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Does Balancing a Total Hip Arthroplasty Require a New Paradigm? Functional 3-Dimensional Balancing in Total Hip Arthroplasty

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Abstract

Background Traditional principles for successful outcomes in Total Hip Arthroplasty (THA) have relied largely on placing the socket in the native position and trying to restore static anatomical femoral parameters gauged on X-rays or intra-operative measurement. Stability is conventionally achieved by making appropriate changes during the time of trial reduction. Post-operative complications of dislocation and significant Limb Length Discrepancy (LLD) requiring foot wear modification represents opposite ends of the spectrum from a biomechanical perspective and these continue to be relatively high. A move towards giving more importance to functional dynamic parameters rather than static anatomical parameters and less reliance on stability testing at trial reduction is warranted.

Methods Intraoperative 3D functional balancing of THA without stability testing at trial reduction was practiced in all subjects undergoing THA in our unit from April 2014. To date 1019 patients have had their hips replaced with the same technique. They were followed up till April 2020 for post-operative complications of dislocation and significant LLD needing footwear modification. A secondary cohort of 114 patients from 1st January to December 31st 2017 within this primary group were analyzed clinically and radiologically to ascertain the implications of functional 3D balancing on X-ray parameters, clinical outcome scores (Harris Hip Score and Oxford Hip Score), ability to squat, and subtle subjective post-operative perception of limb lengthening (POPLL).

Results In the primary group of 1019 patients, there were only two dislocations and no patient needed footwear modification for LLD. In the detailed analysis of the secondary cohort of 114 patients, the correlation with restoration of static radiological parameters was inconsistent. 40 patients could not squat and 4 patients had subtle subjective post-operative perceived limb lengthening (POPLL). Measured outcomes such as HHS and OHS were improved in all patients with significant statistical significance (P < 0.001).

Conclusion This study underlines the fact that more importance must be given to functional dynamic parameters by 3D balancing of the THA and not on static anatomical X-rays parameters and stability testing during trial reduction. This represents a paradigm shift in the evolution of total hip arthroplasty.

Level of Evidence A Level II study. (Data collected from the ongoing prospective study) (http://www.spine.org/Documents/ LevelsofEvidenceFinal.pdf).

Keywords Primary total hip arthroplasty \cdot 3D Balancing \cdot Coaxial stitch \cdot Combined anteversion \cdot Composite length \cdot Cumulative offset

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Introduction

Traditionally, for Total Hip Arthroplasty (THA), surgeons have always stressed the principles of restoring the native hip centre and normal biomechanics by reproducing the anatomical horizontal and vertical offsets of the femoral head and ensuring a stable prosthetic joint at trial reduction as vital for a favorable surgical outcome. This approach is intuitively compelling, since it presumes that reproducing native anatomy will restore the original biomechanics of the hip joint. Numerous studies over the past few decades have expounded on the accurate and ideal positioning of the prosthetic implants in the proximal femur as well as in the acetabulum [1]. There has been several biomechanical studies based on theoretical mathematics, in vitro, in vivo, in silico models and many more to evolve [2]. However, intrinsic femoral implant design limitations along with our improved understanding of the dynamic biomechanical considerations between the spine, pelvis and femur have exposed the fallacy of this premise. True recreation of anatomy can be achieved only with custom made femoral implants replicating the patient's neck–shaft angle and offset in the sagittal plane.

Restoration of leg length is a complex issue with many confounding variables, namely, the influence of the other joints of the lower limb, the spine, socket placement and most importantly the subjective perception of equality or otherwise by the patient [3]. Post-operative WOMAC score and self-perceived limb length correlates more closely with patient satisfaction than with radiological restoration [4]. Clinical post-operative LLD of more than 10 mms was present in 9% of THA patient who had no LLD based on measurements on pelvis X-ray [5]. Thus, a functional restoration has more clinical relevance than an anatomical restoration based only on uniplanar X-ray assessment. Limb length adjustments based on absolute femoral parameters when the patient does not perceive LLD will risk post-operative dissatisfaction. Traditional intraoperative tests for hip stability continue to be performed universally at trial reduction, which at times detects spurious instability as it does not take the variable soft-tissue tension into consideration. Surgeons frequently overcompensate by increasing the length and / or offset of the construct which compromises the functional outcome.

