Simulated operation combined with patient-specific instrumentation technology is superior to conventional technology for supramalleolar osteotomy: A retrospective comparative study

Chenggong Wang

Xiangya Hospital Central South University

Can Xu

Xiangya Hospital Central South University

Yusheng Li

Xiangya Hospital Central South University

Mingqing Li

Xiangya Hospital Central South University

Da Zhong

Xiangya Hospital Central South University

Long Wang

Xiangya Hospital Central South University

Hua Liu (✉ dr_liuhua_xyyy@126.com)

Xiangya Hospital Central South University <https://orcid.org/0000-0003-2034-6407>

Research article

Keywords: Supramalleolar osteotomy, Simulated operation, Patient-specific guide, Accuracy of preoperative planning, Practicability of application

Posted Date: April 21st, 2020

DOI: <https://doi.org/10.21203/rs.3.rs-22349/v1>

License: (cc) (i) This work is licensed under a Creative Commons Attribution 4.0 International License.

[Read Full License](#)

Abstract

Background

Over the past seven years, our team has designed a simulated operation combined with patient-specific instrumentation (SO-PSI) assisted supramalleolar osteotomy (SMOT) method and applied it in the clinic. This study aimed to evaluate the differences between SO-PSI technology and conventional operation (CO) technology for SMOT in preoperative planning, intraoperative application, and postoperative curative effect.

Methods

We retrospectively analyzed SMOT data collected from our hospital between October 2014 and December 2018. Patients (n = 28) were enrolled and divided into CO (n = 17) and SO-PSI (n = 11) groups; mean follow-up time was 33.4 (range, 13 to 59) months. We statistically analyzed and compared perioperative data, accuracy of preoperative planning, and intraoperative application; difference between pre- and post-operative radiologic ankle angles; and changes in American Orthopaedic Foot & Ankle Society (AOFAS) score, visual analogue scale (VAS) score, range of ankle motion, and Takakura stage after surgery.

Results

All ankle alignments and positions were recovered for both groups. Compared with the CO group, the SO-PSI group had a shorter mean operating time and postoperative hospital stay, a decreased number of fluoroscopy examinations, lower albumin reduction, longer preoperative planning time and preoperative hospital stay, and increased hospitalization expenses. In the SO-PSI group, comparison of ankle angles at preoperative planning and postoperatively revealed good correlation, while this was not the case in the CO group. Mean tibial ankle center discrepancy for the SO-PSI group was 1.86 ± 1.06 mm. On follow-up, all radiologic parameters for the two groups improved significantly; however, the improvement of the tibial anterior surface angle and tibiotalar tilt angle for the SO-PSI group were more obvious than those for the CO group; AOFAS score, VAS score, ankle range of motion, and Takakura stage improved after surgery in both groups; however, the improvements in the SO-PSI group were greater than those in the CO group overall.

Conclusions

SO-PSI technology can facilitate accurate and rapid preoperative planning for SMOT. In general, compared with conventional technology, SO-PSI has advantages for preoperative planning, intraoperative application, and postoperative curative effect.

Background

Supramalleolar osteotomy (SMOT) is an effective procedure for treatment of midstage asymmetric ankle osteoarthritis [1–4]. Studies have demonstrated that the key factors affecting the postoperative curative effect of SMOT are postoperative ankle Takakura stage[5], lower limb power line[6], and ankle angles[7]; however, SMOT using conventional operation (CO) methods often does not perfectly accomplish these surgical aims, leading unsatisfactory outcomes for some patients[8, 9]. Reasons for these issues include the dependence on freehand drawing for preoperative planning, and surgeons determining the operating procedure, which depend on the surgeon's experience and fluoroscopy imaging [10].

Some studies have demonstrated that simulated operation combined with patient-specific instrumentation (SO-PSI) can be used to optimize preoperative planning and the operative process, allowing personalized and precision surgery [11–13]. Over the past seven years, our team has designed a SO-PSI assisted SMOT method and applied it in the clinic. Surgeons can complete preoperative evaluation and surgery simulation using a three-dimensional (3D) digital model, to optimize planning by repeated confirmation, then accurately execute the preoperative planning with the help of PSI during surgery.

Here we report collected data on preoperative planning, intraoperative application, and postoperative follow-up of SMOT performed by CO and SO-PSI technology, and a retrospective comparative study to determine whether CO or SO-PSI was more effective.

