbers of daily manual operations increase. The results showed that the Auto Strut system is highly accurate (94%) indicating high precision of the automatic adjustment ensuring full compliance with the preplanned schedule.

An additional advantage of Auto Strut utilization is the elimination of the burden associated with the manual

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Table 2 Planned treatment and outcomes

| Patient | Treated limb | Deformity correction | Treatment period | Distraction phase | Consolidation phase |
|---------|--------------|----------------------|------------------|-------------------|---------------------|
|         |              | Axial – lengthening, mm short | Axial – angulation, internal/external | AP – angulation, varus/valgus | Lateral – angulation, posterior/anterior | Length, cm | Time to consolidation, days | Consolidation index, days/cm |
| 01 Left | 30           | -                    | 15° varus       | -                 | 24                  | 8               | 3                  | 93                  | 31                  |
| 02 Left | 40           | -                    | 5° varus        | -                 | N/A                | N/A             | 4                  | N/A                | N/A                |
| 03 Left | 60           | -                    | -               | 24                | 8                  | 3               | 93                  | 31                  |
| 04 Left | 25           | 5° internal          | 17° varus       | -                 | 33                  | 13.2            | 2.5                | 62                  | 24.8               |
| 05 Left | 35           | -                    | 15° varus       | -                 | 35                  | 10              | 3.5                | 64                  | 18.3               |
| 06 Left | 10           | 15° internal         | 20° varus       | -                 | 10                  | 10              | 1                  | 108                 | 108                |
| 07 Right| 10           | -                    | 50° plantar flexion | 49                | -                  | 1               | N/A                | N/A                |
| 08 Left | 60           | -                    | 16° valgus      | 15° apex anterior | 63                  | 10.5            | 6                  | 135                 | 22.5               |
| 09 Right| 60           | 5° internal          | 15° varus       | 6° apex anterior  | 60                  | 10              | 6                  | 128                 | 21.3               |
| 10 Right| 60           | 5° internal          | 15° varus       | 6° apex anterior  | 60                  | 10              | 6                  | 128                 | 21.33              |

AP, anteroposterior; N/A, not available

**Fig. 3** Automatic strut adjustment versus planned readings of a representative patient (patient 08). The actual automatic adjustment (blue) is presented against the office visits readings (orange) for each of the six struts of the hexapod external fixator. Readings of the scale numbers of the struts were carried out on six time points during the treatment course (x-axis). Y-axis represents number on the struts.

Adjustments. This, in turn, enables a more independent life during treatment and reduction in the loss of working days lost for both the patients and caregivers.

Auto Strut is easy to use. No alteration of the standard surgical procedures is required. The mounting of the device onto a fixator is intuitive and does not require
any additional training. Uploading the treatment plan to
the device can be easily done, using a computer with
a USB-cable-mediated connection to the central control
box.

Auto Strut provides numerous technical possibili-
ties. As a programmable multi-purpose device, it allows
the implementation of diverse treatment schedules and,
therefore, is applicable to the treatment of diverse bone
impairments, including, nonunion, correction of bone
deformites and segmental defects.

Further treatment schedules will be based on smaller
increments, which will be implemented more frequently,
from four to 20 or more steps. This could improve the
quality and speed of bone formation during correction.
The system can be adjusted to perform a continuous dis-
traction compression schedule, the ‘accordion’ motion
(an accepted technique to speed bone healing in cases
delayed or nonunion), as well as any other appropriate
schedules.

Future developments will increase its modularity,
allow the collection of information associated with
bone healing, such as the parameters of bone resistance
during various treatment stages, which may be indica-
tive of the maturity/strength of the newly formed bone.
The availability of such information, recorded online,
during the treatment, could advance research of bone
formation and shed light on the clinically significant
details of bone healing. This knowledge will lead to the
construction of improved and personalized treatment
plans.

We believe that Auto Strut can successfully replace
the manual strut adjustment method and provide sev-
eral important advantages that benefit the patient, the
caregiver, the surgeon and may have important future
research implications.

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COMPLIANCE WITH ETHICAL STANDARDS

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**ETHICAL STATEMENT**

**Ethical approval:** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

**Informed consent:** The research study and consent form have been explained clearly to the parent/legal guardian and study subject, if applicable. All questions have been satisfactorily answered. Verification of the understanding of the information conveyed was completed.

**ICMJE CONFLICT OF INTEREST STATEMENT**

Dr Jacob Mor reports personal fees from Orthospin Ltd, outside the submitted work. Dr Eitan Segev reports he is Chief Medical Consultant to Orthospin company. All other authors declare that they have no conflict of interest.

**AUTHOR CONTRIBUTIONS**

RG: Study design, Data acquisition and analysis, Interpretation of data, Manuscript writing and revision.

JM: Manuscript writing and revision.

IL: Data acquisition, Interpretation of data, Revision of manuscript.