A paradigm shift in the concept of defining and execution of biomechanics restoration in THA is needed which will give weightage exclusively to a combination of both socket and proximal femoral parameters and not on either one individually. Estimation of combined parameters across a mobile joint will automatically factor in the soft-tissue tension and will represent a functional biomechanical restoration and not an anatomic one as commonly practiced. We have termed this new paradigm as Functional 3-Dimensional balance in THA. The 3 global intraoperative pelvi-femoral parameters relevant in this approach would be 1. Composite Length (CoL) 2. Cumulative Offset (CuO) 3. Combined anteversion (CAV). To achieve a functional 3-D balance, we have described two tools, namely, the co-axial stitch and combined version wedges. Both these are extremely cost effective and have the potential for being adopted widely. Many authors have described techniques using sutures for intra operative measurements during surgery and these have been found to be as reliable as more elaborate methods using calipers or navigation [6]. We have been using a modified version of the suture method since 2014 by including two axes which can be aligned coaxially to ensure consistent position of the limb when readings are taken rather than just using two points as in previous techniques without standardization of limb position. A simple customized clamp which has a vertical and horizontal ref bar to enable it being held in a consistent position during measurements has been designed. Two (CAV) custom wedges that can be sterilized and subtending an internal angle of 35° for male patients and 45° for female patients were fabricated and used.

We describe in this paper our way of ensuring a stable and functional total hip replacement which will not require any immediate post-operative precautions or long-term activity restrictions. The technique does not use pre-operative templating or intra-operative stability tests during trial reduction but instead employs precise intra-operative steps to achieve a functional 3-D balance. We also present our mid-term functional and radiological results in a smaller representative secondary cohort of 119 consecutive THA patients.

Materials and Methods

1045 primary THAs using the functional 3-D balancing protocol were performed at a specialty lower limb reconstruction unit at a tertiary care hospital in urban settings dating from April 2014 till December 2020. After obtaining informed consent, 1019 Patients who did not have residual disease in the contralateral hip or a shortening of more than 2cms on the side of surgery, were prospectively followed up for dislocation and usage of shoe raise for postoperative LLD. Ethical clearance and Institutional Review Board approval was obtained to critically examine a secondary cohort of 119 primary THAs in this group performed between January to December 2017 to evaluate clinical and radiological parameters. All subjects underwent routine pre-operative assessment for surgical fitness. Standard radiological studies included antero-posterior and lateral views of the hip. Patients with fixed spinal deformities had a different X-ray protocol as described by Dorr et al. [7]. All radiographs were standardized with use of a 3 cm magnification marker placed close to the femur. All pre-operative radiographs were retrieved from the Hospital PACS as deidentified files and assessed using ImageJ (V1.50, National Institute of Health, Bethesda, MD) digital analysis software. Preoperative Harris Hip Score and Oxford Hip Score were obtained. Patients with a pre-operative clinical shortening of more than 2 cm were excluded as they were outside the purview of functional restoration due to soft-tissue contractures.

With the patient in a lateral decubitus position, a modified posterolateral approach was used in all patients ensuring a

stable pelvis using supports over the sacrum and pubic rami. All surgeries were performed by one of the two senior surgeons (VCB, PS). Care was taken to identify and isolate the hip short external rotators and the hip capsule was incised as a separate layer using the Neck Capsule Preserving (NCP) approach, [8] so as to enable anatomical capsule to capsule optimum tension repair during closure. After exposing the bone and adequate capsular releases, the co-axial stitch was applied with the hip in a comfortable position of flexion and knee in 90° flexion ensuring that further adjustments of the Charnley retractor or incision length were not required. The femur reference line was marked on the long axis of the femur in the mid coronal plane with a marker pen and sterile ruler. The same sterile ruler was used to extend this line proximally on the skin overlying the pelvis (Fig. 1). Skin sutures were taken with two wide bites on the pelvis line from distal to proximal with No.2 Ethibond and was retraced back on the same line with two more wide bites so as to capture a long segment of skin making the stitch relatively stable over the pelvis. The two strands of the suture are held parallel to the femoral line without slack but not unduly tight so as to wrinkle the captured skin (Fig. 1). The coaxial stitch clamp is used to hold the suture at an appropriate length and depth to contact the femoral line at the base of the greater trochanter ensuring consistent clamp orientation with the help of the reference bars. This reference point on the femur is marked with electrocautery to indicate the pre hip dislocation status. The aim is for the clamp to contact the same point during trial reduction if patient did not complain of LLD before surgery.