Methods

Study design and patients

This study was approved by the Ethics Committee of our hospital. We retrospectively reviewed the clinical and imaging data of patients with SMOT, using SO-PSI or not, between October 2014 and December 2018. The inclusion criteria were as follows: (1) > 18 years old; (2) primary surgery; (3) unilateral SMOT; (4) Takakura stage II, IIIA, or IIIB; (5) clinical symptoms, including pain and limitation of daily activities; (6) treated with SMOT, with at least one year follow-up. The exclusion criteria were: (1) refused to participate in the study; (2) Charcot arthropathy, rheumatoid arthritis, or ankle infection; (3) physical activity disorders, caused by other disease, such as neurologic disorders; (4) mental illness.

In total, 28 patients were included and divided into CO (n = 17) and SO-PSI (n = 11) groups. The basic characteristics of the patients are presented in Table 1. There were no significant differences in demographic factors or preoperative characteristics between the two groups. Follow-up was conducted at 3, 6, and 12 months postoperatively, with at least one follow-up after 12 months postoperative. Mean follow-up time was 33.4 (range, 13 to 59) months.

Table 1
Basic information of the patients.

	CO group	SO-PSI group	P values [#]
Number of patients	17	11	
Gender (male/female)	5/12	4/7	0.700
Mean of Age (years)	46.4 ± 11.6	53.8 ± 14.4	0.147
Mean of BMI (kg/m ²)	24.8 ± 4.4	25.6 ± 4.6	0.622
Etiology (No. and %)			
Osteoarthritis	4 (23.5%)	3 (27.3%)	0.823
Posttrauma arthritis	13 (76.5%)	8 (72.7%)	0.823
Diabetes (No. and %)	2 (11.8%)	2 (18.2%)	0.636
Smoker (No. and %)	3 (17.6%)	4 (36.4%)	0.264
Takakura stage (No. and %)			
Takakura II	3 (17.6%)	1 (9.1%)	0.527
Takakura IIIA	9 (52.9%)	5 (45.5%)	0.699
Takakura IIIB	5 (29.4%)	5 (45.5%)	0.387
Mean of pre-op AOFAS score	52.5 ± 10.6	51.7 ± 10.9	0.860
Mean of pre-op VAS	7.7 ± 1.4	7.3 ± 1.6	0.463
Mean of pre-op ROM of ankle (°)	31.2 ± 6.8	31.8 ± 8.4	0.850
Mean of follow-up time (months)	28.6 ± 12.4	35.9 ± 12.9	0.150
Abbreviations: CO: Conventional operation group; SO-PSI: Simulated operation combines Patient-specific guide; BMI: body mass index; AOFAS score: the American Orthopedic Foot and Ankle Society score; VAS: visual analogue scale; ROM: range of motion; pre-op: preoperative.			
[#] P values, $\alpha = 0.05$, (Age, BMI, AOFAS score, VAS, ROM of ankle and follow-up time: independent-samples t-test; Gender, Etiology, Diabetes, Smoker and Takakura stage: Chi-squared test)			

Preoperative evaluation and planning

In the CO group, preoperative planning was based on radiography images and the surgeon's experience. First, the anatomical axis of the tibia and angles of the ankle were drawn (Figs. 1a and 1b), including the tibial anterior surface angle (TAS), tibiotalar tilt angle (TTA), malleolar angle (MA), and tibial lateral surface angle (TLS). Then an osteotomy plan was drawn on the X-ray. The aim of osteotomy was to generate ideal ankle angles, while retaining the correct force line [7, 14–17] (Fig. 1c); however, only target values of TAS and TLS could be accurately designed in the preoperative plan.

In the SO-PSI group, initially, to achieve a quick understanding of the disease condition, the anatomical axis of the tibia and ankle angles were drawn, as for the CO group (Figs. 1a and 1b). Next, computed tomography (CT) data were entered into E-3D V17.08 software (Huiqing, LTD., Nanjing, China) and incorporated into a 3D digital model. Then simulated surgery was conducted on the digital model (Fig. 1d). The simulated operation was usually divided into five steps: (1) The axis and angles were drawn on the digital model to further understand the disease condition. (2) Osteotomy, reduction, and other specific operative steps were conducted on the digital model. At this point, the osteotomy, reduction, and specific operative steps could be repeatedly adjusted to optimize the parameters (Fig. 1c). (3) One to four suitable plates and appropriate screws were chosen from our virtual database of internally fixed models, then the virtual internal fixation was installed on the digital model. (4) PSI was designed to assist with the operation. Usually, an osteotomy guide plate was constructed to assist in osteotomy, as well as a temporary fixation guide plate to maintain the normal position of bone blocks. (5) Repeated checks were conducted to determine whether the simulated operation was satisfactory, and active modifications conducted until it was optimal. Finally, after a satisfactory simulated operation had been conducted, all procedures, tools and internal fixations were recorded and prepared accordingly. Nylon material was used to construct the PSI and life-sized 3D model, using selective laser sintering (SLS) (Fig. 1e).

