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The 21st Century Silicone Breast Implant

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According to some, conventional anatomically shaped breast implants provide a more natural appearance as compared to round implants. However, despite this possible advantage, three critical drawbacks associated with anatomical implant shave limited their adoption and created concern amongst both plastic surgeons and patients alike:

1. Anatomically shaped breast implants have the potential to rotate and shift thus causing distortion leading to revision surgery and likely implant replacement. Rotation by definition is not an issue with round implants [1-3].
2. Macro textured surfaces were developed to improve tissue adherence and reduce the incidence of implant rotation. However, this shift to aggressive macro textured surfaces lead to an unanticipated increase in the occurrence of double capsules and late seroma.

Implant firmness, as well as a rigid shape that does not adjust to a woman´s natural movements, are limiting factors for patients looking for a natural aesthetic result.

With these three disadvantages of conventional anatomical implants in mind, engineers and surgeons created a multidisciplinary design team that took on the challenge to rethink what a natural implant should be and how to create such an implant using the latest technology available. The answer came from the skillful application of the principles of Ergonomics.

A New Design

Ergonomics is the scientific field that studies human interaction with other elements of a system. It applies theory, principles, data and methods to design in order to optimize human wellbeing and overall system performance. Up to now, none of the breast implants manufactured and available in the market have involved designs or technology that embraced the science of Ergonomics. The design of a breast implant respecting Ergonomic principles will allow women to have a breast implant that offers a more natural look and feel; this new device will move together with the breasts natural movements, providing them with enhanced adaptation during their daily lifestyle activities.

The novel concept had the challenge to create an implant that morphs its shape after implantation to give the natural look of the conventional anatomical implants, without the complications associated to them. These devices will have a round base, but will not be round implants. They will adjust with gravity to the patient's position to provide a very natural result in addition to the 100% filled device that reduces the rippling formation.

Initially, new developments on the rheology of the materials used in breast implants were mandatory. Rheology is the study of the flow of matter, primarily in the liquid state, but also as 'soft solids' or solids under conditions in which they respond with plastic flow rather than deforming elastically in response to an applied force. Their viscoelastic properties determine the mechanical performance of the final products, and also the success of processing methods at intermediate stages of production. Innovation demanded the creation of an implant that will not only make the breasts look natural but also feel natural. This new cohesive gel (Progressive Gel Ultima™, Motiva, Coyol, Costa Rica) allowed a better control of its viscosity (low) with great increase of its elasticity for a very natural soft feeling. This new gel uses Nusil Technology's (Nusil, Santa Barbara, California) raw materials, which due to their super high elasticity and elevated point of plasticity, will not fracture during implantation. At the same time, there was a need for the creation of a breast implant shell that was designed to act in sync with a very elastic silicone elastomer shell and highly elastic silicone gel (True Monobloc®, Motiva, Coyol, Costa Rica) (Figure 1). This new implant was designed to shift the maximum point of projection (MPP) to the lower pole when the patient is standing (Figure 2). A new integration shell/gel technology allows that when the patient lays flat on her back, the implants will react as a natural breast and the maximum point of projection will shift up, closer to the middle point of her breast, mimicking the natural behavior of the breast (True Tissue Dynamics™, Motiva, Coyol, Costa Rica). The combination of all these engineering advancements, delivered a technology that should inevitably be the new gold standard for the natural behavior of breasts after implantation.

The studied devices incorporated a proprietary surface (Silk Surface®, with its Nano-surface Technology™, EL, Coyol, Costa Rica) and does not adhere to surrounding tissues (Figure 3). Therefore, it allows the implant to adapt to the natural movement and is designed to eliminate the abrasion problems associated with other methods of breast implant texturing.

These very elastic implants can be used with any surgical technique, as the softness of the device facilitates smaller incisions around 2, 5-3 cm for smaller sizes and 4 cm to bigger sizes (over 400 cc). This is particularly important with the axillary approach where scar reduction is important but also flexibility of the device to facilitate its placement.

These implants can be used in any surgical pocket including subglandular, subfascial, dual-plane and submuscular [4-6]. The gravitational effect on the gel can be verified independently of the surgical pocket with the alteration of the MPP from 50% to 45%. However, using the dual plane or subfascial technique, the estimate is that the MMP can be pushed lower to 40% (Figure 4). Furthermore, when the 5-year clinical post vigilance market data from all the adverse events reported back to the manufacturer in over 120000 devices implanted is analysed, we can verify that the number of capsular contracture cases is less than 1% and the report of double capsules is inexistent [7]. The hypothesis presented in

Figure 1: TrueMonoblock technology demonstrating that Shell/Gel/Patch behaves as a single very elastic unit, which allows smaller surgical incisions.

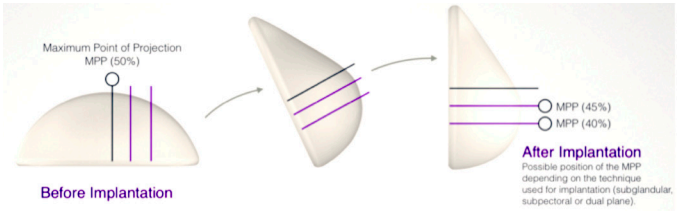

Figure 2: Ergonomix concept where the maximum projection point (MPP) changes to from 50% to up to 40% according to gravity plus the surgical technique used (when considering the measurement from the bottom of the implant).

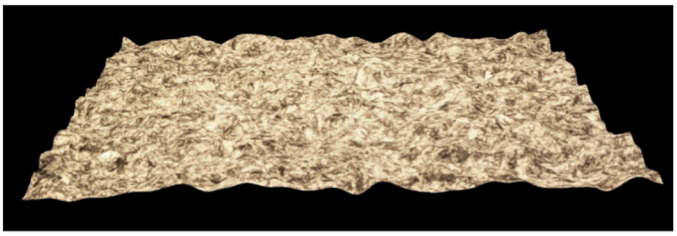

Figure 3: Silk Surface at 50X magnification demonstrating the dense population of the nano textured surface with 8000 points of contact per cm^2.

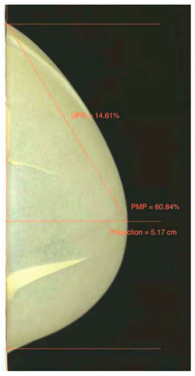

Figure 4: Simulated *In-vivo* model of dual plane technique. Implant positioned 90° with overlying pressure applied by latex membrane demonstrating shift of point of maximum projection (PMP) from 50% to 60% (10% lower when considering the top of the implant).

this editorial are yet to be fully validated by further clinical research, but the trends of the data are present and very promising.

Conclusion

Over 20 years following the last innovation on the manufacturing of breast implants, this industry seems on the verge of liberation from a state of oblivion into developing a new device for the 21st century patient.

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