DO: Interpretation of data, Manuscript writing and revision.

ES: Study design, Data acquisition and analysis, Interpretation of data, Manuscript writing and revision.

**REFERENCES**

1. D’Ambrosia R. The Ilizarov technique. *Orthopedics* 1989;12:495.

2. Morasiewicz P, Konieczny G, Dejnek M, et al. Assessment of the distribution of load on the lower limbs and balance before and after ankle arthrodesis with the Ilizarov method. *Sci Rep* 2018;8:15693.

3. Szelerski Ł, Żarek S, Górski R, et al. Surgical treatment outcomes of the Ilizarov and internal osteosynthesis methods in posttraumatic pseudarthrosis of the tibia—a retrospective comparative analysis. *J Orthop Surg Res* 2020;15:179.

4. Teplenky M, Mekki W, Oleinikov E. Técnica de Ilizarov nas osteotomias do fêmur proximal e pélvica tripla para o tratamento da displasia do desenvolvimento do quadril em adolescentes. *Rev Bras Ortop* 2020;55:232-238.

5. Horn J, Steen H, Huhnstock S, Hvid I, Gunderson RB. Limb lengthening and deformity correction of congenital and acquired deformities in children using the Taylor Spatial Frame. *Acta Orthop* 2017;88:334-340.

6. Dammerer D, Kirschbichler K, Donnan L, et al. Clinical value of the Taylor Spatial Frame: a comparison with the Ilizarov and Orthofix fixators. *J Child Orthop* 2011;5:343-349.

7. Henderson DJ, Rushbrook JL, Harwood PJ, Stewart TD. What are the biomechanical properties of the Taylor Spatial Frame™? *Clin Orthop Relat Res* 2017;475:1472-1482.

8. Liu Y, Yushan M, Liu Z, et al. Complications of bone transport technique using the Ilizarov method in the lower extremity: a retrospective analysis of 282 consecutive cases over 10 years. *BMC Musculoskelet Disord* 2020;21:354.

9. Feldman DS, Shin SS, Madan S, Koval KJ. Correction of tibial malunion and nonunion with six-axis analysis deformity correction using the Taylor Spatial Frame. *J Orthop Trauma* 2003;17:549-554.

10. Eidelman M, Bialik V, Katzman A. Correction of deformities in children using the Taylor spatial frame. *J Pediatr Orthop B* 2006;15:387-395.

11. Naude J, Manjra M, Birkholtz FF, et al. Outcomes following treatment of complex tibial fractures with circular external fixation: a comparison between the Taylor Spatial Frame and TrueLok-Hex. *Stratagy Trauma Limb Reconstr* 2019;14:142-147.

12. Kristiansen LP, Steen H, Reikerås O. No difference in tibial lengthening index by use of Taylor spatial frame or Ilizarov external fixator. *Acta Orthop* 2006;77:772-777.

13. Ariyawatkul T, Chotigavanichaya C, Kaewpornsawan K, Eamsobhana P. The comparison between computer-assisted hexapods and Ilizarov apparatus in gradual tibial deformation correction: a preliminary study. *J Med Assoc Thai* 2016;99:1126-1130.

14. Manner HM, Huebi M, Radler C, et al. Accuracy of complex lower-limb correction with external fixation: a comparison of the Taylor Spatial Frame with the Ilizarov ring fixator. *J Child Orthop* 2007;1:55-61.

15. No authors listed. DePuy Synthes products. Technical guide MAXFRAME™ Multi-Axial Correction System. 2018. https://www.jnjmedicaldevices.com/en-EMEA/product/maxframe-multi-axial-correction-system (date last accessed 01 March 2021).

16. No authors listed. DePuy Synthes. sx(i)™ Summary MAXFRAME™ Multi-Axial Correction System 2016. http://synthes.us.llnwd.net/016/LLNWMB8/INT%20Mobile/Synthes%20International/eEU-EMEA/77991/77992/AMeng.pdf (date last accessed on March 2021).

17. Richard HM, Nguyen DC, Birch JG, et al. Clinical implications of psychosocial factors on pediatric external fixation treatment and recommendations. *Clin Orthop Relat Res* 2015;473:3154-3162.

18. Bright AS, Herzenberg JE, Paley D, Weiner I, Burghardt RD. Preliminary experience with motorized distraction for tibial lengthening. *Strategies Trauma Limb Reconstr* 2014;9:97-100.

19. Eren I, Eralp L, Kocaoglu M. Comparative clinical study on deformity correction accuracy of different external fixators. *Int Orthop* 2013;37:2247-2252.

20. Rozbruch SR, Segal K, Ilizarov S, Fragomen AT, Ilizarov G. Does the Taylor Spatial Frame accurately correct tibial deformities? *Clin Orthop Relat Res* 2010;468:1352-1361.