Operation and rehabilitation

In the CO group, as for conventional SMOT [1, 2, 7, 15–17], the medial point of the osteotomy line was approximately 3–5 cm above the joint surface. According to the preoperative plan, osteotomy and other steps were conducted to optimize the ankle alignment and position, assisted by multiple intraoperative fluoroscopies.

In the SO-PSI group, most steps were as same as those for the CO group; however, there were differences, as follows: (1) The position of the osteotomy line was determined according to the osteotomy guide plate, allowing osteotomy to be performed accurately, without repeated confirmations and attempts (Fig. 1f); (2) Optimal axes and angles were obtained with the assistance of a temporary fixation guide plate; when the plate was installed on bone blocks and then used to reciprocally form a rigid whole, the ankle alignment and position were consistent with the preoperative plan (Figs. 1d and 1 g); and (3) Suitable plates and appropriate screws were installed in the skeleton according to the preoperative plan (Fig. 1d). Ankle alignment and position in the mortise were verified fluoroscopically before and after final fixation.

For both groups, the patient wore a plaster slab until the stitches were removed from the wound, then a below-knee protective plaster cast was worn. Patients were encouraged to mobilize, with partial weight-bearing for the first 3–6 weeks; subsequently, full weight-bearing, without a plaster cast, began after the osteotomy site achieved bony union, according to radiography.

Measurement and follow-up

To compare parameters between the two groups during the perioperative period, we carefully searched and collected the following data: pre-operative planning time, number of plates, operation-specific steps,

operation-time, number of fluoroscopic examinations, operative blood loss, reduction of albumin (ALB, the difference between the albumin value two days pre-op and two days post-op), total hospital stay, hospitalization expenses, complication rate, and union time.

To evaluate the accuracy of preoperative planning and intraoperative application, actual imaging data for preoperative planning and at three to six months postoperatively were compared. In the CO group, TAS and TLS values were compared, while in SO-PSI group, the values compared were TAS, TTA, MA, TLS, and tibial ankle center discrepancy (TACD; the distance between tibial ankle center in the preoperative SO plan and the actual postoperative position on three to six month CT) (Figs. 1h to 1j).

To compare postoperative follow-up between the two groups, we carefully searched and collected imaging data to evaluate changes in the ankle angle and Takakura stage. Moreover, the pre- and post-operation American Orthopaedic Foot & Ankle Society (AOFAS) ankle-hindfoot score[18], ankle range of motion (ROM) [19], and visual analogue scale (VAS) [20] were used to assess functional outcomes.

Statistical analysis

An independent Samples t-test was used to evaluate differences in age, body mass index, AOFAS score, VAS, ankle ROM, follow-up time, pre-operative planning time, operating time, number of fluoroscopies, operative-blood loss, reduction of ALB, hospital stay, pre-operative hospital stay, post-operative hospital stay, hospitalization expenses, union time, and changes in angles before and after surgery. Chi-squared tests were used to analyze differences in sex, etiology, diabetes, smoker status, Takakura stage, number of plates, specific operation steps, and complication rate. The accuracy of pre-operative plans in both groups was analyzed by linear correlation analysis. Significance was defined as $p < 0.05$. Statistical analyses were performed using SPSS 20.0 software (SPSS Inc., Chicago, IL, USA).

Results

Perioperative outcomes

Mean pre-operative planning time for the SO-PSI group (289.1 ± 44.4 min) was significantly greater than that for the CO group (31.5 ± 9.1 min) ($P < 0.0001$). The mean operating time for the SO-PSI group (101.8 ± 16.0 min) was significantly less than that for the CO group (134.1 ± 23.2 min) ($P < 0.0001$). Patients in the SO-PSI group underwent significantly fewer fluoroscopy examinations (mean 7.4 ± 2.1) than those in the CO group (10.3 ± 3.3) ($P = 0.008$). Mean ALB reduction in the SO-PSI group (1.3 ± 0.3 g/L) was significantly less than that in the CO group (2.7 ± 1.1 g/L) ($P < 0.0001$). The mean pre-operative hospital stay of patients in the SO-PSI group (5.5 ± 1.4 days) was significantly longer than those in the CO group (2.0 ± 0.8 days) ($P < 0.0001$); however, the post-operative hospital stay of patients in the SO-PSI group (6.6 ± 1.8 days) was significantly shorter than that of the CO group (9.2 ± 1.7 days) ($P = 0.001$). The mean hospitalization expenses for the SO-PSI group (11369.1 ± 1700.3 dollars) was significantly greater than for the CO group (9888.2 ± 1472.6 dollars) ($P = 0.028$). No significant differences were detected in other parameters between the two groups (Table 2).