Provisional femoral cut is made in the top of the upper 3rd of the neck for patients with coxa valga morphology, and in the top of lower 3rd for those with coxa vara. The neck cut is made at top of the middle 3rd for the remaining patients.



Fig.1 Application of the Coaxial Stitch pre dislocation: knee is at 90° and hip at a comfortable flexion angle. Coaxial clamp in a consistent orientation is used to mark the pre-dislocation status, while the suture is held by the surgeon without slack or wrinkling of the captured skin

The acetabular cup is sized correctly by its A-P dimension and medialized till the true floor and implanted collinear with the medial inner edge of the Transverse Acetabular Ligament (TAL) in respect to the version and inclination. The aim is to reproduce the native anteversion. By satisfying the two prerequisites of correct socket sizing and using implants with Cup Articular Arc Angle (CAAA) within 175–180°, we aim to achieve an angle of 40–45° inclination by aligning the inferior edge of socket to the medial border of TAL in the coronal plane. Superior reference marks are not used and overhang or underhang of the socket superiorly is disregarded. Intentional change of version from native is done only in patients with a rigid spine and is based on the pelvic tilt [9]. If the native hip has migrated proximally with good bone remodeling, no attempt is made to bring the hip centre down, so as to preserve bone and place the noncemented socket in the best available bone stock, accepting a mild to moderate high hip centre (HHC).

The appropriately sized trial femoral implant is inserted to the neck resection level. Trial reduction is done with the zero offset modular head and coaxial stitch reading is noted, while ensuring that the knee is in 90° flexion and the hip in the flexion position that would make the femoral axis coaxial with the pelvis axis. The reading now will typically show the limb to have been lengthened due to the conservative neck resection. Further calcar milling / neck resection is done to fine tune the length so as to match accurately the pre dislocation mark on the coaxial stitch. At this point, higher offset modular heads are progressively trialed. The highest offset modular head that the construct accommodates without producing a lengthening on the co-axial stitch reading is the correct functional cumulative pelvi-femoral offset which factors in the socket placement on all planes and the limitation of the stem, to recreate native femoral biomechanics. In patients with low offset, the trial reduction is begun with the lowest offset modular head available in the system in place of the zero offset modular head. In patients with a large offset femurs, we use a high offset stem option if the modular head required to 3D balance the hip is more than + 6 to prevent the incidence of trunnionosis. For patients with pre-operative LLD, the co-axial stitch is used in similar fashion so as the final reading will reflect the increase in length required in mms with a ratio of 1:3. Lengthening is not attempted if the patient did not perceive LLD pre-operatively, even in the presence of radiological shortening (Fig. 2).

Combined anteversion is adjusted using the custom made CAV wedges (Fig. 3). The tibia rests on the wedge with the hip in 10–15° of flexion during trialing. The surgeon assesses the coplanarity of the post hemisphere of the trial head with the post hemisphere of the socket. Precise target CAV is achieved by doing version adjustments of the stem trial till coplanarity is achieved when the tibia is resting on the CAV wedge. If adequate versional adjustment of



Fig. 2 Determining Composite Length and Cumulative Offset at trial reduction: A co-axial stitch reading when -3 offset (green) head is used which matches the pre dislocation mark. B Reading with 0 offset (yellow) head, also matching pre dislocation mark. C Reading



Fig. 3 Custom Combined Ante Version (CAV) Wedge of 35° shown being used in a male patient denoting coplanarity of the posterior half of socket and trial head with the tibia resting on the wedge. Similar CAV wedge of 45° is used in female patients

the femoral trial is not possible, a non-cemented femoral component with complete versional freedom (SROM / cone Wagner) is used to achieve target CAV (Fig. 3). The hip is dislocated and the versional relationship between an inverted Judd pin placed on the femoral trial neck and the tibia held vertically is measured with a sterile metallic goniometer. This represents the Effective Lower Limb Version (ELLV) and an additional requirement is for the ELLV to be in the range of 10-35° (Fig. 4). Rarely when ELLV falls outside this compatibility range, the socket is repositioned as the entire CAV cannot be derived exclusively from one side. If this is anticipated as in cases of grossly deranged anatomy, we leave the trial socket in place till the time of trial reduction to avoid redoing the definitive socket. The shuck test, dropkick test and manoeuvres to provoke dislocation are not performed to avoid detection of spurious instability. Presence of impingement due to osteophytes is carefully assessed and addressed. Post operatively no immediate precautions with +3 offset (red) head showing lengthening on the coaxial stitch. Correct offset head is +0 for this patient with the 3D balancing technique as it is the highest offset that does not produce lengthening. Trialing with the +8 (white) head is not required



Fig. 4 Effective Lower Limb Version (ELLV) measurement A figure showing the angle between the inverted Judd pin (held by a Kocher's forceps) placed over the femoral trial neck and the tibia held vertically. B Measurement of ELLV using sterile metal goniometer

are given and all terminal ROM activities such as squatting and sitting cross-legged on the floor and yoga is permitted in the long term. Contact sport is the only activity disallowed.

Results

Postoperative standardized pelvis AP radiographs taken at a minimum of 6 month follow-up post-surgery were used for assessment. The contralateral normal side was presumed to represent native anatomical acetabular and femoral anatomical parameters and measured (Fig. 5).

In the primary group of 1019 patients followed up prospectively, two patients had a dislocation, and no patient was using a shoe raise (significant LLD). Both the dislocations occurred within 6 weeks of surgery and both have continued



Fig. 5 Post-operative Radiograph showing the calculation of radiographic parameters. Composite Length (CoL): The distance between a line joining the top of the lesser trochanters (4) and another line joining the upper most part of the Iliac crests (3) is measured on the normal side (I, J) and operated side (D, E), respectively, at level of the femoral head centre. Cumulative Offset (CuO): One line is drawn along the medial border of tear drop (H) and another line (1) is drawn along the axis of femur. A horizontal line (F-H) on non-operated and A-C on operated side is drawn between these two lines at the level of hip center and measured as CuO. Femoral vertical offset: Distance in the vertical between the line joining between the lesser trochanters (4) and the centre of the femoral head (G-I) on non-operated side and (B-D) on operated side). Femoral Horizontal offset: Horizontal distance between the femoral head and a line drawn along the long axis of the femur (F-G) on non-operated side and A, B on the operated side. 3 cm magnification marker is used (5)

to be stable after closed reduction and an extension knee brace for 3 week post-reduction. In the secondary cohort of 116 subjects (124 hips), 3 subjects (5 hips) did not have a satisfactory radiographs and hence were not included in the final analysis. All subjects were interviewed in person or at least by telephone to record the PROMs. The demographics and distribution of diagnoses is shared in Table 1.

All patients showed improved scores on all the Patient reported outcome measures that were evaluated which were statistically significant. (Paired *t* Test p < 0.001) (Fig. 6). None of the patients in this cohort have reported any dislocations or symptoms suggestive of instability. 40/119 hips reported inability to squat post-surgery. 4 patients reported post-operative perception of limb lengthening (POPLL) but were not using any form of orthotics or shoe raises. All 4 patients who reported POPLLD did not perceive LLD before surgery. In 3 out of the 4 patients, the co-axial stitch reading was indicative of lengthening per operatively (Table 2). However, alterations could not be done as the femoral implant had been taken to the lowest possible level and the least available offset modular head in the system was already deployed.

The radiographic assessments were done by 2 pairs of observers with orthopaedic training, (one post graduate trainee and one fellowship trainee, with at least 2 years of experience). A Single reading was obtained by each

Table 1	Demograph	nics, diagn	oses o	distribution	1 and	outcome	measur	es
and imp	lants used							
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Demographics	Average \pm SD (range)				
		116 subjects (124 Hips)			
Gender	77 M: 47 F	72 M: 44 F			
Age (years)	43.6±14.7 (22–81)				
BMI	27.1±5.5 (15.6–44.6)				
Diagnosis					
	Ankylosing spondylitis	11			
	AVN	48			
	Dysplasia	4			
	IFA	8			
	OA	35			
	OA + dysplasia	11			
	Protrusio	3			
Implants used	Femoral stem				
	Accolade-Stryker	3			
	CLS-Zimmer	14			
	Corail–Depuy	86			
	MS30–Zimmer	1			
	Polar–Smith and Nephew	5			
	S-ROM–Depuy	14			
	Cone Wagner–Zimmer	1			
Outcome measure		114 subjects (119 Hips)			
	Pre-operative	Post-operative			
Harris Hip Score	66.9±14.6 (11-89)	93.8±2.8 (86.2–95.8)			
Oxford Hip Score	10.7±1.8 (8–18)	$47.2 \pm 1.6 (41 - 48)$			

observer and verified independently by senior authors with over 20 year experience in arthroplasty. All post-operative radiographs were evaluated to determine Horizontal, Vertical offset of the femur and Cumulative Offset along with composite length. The difference between the average preand post-operative values are depicted in Fig. 7.