Table 2
Perioperative outcomes.

	CO group (n = 17)	SO-PSI group (n = 11)	P values [#]
Mean of pre-op planning time (min)	31.5 ± 9.1	289.1 ± 44.4	0.000
Number of plate (No. and %)			
One plate	3 (17.6%)	1 (9.1%)	0.527
Two plates	5 (29.4%)	3 (27.3%)	0.903
Three plates	6 (35.3%)	3 (27.3%)	0.657
Four plates	3 (17.6%)	4 (36.4%)	0.264
Special op-step (No. and %)			
Calcaneal osteotomy	13 (76.5%)	9 (81.8%)	0.736
Fore/mid-foot osteotomy	5 (29.4%)	3 (27.3%)	0.903
Tibia lengthening	2 (11.8%)	1 (9.1%)	0.823
Other	1 (5.9%)	1 (9.1%)	0.747
Mean of op-time (min)	134.1 ± 23.2	101.8 ± 16.0	0.000
Mean of number of fluoroscopies	10.3 ± 3.3	7.4 ± 2.1	0.008
Mean of op-blood loss (ml)	104.5 ± 41.6	139.2 ± 54.6	0.076
Mean of reduction of ALB (g/L)	2.7 ± 1.1	1.3 ± 0.3	0.000
Mean of hospital stay (days)	11.2 ± 1.6	12.2 ± 1.5	0.132
Mean of pre-op hospital stay (days)	2.0 ± 0.8	5.5 ± 1.4	0.000
Mean of post-op hospital stay (days)	9.2 ± 1.7	6.6 ± 1.8	0.001
Mean of hospitalization expenses (dollars)	9888.2 ± 1472.6	11369.1 ± 1700.3	0.028
Complication* rate (no. and %)	4 (23.5%)	1 (9.1%)	0.330
Abbreviations: CO: Conventional operation group; SO-PSI: Simulated operation combines Patient-specific guide; Pre-op: preoperative; Op: operative; Reduction of ALB: The difference of albumin value between preoperative 2 days and postoperative 2 days; Post-op: postoperative.			
[#] P values, α = 0.05, (Pre-op planning time, op-time, number of fluoroscopies, op-blood loss, reduction of ALB, hospital stay, pre-op hospital stay, post-op hospital stay, hospitalization expenses and union time: independent-samples t-test; Number of plate, Special op-step and Complication rate: Chi-squared test)			
* Four patients of CO group and one patient of SO-PSI group occurred delayed wound healing after operation, and all of them have healed completely 3 to 5 weeks after operation.			

	CO group (n = 17)	SO-PSI group (n = 11)	P values [#]
Mean of union time (weeks)	14.1 ± 1.2	13.5 ± 0.8	0.201
Abbreviations: CO: Conventional operation group; SO-PSI: Simulated operation combines Patient-specific guide; Pre-op: preoperative; Op: operative; Reduction of ALB: The difference of albumin value between preoperative 2 days and postoperative 2 days; Post-op: postoperative.			
[#] P values, $\alpha = 0.05$, (Pre-op planning time, op-time, number of fluoroscopies, op-blood loss, reduction of ALB, hospital stay, pre-op hospital stay, post-op hospital stay, hospitalization expenses and union time: independent-samples t-test; Number of plate, Special op-step and Complication rate: Chi-squared test)			
* Four patients of CO group and one patient of SO-PSI group occurred delayed wound healing after operation, and all of them have healed completely 3 to 5 weeks after operation.			

Accuracy of preoperative planning and intraoperative application

Based on examination of postoperative imaging, ankle alignments and positions were recovered to varying degrees for all cases (Fig. 2). In the CO group, correlations between TAS ($R^2 = 0.100$, $P = 0.271$) and TLS ($R^2 = 0.111$, $P = 0.192$) during pre-operative planning and at three to six months post-operative were poor (Figs. 3a and 3b). In contrast, in the SO-PSI group, correlation between TAS ($R^2 = 0.667$, $P = 0.002$), TTA ($R^2 = 0.438$, $P = 0.027$), MA ($R^2 = 0.709$, $P = 0.001$) and TLS ($R^2 = 0.925$, $P < 0.0001$), during pre-operative planning and at three to six months post-operative were good (Figs. 3c to 3f). Moreover, the mean TACD in the SO-PSI group was 1.86 ± 1.06 mm (range, 0.51 to 4.2 mm) (Table 3).