All clinical assessments and outcome scores of HHS and OHS were done by the clinical fellows and senior consultants.

Discussion

Some concepts in THA have undergone a dramatic progressive rethink in the 21st century such as that of spino-pelvic parameters after the functional Combined Sagittal Index (CSI) was described [6]. Numerous other publications have appeared in recent times on this topic. This has led to surgeons adopting techniques to compensate for deranged spino-pelvic parameters, if present leading to a reduced dislocation rate [10, 11]. It is now well accepted that the relationship between the spine and pelvis is dynamic, and



Table 2 Self-reported post-

operative status



YesNoH/O dislocation0119Ability to squat7940Post Op perceived4115limb length115

therefore, static parameters are not valid. Similarly, the relationship between the acetabular socket and proximal femur is dynamic with non-anatomical parameters such as soft-tissue tension playing a pivotal role. The Lewinneck safe zone concept [12] of the previous century has been almost given up with the description of dynamic spinopelvic parameters [7, 13]. However, static anatomic variables gauged from uniplanar X-rays continues to be the basis of pelvi-femoral biomechanical restoration in THA till date.

The static unidimensional concept of restoration of vertical and horizontal offset of the proximal femur is flawed in many aspects [14]. Over simplifying the biomechanics of the complex dynamic hip joint with multi directional movement with varying muscle forces and soft-tissue tension to singular coronal plane parameters would be inaccurate, with possible clinical significance. Furthermore, most femoral implants of THA are not custom made for the patient and only one or two neck shaft angles available to the surgeon. Many studies bring out the fact that the Neck Shaft Angle (NSA) is very variable in populations [15, 16].

Comparison of Outcome Measures

If the prosthetic NSA is different from the native NSA of the patient, it brings a 3-dimensional variability on the vertical and horizontal offset due to the inherent ante version of the proximal femur to varying degrees. The need to modify the horizontal and vertical offset to compensate for the different prosthetic NSA to reproduce the femoral head centre underlines the fact that the concept of anatomic reconstruction is flawed and true recreation of anatomy can be achieved only with custom made femoral implants replicating the patient's neck–shaft angle and offset in the anteroposterior plane.

Accurate socket positioning with reference to inclination and version has improved significantly in the 21st century due to the appreciation and application of dynamic spinopelvic parameters [17, 18] and local anatomical marks of transverse acetabular ligament (TAL) and anterior wall notch [19]. A mild to moderate high placement of the noncemented biological socket in the best available bone stock and not compromising the anteroposterior bone stock by expanding the socket to accommodate a larger shell in native centre is preferred by many surgeons currently. Excellent long-term results have been published with mild to moderate high hip centres [20]. High hip center concept proposed by Russotti and Harris for acetabular cup placement in revision THA is nowadays more widely used for acetabular cup placement in Crowe II-III dysplastic hips. HHC concept reduced the operative time, financial burden, increased bone ingrowth with greater host bone contact area [21, 22]. Socket placement can be very variable in the medio-lateral plane in patients with post acetabular fracture situations and protrusio caused by different pathologies. The socket placement is generally regarded as the prime driver for outcomes following THA and one must give preference for the same [23]. If that is the case, then surely compensation must be given on the femoral side for non-anatomic placement of the socket rendering conventional exclusive femoral vertical and horizontal offset restoration invalid. Thus, it stands to reason that assessing global pelvi-femoral parameters in different planes during surgery to dial the length and offset in a 3-dimensional way is a more functional approach.

Limb length discrepancy after THA, is a commonly encountered problem and its incidence in various studies have been reported from 5% [24] to 95% [25, 26]. LLD is perceived when shortening exceeds 10 mm and lengthening exceeds 6 mm [27]. Hip pain, back pain, limp, neuronal injuries, and dislocations following hip arthroplasty have been attributed to LLD [25, 28–30]. LLD following hip arthroplasty, particularly lengthening, is poorly tolerated and is associated with poor patient satisfaction [31]. Aiming for the conventional concept of radiological restoration has a risk of patient dissatisfaction if the patient does not perceive LLD pre-operatively. Techniques using sutures have shown to show the same reliability as more cumbersome techniques using calipers and navigation systems [32]. Common techniques to test prosthetic hip stability, namely, the Shuck test and drop kick test, are very error prone as the soft-tissue tension in the hip is not uniform and influenced by many variables, such as age, sex, presence of generalized laxity, muscle status, duration and type of pathology [32]. Further testing for stability by various provocative maneuvers putting the prosthetic hip in extremes of ROM during trial reduction can be extremely misleading. Very often during exposure for the surgery, the native hip dislocates easily without the need for taking the hip to extremes of ROM after the capsule is incised. Similarly, the prosthetic hip at trial reduction before capsular repair can be found to be spuriously unstable by the surgeon even if it has the same stability and functional biomechanics of the native hip. Surgeons frequently increase the length and / or offset in this situation to achieve an unneeded artificial constraint which compromises the functional outcome.