Table 3
Imaging parameters outcomes.

	CO group (n = 17)	SO-PSI group (n = 11)	P values [#]
Mean of tibial ankle center discrepancy* (TACD, mm) (post-op 3 to 6 months)	N/A	1.86 ± 1.06	N/A
Mean of TAS (°)			
Pre-op	80.1 ± 4.7	74.4 ± 10.5	0.118
Post-op 1 year	87.0 ± 2.6	89.5 ± 1.8	0.006
P value (Paired-samples t-test)	0.009	0.000	
Mean of TTA (°)			
Pre-op	7.4 ± 3.3	6.6 ± 2.7	0.513
Post-op 1 year	3.8 ± 2.7	1.4 ± 1.5	0.005
P value (Paired-samples t-test)	0.002	0.000	
Mean of MA (°)			
Pre-op	75.3 ± 3.5	74.4 ± 3.6	0.488
Post-op 1 year	84.3 ± 2.4	85.7 ± 1.9	0.097
P value (Paired-samples t-test)	0.000	0.000	
Mean of TLS (°)			
Pre-op	73.8 ± 3.3	75.1 ± 3.9	0.371
Post-op 1 year	78.8 ± 2.9	79.2 ± 4.7	0.816
P value (Paired-samples t-test)	0.000	0.000	
Abbreviations: CO: Conventional operation group; SO-PSI: Simulated operation combines Patient-specific guide; TACD: Tibial ankle center discrepancy (the distance between tibial ankle center of preoperative SO plan data and actual postoperative three to six months CT data); TAS: Tibial anterior surface angle; TTA: Tibiotalar tilt angle; MA: Malleolar angle; TLS: Tibial lateral surface angle.			
[#] P values, α = 0.05 (Independent-samples t-test)			
* Tibial ankle center discrepancy: The distance between tibial ankle center of pre-op SO plan data and actual post-op 3 to 6 months CT data.			

Follow-up outcomes

All patients were followed up for radiologic evaluation at one year post-operative and all included parameters improved significantly in both groups; however, the improvement in TAS and TTS were more

obvious in the SO-PSI than the CO group (TAS, $P = 0.006$; TTS, $P = 0.005$) (Table 3). The AOFAS scores for SO-PSI and CO groups increased from 51.7 ± 10.9 and 52.5 ± 10.6 before surgery to 88.2 ± 5.7 and 83.1 ± 4.5 , respectively, at final follow-up. Further, the AOFAS scores for the SO-PSI group were better than those for the CO group at six months ($P = 0.014$) and one year ($P = 0.048$) post-operative, as well as at final follow-up ($P = 0.024$) (Fig. 4a). The VAS scores for the SO-PSI and CO groups decreased from 7.3 ± 1.6 and 7.7 ± 1.4 before surgery to 3.7 ± 0.7 and 3.1 ± 0.9 , respectively, at final follow-up; the VAS score for the SO-PSI was only significantly better than that for the CO group at six months post-operatively ($P = 0.006$) (Fig. 4b). The mean ankle ROM values in the SO-PSI and CO groups increased from 31.8 ± 8.4 and 31.2 ± 6.8 before surgery to 37.8 ± 4.4 and 35.9 ± 5.5 , respectively, at final follow-up; ankle ROM did not differ significantly between the two groups at any time point (Fig. 4c). Takakura stage improved after surgery in both groups; however, the improvement in the SO-PSI group was more marked than that in CO group. In the CO group, four patients improved their Takakura stage by two levels (23.5%), nine patients by one level (52.9%), three patients had similar stage (17.6%), and one patient became worse (5.9%) at final follow-up, relative to preoperative (Fig. 5a). In the SO-PSI group six patients improved their Takakura stage by two levels (54.5%), four patients by one level (36.4%), and one patient was at a similar stage (9.1%) at final follow-up, relative to preoperative (Fig. 5b).

Discussion

This study aimed to determine whether there is a difference between CO and SO-PSI technology in terms of preoperative planning, intraoperative application, and postoperative follow-up for SMOT. Reference to relevant studies combined with our own experience, strongly suggests that accurate preoperative analysis of the condition and optimal postoperative ankle angles, line of force, and arthritis stage are vital factors influencing SMOT, and have become the focus of current research [1, 2, 6–10, 15–17, 21].

The results of our study demonstrate that SO-PSI technology has advantages over CO technology in preoperative planning, intraoperative application, and postoperative follow-up. There are four reasons for these findings, as follows: (1) Preoperative 3D computer analysis can assist in accurate understanding of the original state of the disease, and is considerably more reliable than conventional, hand-drawn, two-dimensional analysis, and simple observation of three-dimensional reconstruction of CT images. Numerous studies have reached similar conclusions, and it is generally considered that preoperative 3D digital analysis will substantially improve the surgeons' grasp of the original disease state [22, 23]. (2) Also consistent with similar studies, the surgeons performed repeated simulated operations on a digital model prior surgery; hence, they were required to confront difficulties and prepare details in advance; hence, the feasibility and optimization of preoperative planning were superior because they were well thought through [24]. (3) Compared with conventional technology, the use of PSI during surgery can speed up the process of traditional osteotomy and alignment and make them more accurate. PSI can reduce the number of surgical procedures and fluoroscopic examinations conducted during surgery, and many procedures do not require repeated attempts when PSI is used [11]. (4) Another possible reason is that the rich digital orthopedic surgery experience of our team provided good personnel, technical reserves, and the ability to execute this new technology [12].

Nevertheless, SO-PSI technology also has some shortcomings. First, the preoperative planning time was much longer for the SO-PSI group than that for the CO group, due to the addition of numerous preoperative steps, including copying the original CT data, 3D digital model reconstruction, completion of simulated surgery, and PSI 3D printing, which are very time-consuming [25]. Second, the average hospitalization expenses of the SO-PSI group were 1,400 dollars higher than those of the CO group, because the fees for design labor and 3D printing production were high, and are not included in medical insurance in our country; however, with the improvement in health care policies, software upgrades, and the rapid development of 3D printing technology [26, 27], completion of these steps is gradually becoming easier and faster for doctors, and the corresponding costs will also gradually reduce.

This study had some limitations. First, designing the PSI is a complex procedure, and surgeons usually need a technologist who is skilled at using the software to assist with this part of the process. Second, it will be necessary to research the survival rate of the ankle joints in each group after surgery, based on long-term observation in the future. Third, this study was retrospective; a prospective study should be conducted, or potentially a randomized controlled trial.

Conclusions

Our results indicate that SO-PSI technology can be used to accurately and rapidly conduct preoperative planning for SMOT. In general, compared with conventional technology, SO-PSI has advantages for preoperative planning, intraoperative application, and postoperative curative effect.

Abbreviations

SO-PSI

simulated operation combines patient-specific guide

SMOT

supramalleolar osteotomy

CO

conventional operation

AOFAS

American Orthopaedic Foot & Ankle Society

VAS

visual analogue scale

3D

three-dimensional

BMI

body mass index

TAS

tibial anterior surface angle

TTA

tibiotalar tilt angle

MA

malleolar angle

TLS

tibial lateral surface angle

SLS

selective laser sintering

ALB

albumin

TACD

tibial ankle center discrepancy

ROM

range of motion

Declarations

Acknowledgements

This study was strongly supported by the Digital Research Institute of Orthopedics of Xiangya Hospital, the Ethics Committee of Xiangya Hospital, the registration system of foot and ankle surgery department, the medical record information system and the follow-up system of patients' service center of Xiangya Hospital.

Availability of data and materials

The datasets used and/or analyzed during the study are available from the corresponding author upon reasonable request.

Authors' contributions

Liu.H and Wang.CG contributed to the investigation, methodology, data curation, and preparation of the original draft. Xu.C and Li.YS contributed to the formal analysis, data curation, and preparation of the original draft. Xu.C and Wang.CG prepared the original draft. Zhong.D, Wang L and Li.MQ did the validation of data. Liu.H and Wang.CG contributed to the design of the SO-PSI. Zhong.D and Liu.H contributed to the surgical guidance. Liu.H performed all the operations as the leader. Liu.H and Wang.CG edited and reviewed the manuscript. All authors read and approved the final manuscript.

Conflicts of interest/Competing interests

The authors declare that they have no conflict of interest.

Ethics approval and consent to participate

This study has been approved by the ethics committee of our hospital (No.201906012). All procedures performed in studies were in accordance with the ethical standards of our institutional ethical committee. Informed consent was obtained from all individual participants included in the study.

Consent for publication

All patients involved had given informed consent.