Though dislocation rates following primary THA have reduced in recent years, it continues to be an important cause for failure. In a recent report published in 2020 from the Danish Hip Registry the cumulative dislocation rate at 2 years after primary THA was 3.5% [33]. Based on our experience, we feel that restoration of the 3 global pelvifemoral functional parameters would bestow stability of the hip intrinsically, obviating the need for assessing stability at extreme ROM and thereby eliminate the detection of spurious instability. From April 2014 to April 2020 there were only 2 dislocations in our series of 1013 routine and complex primary THA when the functional 3D balance protocol was used without stability testing at trial reduction giving a low dislocation rate of 0.19%.

Several different techniques have been described for intra operative measurement of limb length involving placement of pins in ilium with or without separate skin incision, use of calipers or similar measuring devices. Most of the described techniques use a pelvic and femoral reference point and fail to standardize the flexion position of the limb. This inconsistency may be the reason for them not being adopted widely. Co-axial stitch is a simple technique which ensures consistent limb position during measurements by aligning the pelvic and femoral lines co-axially. It is often noted during surgery that minor changes in the flexion position of the limb can alter the readings significantly. Our results show that the described 3-D functional method of hip balancing has a very high success rate in avoiding both instability and significant limb lengthening. The co-axial stitch technique is good (3 out of 4 patients) in predicting post-operative perception of limb lengthening. Our results show that static anatomical parameters have poor correlation to POPLL. Global parameters of CoL and CuO have better correlation but still do not accurately reflect POPLLD.

Combined Anteversion (CAV) is now a well-established concept. Fukunishi et al. [34] showed that CAV is very

inconsistent even if imageless navigation is used for acetabular component positioning. During surgery it is commonly gauged by the position of the tibia in space with relation to the table or floor using only visual cues which are subject to large observer dependent variations. However, in our method, when the tibia is stable over the CAV wedge, estimating the coplanarity of the post half of the implanted socket and trial head which are in close proximity would have high accuracy.

A limitation of the radiographic analysis was that the observers were not blinded to the surgical technique as all hip arthroplasties in our unit underwent surgery with the same technique. However, each reading was obtained by 2 observers and independently verified by senior authors.

Conclusion

Post op dislocation and leg lengthening are two relatively common causes of dissatisfaction following THA. These two represent opposite ends of the spectrum from a biomechanical perspective. Instability of the prosthetic hip can occur if proximal placement or medialization of the socket is done intentionally or inadvertently and is not compensated for on the femoral side. Traditional concept of aiming to restore only static femoral parameters inherently runs this risk. Conversely, error prone conventional stability tests done at trial reduction can lead to overcompensation by rendering the socket-stem couple artificially more stable than the native hip by abnormal increase in length and offset. 3D functional balancing with the co-axial stitch in combination with the CAV wedge is a simple, precise and cost effective technique to achieve a very functional THA without the need for any imposed post op restrictions and minimize the complications of limb lengthening and dislocation concurrently. Modern navigation and robotic technologies could expand on the 3D functional balance concept in future.

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Author Contributions VCB: manuscript writing and chief operating surgeon. SP: manuscript edit and chief operating surgeon. AK: data collection and operating surgeon. KK: manuscript writing and operating surgeon. SY: data collection, analysis, and manuscript writing. SP: statistics workup, manuscript writing, and edit.

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Declarations

Conflict of Interest The authors declare that they have no conflict of interest.

Ethical Standard Statement This article does not contain any studies with human or animal subjects performed by the any of the authors.

Ethical Approval This manuscript has been read and approved by all the authors and presents trustworthy and reliable scientific data obtained in our facilities.

Consent for Study The study was approved by SIMS Institutional Review Board and informed consent from patients was obtained.

Informed Consent For this type of study informed consent is not required.

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