References

1. Kobayashi H, Kageyama Y, Shido Y. Treatment of Varus Ankle Osteoarthritis and Instability With a Novel Mortise-Plasty Osteotomy Procedure. *J Foot Ankle Surg.* 2016;55:60–7.
2. Nüesch C, Huber C, Paul J, Henninger HB, Pagenstert G, Valderrabano V, et al. Mid- to Long-term Clinical Outcome and Gait Biomechanics After Realignment Surgery in Asymmetric Ankle Osteoarthritis. *Foot Ankle Int.* 2015;36:908–18.
3. Zhao H, Liang X, Li Y, Yu G, Niu W, Zhang Y. The role of fibular for supramalleolar osteotomy in treatment of varus ankle arthritis: a biomechanical and clinical study. *J Orthop Surg Res.* 2016;11:127.
4. Qu W, Xin D, Dong S, Li W, Zheng Y. Supramalleolar osteotomy combined with lateral ligament reconstruction and talofibular immobilization for varus ankle osteoarthritis with excessive talar tilt angle. *J Orthop Surg Res.* 2019;14:402.
5. Takakura Y, Tanaka Y, Kumai T, Tamai S. Low tibial osteotomy for osteoarthritis of the ankle. Results of a new operation in 18 patients. *J Bone Joint Surg Br.* 1995;77:50–4.
6. Haraguchi N, Ota K, Tsunoda N, Seike K, Kanetake Y, Tsutaya A. Weight-bearing-line analysis in supramalleolar osteotomy for varus-type osteoarthritis of the ankle. *J Bone Joint Surg Am.* 2015;97:333–9.
7. Lee WC, Moon JS, Lee K, Byun WJ, Lee SH. Indications for supramalleolar osteotomy in patients with ankle osteoarthritis and varus deformity. *J Bone Joint Surg Am.* 2011;93:1243–8.
8. Ahn TK, Yi Y, Cho JH, Lee WC. A cohort study of patients undergoing distal tibial osteotomy without fibular osteotomy for medial ankle arthritis with mortise widening. *J Bone Joint Surg Am.* 2015;97:381–8.
9. Hongmou Z, Xiaojun L, Yi L, Hongliang L, Junhu W, Cheng L. Supramalleolar Osteotomy With or Without Fibular Osteotomy for Varus Ankle Arthritis. *Foot Ankle Int.* 2016;37:1001–7.
10. Pagenstert G, Knupp M, Valderrabano V, Hintermann B. Realignment surgery for valgus ankle osteoarthritis. *Oper Orthop Traumatol.* 2009;21:77–87.
11. Jud L, Vlachopoulos L, Beeler S, Tondelli T, Fürnstahl P, Fucentese SF. Accuracy of three dimensional-planned patient-specific instrumentation in femoral and tibial rotational osteotomy for patellofemoral instability. *Int Orthop.* 2020.

12. Wang C, Xiao H, Yang W, Wang L, Hu Y, Liu H, et al. Accuracy and practicability of a patient-specific guide using acetabular superolateral rim during THA in Crowe II/III DDH patients: a retrospective study. *J Orthop Surg Res.* 2019;14:19.
13. Xing QQ, Zhong D, Pan YX, An SB, Wang CG, Su SL, et al. A Comparative Study of Patients' Subjective Feelings Toward Total Hip Arthroplasty with Patient-Specific Instruments and Traditional Total Hip Arthroplasty. *Orthop Surg.* 2020;12:269–76.
14. Siddiqui NA, Lamm BM. Digital planning for foot and ankle deformity correction: Evans osteotomy. *J Foot Ankle Surg.* 2014;53:700–5.
15. Kim YS, Park EH, Koh YG, Lee JW. Supramalleolar Osteotomy With Bone Marrow Stimulation for Varus Ankle Osteoarthritis: Clinical Results and Second-Look Arthroscopic Evaluation. *Am J Sports Med.* 2014;42:1558–66.
16. Tanaka Y. The concept of ankle joint preserving surgery: why does supramalleolar osteotomy work and how to decide when to do an osteotomy or joint replacement. *Foot Ankle Clin.* 2012;17:545–53.
17. Knupp M, Stufkens SA, Bolliger L, Barg A, Hintermann B. Classification and treatment of supramalleolar deformities. *Foot Ankle Int.* 2011;32:1023–31.
18. Schneider W, Jurenitsch S. Normative data for the American Orthopedic Foot and Ankle Society ankle-hindfoot, midfoot, hallux and lesser toes clinical rating system. *Int Orthop.* 2016;40:301–6.
19. Rabin A, Portnoy S, Kozol Z. The Association of Ankle Dorsiflexion Range of Motion With Hip and Knee Kinematics During the Lateral Step-down Test. *J Orthop Sports Phys Ther.* 2016;46:1002–9.
20. Naunheim MR, Dai JB, Rubinstein BJ, Goldberg L, Weinberg A, Courey MS. A visual analog scale for patient-reported voice outcomes: The VAS voice. *Laryngoscope Investig Otolaryngol.* 2020;5:90–5.
21. Zhao HM, Wen XD, Zhang Y, Liang JQ, Liu PL, Li Y, et al. Supramalleolar osteotomy with medial distraction arthroplasty for ankle osteoarthritis with talar tilt. *J Orthop Surg Res.* 2019;14:120.
22. Qiang M, Zhang K, Chen Y, Jia X, Wang X, Chen S, et al. Computer-assisted virtual surgical technology in pre-operative design for the reconstruction of calcaneal fracture malunion. *Int Orthop.* 2019;43:1669–77.
23. Lei PF, Su SL, Kong LY, Wang CG, Zhong D, Hu YH. Mixed Reality Combined with Three-Dimensional Printing Technology in Total Hip Arthroplasty: An Updated Review with a Preliminary Case Presentation. *Orthop Surg.* 2019;11:914–20.
24. Chen Y, Jia X, Qiang M, Zhang K, Chen S. Computer-Assisted Virtual Surgical Technology Versus Three-Dimensional Printing Technology in Preoperative Planning for Displaced Three and Four-Part Fractures of the Proximal End of the Humerus. *J Bone Joint Surg Am.* 2018;100:1960–8.
25. Mitsouras D, Liacouras P, Imanzadeh A, Giannopoulos AA, Cai T, Kumamaru KK, et al. Medical 3D Printing for the Radiologist. *Radiographics.* 2015;35:1965–88.
26. Zastrow M. 3D printing gets bigger, faster and stronger. *Nature.* 2020;578:20–3.
27. Wang J, Cai L, Xie L, Chen H, Guo X, Yu K. 3D printing-based Ganz approach for treatment of femoral head fractures: a prospective analysis. *J Orthop Surg Res.* 2019;14:338.

Figures

Figure 1

Application of SO-PSI technology for SMOT (A–C and H–I also apply for conventional technology). (A, B) Measurement of relative Takakura stage, ankle angles, and axes on preoperative (A) anteroposterior and (B) lateral radiographs. (C) Preoperative design aim for the angles. (D) Flow chart for the simulated

operation. (E) Model and patient-specific guide generated by 3D printing. (F) Application of osteotomy guide plate during surgery. (G) Application of a temporary fixation guide plate during surgery. (H, I) Measurement of relative Takakura stage, ankle angles, and axes from postoperative (H) anteroposterior and (I) lateral radiographs. (J) TACD was measured after coincident preoperative planning and postoperative CT data.

Typical case of CO group

Typical case of SO-PSI group

Figure 2

X-rays of typical cases from the two groups. (A–C) A typical case from the CO group: Anteroposterior radiographs at (A) five days preoperative, (B) three months postoperative, and (C) one year postoperative, and measurement of relative Takakura stage, ankle angles, and axes. (D–F) A typical case from the SO-PSI group: Anteroposterior radiographs at (D) nine days preoperative, (E) three months postoperative, and (F) one year postoperative, and measurement of relative Takakura stage, ankle angles, and axes.

Figure 3

Linear regression analysis of preoperative planning and postoperative actual data from the two groups. (A, B) Under these conditions, correlations of (A) TAS ($R^2 = 0.100$, $P = 0.271$) and (B) TLS ($R^2 = 0.111$, $P = 0.192$) were poor for the CO group. (C–F) Under these conditions, correlations of (C) TAS ($R^2 = 0.667$, $P = 0.002$), (D) TTA ($R^2 = 0.438$, $P = 0.027$), (E) MA ($R^2 = 0.709$, $P = 0.001$), and (F) TLS ($R^2 = 0.925$, $P < 0.0001$) were good for the SO-PSI group.

Figure 4

Bar charts showing that, compared with the CO group, AOFAS score, VAS, and ankle ROM of the SO-PSI group gradually improved following surgery. Specifically: (A) the AOFAS score for the SO-PSI group was better than that for the CO group at each time point; (B) the VAS for the SO-PSI group was better than that for the CO group at six months postoperative; and (C) there was no significant difference in ankle ROM between the two groups at each time point.

Figure 5

Graph showing individual changes in Takakura stage for (A) the CO group and (B) the SO-PSI group with time. Each circle represents one ankle (patient). Takakura stage improved in both groups following surgery; however, the improvement in the SO-PSI group was more marked than that in the CO group.